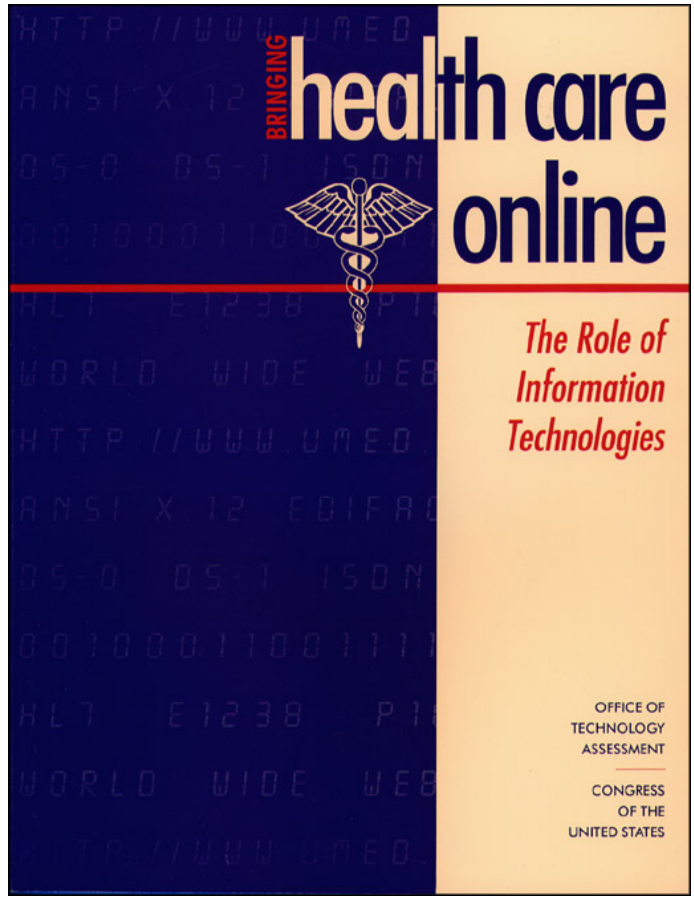
Bringing Health Care Online: The Role of Information Technologies

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Foreword

Information technologies are transforming the way health care is delivered. Innovations such as computer-based patient records, hospital information systems, computer-based decision support tools, community health information networks, telemedicine, and new ways of distributing health information to consumers are beginning to affect the cost, quality, and accessibility of health care. Changes in the health care delivery system, including the emergence of managed health care and integrated delivery systems, are breaking down the organizational barriers that have stood between care providers, insurers, medical researchers, and public health professionals. Old distinctions between clinical health information and administrative health information are gradually eroding as new health care delivery patterns emerge that are supported by, and in some cases reliant on, the widespread use of networked computers and telecommunications.

Bringing Health Care Online: *The Role of Information Technologies* discusses the synergy between information technologies and new trends in the health care delivery system as health care is brought online. It identifies some of the opportunities to improve health care delivery through increased use of information technology, and discusses some of the conceptual, organizational, and technical barriers that have made its adoption so uneven. The report identifies key technologies and shows how they are being used to communicate clinical information, simplify administration of health care delivery, assess the quality of health care, inform the decisionmaking of providers and administrators, and support delivery of health care at a distance.

OTA appreciates the assistance of the project advisory panelists, workshop participants, and contractors, as well as the many other individuals who participated in the study. OTA values their perspectives and comments; the report is, however, solely the responsibility of OTA.



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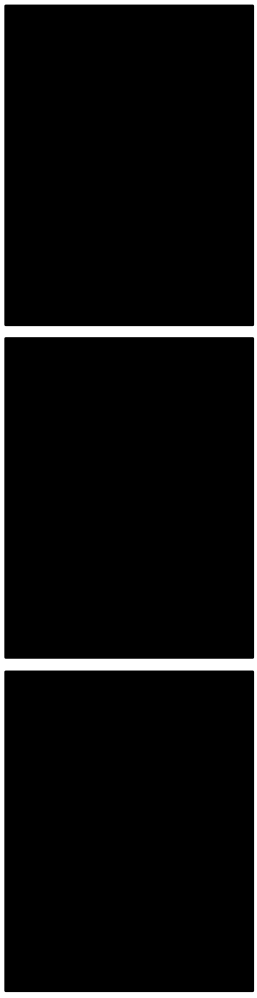
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Introduction, Summary, and Options 1

Information technologies are transforming the way health care is delivered. Innovations such as computer-based patient records, hospital information systems, computer-based decision support tools, community health information networks, telemedicine, and new ways of distributing health information to consumers are beginning to affect the cost, quality, and accessibility of health care. The technologies that support these applications—relational databases, network communications, distributed processing architectures, optical disk storage, and others—are used today by some health care providers and payers. Yet information technology is often found in isolated "islands of automation" in health care provider and payer institutions. Despite the incorporation of high technology into almost every other aspect of clinical practice, information technologies have not been fully embraced.

Meanwhile, transformations in the way health care is delivered are creating new opportunities for innovative applications of information technologies. The health care delivery system is currently undergoing many changes, including the emergence of managed health care and integrated delivery systems that are breaking down the organizational barriers that have stood between care providers, insurers, medical researchers, and public health professionals. These barriers have supported a clear demarcation between clinical health information and administrative health information and reinforced a long-standing distinction between treatment of disease and preservation of health. These distinctions are gradually eroding as new health care delivery patterns emerge that are supported by, and in some cases reliant on, the widespread use of networked computers and telecommunications.



This report discusses the synergy between information technologies and new trends in the health care delivery system as health care is brought online. It identifies some of the opportunities to improve health care delivery through increased use of information technology, and discusses some of the conceptual, organizational, and technical barriers that have made its adoption so uneven. The report identifies key technologies and shows how they are being used to communicate clinical information, simplify administration of health care delivery, assess the quality of health care, inform the decisionmaking of providers and administrators, and support delivery of health care at a distance.

CHALLENGES AND OPPORTUNITIES FOR INFORMATION TECHNOLOGIES

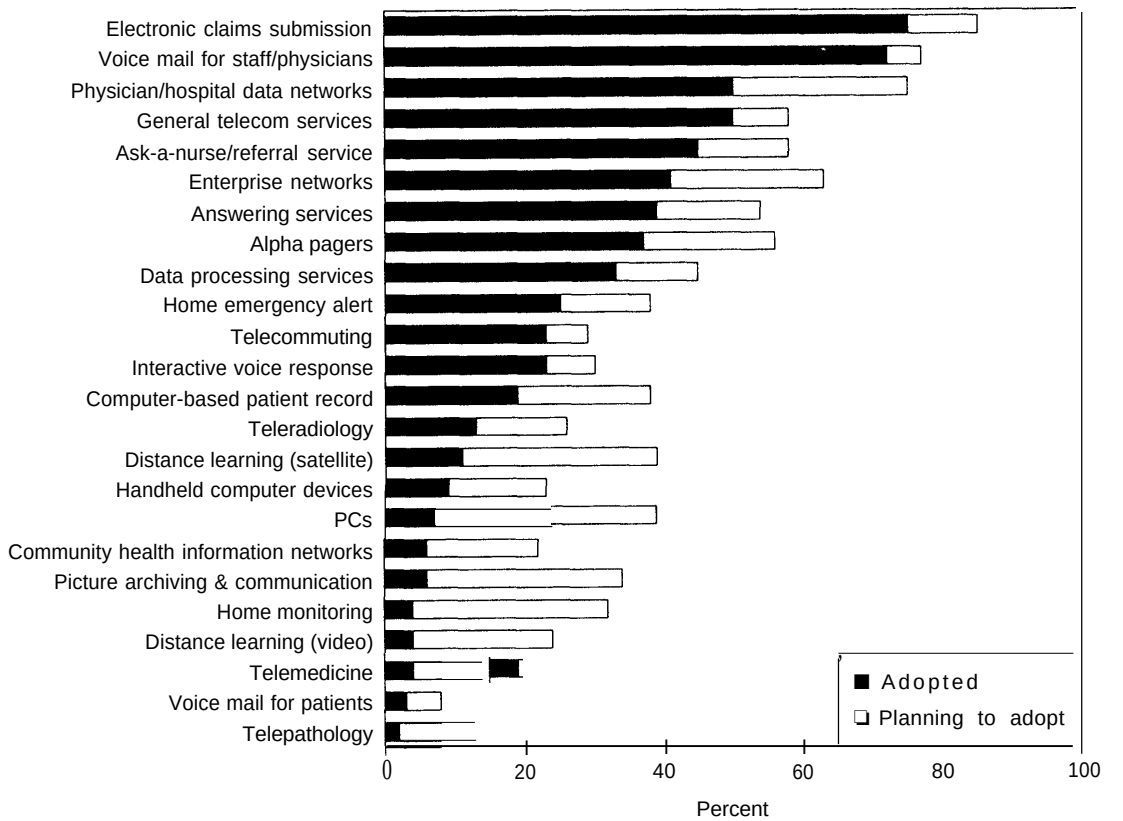
The technologies used for collecting, distilling, storing, protecting, and communicating data are widely used throughout American industry. In the health care industry, however, their application has been limited to scattered islands of automation, usually limited to discrete departments within hospitals. Computers are widely deployed, but not widely connected. Clinical and administrative health information are rarely commingled. Both types of health information are still stored and conveyed primarily in paper form. Health information is rarely converted to digital form and shared among the clinics and primary care offices where most health care occurs, the hospitals and critical care units where most health care dollars are spent, or the population-based health services that address community-wide health issues. Computers are typically used to organize and administer specific, limited types of health information, but are not linked into an infrastructure that might allow broader efficiencies or higher quality health care.

Figure 1-1 shows the level of adoption of some selected information technology applications as reported by chief information officers (CIOs) of primarily large health care institutions. As the figure indicates, almost 70 percent of those responding have introduced electronic systems for submitting insurance claims, and more are in the process of adopting them. Technologies that allow communication between computers at disparate locations, for example physician-hospital data networks or enterprise-wide networks, are being adopted or planned by a substantial number of these institutions as well. Computer-based patient record (CPR) systems, which are difficult to implement because they require such close integration between many different systems, are at least in the planning process, according to 50 percent of responding CIOs, but so far only about 20 percent consider that they have CPRs operating at least at an experimental level. When asked which technologies they were currently evaluating conceptually for future implementation, the two most frequently mentioned by CIOs were community health information networks and telemedicine.[1]

The health care delivery system has several unique characteristics that discourage the spread of information technologies. Health professionals perform a wide variety of tasks including rapidly changing combinations of "hands-on" care, inductive and diagnostic thinking, detailed record-keeping, patient education, and communication with colleagues. Most of the hardware and software approaches that address one of these aspects of medical practice intrude unacceptably on some other aspect: computers are not yet as useful, ubiquitous, and handy as the stethoscope and other common medical technologies. In addition, medical practice is extraordinarily complex and it changes rapidly. Systematizing even the process of performing medical procedures, much less rationalizing the language and scientific knowledge underlying those procedures, is an almost intractable problem. Despite the ongoing efforts of standards-setting bodies, no unified conceptual model exists that is powerful enough to construct the mapping between the information that must be

[1] College of Healthcare Information Management, *Telecommunications in Health Care Survey, 1994* (Ann Arbor, MI: 1994), pp. 20-21.

FIGURE 1-1: Information Technology Applications Currently Being Adopted



SOURCE: Center for Healthcare Management Information, *Telecommunications in Healthcare Survey,* 1994 (Ann Arbor, MI. 1994)

stored in computer databases and medicine as it is practiced. In a sense, there is not yet a consensus about what information should be kept in computer-based patient records or how it should be described, organized, and indexed.

Apart from the complexity of clinical knowledge and practice, there are structural reasons that discourage implementation of information technologies in health care settings. 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 medical practice (see box l-l). Many types of organizational changes will emerge throughout the health care system if information technologies are widely adopted. In other industries, changes associated with the introduction of information technologies have included large reductions in the demand for some types of workers (e.g., mid-level managers and bank tellers), increased responsibilities for workers in jobs that traditionally involved little decisionmaking (line workers in manufacturing industries), and an increase in

BOX 1-1: Effects on the Health Care Workforce

Increased use of information technology will continue to affect the jobs of the 10 million Americans who work in health care. This workforce is currently growing at about 3.9 percent per year. Changes in the structure of health care delivery are affecting the composition of the workforce. For example, hospital employment, while it still represents half of people employed in health care, is the slowest growing sector at 1.7 percent per year. Home health care however, is growing at about 18 percent annually, although it still accounts for only a small portion of the workforce.1

This report does not analyze the changes that information technology might bring to jobs in health care, or the effects that these changes might have on the quality of the work environment. These would be fruitful areas for future research. In general, it appears that information technology applications could reduce the need for some types of work and could redefine some job roles.

For example, electronic data Interchange (EDI), defined as the *application-to-application exchange of business documents,* is increasingly being used to carry out medical payments and other administrative transactions between health care providers and insurance payers. *Application-to-application* means that computer programs at different firms exchange information and complete transactions directly, without human intervention. Physicians' office staffs, for example, often notice a decrease in the number of telephone calls they make and letters they write after being linked with Insurers through online systems. Much of the potential savings foreseen through "administrate simplification" of the health care payments process comes from reduced personnel costs.[2] The systems currently being implemented do not totally eliminate human intervention, and within many provider and payer organizations some of the employee time saved by automated payment systems will be spent on other tasks. Nevertheless, a likely outcome of widespread use of electronic medical payments IS the elimination of some jobs in both provider and payer organizations.

(continued,)

[1] U S Department of Commerce, U.S. *Industrial Outlook, 1994* (Washington, DC: 1994), pp. 42-1 to 42-6

[2] See, for example, Workgroup on Electronic Data Interchange, 1993 *Report* (Hartford, CT and Chicago, IL October 1993), p 7-30

competition for local experts from nonlocal sources (discount stockbrokers, for instance). Similar changes are likely to occur for health professionals, along with a redistribution of status, responsibilities, and remuneration associated with the various health disciplines.

Information technologies not only redefine jobs, but they may have more subtle ramifications as well. The widespread adoption of integrated information systems will challenge the legal system. Information technologies facilitate alliances between geographically separate parties. Thus, they may challenge the existing structure of state medical licensing and malpractice laws, as well as "pen and quill" laws that require paper-based medical recordkeeping. Consolidations and mergers among the many companies offering managed health care reflect the ability of computer networks and digital telecommunications to act as a nervous system that can connect previously independent parts of the health care delivery and administrative systems, forming new bodies known as integrated delivery systems. These new corporate structures may pose antitrust questions as they challenge traditional providers of health care in isolated markets.

Information technologies diffuse decisionmaking and responsibility y because they are developed, maintained, and employed by a variety of people. Physicians—who have held unique positions of status and compensation, as well as legal responsibility and risk, under the traditional systems of licensure and malpractice law—may be put in the uncomfortable position of being solely responsi-

BOX 1-1: Effects on the Health Care Workforce (Cont'd.)

Information technology also can change job roles. For example, when physicians place medication orders at a computer terminal, they take on a data entry task that might previously have been done by a ward clerk, a pharmacist, or a pharmacy clerk. With proper design, the technology can help integrate this task with others the physician performs—retrieving information about the patient's condition, looking up the proper dosage and use of medications, or making judgments and decisions about additional tests and treatments. Whether data entry is an additional burden, or an integral part of an improved and more efficient process for rendering care, depends on a wide variety of personal, institutional, hardware, software, and interface design factors.

In some cases, role changes are induced by other organizational changes in which information technology is a facilitator. For example, one way that health care organizations are reducing costs is by redesigning work so that tasks once done by high-cost personnel are now done by lower cost personnel. For example, much primary health care previously done by physicians is now being done by *physician extenders* like physician assistants and nurse practitioners. In some hospitals, work previously done by licensed and registered nurses is now done by nursing aides—sometimes labeled *patient care technicians,*[3] while nurses take on the role of managing a team of caregivers.[4] This trend is typical of a "reengineering" movement in hospital management known as *patient-centered care* or *patient-focused care—as* opposed to department-focused care. Computer technologies—including computer-based decision support tools and treatment protocols, online patient information systems, patient monitoring devices, and teleconferencing systems—can support and assist people giving care in these new ways.

SOURCE: Office of Technology Assessment, 1995.

[3] *Wall Street Journal,* Feb. 10, 1995, p. 61.

[4] M.L. Parsons and C.L. Murdaugh, *Patient-Centered Care, A Model for Restructuring* (Gaithersburg, MD Aspen Publishers, 1994)

ble for implementing complex policies resulting from a mix of research findings, technical constraints, and business priorities. Networked information technologies may pose new challenges to the traditional legal assumption that consumers are adequately protected against poor quality of care through the ability to file lawsuits against their providers, and alternate guarantees of high-quality care may need to be designed to replace the current legal remedies.

Finally, information technologies are expensive to implement and their benefits may be difficult to directly measure, even when all parties are happy with the results. This may 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.

TRENDS IN THE HEALTH CARE SYSTEM

Aggressive Cost Management

A major concern for providers, payers, policymakers, and consumers alike is the rising costs of delivering care. Health care expenditures increased from 5.9 percent of gross domestic product in 1965 to 13.9 percent in 1993.[2] Total expenditures for health care in 1993 were $884.2 billion. Government sources pay for about 43 per-

[2] Katharine R. Levit et al., "National Health Expenditures, 1993," *Health Care Financing Review,* vol. 16, No. 1, fall 1994, pp. *247-294.*

cent of this total; the federal government alone pays nearly 32 percent. Health care is also a major segment of the economy, employing approximately 10 million people, about 2.6 million of whom do primarily administrative work.[3]

As the costs of health care have continued to rise, there have been concerns in government and in the industry itself about how to contain and reverse the increase. In the 1990s, particularly in the 103d Congress, a number of proposals were made for far-reaching reforms in the health care industry. At the same time, within the health care and insurance industries, many initiatives to control costs are already under way. In fact, perhaps due in part to these efforts, the growth rate of health care costs appears to have slowed during the 1990-93 period.

One of the major influences in the health care industry has been the growth of managed health care. "Managed care" is a somewhat nebulous term, but generally refers to a "system of managing and financing health care delivery to ensure that services provided to managed care plan members are necessary, efficiently provided, and appropriately priced."[4] Managed care organizations use a number of techniques to control access to providers, contain costs, manage utilization of resources, and ensure favorable outcomes for patients.

The number of people enrolled in managed care plans has increased dramatically in the past 20 years. By 1992, enrollment had grown to over half of all employees covered by employer group health insurance.[5] As shown in box 1-2, the concept of managed care has expanded to include many types of health plans and delivery systems. Many traditional fee-for-service health insurance plans (those that reimburse members for health care payments) are also using at least some care management techniques to manage their costs.

Integration of Health Services

Health care has historically been a very fragmented industry. Routine medical care, crisis medical care, medical insurance, medical research, and management of public health typically have been handled by entirely separate organizations in business, government, and universities, and a large number of intermediary institutions as well. There are more than 1.2 million health care providers—ranging from solo practitioners to 1,000-bed hospitals—and they are often isolated in separate corporate entities from the more than 3,000 private insurance payers that distribute payments for health care services. The providers and insurance companies 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. It is unlikely that any of these entities will be willing to collect or organize data that save money or effort for some other organization, but deliver the intermediary no immediate benefit; systemic savings may be irrelevant in a vertically fractured industry.

Some of this fragmentation may be reduced with the current trend toward vertical and horizontal integration of providers and payers into systems that offer the full "continuum of care" to covered populations. An integrated delivery system is one that brings together hospitals, primary care providers, nursing homes, home health care providers, pharmacies, and other services into a single system through purchase, merger, joint venture, contract, or other means. As hospital ad-

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[3] U.S. Congress, Office of Technology Assessment, *International Comparisons of Administrative Costs in Health Care*, OTA-BP-H-135 (Washington, DC: U.S. Government Printing Office), September 1994.

[4] Marrianne F. Fazen, *Managed Care Desk Reference* (Dallas, TX: HCS Publications, 1994), p. 149.

[5] U.S. Congress, General Accounting Office, *Managed Health Care: Effect on Employers' Costs Difficult To Measure*, GAO/HRD-94-3 (Washington, DC: U.S. Government Printing Office), October 1993.

BOX 1-2: Managed Care

Managed care can refer to both the elements of managing care and the institutional structures within which care is managed, To some, managed care means the use of management tools such as preadmission certification (for ensuring that only members who need hospital care are admitted to the hospital), concurrent review (ensuring that necessary and appropriate care is delivered during a hospitalization), or financial Incentives or penalties for both providers and plan members. To others the term is equated with alternative delivery systems that are variously known by names such as health maintenance organization (HMO) or preferred provider organization (PPO).

In contrast to traditional fee-for-service or indemnity insurance plans where the insurer simply reimburses the insured individual for incurred health expenses and has no direct relationship with the providers of care, managed care organizations create a direct relationship between the insurer and the provider of care, Whether physicians are salaried employees or contractors, they have a relationship with the managed care plan wherein they give up some clinical and financial autonomy to that organization. The consumer who *joins* a managed care plan also surrenders some freedom of choice. The HMO or PPO in turn takes on a managerial role with the hope of containing costs and enhancing the quality of care.

One concept used in certain forms of managed care is cavitation. Under capitated payment systems, providers receive a set payment per patient per period, regardless of the amount of services they provide Providers who exceed their budgets will suffer losses. A second concept common to managed care is the limitation on the patients' choice of providers. Some plans only allow patients to choose from a panel of providers associated with the plan ("closed panel"). Others permit patients greater flexibility, but require patients to pay a higher share of costs when using outside providers. While the concepts of capitation and limitations on the patient's choice originated with early HMOs, they are now pervading the whole health care industry, and many insurance plans, including traditional indemnity plans, may include these features to some degree. Some managed care organizations have tighter controls—both over payments and over patient-provider relationships; others maintain looser controls. Closed-panel HMOs are generally the most restrictive, while independent practice associations (IPAs)—HMOs where physicians work under nonexclusive contracts and may also have fee-for-service patients—are less so, as are PPOs.

Managed Care and Cost Savings

According to recent studies, care management techniques reduce health care costs, primarily through the reduced use of services. For example, the Congressional Budget Office (CBO) reports that, compared to indemnity plans, closed-panel HMOs reduce the use of medical services by about 196 percent and IPAs reduce use by about 0.8 percent. The combined average effect of all HMOs is a reduction in services of 7.8 percent when compared with the current mix of indemnity plans. [1] Less restrictive types of managed care have not shown such significant reductions, according to CBO.

SOURCE: Adapted from U.S. Congress, Office of Technology Assessment, *Understanding Estimates of National Health Expenditures Under Health Reform, OTA-H-594* (Washington DC: U.S. Government Printing Office, May 1994), p. 76

[1] U.S. Congress, Congressional Budget Office, The Effects *of Managed Care and Managed Competition* (Washington, DC Congressional Budget Office, 1995)

missions and inpatient days have declined because of cost control efforts begun in the 1980s, many hospitals have entered these other lines of business. Some integrated delivery systems are being organized by insurers or managed care organizations.

Increasing Value of Digital Information

New patterns in health care delivery are enhancing the value of clinical health data and creating incentives for collecting and disseminating health information electronically within and between organizations. As managed care organizations grow and fee-for-service care wanes, doctors and other practitioners have both a financial interest in delivering low-cost care and incentives for documenting and analyzing their care practices. Administrators in Health Maintenance Organizations (HMOs) and integrated delivery systems have long sought to reduce transaction costs (after an initial investment in equipment and software) by computerizing internal communications and automating communications with suppliers and other business partners. In addition, they have a vested interest in understanding the clinical details of how care is delivered in order to efficiently manage resources.

For example, it is possible to use administrative records alone to limit overuse of optometry services by approving eye examinations purely on the basis of elapsed time since the last exam. However, care can be more prudently and perhaps compassionately managed by considering not only the time of the last billing, but also the clinical record of that visit and other health information about the patient. Were the previous results normal, or did they indicate a problem? Does the patient have any other conditions that might warrant frequent eye examinations? Could the current complaint be due to an adverse reaction to a prescribed medication and, hence, warrant a visit to the prescribing physician rather than an optometrist? This fine-grained analysis of clinical records is contingent on standardization and digitization of clinical records because paper records are generally inadequate for these purposes.

Finally, the government has a stake in helping to develop inexpensive, standardized approaches to information exchange so it can effectively fund medical research, manage widespread public health problems, reduce its administrative costs, and reduce the cost of the health care it purchases and provides through Medicare, Medicaid, veterans' care, and employee insurance programs. An indication of the magnitude of this interest is the designation of health care applications as a key component of the National Information Infrastructure (NII) by the Administration's Information Infrastructure Task Force (IITF). Appointed by the President, the IITF is comprised of high-level representatives of the federal agencies that play a role in developing and applying information and telecommunications technologies. The IITF's Committee on Applications and Technology coordinates efforts to develop, demonstrate, and promote applications of the NII and develops and recommends technology strategy and policy to accelerate its implementation. One part of this committee is the Health Information and Applications Working Group. This group is again divided into subgroups in the categories of telemedicine, consumer health information, standards, and emergency medicine.

These private and governmental interests in digitizing health information in order to manage costs and integrate delivery of health services are manifest in a slow but perceptible trend toward standardization of health care information and optimization of care delivery. These processes are occurring on many levels. The medical and computing communities are slowly developing: a) lexicons for consistently describing medical care, b) consensus standards for exchanging medical data between computers, and c) models for how to collect and organize medical information digitally. Protocols for standardizing delivery of care and metrics for measuring the quality of health care services are being developed, as well as decision support systems that may increase the efficacy of medical decisions. And throughout the health care delivery system, innovative applications of in-

formation technologies are being studied, tested, and implemented.

CONGRESSIONAL INTEREST

Recognizing the changes occurring in both health care and telecommunication technology and their relevance to the congressional agenda, the Chairman of the Senate Committee on Labor and Human Resources asked the Office of Technology Assessment (OTA) to conduct a study on the impacts of information technology on the health care system. The request was supported by the Chairman of the House Committee on Energy and Commerce.[6]

Recently, there have been numerous legislative initiatives addressing aspects of incorporating information technologies into the delivery of health care. In the 103d Congress, several comprehensive health care reform bills were introduced,[7] and this pattern has continued in the 104th Congress. These bills seek to restructure various aspects of the payment and insurance framework of the health care industry, but, in addition, they often specify procedures for simplifying administration of health care delivery through the use of information technologies. For example, several recent bills direct the Secretary of the Department of Health and Human Services (DHHS) to adopt uniform standards for various medical data, based on the work of standards committees accredited by the American National Standards Institute and on the advice of groups such as the Workgroup for Electronic Data Interchange and the Computer-Based Patient Records Institute.[8]

The bills call for standards for:

1. defining common sets of data elements to be stored electronically in patient records,
2. performing administrative transactions,
3. assigning uniform patient and provider identification numbers,
4. assigning codes to medical procedures and descriptions,
5. applying electronic signatures, and
6. ensuring patient privacy and data security.

Most bills specify the adoption of the standards by DHHS within two years or less, and, following the adoption, provide various measures designed to encourage rapid adoption of the standards by nearly all health care providers. These measures may include direct incentives, such as requirements that all health plans implement the standards for all transactions, or indirect incentives, such as requirements that all transactions regarding Medicare patients be filed electronically. The incentives may also be provisional: they may direct the Secretary to assess whether sufficient numbers of health plans are utilizing the standards and to require full participation, should it prove to be cost-effective. Most bills include exceptions for small hospitals and those that can show they are in the process of installing an adequate information system. Some of the bills override state laws requiring the maintenance of paper-based patient records.

Several bills seek to establish national or state databases of health information for quality assessment purposes, control of fraud, or tracking disease patterns.[9] Other bills would authorize grants

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[6] This committee is now known as the House Committee on Commerce.

[7] Two examples are U.S. Congress, Senate, S. 1757, *Health Security Act*, and S. 1494, *Health Care Information Modernization and Security Act of 1994* (Washington, DC: U.S. Government Printing Office, 1994).

[8] U.S. Congress, House of Representatives, H.R. 1200, *American Health Security Act of 1995* and H.R. 1234, *Basic Health Care Reform Act of 1995* (Washington, DC: U.S. Government Printing Office, 1995); and U.S. Congress, Senate, S. 7, *Family Health Insurance Protection Act* (Washington, DC: U.S. Government Printing Office, 1995).

[9] U.S. Congress, House of Representatives, H.R. 798, *Veterans' Benefits, Title 38 U.S.C., Amendment* (Washington, DC: U.S. Government Printing Office, 1995), and H.R. 1200 and S. 7, ibid.

for rural telemedicine efforts[10] or establish a telemedicine commission to formulate plans for widespread implementation of telemedicine.[11]

Finally, there have been efforts in both the 103d and 104th Congresses to reform and deregulate telecommunications.[12] Such reforms may affect the price of telecommunications services and, therefore, help determine the feasibility of incorporating telecommunications into health care delivery on a large scale. In addition, current bills have certain direct influences on health care, including a requirement that prices for telecommunications service to rural health care providers be comparable to those for urban providers.[13]

REPORT SUMMARY

Scope of the Analysis

In chapters 2 through 5, this report discusses some of the challenges and opportunities for using information technology to improve the health care system. First, it addresses the potential impact of information technologies on health care delivery and introduces a variety of technologies that are being used to collect, organize, and share clinical information needed for providing patient care. The report then explores the exchange of health information for administrative purposes among the many stakeholders including providers, payers, employers, consumers, and government agencies. It discusses how the quality of health care might be improved by providing health care professionals with high-quality information and decision support tools at the point of care. Finally, the report explores the potential for addressing the needs of those in rural or other underserved areas through telemedicine.

Advanced information technologies offer an array of other possibilities for influencing delivery of health care services. It was impossible to address all applications in this report. Those selected were viewed as having the most potential for decreasing costs and improving quality and access in health care. Particular emphasis is placed on administrative simplification, quality assessment, and telemedicine, as specified by the congressional committee requesting the report. The report also briefly mentions the potential for telecommunications to assist consumers in becoming better informed and more involved in decisions affecting their health care, and points to the need for additional study. Emerging applications of information technology, including remote surgery and virtual reality applications, were not considered, nor were issues related to the reform of medical education to include greater use of information technology. These are, however, fertile areas for future research.

Before computers were introduced into the health care delivery system, clinical and administrative records were kept separately in paper form, patient utilization of services was rarely scrutinized systematically, and clinical information was seldom exchanged between business organizations (or even among the various clinicians an individual might see). Thus, paper-based technologies and common organizational policies worked along with various state laws to provide an ad hoc level of protection for individual privacy that is clearly inadequate in the emerging world of com-

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[10] U.S. Congress, House of Representatives, H.R. 851, *Rural Telemedicine Act of 1995* (Washington, DC: U.S. Government Printing Office, 1995), and U.S. Congress, Senate, S. 7, op. cit., footnote 8.

[11] U.S. Congress, House of Representatives, H.R. 426, *National Committee on Telemedicine Act* (Washington, DC: U.S. Government Printing Office, 1995).

[12] U.S. Congress, House of Representatives, H.R. 3626, *Antitrust and Communications Reform Act of 1994; Antitrust Reform Act of 1994* (Washington, DC: U.S. Government Printing Office, 1994), and U.S. Congress, Senate, S. 1822, *Communications Act of 1994; Telecommunications Equipment Research and Manufacturing Competition Act of 1994*, and S. 2111, *Telecommunications Services Enhancement Act of 1994* (Washington, DC: U.S. Government Printing Office, 1994).

[13] U.S. Congress, Senate, S. 652, *Telecommunications Competition and Deregulation Act of 1995* (Washington, DC: U.S. Government Printing Office, 1995).

puterized patient records, integrated delivery services that operate on a nationwide basis, and instant electronic messaging. New combinations of legislative protections and technical safeguards will be necessary to protect individual privacy as health care information is computerized and standardized. These issues are discussed briefly throughout this report, but were discussed in detail in the OTA report *Protecting Privacy in Computerized Medical Information*.[14]

The issues and policy options that emerge from each chapter of this report are briefly summarized in the sections that follow. First, however, two key themes are introduced that echo throughout the chapters. These are *cost containment* and *standards development*, and they reflect congressional concerns about containing health care costs and enabling administrative simplification that are manifest in the bills of the 103d and 104th Congresses.

Cost Containment

Reducing the cost of delivering health care is perhaps the prime motivation for congressional interest in exploring the use of information technology. Anticipated cost savings are based on analogous reductions in transaction costs for industries such as banking—which built information infrastructures supporting automated teller machines and point-of-purchase credit card verification—and on the increase in productivity and product quality in domestic manufacturing industries associated with just-in-time inventory control, continuous quality improvement, and other techniques that are highly dependent on information technologies. Although similar efficiencies and improvements may be possible within the health care system, the magnitude of the savings is very difficult to predict for several reasons.

Most cost containment predictions maintain the traditional fault line between administrative information and clinical information. Administrative processes include activities such as transmitting and processing claims, utilization review, purchasing supplies and tracking inventory, paying bills, managing internal finances, negotiating contracts, complying with regulations, and controlling quality. Administrative costs of providing health care have been estimated at between $108 billion and $135.1 billion per year in 1991,[15] or between 12 and 15 percent of the health care bill. Estimates of annual savings that could be realized through increased use of information technology in administrative functions have ranged from $5 billion to $36 billion,[16] or enough to reduce administrative costs between 0.5 and 3.6 percent.

These estimates, discussed in more detail in chapter 3, may be somewhat optimistic because they assume rapid adoption of electronic data interchange and high rates of market penetration that do not appear to be materializing. The deeper problem with such predictions is that they are often based on merely converting all transactions within the existing system of fee-for-service health care to electronic form. However, the shifting landscape of health care delivery patterns cannot be treated as a perturbation within a more rapid process of digitizing health information. Such digitization did not happen over the past two decades despite the availability of increasingly capable computer and telecommunication systems; indeed, several organizational and technological impediments (discussed in chapter 2) make it likely that widespread digitization will happen only in

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[14] 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).

[15] Allen Doubloon and Matthew Bergheiser, "Reducing Administrative Costs in a Pluralistic Delivery System Through Automation," prepared by Lewin-VHI for the Healthcare Financial Management Association, Apr. 30, 1993.

[16] Project HOPE, Center for Health Affairs, "Estimating the Cost-Effectiveness of Selected Information Technology Applications," unpublished contractor report prepared for the Office of Technology Assessment, March 1995.

synergy with the progressive adoption of managed health care practices and development of integrated service delivery systems.

A second class of economic considerations concerns the effectiveness of encouraging specific information technology implementations. These are of concern to Congress for purposes of guiding procurement decisions and research priorities. In recent years, the field of economic evaluation of medical technologies has expanded rapidly. Rising spending on health care has stimulated the use of formal techniques such as *cost-effectiveness analysis* and *cost-benefit analysis* to assess the cost and health effects of using particular medical technologies.

Cost-effectiveness analysis (CEA) has emerged as the most popular technique for economic evaluations. CEA involves a structured, comparative evaluation of two or more health care interventions. Analyses are designed to show the relationship between resources used (costs) and health benefits achieved (effects) for given technologies or programs. In CEA, the cost per specified health effect, such as lives saved or quality-adjusted life-years saved, is calculated for particular technologies or programs. If the ratio is measured similarly for different technologies or programs, the cost per effect can be compared. Formal CEA involves a number of explicit steps, including:

1. identifying the perspective of the study,
2. identifying the competing interventions,
3. defining costs,
4. defining effects,
5. discounting future costs and effects to their present value,
6. adjusting for quality-of-life factors,
7. analyzing the incremental costs and consequences of one option over another, and
8. examining uncertainties underlying the analysis.

In cost-benefit analysis (CBA), the net costs of an intervention are compared with the net savings: the benefits of a program or technology are expressed entirely in monetary terms. Because the benefit of medical technology generally involves health effects such as life-years saved, CBA requires that these effects be valued in monetary terms. One of two techniques—the *human capital approach* or the *willingness-to-pay approach*—is generally used to measure benefits. The human capital approach considers the value of a human life by estimating an individual's projected future earnings. The willingness-to-pay approach considers how much individuals are willing to pay for a reduction in the risk of death or illness.

Applying the formal techniques of CEA and CBA to information technology applications in health care is difficult for a number of reasons. Some of the difficulties are general to all medical technologies: the competing alternatives for a technology are not always known; a technology may be cost-effective in some patient groups and not in others; technologies constantly undergo change; there are no standards on how to define costs (e.g., whether and how to consider indirect costs such as productivity losses, or intangible costs such as pain and suffering); there are no standards regarding the length of patient followup time to consider; analysts differ in their use of methodologies by which to adjust health effects for quality-of-life factors; and there are many uncertainties underlying such analyses. A general problem with CBA involves trying to place a monetary value on reductions in mortality or morbidity.

Beyond these general difficulties, evaluating information technologies presents some unique problems. It is difficult to conduct comparative studies because system features and levels of service vary widely across institutions and users. In addition, many applications have been in existence only a short time. Information technologies and applications change frequently, making analyses difficult—and making even some well-conducted analyses quickly obsolete. In general, it is difficult to identify and quantify appropriate costs, savings, and health effects. For most evaluations of information technology, direct costs would include equipment and operating costs, the value of the technician's time, and the cost of maintaining equipment. However, it is hard to accurately identify and quantify indirect costs such

as productivity gains or losses. In general, it is very difficult to tie the use of information technologies to health consequences.

As a result of these limitations, most existing economic evaluations do not constitute formal cost-effectiveness or cost-benefit analyses. Instead, most have attempted to estimate savings in terms of productivity gains to the system. Some have also speculated about how various applications will ultimately influence patient care. The design and scope of such analyses vary widely across studies, as does the level of rigor.

Congressional Options

Recognizing that implementation of information technologies will bean incremental process, Congress may wish to attempt to evaluate the possible systemic savings associated with implementation of information technologies in a way that recognizes the shifting patterns of health care delivery. Alternatively, Congress could evaluate, for administrative purposes, the costs and benefits of implementing various specific technologies or sets of technologies. These are difficult challenges. However, should Congress wish to pursue such analyses, it could direct agencies or congressional support services to implement one or more of the following options:

OPTION 1: *Analyze systemic savings that might be associated with implementation of information technologies and related changes in health care delivery systems using realistic estimates for the pace of implementation.*

OPTION 2: *Conduct or fund research to evaluate the costs and effectiveness of individual information technologies, such as order-entry systems, clinical protocols, and electronic interchange of claim and payment information.*

OPTION 3: *Evaluate the potential for synergies between information technologies by funding research in the implementation of multiple simultaneous applications in test and control facilities.*

OPTION 4: *Establish baseline data for the costs of current information structures in the health care delivery system so that future implementations can be objectively evaluated.*

Given these possibilities for cost-benefit analyses and systemic cost analyses, it should be noted that some stakeholders who contributed to this assessment indicated that *rigorous cost-benefit or cost-effectiveness analyses would not play a major role in their decisions to implement information technologies.* Rather, these technologies and systems of technologies were considered by many stakeholders to be as fundamental and as immune to cost-benefit analysis as the telephone: adoption of the technologies would be necessary to remain competitive in the health care industry.

■ Standards Development

The second major theme that recurs throughout this report is the central role of standards development for systematizing the compilation and exchange of health care information. One value of digitized health information is that it can be manipulated quickly and accurately by computers without human intervention. The accuracy, speed, and cost of machine-processing are adversely affected by novelty, diversity, and frequent changes in the rules. Until standards are in place and compliance is widespread, costly activities—such as maintaining multiple formats for health care information, dealing with exceptions, and developing new interface software as new proprietary approaches to managing health information become fashionable—will continue to offset some potential savings of processing health care records and transactions electronically.

Standards development is an ongoing process. A number of organizations are working on standards for the content and format of electronic health information. Standards for the format of billing and core insurance transactions are well developed, and the Health Care Financing Administration (HCFA) has adopted some of them. Another area of standardization that could facilitate electronic transactions is a system of unique

identifiers for individuals, providers, and sites of care. At present, each provider uses its own numbering system, which can create confusion when health information is exchanged between different institutions.

The development of technical standards is primarily a private-sector activity. However, it could be accelerated through federal participation in developing standards that would encourage information exchange and protect the privacy of participants in the health care system, and through expeditious implementation of such standards in all federal health care matters as a catalyst for their adoption by the private sector. This should not be construed as a call for federal agencies to independently establish standards for implementing information technologies—such efforts would almost certainly fail to meet the needs of various stakeholders. Rather, federal agency participation in existing standards activities would preempt duplicative development of federal regulations and requirements. Further discussion of standards appears in individual chapters of this report.

Information Technologies for Transforming Health Care

The potential for new computing and telecommunications technologies to reduce the cost of delivering health care, while facilitating broad structural changes in the health care industry, may presage a rapid expansion in the application of information technologies to the health care system. Chapter 2 charts the technological and organizational factors that will help guide the path of that expansion should it occur.

Policy Issues

Many of the practical frustrations encountered by participants in the health care system can be traced to the inability of current information systems to provide accurate, timely information where it is needed in the health care process. Poor information mobility has become an impediment to efficient delivery of high-quality health care. This impediment becomes more prominent, expensive, and problematic for health care delivery organizations as they grow larger and more complex. One approach to solving this problem is to liberate health information from its traditional paper medium by creating, transmitting, and processing it through more flexible electronic means. Electronic information can be used again and again, in different forms for different purposes. It can be reformatted easily and transmitted cheaply once the infrastructure to do so is in place.

Chapter 2 identifies the broad currents of information flowing within the health care system, and then describes various approaches to computerizing clinical information within hospital and ambulatory care units. One portion of this clinical information is the patient's medical record, which has conventionally been kept as a thick folder of paper forms and films. The chapter describes the design of paper recordkeeping systems and the reasons they are inadequate for documenting care in an integrated health care delivery organization. It discusses ways that this information might be digitized and then disseminated (with appropriate security measures) through standardized communications protocols.

A diverse suite of key computer and communication technologies supports the digitization and dissemination of clinical records. The chapter describes technologies for: a) capturing data as it is generated by caregivers and the machines they use to monitor and treat the patient; b) compressing, storing, securing, and retrieving data; c) networking and telecommunications technologies sharing information; and d) refining data and comparing data streams so computers can support medical decisionmaking. Insight and wisdom must somehow be culled from an overwhelming flood of bits and bytes.

This suite of advanced information technologies is also the context for discussions in subsequent chapters of the report that address administrative health data management, quality assessment and decision support, and delivering health care services and information at a distance.

Congressional Options

Many of these core technologies have been developed by the private sector for nonmedical pur-

poses and will be adopted within the health care system as needed. Nonetheless, Congress may wish to consider certain policy options that could encourage harmony in how that adoption proceeds.

OPTION 1: *Support standards-setting activities.*

Congress could direct relevant agencies to supply personnel to actively participate in standards-setting meetings. This would proactively obviate any federal regulatory activity that might be at odds with consensus standards by making sure that government interests are represented within the standards-setting process. Congress could also provide financial support for the process, including funding research support to help resolve any technological roadblocks that impede standards development. Congress could also direct federal agencies to set aggressive schedules for implementation of consensus standards in their own health care delivery and administrative activities as a catalyst for similar private-sector action.

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

These efforts could include research into human-computer interface technologies for use in health care settings and research into large-scale, open architecture implementations of information technologies in health care settings.

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

The agencies or committees charged with this coordination could:

1. establish procedures for expediting approval and distribution of medical software;
2. establish mechanisms (or support similar private-sector efforts) for reviewing and disseminating clinical protocols;
   advise Congress on specific needs of the medical, technical, and consumer communities with respect to legislation establishing regulations and policies pertinent to information technologies; and
- set national standards for patient and institutional identification numbers and security procedures to be used with patient records.

Networks for Health Administration

Chapter 3 explores the exchange of health information among the many stakeholders—providers, payers, employers, consumers, and government agencies—particularly for administrative purposes.

Policy Issues

As part of a larger effort to reduce costs, improve quality of care, and improve access to health care, efforts to effect administrative efficiency through greater use of electronic commerce in health care are an important component. Today, about 75 percent of hospital claims are submitted electronically, the vast majority of these being Medicare claims submitted to HCFA. Physicians submit some 47 percent of their Medicare claims electronically, but only about 16 percent of total claims.[17] Between some payers and providers, the process of billing and being paid has been totally automated, with the organizations exchanging electronic claims, remittance advice (documents that explain how much of the claim is paid), and electronic funds transfers. However, such levels of automation are still unusual. Electronic claim services help providers deal with the multitude of different formats and requirements of payers. They offer software and services for translating and reformatting claims and other electronic transactions among the 400 or so different systems in use.

Compared with a paper-based system, it appears that electronic information reduces costs for some users. Most of the estimates for savings re-

[17] "Automated Medical Payments Statistical Overview," *Automated Medical Payments News,* Feb. 8, 1993, p. 3.

sulting from the use of information technology are based on cost reductions in payer-provider transactions resulting from automation in a fee-for-service environment. Managed care organizations can have equivalent transactions that presumably will cost less using information technology. However, the major savings that are expected to accrue from managed care come from better management of both resources and patient and clinician behavior—for example, reduction of unnecessary services. Information technology should assist in this as well. For example, having up-to-date patient records available at the point of service should reduce duplicate testing or the provision of nonallowed treatments. While it has been argued that information technology fosters better management, actual evidence of its contributions to cost reduction in this area is difficult to find.

Community health information networks (CHINs) facilitate exchanges of clinical or administrative data among providers and payers in a particular community or region. CHINs can help offset the lack of standardization by providing translations and interfaces between incompatible computer systems used by different network subscribers. Some networks, often called CHMISs (Community Health Management Information Systems), may also maintain a repository of administrative information for use in performing outcome research and quality assessments of providers and insurance plans in the community. At this point it is not clear whether community networks, which offer service to competing providers in the community, will survive as more vertically integrated health care organizations build proprietary information networks.

While exchanging health information electronically offers advantages, it also raises fears that privacy and confidentiality of health information may not be protected. Many consumers already fear that too many people have access to their health information. Most information needed for health care administrative transactions comes ultimately from the patient record. Clinical information in coded, abstracted form becomes administrative information. The provider attempts to capture, either through manual or automated means, everything that is done for the patient during a stay or visit, and to document information about resource utilization and costs in order to prepare an appropriate bill. Electronic patient records are under development in many locations throughout the country. In addition to technological and organizational barriers, there are a number of regulatory and legal barriers to complete implementation of electronic patient records, including conflicting state laws and regulations about how patient records must be maintained and the way privacy and confidentiality of records should be protected.

Health information is not limited to the patient record. Rights of patient access and procedures for protection of privacy and confidentiality are not clearly defined for secondary and tertiary users of health information (e.g., payers, researchers, and organizations maintaining health data repositories) under federal or most state laws. While most health care is local, in that people usually see caregivers in their own communities, health information often needs to cross state lines because the payer, provider, patient, and/or employer may be in different states.

Congressional Options

Savings may be available to the health care system as a whole as a result of universal implementation of electronic medical payments. However, at current implementation rates, universal compliance may not be achieved for some time, if ever. Getting started with electronic commerce requires a solid organizational commitment and a significant investment in equipment, software, process redesign, and education, but some organizations have weak financial incentives to make the investments needed to institute electronic payments. Others are forging ahead, unwilling to wait for standards. The health care industry in the United States is not organized as a "system" with a central focus or consensus on how to deal with system-wide problems. The different parts of the fragmented system have diverse incentives, and efforts by participants to control costs in their own area can tend to increase costs elsewhere. However, these shifted costs are so subtle and spread

over so many participants in a complex system that they are difficult to quantify.

The federal government has provided some leadership in helping the health care industry move toward greater use of electronic information, and may wish to continue this leadership role. There are three major areas in which government action might be considered: 1) providing leadership in the adoption of standards for electronic medical payments and other transactions and exchanges of health information; 2) establishing a system of unique identifiers for people, providers, and payers; and 3) establishing a more consistent regulatory environment for interstate exchanges of health information.

OPTION 1: *Continue to influence the standardization of health care information primarily through the federal government role as a major insurer.*

The Health Care Financing Administration's (HCFA's) adoption of claims submission standards, along with incentives such as faster payment of electronic claims, has already been instrumental in encouraging some payers and providers to begin use of electronic payment systems.

OPTION 2: *Require the adoption of industry-developed standards for core electronic transactions, including minimum and maximum data sets, and set timetables for their implementation.*

If it is believed that HCFA's influence alone will not ensure high enough levels of participation in a standardized electronic health payment system, then a more active federal role may be considered. A corollary to this option may be:

OPTION 3: *Charge a government agency with responsibility and authority to set standards and data definitions for administrative transactions in consultation with industry groups, and to manage changes to standards over time; alternatively create an agency or commission for this purpose.*

OPTION 4: *Establish a system of unique identifiers for patients, providers, and sites of care.*

A national system of electronic commerce for health information will operate more smoothly if there is a better system for uniquely identifying participants in that system, both to prevent duplication and loss of information and to facilitate coordination of benefits when multiple providers and payers are involved in a patient's care. Because of its national reach, the federal government may be in the best position to establish systems of identifiers.

In order to create a consistent legal and regulatory environment for electronic health information, Congress may wish to consider the following options:

OPTION 5: *Encourage the passage of uniform state legislation with regard to privacy and confidentiality allowable storage media, and standards for health information.*

A number of industry groups have been working with state governments to encourage adoption of uniform legislation, and the Department of Health and Human Services has been assigned the lead role in designing model state privacy laws. An alternative or supplement to this option may be:

OPTION 6: *Establish federal legislation and regulation regarding privacy and confidentiality of medical information, storage media for patient records, and standards for storage and transmission of medical information.*

Additional federal legislation may be necessary as a framework for state legislation, or to replace state laws, if the process of revising legislation on a state-by-state basis is seen as ineffective or too time-consuming.

OPTION 7: *Charge a government agency with responsibility to oversee the protection of health care data; provide ongoing review of privacy issues; keep abreast of developments in technology security measures, and information flow; and advise Congress about privacy matters in the area of health care information.*

Because of the importance of privacy and confidentiality to the public, the continually changing uses for health information, and the constantly changing nature of threats to privacy and confidentiality, it may be necessary to establish one organization as an ongoing locus of responsibility.

Improving the Quality of Health Care

Chapter 4 finds that advanced information technologies—computer-based patient records, structured data entry, advanced human-computer interface technologies, portable computers, automated data capture, online query, knowledge-based information systems, and computer networks—can potentially improve the quality of health care by enhancing clinical decision support, and by improving data for assessing both the effectiveness of health services and the performance of health care providers and insurance plans.

Information technologies could facilitate faster and easier collection of information about the patient and the health problem at hand. Portions of that information could be entered by clinicians at or near the point of care, captured directly from diagnostic and monitoring equipment, or entered by the patient prior to care. Technologies such as relational databases with online query could support faster and easier search and retrieval of previously collected information about the patient, as well as information from local or remote knowledge bases. Development of computer-based clinical protocols and other forms of clinical decision support systems (CDSSs) that apply decision rules and other knowledge-based approaches to information about the patient and health problem at hand could recommend diagnoses, tests, treatments, and preventive care. They could also lead to more rigorous construction and analysis of measures of service effectiveness and performance of providers and plans. Computer networks, high capacity telecommunications, advanced human-computer interface technologies, and improved graphics software could lead to more flexible organization and display of this information as appropriate for individual clinicians, and more rapid and widespread dissemination of the results of performance measures to various parties.

Empirical evidence demonstrating the ability of these technologies to achieve these goals is limited, mixed, or incomplete. Moreover, concerns have been raised about possible adverse effects on the quality of health care arising from these technologies, including:

1. incorrect parameters or criteria, or omitted or altered steps, in CDSSs that could lead to inappropriate care;
2. excessive reliance on monitoring equipment and CDSSs, which could undermine the ability of clinicians to exercise professional judgment in nonroutine cases and reduce the interpersonal aspects of patient care (the "quality of caring"); and
3. the temptation to use readily available administrative data for assessing the effectiveness of specific health services or the performance of providers or insurance plans.

If the data are incomplete or inaccurate, the results could be misleading.

Policy Issues

The private sector has been largely responsible for the development and application of information technologies in clinical decision support and performance assessment of health care providers and insurance plans. The federal government's role has mainly involved:

1. developing information systems and performance measures for its own health insurance and health care delivery programs, most notably Medicare;
2. funding of intramural and extramural research and demonstration projects; and
3. participating in voluntary standards-setting activities with private-sector organizations.

All of these activities in both the private and public sectors are likely to continue, with some increasing and others decreasing. In an era of budgetary and regulatory restraints, however, major new government initiatives, such as funding for

technology development or mandated regulation of clinical information systems, are unlikely. It can be argued that this is appropriate—in other words, that the federal government should not interfere in private market decisions regarding the selection of new technologies or their applications.

On the other hand, the federal government—specifically HCFA—is responsible for ensuring tight the quality of health care rendered to Medicare and Medicaid beneficiaries.[18] Recent efforts to move more beneficiaries into managed care have underscored quality concerns, given the expectation that cavitation creates an incentive for underservice. [19] Several policy issues regarding the potential impact of information technology on the quality of care delivered to Medicare and Medicaid beneficiaries deserve the attention of federal policymakers.

The foremost issue is the extent to which clinical information systems actually change clinical practice patterns and patient outcomes, and whether those changes are beneficial to providers and patients. Empirical research on this issue remains limited, mixed, or incomplete, and more solid evidence regarding these impacts needs to be obtained. To pursue such research, Congress could consider the following options.

Congressional Options

OPTION 1a: *Maintain or increase funding for intramural research and extramural grants and contracts to private-sector organizations for research and demonstration projects designed to:*

- develop and test the reliability and validity of various methods of measuring and assessing (with risk adjustment) the performance of providers and health plans;
- develop, implement, and evaluate specific systems of risk-adjusted performance indicators;
- evaluate the effectiveness and safety of clinical information systems, including CDSSs.

OPTION 1b: *Maintain or increase funding for HCFA to develop and evaluate performance assessment methods and systems suitable for Medicare and Medicaid enrollees, using intramural research and extramural grants and contracts to private sector organizations for research and demonstration projects as needed.*

OPTION 1c: *Assign the task of coordinating the development and evaluation of performance assessment methods and systems and clinical information systems to a single federal agency.*

OPTION 1d: *Reduce funding for development and evaluation of performance assessment methods and systems and clinical information systems, and direct HCFA to employ performance assessment methods and systems developed and evaluated in the private sector with minimal adaptation.*

Until more solid evidence is available regarding the effectiveness and safety of existing clinical information systems and the reliability and validity of performance assessment systems, more drastic action—such as mandating the testing and certification of ail such systems—is probably not justified. Legal questions regarding who should be held liable in situations in which such systems lead clinicians to make decisions that harm patients are probably best left to the courts to resolve.

Assuming that clinical information systems are found to be effective and safe in terms of their impacts on practice patterns and patient outcomes, the next set of issues focuses on the most efficient means of developing and implementing those systems.

One issue regarding government involvement in the development of standards and technology concerns the classification and coding of health services. Many major payers currently employ

[18] The state governments share responsibility for the Medicaid Program with the federal government.

[19] Given a fixed payment per plan member, providers may be tempted to minimize the volume and/or intensity of services rendered for each patient.

two separate systems for coding health services: ICD-9-CM [20] for billing by inpatient hospitals and other institutional providers, and CPT-4[21] for "professional" billing by clinicians and other non-institutional providers and suppliers.

For payment and other purposes, services rendered by a clinician in an inpatient setting must be coded using both of these systems, creating additional costs for providers. For many services, however, the codes in ICD-9-CM cannot be equated ("crosswalked") with those in CPT-4 because of substantial structural differences between the two coding systems. Moreover, both ICD-9-CM (Vol. 3) and CPT-4 have serious technical limitations, such as overlapping and duplicative codes and inconsistent and noncurrent use of terminology. Most importantly, neither has adequate room for expansion, so both are running out of codes as new services are created or different uses of existing services are distinguished. In addition, neither system provides sufficient clinical detail to support the creation of the kinds of databases required to accurately assess patient outcomes using advanced information technologies.

Citing these and other problems, the National Committee on Vital and Health Statistics, an advisory body to the Secretary of Health and Human Services, has recommended developing a unified classification and coding system for health care services. [22] However, in 1994, even HCFA reaffirmed its intention to continue this dual coding system policy in its Medicare and Medicaid programs, despite the substantial barriers this poses to efficient information processing and analysis.

OPTION 2a: *Provide additional funding for intramural and extramural research on the feasibility of developing a single classification and coding system that could be applied to all health care services performed by all providers in all settings.*

OPTION 2b: *Establish a new executive branch program to develop a unified service classification and coding system.*

OPTION 2c: *Once a unified service classification and coding system is developed, mandate that all federa/ agencies that manage health insurance and health care delivery programs use that system in those programs.*

OPTION 2d: *Provide minimal funding for monitoring and facilitating private sector development of a unified service classification and coding system.*

■ Telemedicine: Remote Access to Health Services and Information

Telemedicine can be broadly defined as the use of information technology to deliver medical services and information from one location to another. The use of telecommunications to deliver health care services and exchange information is not new. Chapter 5 discusses how recent technological advances—such as fiber optics, integrated services digital networks, and compressed video —have eliminated or minimized some of the problems (e.g., poor quality images and slow transmission speeds) that limited earlier applications.

Currently, there is much interest in the potential of telemedicine to lower costs, improve quality, and increase access to health care, especially for those who live in remote or underserved areas. Pilot tests are also under way to test the feasibility of delivering a variety of services directly to consumers in their homes.

[20] Practice Management Information Corp., International Classification of Diseases, 9th Revision, Clinical Modification, Fourth Edition, 1993 (Los Angeles, CA: 1993).

[21] American Medical Association, Physicians' Curreny Procedural Terminology, 1994 (Chicago, IL: September 1993).

[22] U.S. Department of Health and Human Services, Public Health Service, National Committee on Vital and Health Statistics, The National Committee on Vital and Health Statistics, 1993 (Washington, DC: May 1994), pp. 8-10,54-75.

Although there are no studies that prove the cost-effectiveness of telemedicine, in some cases it would seem to have the potential to reduce costs for some participants. For example, telemedicine can eliminate the time and wages lost at work and traveling expenses incurred when specialists and/or patients have to travel for consultations. In addition, keeping patients in their own communities can increase revenues for local hospitals and decrease the cost to patients. The cost of a bed in a community hospital is considerably less than in a large medical center. Costs might also be reduced by staffing hospitals and clinics with allied health professionals, such as nurse practitioners and physician assistants, who would deliver services where there is no resident physician. Overall costs also could be lower using telemedicine if it allows patients to be seen earlier, thus preventing the need for later, more costly care. Using telecommunications to deliver services directly to the home would also reduce the costs of travel, as well as the pressures on clinics, emergency rooms, and doctors' offices.

In the short term, however, costs could increase. Telemedicine could add an extra step to the process if the patient still requires referral to a larger medical center. If it improves access to care, there may be increased use of health services as more people take advantage of their availability. If reimbursement for telemedicine services becomes widespread, the system may be vulnerable to abuse through overuse or fraudulent claims. Cost is not the only criterion, however. It is important to consider the "value" of delivering services to those who might otherwise not get them at all because of their physical location.

Telemedicine can increase access to health care for populations in rural or inner city areas. It can do so by making these areas more attractive to health care providers by giving them immediate electronic access to up-to-date information and resources, specialists for consultative purposes, continuing medical education, and other colleagues. Enabling local hospitals to remain economically viable by keeping patients in their own communities is another benefit for access, as well as for the economic stability of the community.

Telemedicine appears to have the potential to improve the quality of care, but this has not yet been proven. It can provide faster, more convenient treatment and minimize the disruption of the patient's life. By reducing the need for referrals, the continuity of patient care is ensured. The quality of care may be better for a patient who has the benefit of family support in the local area. For providers, ready access to information to help them make more informed decisions will improve the quality of the care they deliver. Electronic access will help them stay up to date and enable them to receive continuing medical education credits without leaving their communities. Some believe that the establishment of clinical practice guidelines for telemedicine could help to provide a more consistent level of care.

While telemedicine has been practiced for 30 years, its current iteration is still in the early stages of development. It will take a number of years before it is used widely enough and evaluated sufficiently in terms of its effectiveness and efficiency for definitive statements to be made about its overall value and recommended uses. Like all new technologies, there will be impacts that cannot be anticipated in advance. Rigorous evaluation studies are needed to determine telemedicine's potential benefits, and such research is currently being supported by a number of federal agencies. The results should provide policymakers with the data they need to make decisions about the efficacy of telemedicine. Proposed federal budget cuts, however, are likely to have a negative impact on telemedicine research efforts.

Policy Issues

While the use of telecommunications in delivering health services has great potential, it also raises a number of issues that need to be resolved if telemedicine is to thrive. In general, patient consultations using telemedicine are not reimbursable (except for teleradiology and telepathology). This will have a negative effect on its diffusion until HCFA promulgates a national policy. One of the reasons for HCFA's reluctance is the fact that there is a lack of research available to support the

safety, efficacy, clinical utility, and cost-effectiveness of telemedicine.

Another issue is the cost of the telecommunications links required for telemedicine. In many rural areas, the communication infrastructure is unable to support the bandwidth necessary to carry the signals for telemedicine using two-way interactive video. In addition, the costs of connections between local and long-distance telecommunication carriers can pose a significant barrier to telemedicine projects. Under the existing tariff structures, telephone calls placed to locations inside the local access transport area boundaries are often more expensive than those placed outside the same service area.

Telemedicine raises some difficult legal and regulatory issues as well. Remote diagnosis and treatment across state lines could bring different laws and regulations into play. A previous OTA report found that the present legal scheme does not provide consistent, comprehensive protection of privacy in health care information, whether it exists in a paper or computerized environment. Clearly the privacy implications for telemedicine will continue to receive careful scrutiny. Physician licensing becomes an issue because telemedicine facilitates consultations without respect to state borders and could conceivably require consultants to be licensed in a number of states. This would be impractical and is likely to constrain the diffusion of telemedicine projects. Telemedicine may, in fact, decrease the threat of malpractice suits through improved recordkeeping and databases, and the fact that taping the consultations will automatically provide proof of the encounter. However, it may also raise other liability issues, such as the lack of a "hands-on" examination by the consultant.

Congressional Options

Responsibility for telemedicine policy is shared among federal, state, and local lawmakers, and many of the decisions affecting the diffusion of telemedicine are influenced largely by the private sector. Federal efforts to reform both the health care and telecommunications systems, each traveling its separate path, will have an effect on telemedicine's progress.

Implementation of telemedicine is likely to proceed with or without federal support as providers recognize its benefits to their practices. However, federal government support will be required if it is to benefit those who need it the most—people living in rural and inner-city areas where market forces are unlikely to provide the services needed. In a time of tight fiscal constraints and shrinking research budgets, federal funding provided will need to be carefully monitored to ensure it is being used wisely. If Congress wishes to encourage the diffusion of telemedicine to help solve the disparities in health care availability, it can have the most impact in the areas of research funding and reimbursement for telemedicine consultations. The two are closely connected, in that formulating a standard reimbursement policy is dependent on obtaining satisfactory answers to many of the questions raised about telemedicine's efficacy and cost-effectiveness. Congress may wish to:

OPTION 1: *Continue to support demonstration and evaluation projects.*

The research currently under way is crucial to answering many of the questions about the benefits of telemedicine. To ensure that projects are sustainable when funding ends, agencies need to build in certain requirements. This is currently achieved by requiring that grantees make a financial investment in the project, often through matching funds. Many of the current funding opportunities for telemedicine projects focus on rural areas. Telemedicine also offers potential for solving some of the problems of inner-city health facilities. After assessing these needs, Congress could target support for depressed areas where the needs are great and a limited investment might be highly leveraged.

Because the data that would support a uniform reimbursement policy for telemedicine consultations are not yet available, HCFA is moving slowly and deliberately in accumulating the necessary information on which to base a sound decision.

This seems a prudent strategy. Experimenting with reimbursement in a small number of demonstration sites will provide valuable insights that will eventually enable the agency to craft a careful policy based on actual results. *Congress may wish to ensure that adequate finding is provided to support those experiments.* As the results become available, *Congress may wish to provide oversight and conduct hearings to determine what further action may be warranted.*

Until recently, there was a lack of coordination of federal efforts in research, policymaking, and implementation of distance care. This has been remedied considerably by the creation of the telemedicine working group of the Administration's Information Infrastructure Task Force.

The costs of implementing telemedicine can be a barrier to its diffusion, especially for small communities and facilities. To address this barrier, Congress may wish to:

OPTION 2: *Create incentives for cooperative efforts and consortia.*

In many small communities, it makes economic sense for groups to share the costs of implementing, operating, and maintaining a telecommunications network. For example, schools, medical clinics, libraries, social services, and others who would benefit from improved information services may need to join forces to get started. The Department of Defense and the National Aeronautics and Space Administration (NASA) have been leaders in research related to telemedicine applications, and the military has health facilities in a number of locations. In some sites the military has cooperated with civilian health care personnel to deliver services using telecommunications. Where possible, the expertise that exists in the military and NASA should be shared with the civilian sector. Agencies such as the Department of Veterans Affairs could also be involved in cooperative efforts with the civilian sector.

OPTION 3: *Ensure that information about telemedicine is widely disseminated.*

In many cases, those who might benefit most from telemedicine applications know very little about them. While information dissemination is increasing in a variety of formats, there is a need for a centralized, online database of telemedicine information. Such coordination might include creating an electronic clearinghouse that would provide a range of information about telemedicine projects, including funding opportunities, current projects, and people to contact for assistance and advice. Congress might wish to ensure that mechanisms exist, either in the public or private sectors, to widely disseminate research results and other information about telemedicine.

One of the goals of the IITF telemedicine working group is to investigate the feasibility of setting up an online database of telemedicine activities, and work is continuing to determine the best way to achieve this. Such a clearinghouse could be established in a designated federal agency within DHHS, such as the National Library of Medicine or the Office of Rural Health Policy. Alternatively, Congress could provide support for a private-sector group, such as the Telemedicine Information Exchange network at the Telemedicine Research Center, Oregon Health Sciences University. This option would avoid duplication of effort and provide a single site where telemedicine information could be maintained and obtained. However, it would also require careful consideration concerning the content of the database and how information would be structured and formatted. Any telemedicine clearinghouse would only be useful if kept up to date, and support for qualified staff would needed to be assured.

OTHER APPLICATIONS

The applications of information technology detailed in chapters 2 through 5 and summarized above were selected because of their potential to improve access to health care, improve the quality of care, and reduce the costs of delivering care. These were of particular interest to the study's requesters. OTA was unable to undertake an in-depth analysis of a number of other applications of information technology that also have potential

for improving health care. Two are mentioned here—consumer health informatics and community networking.

Consumer Health Informatics

Consumer health informatics has been defined as "the study, development, and implementation of computer and telecommunications applications and interfaces designed to be used by health consumers."[23] The basic principle is that of empowering people to play a greater role in their own health care and to be active participants in decisions affecting their health.[24] Information technology can be used to provide more health-related information to consumers, "the largest untapped resource for health care."[25] Taking measures to prevent illness and disease, by adjusting lifestyles or taking safety precautions, for example, could have a positive impact on the health care delivery system and allow people to lead healthier lives.

Shared decision support systems are designed to inform patient/provider decisions regarding prevention, diagnosis, management, and treatment, and ultimately to improve the quality of care and reduce costs. Choices are made collaboratively by patients and their caregivers. An example is the interactive video disk system developed at Dartmouth Medical School that allows men with benign prostatic hyperplasia and early stage prostatic cancer to share in decisions on their course of treatment.[26] Some regard these computer-based systems as transforming the culture of the health care system to one in which patients, physicians, and other providers play equal roles in decisionmaking. [27]

Information technology also could play an important role in reducing a consumer's need for health care services. *Demand management* can be defined as the "the support of individuals so that they can make rational health and medical decisions based on a consideration of the benefits and risks of the options available."[28] Current examples include health risk appraisals, written and audiovisual media, telephone counseling services, and community resources. Although a comprehensive demand management system does not yet exist, information technologies can make interventions more available and effective, and provide a sophisticated, multipurpose information system based on a new concept of the individual health record. When developed, these comprehensive services will allow consumers to understand, choose, and evaluate health services in new ways, and could have a positive impact on health care costs and quality.[29]

Information technology also fosters communication among people who can provide support and encouragement to those dealing with chronic illnesses or a medical crisis. There is a large and growing community of people using computers to provide help and support to one another to address a variety of concerns. For example, as of early

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[23] Tom Ferguson (ed.), "Consumer Health Informatics: Bringing the Patient Into the Loop," *Proceedings of the First National Conference on Consumer Health Informatics*, July 1993, p. 2. The Administration's Information Infrastructure Task Force, Consumer Information Subgroup, defines consumer health informatics as "any information that enables individuals to understand their health and make health-related decisions for themselves or their families."

[24] John Wennberg, "Shared Decision Making and Multimedia," *Health and the New Media: Technologies Transforming Personal and Public Health*, Linda M. Harris (ed.) (Hillsdale, NJ: Lawrence Erlbaum Associates, Inc., 1995).

[25] Vergil Slee and Deborah Deatrick, "Reengineering Health Care Decision Making," *Health Commons Update*, vol. 2, winter 1995, p. 6.

[26] Wennberg, op. cit., footnote 24.

[27] Deborah Deatrick, Executive Director, Health Commons Institute, personal communication, June 9, 1995. See also Slee and Deatrick, op. cit., footnote 25, p. 1.

[28] D.M. Vickery, "Demand Management, Self-Care, and the New Media," Linda M. Harris (ed.), op. cit., footnote 24.

[29] Ibid.

May 1995, America Online reported it had 148 scheduled self-help groups.[30] Some of these groups address health-related concerns, such as diabetes, stroke, AIDS, cancer, or disabilities. Others support the caregivers of people suffering from Alzheimer's disease or other debilitating illnesses. Nonprofit groups, such as the American Self-Help Clearinghouse, provide assistance and information to those wishing to set up an electronic support group or find out about such groups.[31] Information on a variety of online health resources can be obtained from the National Health Information Center.[32]

The CHESS system is an example of one that allows consumers to access information about their illnesses and to support one another using home terminals.[33] Another is the Connect System, a computer and voice-mail system used to monitor inner city drug-using pregnant women in Cleveland, Ohio. At Case Western Reserve University, ComputerLink was a demonstration project that supported the caregivers of persons with Alzheimer's disease and AIDS by delivering information, communication, and decision support, accessed through home terminals.[34] (See ch. 5 for more complete discussion of these systems.) Future systems geared to the needs of consumers are likely to include interactive video to the home.

Participants in an OTA workshop in July 1994 had a number of suggestions regarding what actions are needed to foster greater electronic health resources for consumers. These included:

1. support research and development;
2. support wide access to the NII as it develops;
3. insist on good needs assessment for consumer applications;
4. incorporate medical informatics into the medical education curriculum;
5. support clinical trials of different ways of sharing health data;
6. reduce the cost of telephone links to electronic bulletin boards;
7. subsidize premarket development of tools that private corporations can use and resell;
8. facilitate the use of technology by managed care organizations;
9. educate, support, and train users; and
10. provide grassroots technology "set-asides."

The Administration's Information Infrastructure Task Force has a subgroup of representatives from federal agencies who are addressing consumer health information and the NII. This committee has coordinated the development of a draft white paper outlining key policy issues for the federal government to consider as the public increasingly relies on electronic means of information access and exchange.[35] This paper was released for public comment at a federally sponsored national conference on networked consum-

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[30] Todd Woodward, Self-Help Information Center, America Online, personal communication, May 8, 1995.

[31] Barbara J. White and Edward J. Madara (eds.), *The Self-Help Sourcebook: Finding and Forming Mutual Aid Self-Help Groups*, 4th ed. (Denville, NJ: St. Clares-Riverside Medical Center, 1992).

[32] NHIC's home page on the World Wide Web is located at <URL: http://hic-nt.health.org/ >. NHIC is a service of the Office of Disease Prevention and Health Promotion, Public Health Service, U.S. Department of Health and Human Services, and the George Washington University Himmelfarb Medical Library.

[33] F.M. McTavish et al., "CHESS: An Interactive Computer System for Women with Breast Cancer Piloted with an Under-Served Population," n.d.

[34] Patricia F. Brennan, "Differential Use of Computer Network Services," American Medical Informatics Association, *Proceedings, Seventh Annual Symposium on Computer Applications in Medicine*, Oct. 30-Nov. 3, 1993, Washington, DC, p. 27.

[35] Kevin Patrick and Shannah Koss, "Consumer Information 'White Paper,'" Consumer Health Information Subgroup, Health Information and Application Working Group, Committee on Applications and Technology, Information Infrastructure Task Force, working draft, May 15, 1995.

er health information in May 1995. It will serve as the cornerstone for Administration policy in applications technology development and use.

Key policy issues for the federal government identified in the paper include:

- the need to coordinate federal consumer health information dissemination efforts both within the government (federal, state, and local) and with private providers;
- assurance of privacy and confidentiality;
- assurance of the availability of information critical for public health;
- the need for research and evaluation of the impact of consumer health information;
- the role of standards in vocabularies and data transmission;
- information validity and integrity;
- assurance of telecommunications infrastructure for adequate information delivery; and
- education and training.

Community Networking

Human services, including health care, are often delivered in a fragmented fashion, leading to duplication of effort on the part of providers and consumers. Telecommunications could be used to coordinate and streamline these services through community networking,[36] enabling the providers of a wide variety of social services to share information and communicate with one another. An earlier OTA report discussed the role of the local community infrastructure—schools, libraries, senior centers, and town halls—in delivering federal services to citizens electronically, especially those in rural areas, small towns, inner cities, and people with special needs[37] (see box 1-3). The difficulties of building an infrastructure can be a barrier, however. One group of researchers commented:

> Although there is widespread endorsement of such proposed efforts as managed care and one-stop shop service delivery, the more difficult task in most communities is to build an infrastructure that supports such coordination with a holistic approach to service and care.[38]

One example of a project using telecommunication and computer technologies to support and coordinate health and human services at the community level is the Community Services Network (CSN) in Washington, DC. This is a joint effort of the U.S. Public Health Service, Howard University School of Social Work, Rice University and Baylor College of Medicine, Macro International, Inc., United Seniors Health Cooperative, and Bell Atlantic Corp. Several communities across the country are currently exploring the development of CSNs. The Lawrence Livermore Lab in California is helping Macro and other partners develop test-beds to move CSNs from pilot to early operational status.[39]

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[36] For a discussion of the role of information technology in strengthening community action, see Nancy Milio, *Engines of Empowerment* (Ann Arbor, MI: Health Administration Press, 1995).

[37] U.S. Congress, Office of Technology Assessment, *Making Government Work: Electronic Delivery of Federal Services*, OTA-TCT-578 (Washington, DC: Government Printing Office, September 1993), ch. 5. See also U.S. Congress, Office of Technology Assessment, *Telecommunications Technology and Native Americans: Opportunities and Challenges*, OTA-ITC-621 (Washington, DC: U.S. Government Printing Office, August 1995).

[38] G.A. Gorry et al., "Health Care as Teamwork: The Internet Collaboratory," in *Health and the New Media*, op. cit., footnote 24, p. 97.

[39] Kevin Patrick, Department of Health and Human Services, personal communication, May 10, 1995.

BOX 1-3: Grassroots Computer Networking: Lessons Learned

OTA commissioned two grassroots computer networks to conduct computer conferences on the topic of electronic service delivery. Big Sky Telegraph (BST), headquartered in Dillon, MT, and the National Public Telecomputing Network (NPTN), headquartered in Cleveland, OH, conducted the conferences during late summer and fall of 1992. Lessons learned include:

1. The costs to users of *grassroots computer networking can be minimized.* Almost any personal computer (PC) and modem wiII suffice, high-end, high-speed equipment is not necessary. Online telecommunication charges can be reduced by copying messages to a PC and preparing responses with the telecommunications line turned off, and by using fractional rates and bulk purchase discounts. Use of equipment that transmits messages faster will reduce online charges further.

2 *Any local community can have a community computer bulletin board.* BST has, in effect, created six "Little Skys" where people can dial in with a local call—further reducing online costs. BST IS a rural equivalent of the NPTN's network of "Freeness. " BST is a rural FreeNet. All you need is a PC, modem, telephone line, and inexpensive bulletin board software, And to further reduce costs, the "Little Sky" or "FreeNet" can dial up a host computer once a night at off-peak rates to copy or add bulletin board items.

3. *Community computer bulletin boards really extend a sense of community.* BST and NPTN, like CompuServe and Minitel, found that users participate as much for sociability as for content. Users seek a comfort level and degree of intimacy that is not always prevalent in the community-at-large. Computer conferencing also greatly reduces any biases due to sex, physique, disabilities, speaking ability, etc. It is a leveling technology in this sense.

4. *Community computer networks usually get only limited support from the established government and business community.* The BST and NPTN approach is low-cost and decentralized; the state and federal bureaucracies tend to favor higher cost, more centralized, or at least more controllable, approaches Also the "not invented here" syndrome IS evident. Each organization has a tendency to invent its own solution or approach,

5. *Grassroots computer network utilities like BST and NPTN can facilitate local access to national computer networks that might not be otherwise technically feasible or affordable.* If local residents find computer networks such as the Internet expensive or difficult to access directly, computer utilities can provide low-cost, user-friendly connections.

6. *Grassroots computer conferencing works for children.* Children as young as the third grade can use computer conferencing to learn keyboarding, e-mail, and the concept of communicating among a group electronically (even some first-graders can handle it).

7. *Grassroots computer conferencing has significant potential for government service delivery* For example: a) agricultural extension services, b) small business assistance, c) International trade—global trade networks offer tremendous potential for locally based global entrepreneurial networking, d) Indian reservation services, especially for the Indian schools and hospitals, e) vocational education for displaced homemakers, f) job opportunities—potential for computerized catalogs of jobs and skill requirements, and g) public access to the legislative process.

8. *Training is essential to computer conferencing success.* It is Important for first experiences to be positive in order to develop self-confidence. Help lines work, rather than forcing users to struggle through manuals. As confidence builds, users can do more themselves and handle more complex functions. Initially many people are not ready for searching databases; but eventually users will want to and can do searches.

9. *federal programs largely miss the potential of grassroots computing.* The government does not have good mechanisms to support small, local innovators who lack a major Institutional affiliation. Suggestions mini-grants of up to $5,000 or so to local innovators; more flexibility in the National Science Foundation and other federal grant programs to support individuals and small, grassroots organizations, inclusion of grassroots representatives on federal advisory and peer review panels; technology showcases and demonstrations (e.g., fiber-to-the-school demonstrations in rural, economically disadvantaged areas).

SOURCE: Big Sky Telegraph, National Public Telecomputing Network, and Office of Technology Assessment, 1993

Information Technologies for Transforming Health Care

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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

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[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 heartbeat, 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 addresses—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 boundaries, 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 titan 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.

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[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.

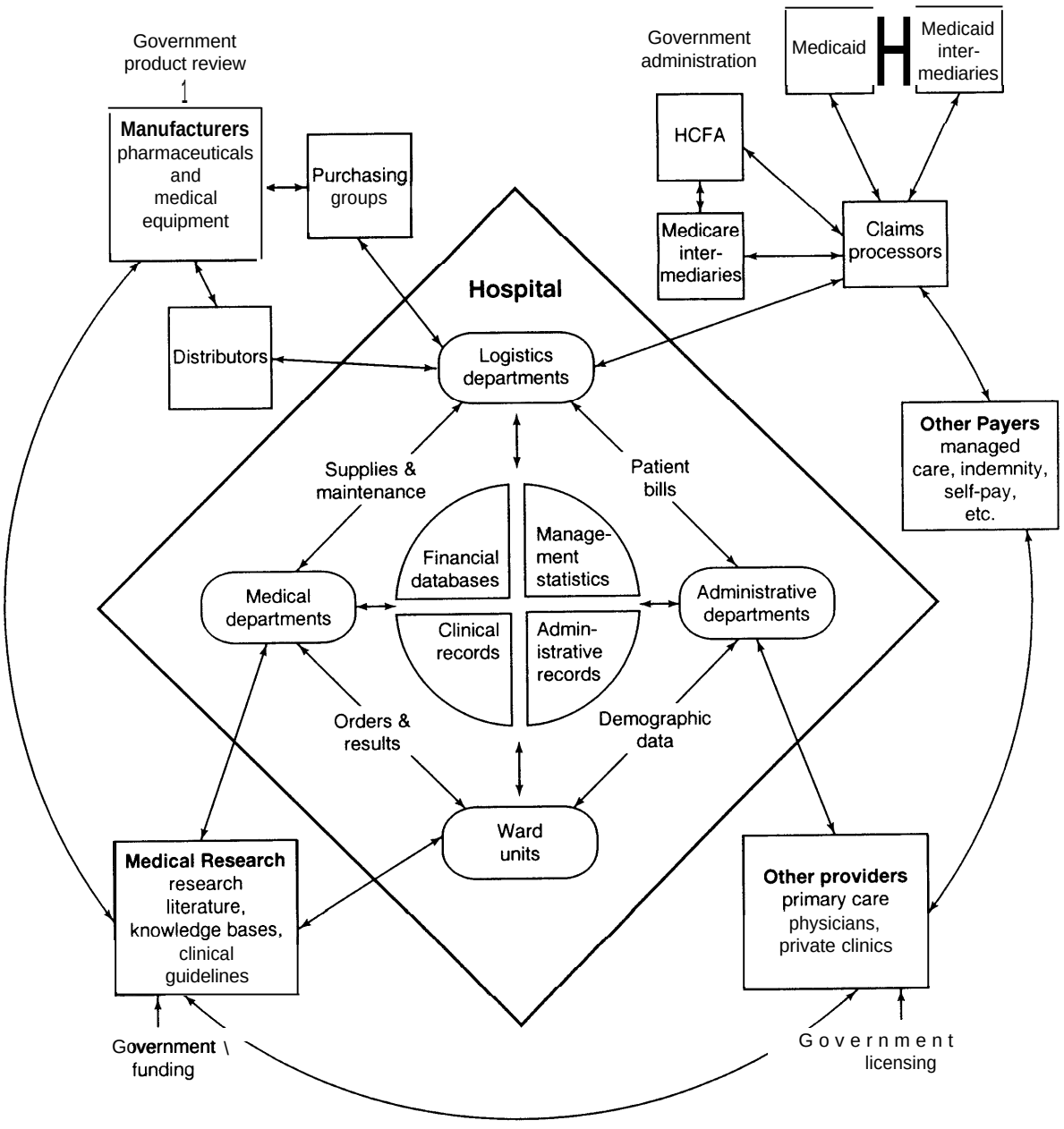
Clinical patient records contain encounter information, bedside data and nursing notes generated in the wards, laboratory reports, pharmaceutical receipts, images, and specialized reports from various institutional departments. The administrative departments exchange information with various external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

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[45] C.J. McDonald and G.O. Barnett, "Medical Record Systems," *Medical Informatics: Computer Applications in Health Care*, E.H. Shortliffe and L.E. Perrealt (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 in 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 recordkeeping 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 retyping 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 Telecom 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 to 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.

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[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

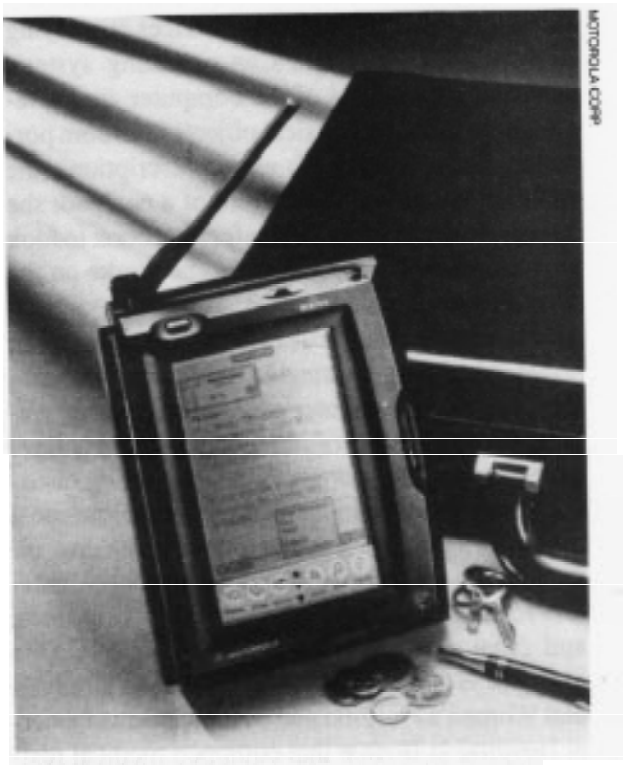
Human-computer interaction	
	handheld computers
	handwriting recognition
	personal digital assistants
	speech recognition
	automated data collection
	structured data entry
Storage, processing, and compression	
	computer-based patient records
	magnetic stripe cards
	smart cards
	picture archiving and 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 difficult to navigate through the series of lists and to back up and correct errors.



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.

Personal digital assistants (PDAs) area 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-***

[57] PC 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 recordkeeping[59] 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]

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[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.

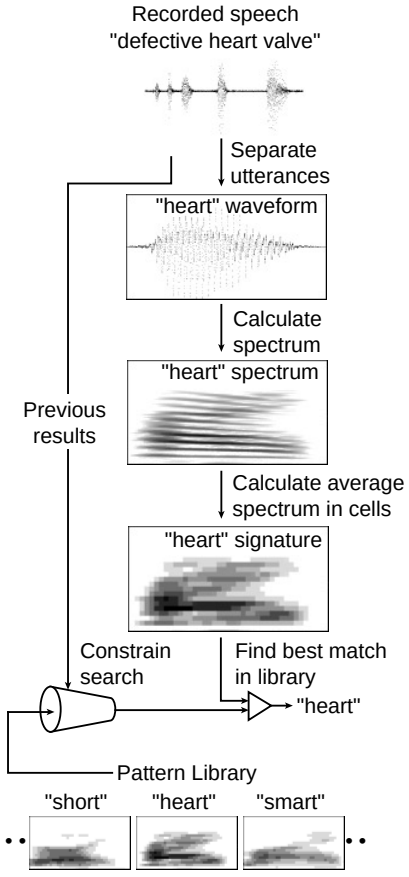
[60] B.W. Childs, "Bedside Terminals: One of the Answers to the Nursing Shortage," *Healthcare Informatics*, vol. 7, No. 12, 1990, p. 37.

[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

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

[2] A.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 handle 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 decisionmaking. 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.

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[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. Perrealt (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."[1] 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 according to their shapes and a library assembled of arrhythmia specific to the patient. Further traces are then compared to the patient 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 wilI 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 Acquistion: 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.

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

processors[65] 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 comprehensive 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-

[65] The 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

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[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 $C0_2$ 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-

[69] J.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 X512	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 information. *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

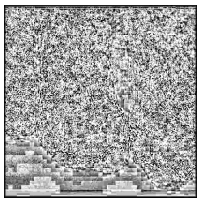
Image compression technologies play a crucial role in enabling the efficient storage and inexpensive dissemination of medical images. The digital images shown in this box are representations of dental x-rays (for illustrative purposes, they have been digitized with a far lower resolution than usual radiographic 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.



Original Image
96kBytes



Compressed Image
21kBytes



Difference
(contrast enhanced)

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

(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 @xc/) 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

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[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. Perrealt (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 images[77] 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

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[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 redun*dant 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-

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[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 mis-laid 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 comput-*er.* 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 in-serted 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 automati-cally to detect attempts to log onto the system or change files, and its presence discourages such at-tempts. 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 mes-sages 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 commu-nications needs. Alternatively, *firewalls* may be put in place that stand between computer networks in-ternal 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, *Informa-tion Security and Privacy in Network Environment,* OTA-TCT-606 (Washington, DC: U.S. Government Printing Office, September 1994)

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[40] Institute of Medicine, *The Computer-Based Patient Record: An Essential Technology for Health Care (Washington, DC: Nation-*al 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 communications 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 wiII 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]"OncoI.ink,'" 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-O 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 predefine 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.

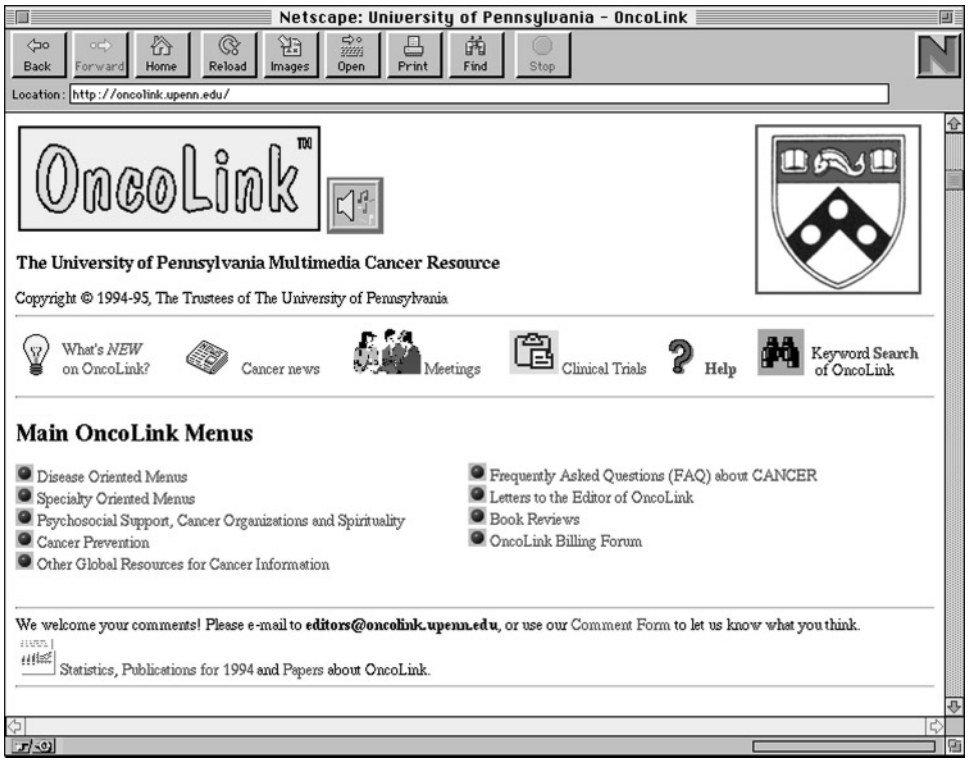
Different computer networks utilize different packet formats and protocols; the packets on different networks might be different sizes or have different addressing schemes. It is inconvenient for a computer launching a packet to have to know what sort of packet is expected by the receiving computer, 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 designed 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.

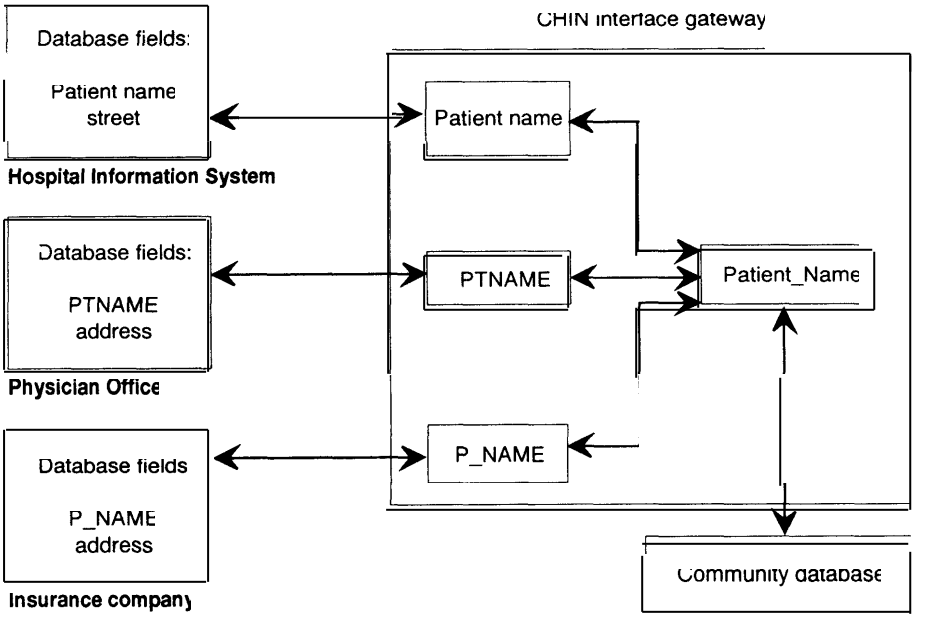
Understanding consensus standards is complicated in that the name of an individual standard is usually an acronym that reflects the identity of the standards committee, rather than the function of the standard. Figure 2-3 shows the alphabet soup of interrelated *messaging standards* for exchanging data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

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[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 global 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

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[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 posit! on, 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^Chlcago^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 "410.1^l9C. " 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.

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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 wiII 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 metropolitan 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

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[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. Kienzle 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 Soc*iety, 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-

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[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 multibillion-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 enable 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; '02 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. 2O.

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:

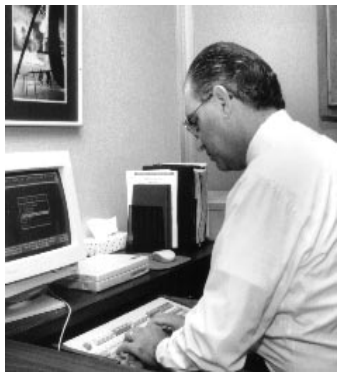
- establish procedures for expediting approval and distribution of medical software. Faulty software is as dangerous and worthy of regulation as poorly designed medical hardware, but software has the unique feature that it can be developed incrementally and distributed electronically.
- establish mechanisms (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.

Networks for Health Information 3

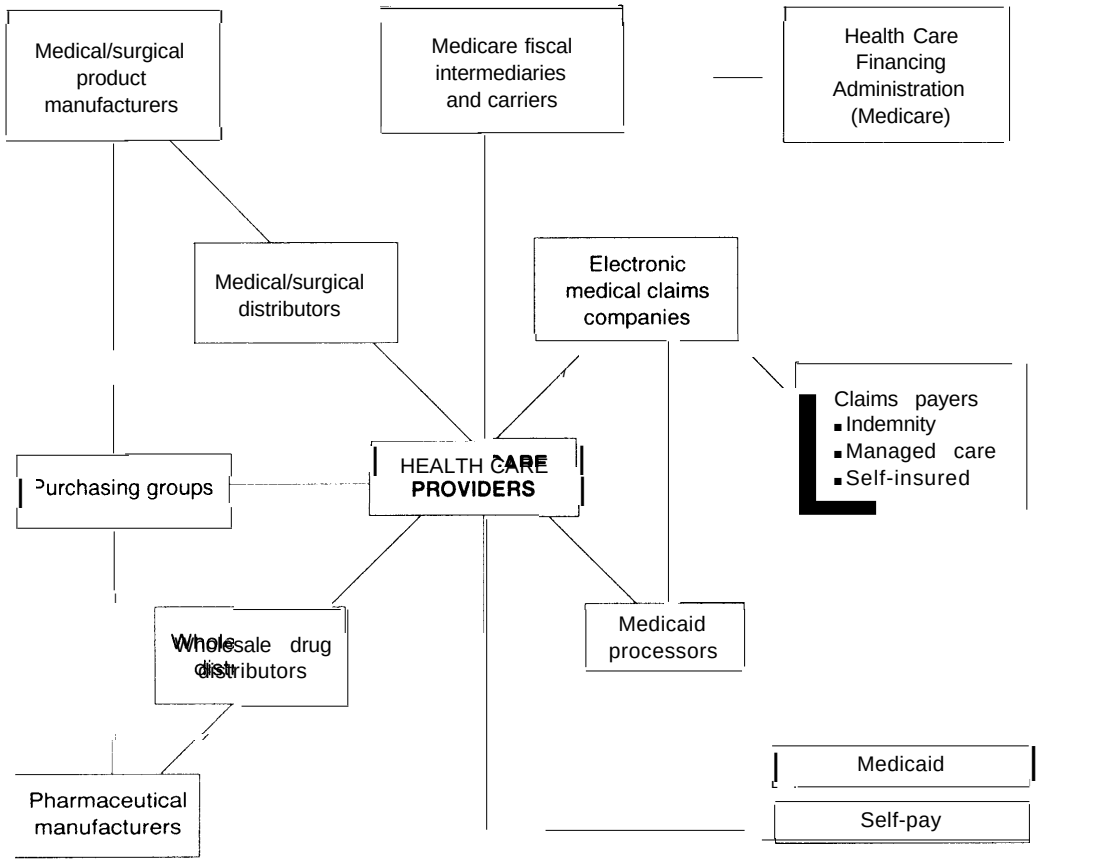
Information technology can be used to automate many administrative processes in the health care system, including transactions between those who provide health care services and those who pay for them. The general term *electronic commerce* is used in the chapter to describe the automation of business transactions and the direct computer-to-computer exchange of information, business documents, and money.

This chapter examines electronic communications between providers and payers (including interactions with electronic medical claims companies, value-added networks, clearinghouses, and others that facilitate this communication). It also discusses electronic commerce between health care providers and medical/surgical manufacturers and distributors, as well as between pharmacies and both pharmaceutical distributors and claims payers. The role of communication networks in facilitating the exchange of health information among health care providers, payers, and others on a community-wide or regional basis is examined. Figure 3-1 illustrates some of the directions in which information needs to be exchanged, or transactions need to be effected, among the various components of the health care delivery system.



Electronic communications can free administrative information from paper, allow it to be processed automatically (without human intervention), and permit it to be readily reused for a number of related purposes. In many cases, it appears that electronic commerce can provide some cost savings to health care system participants and to the system as a whole. Realizing those savings requires investment in equipment and training, as well as industrywide agreement on and compliance with standards for the format and content of messages. The chapter reviews some of the research on costs and cost-effectiveness of various uses of elec-

FIGURE 3-1: Health Care Industry Trading Relationships



SOURCE: J. Moynihan and K Norman "Health Care EDI: An Overview, " *EDI Forum,* vol. 6, No 2, 1991, p 11

tronic commerce and regional networks in health care. In addition, it outlines some of the overarching issues that affect the adoption of the technology by participants-industry fragmentation, the slow development of standards, the fragmented regulatory and policy environment, as well as concerns about privacy, confidentiality, and security of health information in a networked environment.

ADMINISTRATIVE SIMPLIFICATION

Administrative simplification has come to mean streamlining and standardizing the transactions between health care providers and payers to reduce costs. The administrative costs of providing health care have been estimated at between $108 billion and $135.1 billion per year in 1991,1 or between 12 and 15 percent of the health care bill. Es-

[1]Lewin-VHI, "Reducing Administrative Costs in a Pluralistic Delivery System Through Automation," prepared by A. Dobson and M. Bergheiser for the Healthcare Financial Management Association, Apr. 30, 1993.

timates of annual savings that could be realized through increased use of information technology to streamline administrative functions have ranged from $5 billion to $36 billion,[2] or enough to reduce administrative costs between 0.5 and 3.6 percent.

Administrative simplification generally means not only standardizing forms, procedures, and information requirements, but also moving to electronic technologies from paper-based transactions and recordkeeping. This chapter will review some of the technological, legal, and economic issues involved in administrative simplification. It also discusses more generally the concept of "electronic commerce," the exchange of business information and money through computer networks, and specific tools for electronic commerce such as electronic data interchange (EDI). (See boxes 3-1 and 3-2.)

In the traditional "fee-for-service" health care delivery system, the health care provider performs services for the patient and then submits a bill to the patient. If the patient is insured, either the provider or the patient will submit a claim to the payer (insurer) to reimburse the patient or to pay the provider directly on the patient's behalf. The information exchanged between care providers and payers (insurers) can be very complex. The information that a payer requires a health care provider to furnish in order to get a claim paid depends not only on the payer's policies, but on the laws of the states in which the payer, provider, and patient are located. In addition, because many patients are covered by more than one insurance plan, there may be secondary or tertiary payers involved in paying a single bill. From the provider's point of view, getting that bill paid may be quite burdensome. The various payers may not only require different information, in different forms, but may also require the provider to furnish information about the other payers in order to coordinate benefits for the patient.

Several studies of health care administrative costs have suggested that the large number of different payer institutions (over 6,000) and the variety of formats in which they request claim information are factors in making the cost of health care administration much higher for the United States than for other industrialized countries.[3] A government-mandated change to a single-payer system might reduce these costs, but such an action appears unlikely. Administrative simplification, through the introduction of electronic transactions and through standardization of transactions and processes, may offer a way to achieve more modest savings.

Many managed care companies now perform the functions of both payer and provider. However, this does not necessarily reduce the number of transactions or ensure that administrative simplification will be achieved simply by enrolling most of the population in health maintenance organizations (HMOs) or other managed care systems.[4] While some interorganizational transactions are eliminated, they are often replaced by analogous exchanges of information within the managed care company. In addition, managed care organizations are "information hungry" and are creating new management information exchanges between their "provider" and "payer" components.

In some HMOs, where patients are served only by providers employed by the HMO and where all financial risks (the insurance functions) are assumed by the HMO itself, there is usually little need to submit claims to payers, except for occasional referrals to outside specialists. However, managed care is coming to have forms. Managed

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[2] Project HOPE Center for Health Affairs, Bethesda, MD, "Estimating the Cost-Effectiveness of Selected Information Technology Applications," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1995.

[3] U.S. Congress, Office of Technology Assessment, *International Comparisons of Administrative Costs in Health Care*, OTA-BP-H-135 (Washington, DC: U.S. Government Printing Office, spring 1994).

[4] For more description of managed care, see box 1.1.

BOX 3-1: EDI and Electronic Commerce

Electronic Data Interchange (EDI) IS defined as the application-to-application interchange of business data between organizations using a standard data format. [1] A computer *application* is a software system that performs work Information IS routed through telecommunications networks, received by an organization's EDI system, and processed by its computer applications—all without human intervention. Redundant data entry IS thus eliminated, which increases the accuracy of information and reduces administrative costs.

Organizations doing business with one another are called *trading partners.* Companies have used EDI to reduce the costs of exchanging and processing documents for more than 25 years. In the last several years, however, companies and consultants have placed EDI into a larger context called elec*tronic commerce*

Electronic commerce IS a management concept in which all information flows between and within organizations through networked computer systems Work can be done in ways that differ from a paper-based system. In electronic commerce, for Instance, a process made up of discrete tasks may be performed as a series of parallel tasks. Only one person can work on a paper document at a time. When the Information contained on that document is freed from the constraints of paper and ink and is available in electronic form, several people can access, use, and transform the information at the same time.

EDI is not a concept like electronic commerce, it is a technology consisting of rules and standards programmed into computers One could say that EDI is to electronic commerce as statistical process control IS to total quality management, that is, EDI is one of the tools required to put the management concept of electronic commerce into action.[2]

Standardization is the key to EDI. Computers cannot process the Information that moves between organizations electronically unless it is encoded in a manner that the computers at both organizations can recognize. In other words, both computers must be able to *speak the same language.* In Iinguistic terms, they must follow standard usage. EDI provides a set of rules, grammar, and syntax that forms the basis of standard usage in the electronic exchange of business data. EDI is both the means and the language that computers use to "talk business."3

SOURCE: C. Canright, "Electronic Commerce and Networking in Health Care, " unpublished contractor report prepared for the Off Ice of Technology Assessment, U S Congress, Washington, DC, Jan 31, 1995

[1] C. Canright, "The Problem of Data Mapping, " *EDI Executive,* vol. 4, No. 6, June 1989, p 1

[2] G. Gerson, Sr., "Interview with Captain Bruce Bennett, USN, Executive Agent for Electronic Commerce, United States Department of Defense, " *EDI Forum,* vol. 6, *No 3, 1993,* p *42*

[3] R.W. Notto, "EDI Standards: A Historical Perspective, " *EDI Forum,* vol. 1, No. 1, 1988, p. 120.

care organizations can have a variety of relationships with providers (e.g., they may be employees, or they may accept patients under exclusive or nonexclusive contracts). They may also have a variety of relations with payers, assuming some financial risk internally, while still submitting claims to other payers. Thus, these organizational arrangements still involve transactions between provider and insurer organizations.

Managed care organizations also exchange administrative or clinical information internally and with their contract providers. In order to be profitable under flat-rate capitated contracts, managed care organizations must reduce duplicative services and manage each patient's utilization of services. This means that each clinician in the system who encounters a patient should ideally have access to a fairly complete medical record in order

BOX 3-2: What is a Value-Added Network?

Value-added networks (VANS) are the means most companies use to exchange electronic data interchange (EDI) transactions. VANS are the electronic equivalent of a package delivery service Rather than make a direct computer connection with trading partners, companies send their data to a VAN It receives a *bundle* of EDI transactions—representing many types of business documents and bound for many different trading partners—and routes the individual transactions to the appropriate trading partner's electronic mailbox, When the trading partner connects with the network, the EDI transactions are transmitted to its computer. VANS make EDI easier because they eliminate the scheduling problems that arise when making direct computer connections. They can also be more secure than direct computer connections because trading partners are isolated from each other's systems.

SOURCE: C. Canright, "Electronic Commerce and Networking in Health Care, ' unpublished contractor report prepared for the Office of Technology Assessment, U S Congress, Washington DC, Jan 31, 1995

to know what has been done by others. It also means that management should know what resources are expended on that patient, even when there is no need to actually generate a bill. Many managed care organizations are finding the need for "encounter reports" that contain much of the same information that is currently included in insurance claim forms in a fee-for-service system. While the encounter report could be considered an internal communication within the managed care company, in some cases delivering it will take very much the same technology and pose many of the same problems as the delivery of claim information between a provider and payer.

ADMINISTRATIVE ACTIVITIES IN HEALTH CARE

Administrative activities related to health care occur at all levels of the health care system, including health care providers, payers, and local, state, and federal government agencies. These activities include:

- *Health care providers (individual and institutional):* Calculating bills and billing payers; transmitting records to outside providers or payers; internal financial management; regulatory compliance; utilization review; quality assurance; and acquisition, distribution, and storage of equipment and supplies.
- *Payers:* Claims processing; coordinating benefits with other payers; claims payment; managing plan enrollment and eligibility; statistical analyses and quality assurance; and regulatory compliance.
- *Employers and other large purchasers of health care services:* Comparing and selecting plans; and managing enrollment of employees or members.
- *Consumers (patients):* Submitting claims: tracking eligible expenses; and paying copayments and uncovered bills.
- *Government agencies:* All of the above activities in roles as providers, payers, and employers; data collection for vital statistics; health care financing data; and regulatory oversight.

A fuller description of administrative activities and costs is available in a previous Office of Technology Assessment report, *International Comparisons of Administrative Costs in Health Care. -s*

PROVIDER ADMINISTRATIVE ACTIVITIES

Many information exchanges that take place within a single provider's organization (e.g., admiss ion-discharge-transfer messages or billing

[5] Office of Technology Assessment, op. cit., footnote 3.

information) are automated. Use of the Health Level 7 (HL7) standard, discussed in chapter 2, which is used for exchange of clinical information, is also growing for administrative and patient management information. Most vendors of both administrative and clinical information systems are supporting the HL7 standard. Use of computers in administration and patient management is not limited to hospitals or large clinics. Although many doctors' offices still rely on paper patient records and billing systems, a growing number are computerizing at least some of their business and administrative functions. Computerized practice management systems (PMSs) automate functions such as accounts receivable, insurance, billing, and appointments; they also record the patient's diagnoses, procedures, medical history, and financial history. PMSs offer a wide range of functionality and very little standardization; some systems were developed on an ad hoc basis by their users and others were purchased from one of more than 400 vendors. Some PMSs also help physicians deal with the complexities of managed care contracts, for example, by maintaining member lists, posting capitation payments from plans, tracking the number of visits or services provided for each patient, and providing reports on the profitability of the relationship with each plan.

Typically, providers only have information about their own contribution to a patient's care—for example, hospitals maintain records of inpatient stays and doctors' offices keep track of office visits. But to manage patients' use of resources effectively, managed care organizations want to track patient care over several years and integrate different services that were performed at various locations. Integration of financial and clinical information is also important to managed care.[6]

Integrated Delivery Systems (IDSs) are emerging to meet the need of health care organizations to deliver a full range of health care services to their covered populations. An IDS, either through ownership, partnership, joint venture, strategic alliance, or contract, brings together hospitals, ambulatory care facilities, affiliated physicians' offices, nursing homes, home care services, laboratories, wellness programs, and so on. IDSs have been springing up rapidly as managed care companies position themselves to compete; the result is a conglomeration of provider organizations with different levels and types of automation and uses of information technology. Some IDSs are making the investments needed to develop "enterprise-wide" information systems to allow exchange of clinical and administrative information among their various components.

Health care providers perform a variety of administrative activities associated with each admission, visit, or episode of care. These activities begin well before the face-to-face encounter with the patient and last long after the patient has left the institution or professional's office. Preadmission and preregistration cover a variety of logistical, clinical, and financial activities, including eligibility confirmations, certifications, and authorizations for care, which generally require communication with the patient's payer.

EXCHANGING INFORMATION BETWEEN PROVIDERS AND PAYERS

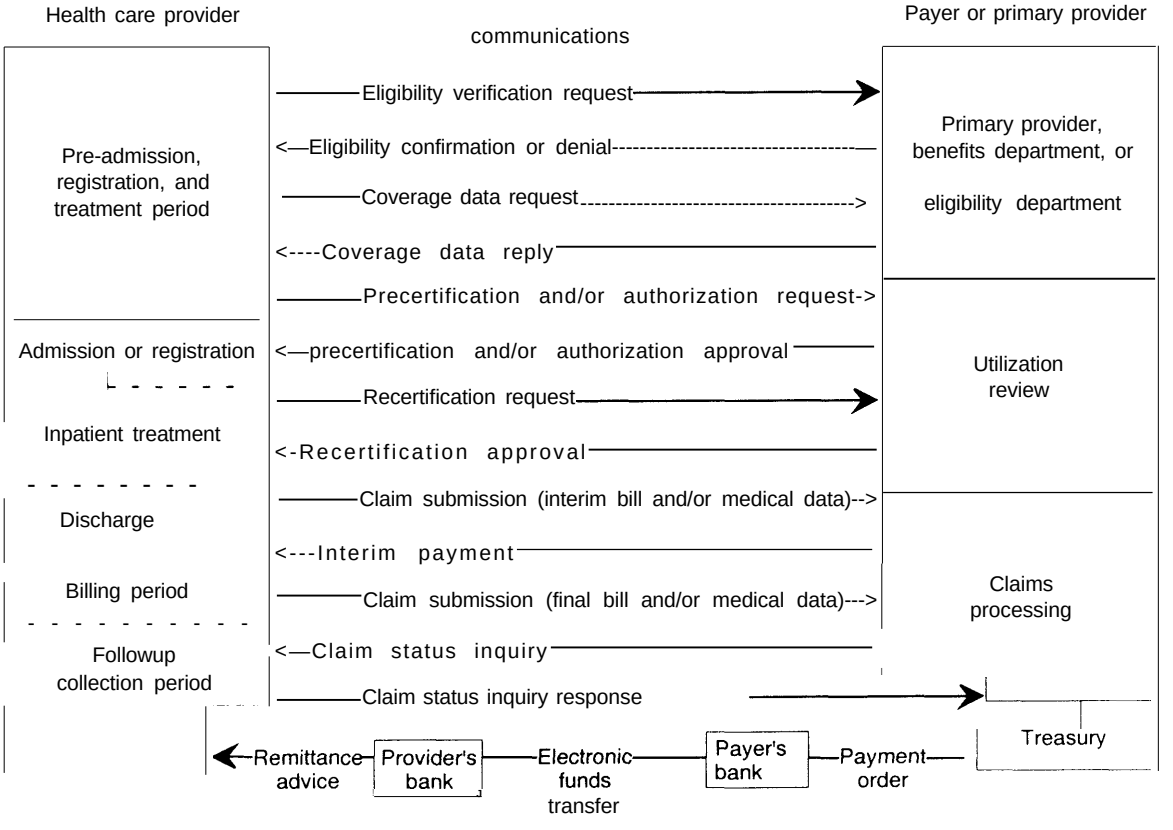
During the course of treatment or admission, additional transactions flow between the provider and payer or care manager, including reauthorizations, recertifications, interim billing, and a variety of review activities. Due to the limits on some health care coverage, the provider might also have to redo the eligibility function as well. Figure 3-2 illustrates some of the information flows between payer and provider at various stages in the process.[7]

At some point during or after treatment, the provider will issue a bill and/or a claim. Copies of the bill might go to the patient, as well as to one or

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[6] D. S. Kolb and J. L. Horowitz, "Managing the Transition to Capitation," *Healthcare Financial Management*, February 1995.

[7] The following description of administrative information exchanges is based on information from D. Rode, immediate past co-chairman, ASC X12 Insurance Subcommittee, Healthcare Task Group, personal communication, May 12, 1995.



SOURCE: Adapted from D Rode, "EDI Holds Potential for Cutting Receivables Processing Costs," *Healthcare Financial Management Association,* March 1990, p 15

more payers. When more than one payer is involved, the provider may send a bill to all parties and work through a very complicated process to coordinate billing (and payment). Even patients who belong to managed care entities that capitate payments or use other reimbursement methods might need to have all or parts of their bill or claim sent for management information purposes.

After the initial claim or billing, the provider may have several followup steps, such as providing additional information to a payer inquiring about the status of a claim previously sent to one or more payers. Because more than one provider may be billing for services rendered during the same episode of care, both providers and payers may have to coordinate and track their information. Many institutions and some individual providers are also required to send additional information as attachments to the claim. Among the required documents are discharge abstracts, surgical reports, first reports of injury, and attestation reports. Late submission of these reports might also delay the payment of the original claim.

Finally, the provider receives a payment or rejection from the payer. This is a two-step process



Information systems allow many caregivers to share clinical and administrative information.

because the provider must reconcile the payment to the original claim, as well as to the posting process at its financial institution. The information received with the payment or rejection (usually called remittance advice) can be as simple as a check number or it may include pages of information responding to each line of the original claim. If the patient has health care coverage from a secondary payer, the provider may then have to repeat the process, submitting a secondary billing claim to that payer, and including with the claim information about what was and was not paid by the primary payer (some institutions bill the patient who is then responsible for collecting from secondary payers). On average, most institutions do not see payment on a claim for well over two months. Individual and professional payments often take longer.[8]

During the course of these provider-payer transactions there can be many telephone contacts and letters exchanged among the parties. In an inpatient environment, which is relatively stable, the cost of carrying out these transactions is relatively low compared to the amount of the claim. However, the opposite is true in an outpatient or ambulatory-care setting. The provider's costs for processing each transaction, claim, or eligibility verification is about the same as in an inpatient setting, but the resulting revenue is much less. The move of health care toward more outpatient care will accentuate this problem.

The traditional model for health payments has been that the provider charges the patient a fee for the services provided. The patient (or the provider on the patient's behalf) files a claim with the patient's insurer (payer) for payment of the covered portion of this fee. There are several types of transactions in the fee-for-service environment where electronic communications could be applied. These transactions are: 1) claims submission, 2) remittance advice, 3) claims inquiry, 4) enrollment, and 5) eligibility inquiry.

Claims submission is the process of preparing and submitting documents to a payer on behalf of a patient. Nearly all claims for hospital services are submitted by the provider. Claims for services in a physician's office may be prepared by either the patient or the provider; in preferred provider networks, the physician usually files the claim. Information required to complete the claim form may have entered the provider's accounting system through either a direct interface with other information systems in the provider organization, or through keyboard input by a data-entry clerk who reads the various paper documents about the patient and enters the data into the patient-accounting system. This system, whether paper-based or computer-based, must prepare a claim document in a form that is acceptable to the payer.

Remittance advice is a document returned to the provider by the payer along with payment after the claim is processed. The remittance advice explains what the payment covers and how the claim was adjudicated by the payer. The provider compares the payment with the original claim to determine whether the amounts match. If the claim and payment do not match, the clerk checks the remittance advice to determine where the differences lie. When the claim and the various payments match, either immediately or after a process

[8] A review of quarterly analyses by Zimmerman & Associates, Hales Comer, WI, shows receivables always exceed 60 days. Ibid.

of negotiating discrepancies, the claim is reconciled with its associated payments and closed. Remittance advice can be a paper document that accompanies a check; an electronic document that accompanies an electronic funds transfer; or an electronic document that is separate from, but related to, an electronic funds transfer sent by other means.

Claims inquiry is a process that providers use either to determine when payment will be made or to negotiate discrepancies in a claim that has been partially paid. Often, inquiries are telephone conversations, but some vendors are beginning to offer online inquiries.

Enrollment is a process that involves the payer and the patient's employer (or sponsor of the health care plan in which the patient enrolls). Enrollment transactions occur when people join a health plan, change their family status, move, change plans, and so on.

Eligibility inquiries are transactions between providers and payers to determine what benefits the patient is entitled to. Patients arriving at the doctor's office, hospital, pharmacy, or other provider location are asked what kind of coverage they have and from whom. This information is confirmed by an inquiry to the payer by mail, telephone call, or an electronic process. Having this confirmation quickly is useful to the provider: it means that correct copayment amounts can be collected right away, for example, or that certain services will not be offered to people who are not entitled to them. EDI standards have been developed for the above transactions. (See box 3-3.)

In a managed care environment, some of these transactions are different. For example, in an HMO, where members are charged a fixed fee per person (capitation) and are not billed for individual services, the traditional insurance claim is unnecessary. In some cases, however, HMOs are using an *encounter report* to provide management information about services provided, and these could be considered surrogates for insurance claims. Enrollment transactions and inquiries about a member's eligibility for services are as important in a managed care environment as in a fee-for-service system; in some cases, they may be internal transactions between parts of the same organization (perhaps at different locations) rather than between different organizations.

Status of Electronic Insurance Transactions[9]

Health Care Financing Administration

As the largest payer of health care claims in the country, the federal government for years has encouraged providers and insurers to do business electronically, especially the submission of Medicare claims. The Medicare program (and the federal portion of the Medicaid program) is administered by the Health Care Financing Administration (HCFA) which, beginning in the 1970s, established electronic links between hospitals and fiscal intermediaries—the insurance companies that process Medicare claims under contract with the government. Currently, 80 different insurance companies process some 730 million Medicare claims annually.[10]

Initially, the shift away from paper involved hospitals submitting bills by either direct-data entry (DDE) terminal, linked directly by leased phone lines to the mainframe computer of the fiscal intermediary, or by computer tape. In either case, clerical personnel would key in the necessary information. For computer tape transactions, they would format the information on computer tape, which was then sent to the fiscal intermediary. For the fiscal intermediary, the volume of information received on tape—and thus the reduced costs of processing as compared with paper submissions—justified writing separate computer interfaces to translate the different tape formats as required.

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[9] This section is based on C. Canright, "Electronic Commerce and Networking in Health Care," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1995.

[10] "Implementing EDI on a Colossal Scale: An Interview with HCFA's Carol Walton," *EDI Forum*, vol. 6, No. 2, 1993, p. 47.

BOX 3-3: EDI Standards

The key to the concept of *administrative simplification* lies in data standar
throughout this report. Indeed, the one thing that nearly everyone involved in health care automation agrees on IS that uniform data standards are required to control health care administration costs.

Roughly speaking, data-processing standards have two components: content and transmission. Data-content standards specify how meaning should be represented. Data-transmission (or messaging) standards specify how information encoded as strings of binary digits should be structured for transmission over wires or through the air.

Data Transmission

EDI standards for business documents structure information in such a way that computers at different organizations can process it. Computers do not process documents like humans read documents. Computers process data. To the computer, EDI is not a facsimile of a document that a computer stores; it is a stream of data that actually causes a computer application to perform a specific action. [1]

Data, however, are not quite enough. Data may be two-character codes that represent an idea or a string of characters that represent, for instance, a Social Security number (SSN). Because all data are represented as strings of 0s and 1s, computers need a means of distinguishing data denoting one idea from data denoting another.

Computers distinguish one bit of data from another through positional relationships. If a health care claim were written as a single line, then the computer would need to know what part of the line represented an SSN and what part represented a patient's name. By cutting that line of characters up into data elements, a computer can recognize one type of reformation from another. The first data element might represent a patient's name and address, while the second represents the line items on a claim. EDI standards provide that type of structure. They provide a common way for computers to structure the data that represent business documents.

The standards for moving the data that appear on common business documents between organizations are called the ASC XI 2 standards for electronic data interchange, named after the American National Standards Institute's Accredited Standards Committee XI 2, which develops them. ASC XI 2 standards define a syntax and provide a structure for moving data between organizations. In that way, EDI standards are external data-transmission standards. The structure that represents a business document is called a *transaction set;* transaction sets are the electronic equivalents of paper business documents.

Transaction sets, then, are composed of an ordered series of data segments. Data segments are analogous to the groups of data that perform specific functions within a business document, such as line items on a purchase order, terms of payment on an invoice, or the identification (name and address) sections that appear on any business document. Segments, in turn, are constructed of an ordered series of logically related data elements. Data elements specify such things as unit of measure, price, quantity, and currency.

Data Content

The content of standards comes to the fore at the data-element level of the X12 standards. Much of the content of a transaction set consists of codes used by a company or an industry to represent the

[1]E.J. Bass, "Introduction to EDI," unpublished paper presented to Accredited Standards Committee X12, St Charles, IL, May 16, 1988

(continued)

BOX 3-3: EDI Standard

specifics of its business. As much as possible, the Xl 2 committee seeks to standardize content across industries. The segment and data elements used in transaction sets to represent a name and address, for Instance, are the same for transportation concerns as for health care concerns.

Just because two organizations support the Xl 2 standards, however, does not mean that communication between them is seamless. On a technical level, both systems are compatible because they are communicating using a common language. On a content level, however, compatibility is nowhere near guaranteed, particularly in health care. The data content of ASC Xl 2 standards comes from industry- and company-specific codes. In health care, for instance, the ASC Xl 2 health care remittance advice standard uses Adjustment Reason Codes maintained by the Blue Cross and Blue Shield Association and Current Procedural Terminology (CPT) Codes maintained by the American Medical Association. In fact, any organization can petition the ASC Xl 2 committee to include its codes into the standard. As long as those codes meet the test of business necessity and perform functions that existing codes cannot perform, the codes are incorporated into the standard,

As a result, ASC Xl 2 standards accommodate a huge amount of data content and they can perform the same business function in many different ways. Most Industries have limited this variability by publishing Implementation manuals specifying how a particular transaction set should be used to conduct business with companies in that Industry.

The data content used in the ASC Xl 2 health care transaction sets IS still too broadly defined, Nearly everyone revolved in EDI in the health care Industry agrees that widespread EDI implementation will require greater uniformity in data content. As the WEDI committee puts it, "A significant barrier to the Implementation of EDI IS the fact that implementation guides have not been developed that Incorporate standard requirements and content across large segments of the health care industry It IS critical that private payers and government programs, including Medicare and Medicaid, use a common set of formats to achieve the highest level of administrative cost savings and accelerate the implementation of EDI."[2]

The health care industry needs a business model that specifies the data required in each transaction and how they should be encoded and structured within the standards. Efficient standards require that all participants in the industry agree on. [1]) what data to collect, 2) when to collect it, and 3) how to collect it.[3]

In the absence of industrywide implementation manuals, many in the industry are relying on implementation guidelines created by the Health Care Financing Administration (HCFA), the first payer to Implement the health care claim payment and advice (ASC Xl 2.835) transaction set and the claim submission (ASC Xl 2.837) transaction set,

SOURCE: C. Canright, "Electronic Commerce and Networking In Health Care, " unpublished contractor report prepared for the Off Ice of Technology Assessment, Jan 31, 1995

[2]Workgroup for Electronic Data Interchange, *1993 Report* (Hartford, CT and Chicago, IL: October 1993), p. 1-7.

[3]G. Arges, Director, Health Data Management Group, American Hospital Association, interview, Chicago, IL, Aug. 25, 1994.

But as large chain-affiliated hospitals found that they were dealing with many different formats, they asked HCFA to establish a standard tape format, which it did in the late 1970s. The standard tape format allowed hospitals and other large institutions to introduce a degree of standardization into their claims submissions process. However, they still faced different data requirements from different fiscal intermediaries in different states.

During the 1980s, with the growing use of personal computers, HCFA also began to encourage physicians to do business electronically. In the mid-1980s, HCFA aggressively put pressure on providers to convert to electronic billing, and by 1985, HCFA received about two-thirds of Part A hospital claims and one-third of Part B supplemental insurance claims electronically.[11] Part A claims are submitted by hospitals and other large institutions for inpatient care. Part B claims are submitted by physicians and clinics.

HCFA's push for electronic claims processing came to a standstill in the late 1980s. Congress, as part of an attempt to balance the federal budget, mandated an extended timeframe for paying all Medicare claims. HCFA, however, had used expedited payment as an incentive for providers to submit bills electronically. Without the incentive of faster payment, many providers saw no reason to make the investments needed to submit claims electronically.

HCFA started to promote electronic billing again in 1991 as part of a short-term strategy to reduce administrative costs. Until then, HCFA had concerned itself solely with automating claims. In 1991, however, the agency turned its attention to automating the remittance advice document, which accompanies a claim payment and explains what the payment covers. Rather than develop its own remittance format, HCFA adopted the EDI format for health care remittance advices that had just been approved by Accredited Standards Committee X12. HCFA became the first organization to test the new EDI remittance advice format and remains its largest user.

In 1992, HCFA established a uniform payment policy and procedures for making electronic payments to medical providers for Medicare claims. Providers who submit at least 90 percent of their Medicare claims electronically can receive claims payments electronically through the banking industry's automated clearinghouse network and their local banks, rather than through paper checks mailed to their offices. HCFA again had a faster payment incentive to encourage electronic claims submissions. Since then, HCFA has adopted the EDI-based claims form as its standard and mandated that all Medicare processors adopt it by July 1, 1996. The agency's long-term goal is to have all Medicare claims handled electronically by the year 2000.

Private Insurers

Because many Medicare beneficiaries also carry private insurance policies that cover deductibles and copayment obligations under Medicare, HCFA's EDI projects also affect the administration of payments by private insurers. In many states, the fiscal intermediary for the Medicare program obtains its own private insurance claims electronically through the same linkages used for Medicare. With Medicare moving toward 100 percent electronic claim submission, "it seems likely that private firms will be making use of the technology as well."[12]

Some large insurers accept and process nearly 80 percent of claims by computer.[13] However, there are many small insurers that are only beginning to accept electronic claims. Today, about 75 percent of hospital claims are submitted electroni-

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[11] M. Buffington, Director of Claims Processing, Health Care Financing Administration, personal communication, Sept. 7, 1994.

[12] D. Fularczyk, Manager, Blue Cross and Blue Shield United of Wisconsin's Proservices subsidiary, quoted in T. Higgins, "Setting Standard for Electronic Claims Could Lead to Paperless Providers," *The Business Journal-Milwaukee*, February 1993, pp. S3-S5.

[13] B. Politzer, "Claims of Excellence," *HMO Magazine*, vol. 32, No. 6, November-December 1991, p. 39.

cally, but the vast majority of these are Medicare claims submitted to HCFA rather than to private insurers. Physicians submit some 16 percent of their claims electronically in total; however, they submit 47 percent of their Medicare claims electronically.[14]

Electronic Medical Claims Services

One of the difficulties of connecting providers and payers is the different data and networking formats that exist in the health care industry. Conventional wisdom, for instance, holds that electronic claims are structured in some 400 different ways. Electronic medical claims companies, including value-added networks and clearinghouses, provide services that connect providers with many payers using a single system.[15]

These services give providers a single point of electronic contact to many payers. In addition to routing information between a provider and its payers, they edit and reformat claims data. This frees providers from the burden of programming their systems to handle the wide variety of electronic formats. For example, a physician's office wanting to send claims electronically generally uses personal computer software that communicates with the service via telephone lines. Physicians using practice management systems can often integrate this software with their systems. This requires that the processing service cooperate with the vendor of the practice management system (there are several hundred in the country) to write the necessary interfaces. For physicians who do not use practice management systems, the service provides software that allows clerical personnel to enter claims data directly into forms that appear on a PC screen.

Provider-specific edits are needed on each claim. Because health care claims are not universally standardized, different payers require data to be presented differently in their claims. One payer may also require data that another payer does not. The software checks the claims that are keyed in or received from a practice management system to make sure they conform to the data requirements of the designated payer.

If the claims meet all requirements, the PC software sends them to the electronic claims service. The service performs further editing and then transmits the claims to payers, in some cases through direct network connections to the payer and in others through a claims clearinghouse that has such a connection.

Many electronic medical claims services can perform some or all of the following transaction types: electronic claims filing; claims-status inquiry and online claims correction; eligibility and benefits inquiry; electronic remittance advice data; automated electronic remittance posting, along with supplemental and secondary billing; and electronic funds transfer. The services available to a provider vary by payer and depend on payer capabilities. Not all payers, for instance, can provide remittance advice data electronically.

Most of the transactions processed by electronic medical claims services are currently not based on EDI standards, particularly the nonclaims transactions. However, use of standard EDI claims may increase as HCFA mandates them. Until then, however, many payers are not accepting standard EDI claims. Nonclaims transactions, such as eligibility verification, are not based on EDI standards because the standards are either brand new or do not exist. Many of these services intend to support EDI standards, but place more emphasis on making transactions electronically, whatever the format. They believe that it is better to begin electronic processing now than to wait for the often slow standards-development cycle.

The initial cost of getting a physician started with an electronic claims service is between $1,500 and $2,500, depending on the size of the

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[14] "Automated Medical Payments Statistical Overview," *Automated Medical Payments News*, Feb. 8, 1993, p. 3.

[15] B. Dodge, Vice President, HCS, Inc., personal communication, Aug. 26, 1994.

practice. Staff training may be an additional expense. There is also a per-transaction fee, which could be on the order of $0.35 to $0.85, depending on the type of transaction. Claims fall toward the upper end of the range because they are more complex documents and contain more data, while transactions such as eligibility inquiries cost less.[16]

In the early years of EDI development in other industries, value-added networks (VANs) offered similar translation services for companies that did not want to develop or install their own EDI management systems. Over time, companies purchased their own EDI systems, rather than pay translation fees to the VANs. A similar development is unlikely in health care. Only larger institutions are likely to have the financial and staff resources to manage an EDI system. For smaller medical practices, claims services and VANs may continue to provide a way to transact business electronically.

Financial Institutions

Completely automating the health care payment process means involving the trading partners' financial institutions. In the 1970s, the banking industry established its own formats for electronic funds transfer (EFT) through the National Automated Clearing House Association (NACHA). NACHA governs the automated clearinghouse (ACH), a network of computer-based check-clearing and settlement facilities for the interchange of electronic debits and credits among financial institutions (note that bank clearinghouses are different entities from the insurance clearinghouses mentioned above).

The banking industry designed its original EFT formats to move money between financial institutions. In the 1980s, NACHA worked with corporations to set ACH formats for corporate-to-corporate payments. At that point, the NACHA formats for EFT began to conflict with, and then migrate toward, industry's formats for EDI. The hybrid of EFT, whose purpose is to move money between financial institutions electronically, and EDI, whose purpose is to move business data between corporations electronically, became known as *financial EDI* (or EFT/EDI).

Since the development of financial EDI formats in the mid 1980s, the number of corporations using the ACH to make payments has steadily risen, showing an average annual growth of between 25 and 30 percent per year for the past several years. In terms of total payment volume, however, financial EDI volume statistics are less impressive. Last year, the estimated 13 million payments made through financial EDI represented only about 0.1 percent of the total estimated volume of 11.7 billion payments.[17]

Financial EDI payments, in all industries, consist of two parts: the payment and the remittance advice. One difficulty faced by the banking industry is that few banks are capable of processing all of the information contained in financial EDI payments. ACH formats themselves are not compatible with the information-laden EDI formats. To move *native* EDI data through the ACH requires *wrapping* an EDI transaction in a NACHA envelope. The financial institution then unwraps and processes the EDI payment transaction. The enveloping process puts some limitations on the amount of data an EDI transaction can carry—a potential problem given the amount of data in a health care remittance advice document.

As a result, many companies are sending EDI payment orders and remittance advices through separate paths—the payment itself as a simple EFT transfer through the ACH and the remittance advice as an EDI transmission through a VAN. In that case, companies receive the payment-deposit information from their banks and reconcile it with the remittance data received from the VAN.

However, some banks that specialize in financial EDI are moving into the health care market.

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[16] Ibid.

[17] National Automated Clearing House Association figures reported in Canright, op. cit., footnote 9.

BankAmerica, San Francisco, CA; Chase Manhattan, New York, NY; Huntington Bancshares, Columbus, OH; PNC Bank Corp., Pittsburgh, PA; and National City Corp., Cleveland, OH, are among the national and regional banks that now process medical bill payments electronically for hospitals, clinics, and other health care providers who are their banking customers. Some of them, in addition to handling EFT payments, are also offering the services of a processing service.

Standardized Forms

The federal government has played a major role in standardizing electronic forms in the health care industry. For instance, institutional providers are encouraged to submit Medicare and Medicaid claims using the UB-92 form, which was created by the National Uniform Billing Committee (NUBC). The difficulty is that each state adds its own requirements to the UB-92 form, which means that some payers and nearly all software vendors have to support nearly 50 different versions of the UB-92.[18] Moreover, the EDI standard for transmitting claims, ASC X12.837 (health care claim), can structure data contained in the UB-92 in several different ways, all of which are correct insofar as the standard is concerned.[19] The result is that the health care industry's standards are not yet standard enough for easy implementation of electronic commerce.

HCFA has developed implementation guides for health care claim and remittance advice transactions. By July 1, 1996, all electronic claims will be submitted to HCFA using the standard forms.[20] The HCFA requirement is expected to stimulate EDI use throughout the industry. To ensure that the health care industry uses a single EDI version of the UB-92, the Workgroup for Electronic Data Interchange (WEDI) and the NUBC are developing EDI implementation guidelines based on the HCFA guide, which is becoming the de facto industry standard.

LINKING HEALTH CARE PROVIDERS WITH SUPPLIERS[21]

In contrast with health care payments, the use of electronic commerce between large health care providers and hospital suppliers has a longer history, dating back to the mid-1970s when the American Hospital Supply Corp. (AHSC) introduced the first electronic order-entry (EOE) system called Analytic Systems Automated Purchasing (ASAP). ASAP initially allowed hospitals to place orders using a touch-tone telephone. As ASAP evolved, hospital purchasing managers could enter orders into terminals connected to AHSC's mainframe computer, which automatically reserved inventory and generated a packing list. The system was so convenient that purchasing managers placed orders with AHSC at the expense of its competitors.[22] Hospitals achieved benefits by: 1) eliminating manual order writing; 2) reducing transcription errors that result when orders are written manually or taken over the phone; and 3) increasing the accuracy and timeliness of order, delivery, and cost information.

The proliferation of other EOE systems became a problem to major hospitals, especially chains and large purchasing groups. Those organizations purchased supplies from several vendors, which meant they had to use several different EOE systems. They faced the same problems that have led to the development of EDI in other industries: higher costs from having to support multiple pro-

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[18] D. Rode, "UB-92, HCFA 1500: The Genesis of EDI?" *Health Care Financial Management*, vol. 47, No. 1, January 1993, pp. 82-83.

[19] D. Hodges, *Integrating Computer-Based Technologies Into HMOs* (Washington, DC: Group Health Association of America, Inc., 1993), p. 41.

[20] M. Buffington, op. cit., footnote 11.

[21] This section is based on Canright, op. cit., footnote 9.

[22] R. Forester, "A History of ASAP at Baxter Health Care: The Journey from Proprietary to X12 Standards," *EDI Forum*, vol. 4, No. 1, 1991, p. 96. (Baxter acquired the ASAP system when it merged with American Hospital Supply Corp. in 1984.)

prietary systems,[23] including additional space for the terminals and additional training for purchasing personnel. Today, most hospital-supply companies are making a transition to EDI and offer EDI-based alternatives to their proprietary electronic order-entry systems.

In addition to the companies that directly supply hospitals and other providers, the companies that manufacture health care supplies and equipment are beginning to use EDI to connect with the smaller companies that they rely on to distribute their products to hospitals, physicians, and other health care providers. For the manufacturers, EDI connections result in cost savings because they no longer need to key purchasing information into their systems. By automating business with all their distributors, the relatively small benefits that come from automating each trading relationship are multiplied over a large base. For distributors, it is not clear whether the conversion to EDI results in net savings or net costs.

When the process of purchasing and paying for supplies is automated through EDI, it can be integrated with a larger automated materials management information system that can include inventory control, automatic replenishment, tracking of chargeable suppliers and equipment, invoicing, and patient cost accounting. Greater use of information systems for these purposes has been shown to improve inventory control and reduce the costs of materials management in other industries. Currently, only a few hospitals and health care groups are using this technology to its full potential.[24]

The movement to electronic systems in hospital materials management has not been pervasive among hospitals. By 1990, hospitals used EDI to place some 24 percent of orders to suppliers.[25] Purchase orders and confirmations still represent the bulk of EDI transactions in hospitals; hospitals have been slow to use EDI for other purchasing functions, such as electronic invoicing and payment.[26] WEDI, for instance, estimated that some 6,000 of 6,138 acute care hospitals require EDI upgrades.[27]

Overall, the health care supply portion of the health care industry has made a good start in automating trading relationships. As suppliers offer and providers adopt more sophisticated materials-management strategies, EDI will become increasingly necessary as well as commonplace.

PHARMACEUTICAL INDUSTRY EDI

The drug distribution chain has been an early and successful adopter of electronic commerce. As early as 1972, a major drug wholesaler began a pilot project to transmit purchase orders directly to the computers of major manufacturers. Industry organizations, such as the National Wholesale Druggists Association and the American Surgical Trade Association, actively supported these activities and encouraged the development of industry-wide standards. Use of electronic ordering was found to reduce order lead-times, which reduced inventory requirements. Some industry analysts believe that adopting electronic ordering is a major factor in alleviating and reversing economic

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[23] The terms "proprietary system" and "proprietary data format" refer to electronic business communications systems that work for a single company—the one that provided the system or software. The terms "standard system" or "standard data format," in contrast, refer to EDI systems that are designed to ease communications with any organization that supports EDI standards.

[24] ECRI, "Computer Information Systems, Materials Management," *ECRI Special Reports*, 202765 424-008 (Butler Meeting, PA: 1995), p. 3.

[25] Arthur Andersen & Co., *Stockless Materials Management: How It Fits Into the Health Care Cost Puzzle* (Alexandria, VA: HIDA Educational Foundation, 1990), p. 56.

[26] J.J. Moynihan and K. Norman, "Health Care EDI: An Overview," *EDI Forum*, vol. 6, No. 2, 1993, p. 11.

[27] Workgroup for Electronic Data Interchange, *Report* (Hartford, CT, and Chicago, IL: October 1993), p. 9-34.

hardships that drug wholesalers had been experiencing in the early 1980s.[28] By 1986, 96 percent of drug wholesalers were using EDI, as were 90 percent of pharmaceutical manufacturers—one of the highest penetration rates of any industry at that time.

Today, electronic commerce has also expanded rapidly to independent drugstores and drug chains. About 95 percent of drugstores are computerized. Many of them order from distributors using either proprietary systems or EDI standards and guidelines developed by the American Society of Automation in Pharmacy.

Because many prescription drugs are paid for or reimbursed by insurance plans, electronic links have also been established between pharmacies and payers. A standard format for communication between pharmacies and insurers is in widespread use. Online eligibility systems have helped to speed processing and payments by enabling pharmacies to check a patient's benefits before filling the prescription. After a physician or patient submits a prescription (either by phone or in writing), the pharmacy enters the information from the patient's prescription benefit card (issued by the insurer, health plan, or employer) and the information from the prescription into an online system using the National Counter Prescription Drug Plan's (NCPDP) standards for real-time transactions. Through this system, the pharmacy contacts a database where it can confirm the patient's eligibility status, find out whether the payer will pay for this drug, determine the copayment amount, and ascertain whether the payer allows or requires generic substitutions.

Pharmacy claims are much less complex than other health care claims, and a much larger percentage of them are submitted electronically. In 1993, over half of the prescription claims reimbursed by insurance payers were submitted electronically and that percentage continues to grow.[29] NCPDP recently introduced a paper-based claim form based on the electronic format to simplify reimbursement for patients whose payers are not yet using electronic pharmacy claim submission.[30]

The existence of large databases of prescription-related information in a standard format is offering new tools to both the pharmaceutical and insurance industries. Databases are being used to analyze the patterns of drug purchase, to develop formularies or lists of preferred drugs, to compare costs of alternative drugs, and to compare the cost-effectiveness of drugs to alternative treatments.

COMMUNITY AND REGIONAL NETWORKING

Community Health Information Networks

A *community health information network* (CHIN) can be either a proper or a generic name for a type of information system that is still undergoing development and definition. Another term used is *community health management information system* (CHMIS), which can also be both a common or proper name. Both of these networks are envisioned as systems that allow the seamless exchange of clinical or administrative information among health care providers, payers, and other authorized users. Currently, there are between 75 and 100 community networks in early stages of startup or implementation that roughly correspond to the CHIN or CHMIS descriptions below.[31] (This report will use the term CHIN as generic and will use CHMIS only when distinguishing features of the CHMIS model).

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[28] P.K. Sokol, *From EDI to Electronic Commerce* (New York, NY: McGraw-Hill, Inc., 1995), pp. 212-219.

[29] Ibid.

[30] G. Muirhead, "Stake Your Rx Claim: NCPDP Issues Standard Paper Form for Reimbursement," *Drug Topics*, Nov. 7, 1994, p. 106.

[31] R. T. Wakerly, remarks at *CHINs and CHMISs: Networks for Community Health Information and Management*, meeting of the National Health Policy Forum, Washington, DC, Oct. 25, 1994.



Small clinics and individual health care providers are beginning to use computer-based systems for practice management, recordkeeping, and communication with laboratories, hospitals, and insurers.

At their most basic, CHINs are electronic systems whereby claims filing, eligibility verification, and other transactions can be performed by a provider (whether a single physician or a major health care organization) and an insurance clearinghouse; or whereby a physician's office can contact a hospital's information system to obtain clinical or administrative information on a patient. However, CHIN developers envision them as expanding into systems that link all participants in the health care system—providers, payers, banks, pharmacies, public health agencies, employers, and others. Moreover, a fully developed CHIN might allow a physician to assemble a single patient's information across different institutions and databases to produce a complete medical record; or it could permit a researcher to aggregate the data for many patients to compare performance of different plans and providers. In future, CHINs might also be a means for sharing access to medical knowledge, remote diagnostic applications, and expert advice based on outcome and effectiveness analyses.[32]

The difference between a CHIN and a CHMIS is primarily one of initial priorities. All of these systems start with some initial features and services and add others as they grow. CHINs, for the most part, were developed to provide connectivity and transport of data among the users. Some of them are concentrating first on linking physicians and clinics with hospitals and labs to access clinical data, and secondarily are providing claim filing and other insurance-related services. Some CHINs have a long-term goal of building a community-wide data repository for outcomes research and for comparing the performance of plans and providers, but they have not yet started that phase of their development. Other CHINs have no plans for building a centralized data repository, but envision that the standardization they provide will eventually allow authorized users to transparently aggregate data across many databases, thus accomplishing the same purpose.

CHMISs, on the other hand, have started with the concept of building a data repository for use in assessing the performance of health care providers and plans. Collection and analysis of management information is a priority. Although there is variation among the CHMISs started so far, most are focusing on providing insurance transaction services (that is, connectivity and services linking providers and payers) and on capturing data from those transactions into the data repository. Services linking providers with providers to exchange clinical data are also planned in 'many cases.

Issues associated with CHINs include ownership and control, and network design and data management.

■ Ownership and Control

There are several possible ownership models for CHINs. One is a joint venture between a health care provider and an information system vendor. This is likely to be a for-profit organization, offering community-wide service, with the goal of providing easier communications among the various

[32] D.L. Zimmerman, *CHINs and CHMISs: Networks for Community Health Information and Management.* Issue Brief No. 657 (Washington, DC: National Health Policy Forum, 1994).

users. The vendor may first implement services for the partner or lead sponsor and then attempt to contract with other users based on demonstrations of the usefulness of the service. An example of this ownership model is the Wisconsin Health Information Network (WHIN), developed by Aurora Health Care Corp. and Ameritech Health Connections (a subsidiary of Ameritech, the regional telephone provider). Initially, WHIN provided physicians with access to laboratory results, patient census data, and other information in the databases of the hospitals where they are affiliated. In addition, the network now offers an electronic claims service for filing claims and performing some other insurance transactions. Besides the Aurora-owned hospitals, 11 other hospitals and their affiliated physicians are now on the system. One difficulty with this ownership model is that the system may be viewed with some suspicion by competing hospitals who may worry that the provider that owns the system is giving itself some advantage. Even in cases where a vendor is sole owner, late adopters may view the system as "belonging" to the early adopters. There are 45 to 50 communities with vendor-owned CHINs.

An alternative model used by some CHINs is to form an understanding among a broad group of potential users before the system is built and create an ownership structure that will be viewed as more neutral by all participants. Although their organization varies, systems under development in Vermont, New York, Washington State, Chicago, Cincinnati, and other locations have attempted to develop a broad coalition of community groups—providers, payers, and employers—before the network is built. These groups then jointly sponsor the creation of a not-for-profit organization to operate the system. This model also has difficulties. Developing community consensus about the goals and operation of the system can take a great deal of time, so systems opting for this model come to market much more slowly. Agreements between stakeholder groups may become fragile when it becomes necessary for participants to actually commit money to the major project. It is not yet clear who should make the biggest investments in community networks because no one knows who will accrue the most benefit from them.

Other ownership patterns, including variations and hybrids of the above, ownership by a consortium of vendors, or ownership by a state or local government agency, are possible, and are being tried in some locations.[33]

Network Design and Data Management

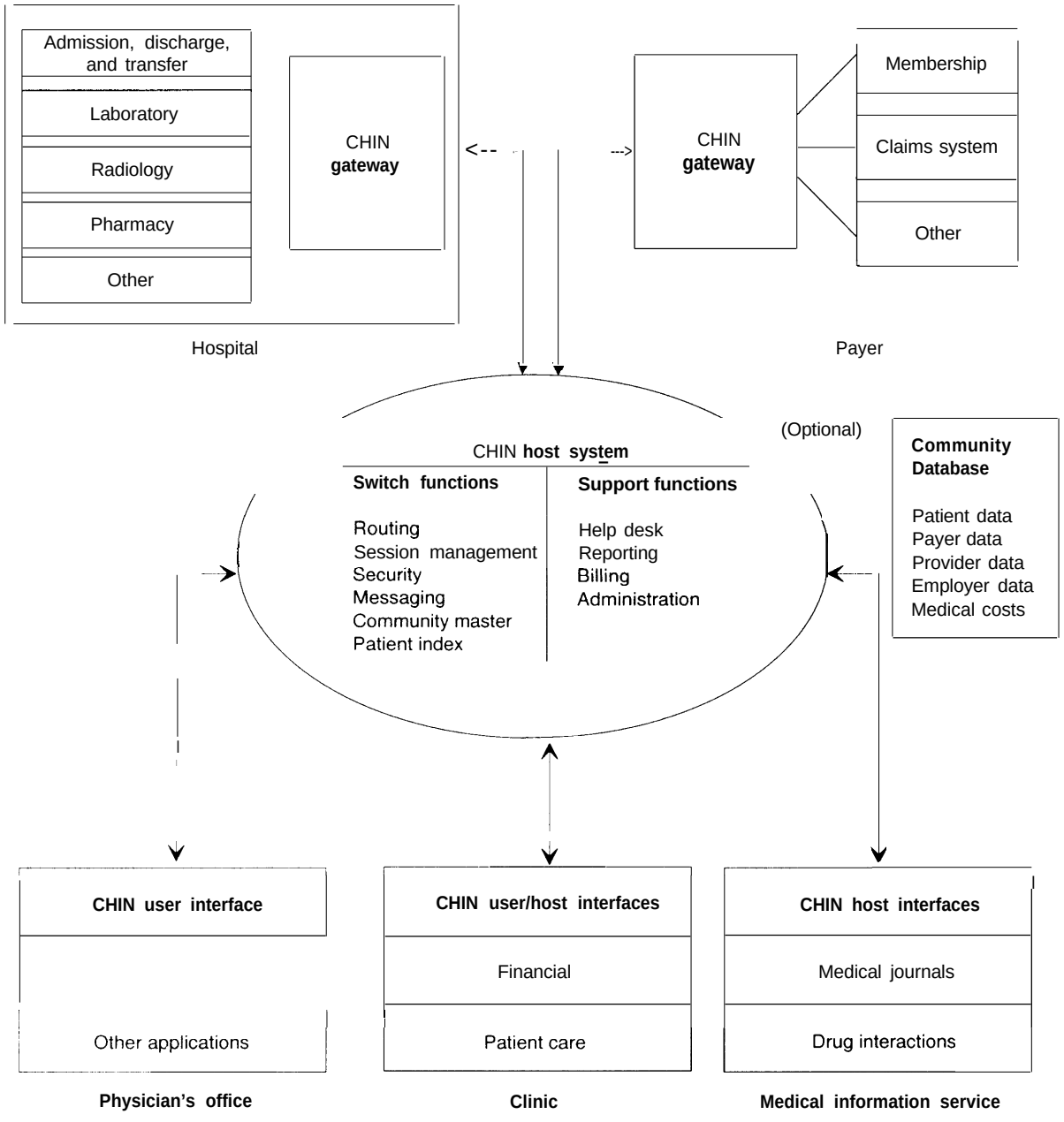
CHINs vary widely in their approach to the function of the network, the content of the information carried on it, and the standards to be used by or imposed on participants. One basic decision facing all CHINs is whether or not the network will maintain a central database of health information. Although creating a central repository is a fundamental goal of some networks, others have actively rejected the idea and use the fact that each participant maintains its own proprietary data as a selling point.

Technology decisions related to designing a CHIN are complex because their goal is to bring together a diverse set of information suppliers and users who are operating incompatible systems. The network must establish "rules of the road" so that participants can share information usefully. This means standardizing formats for data content and structure and creating interfaces so that different computers and different people can use them. In the absence of clear national standards, different CHINs are developing their own ways of doing this.

Figure 3-3 outlines the high-level architecture of a CHIN. The network must interact with a variety of different application systems in the participants' information systems. For the most part, network participants will not be willing or able to

[33] Ibid.

FIGURE 3-3: High-Level Architecture of a Community Health Information Network (CHIN)



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

change their own operations substantially in order to participate, so the network must develop interfaces to diverse systems as well as gateways (sometimes called application interface gateways or translators) to convert messages from one standard to another (e.g., from a proprietary system to HL7 or to a standard EDI format). The network provides a number of value-added services to participants, including switching functions like routing (delivering data between trading partners), security (maintaining passwords and access controls; encryption), session management (e.g., creating audit trails), and messaging (harmonizing disparate e-mail systems and providing access to external databases or networks). Generally the network also provides support functions for user organizations, including a help desk and billing and administrative information on system use.

User interface and point-of-service mechanisms, such as card readers and other devices, can provide access to the network and initiate transactions. For example, scanning a patient's identification card can initiate a verification of the patient's eligibility for benefits. For more information on cards as access and identification devices, see box 3-4.

User interfaces can be customized to allow each user to see data in the form that is most convenient for that user, as shown in figure 3-4. When a physician's office contacts different hospitals for patient information, the user will see the information in that office preferred format, despite the differences in hospital information systems. Similarly, any data from the hospital that need to be downloaded into the physician's practice management system are formatted to be acceptable to that sys-

BOX 3-4: Card Technology and Health Records

Smart cards, magnetic stripe cards, and other small portable devices may offer a low-cost way to store and transfer electronic health information. Cards can be used as identification and authorization tools or as actual storage media. Cards currently play a role in the health care system, predominantly as a means of patient identification and association with a particular health plan.

Types of cards include:

- Paper cards, usually with printed data and perhaps with a barcode or magnetic stripe; these are usually issued by health plans as a means of identification.
- Magnetic stripe cards, such as those widely used in the financial industry (e.g., credit and automated teller machine—ATM—cards). The magnetic stripe on the back can carry a limited amount of information—226 characters in the case of a typical three-track card. They are typically used with online systems for accessing a database.
- Smart cards have an integrated circuit chip with a range of capabilities. They can support security features such as encryption and differential access for different parts of the card. They can be used to interact with online systems or to store varying amounts of data; the typical 24-kilobit card stores one full page of text. A backup copy of stored data may be kept on a provider's computer to protect against loss.
- Laser optical cards carry a wide stripe on the back that contains information that is "burned" into the card with a laser. Once written, data cannot be modified, although new data can be added to some types of laser optical cards. They can carry 2.5 megabytes of digital information (about 1,200 pages of text). They typically do not have security features unless an integrated circuit chip is added to the card for this purpose.

(continued)

BOX 3-4: Card Technology and Health Records (Cont'd.)

In the health care system, cards could be used to: streamline various administrative functions (e.g., claims processing); automate functions that tend to be repetitive in nature (e.g., filling out medical history forms); and improve the quality of care by reducing the likelihood of duplicative testing or possible drug interactions. Potential applications of card technology include:

- Patient Identification, enrollment verification, and eligibility verification
- Emergency Information
- Payments and claim processing
- Prescriptions
- Medical history

Magnetic stripe cards have wide use in health care in the United States, perhaps because of the large installed base of cards and card readers already in use by the financial industry and the public's familiarity with these cards. A number of U.S. health plans use plastic magnetic stripe cards, and at least 22 states use them to identify people eligible for Medicaid benefits. The patient presents the card when entering the hospital, provider's office, or other location. When the card is scanned, Information that already exists about the patient can be linked with newly entered data in an automated fashion. Eligibility for service, the amount of the copayment, and other payment reformation can also be obtained quickly so that accounts can be settled before the patient leaves. Although magnetic stripe cards carry only a small amount of information, they are useful as access devices to link with the provider's or payer's online databases, and the U.S. telecommunications infrastructure is adequate to provide these linkages in almost any location.

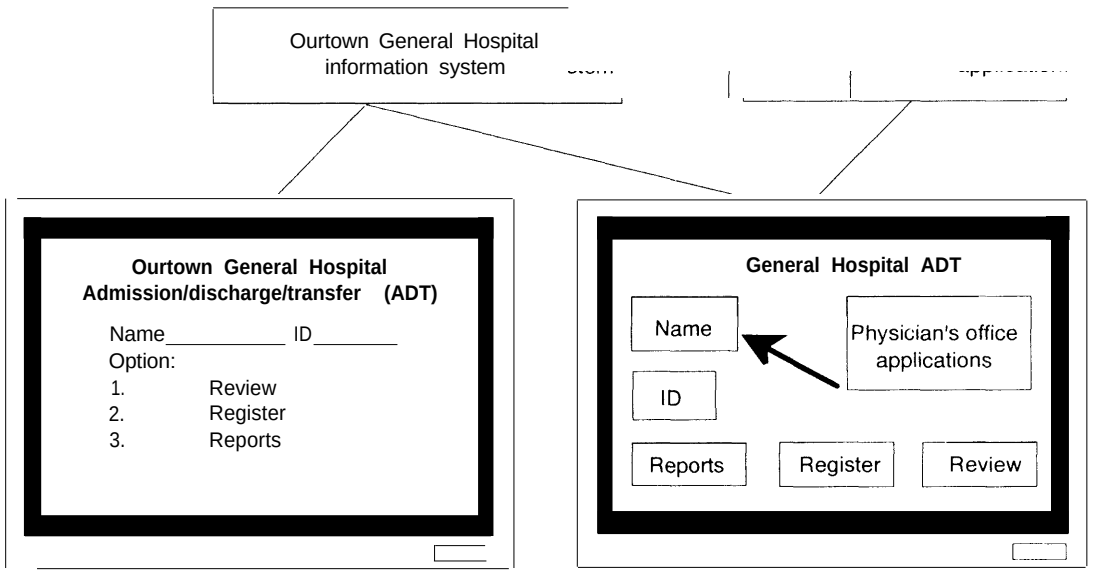
A number of health plans in the United States are testing the use of smart cards. Currently, standards for the data format, encryption, and security features are only beginning to emerge. This means that cards are only being used within closed systems. The Department of Defense is conducting a multimedia (magnetic stripe, bar code, integrated circuit chip, and photograph) identification card pilot program, which wiII test the viability of deploying smart cards for multifunctional purposes with a primary focus on health care. Canada, Great Britain, and Japan are also looking into smart cards for health care informatlon.

Smart cards are used more widely in Europe than in the United States, but even in Europe, their use in health care is primarily for identification and for limited amounts of clinical and administrate information. In Germany, smart cards generally contain only administrative information. In France, cards typically contain some clinical information, but there is no attempt to store a complete medical record; rather, basic information is placed on the card and may be accessed by providers or pharmacies to reduce errors or to speed data processing. The storage capacity of many cards currently in use is usually not sufficient to maintain a complete medical history, although higher capacity cards are becoming available. Widespread use of portable electronic patient records in card form wiII depend on the availability of standardized patient record systems in the computers of all providers who will interact with and update the cards. Such systems are not currently available in Europe or the United States.

Laser optical cards are still an emerging technology and are not widely used. In one pilot project, the Texas Department of Human Resources has issued 2,500 cards containing demographic information and Immunization records. Equipment to read the cards is available at only a few locations, but the project is expected to expand. Experiments with laser optical health cards are also under way in Scotland.

SOURCE: Adapted from Phoenix Planning and Evaluation, Ltd , "Potential Card Applications in the Health Care Industry, " unpublished contractor report prepared for the Off Ice of Technology Assessment, January 1994

FIGURE 3-4: Common User Interface



Note Common user systems sign-on allows for a custom screen (regardless of application) for users according to their profiles

SOURCE Adapted from 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

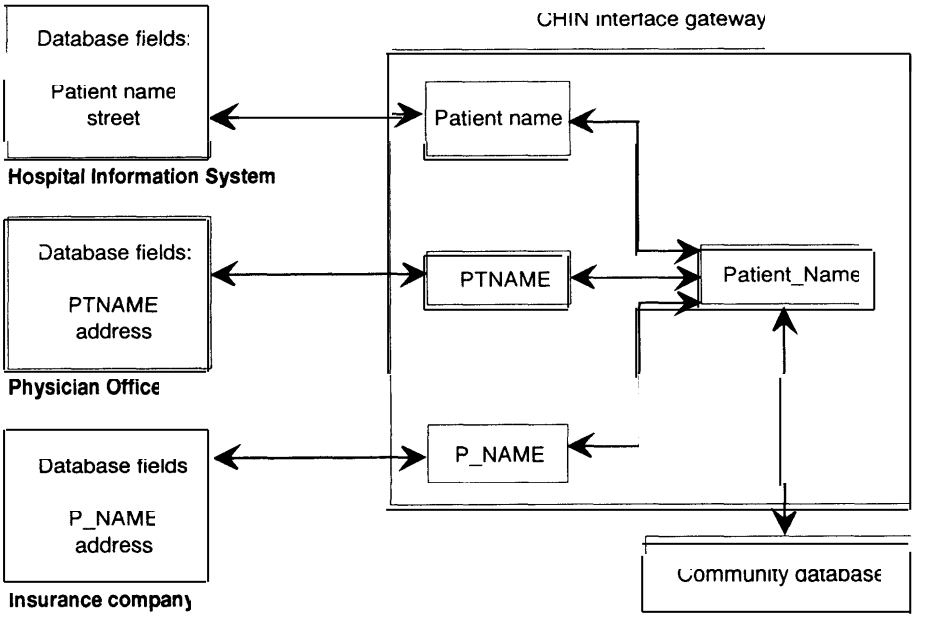
tern. The network system maintains a profile of each user and the way that information must be presented. Similarly, data for claims filing or other transactions can be entered by the physician's office in a single format, regardless of payer. The network, through the application integration gateway function, can then take responsibility for translating or reformatting the information to suit the requirements of each payer. This approach should reduce a participant's training costs because employees only have to learn one set of menus and navigational tools.

While the user's view of data appears integrated through the use of common user interface mechanisms, actually integrating data across multiple databases is another problem entirely. CHINs that include a central data repository are addressing this problem now. A repository is a "central database populated by transactions from several disparate departmental and organizational systems."[34] The repository contains copies of transaction data carried out by various trading partners; it is not the original or sole source of information. Management of information from disparate sources can be a complex task:

> To ensure data integrity, the [application integration gateway] should have data audit and control mechanisms to synchronize replicated data with its various storage locations. The task of determining which transaction system is the

[34] M.R. Gorsage and J.W. Hoben, "Technological Implications of CHINs," in R. T. Wakerly (cd.), *Community Health Information Networks: Creating the Health Care Data Highway* (Chicago, IL: American Hospital Publishing, Inc., 1994), pp. 115-140.

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 global 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.

delivery. CHIN development takes time and, in the meantime, some IDSs may build their own proprietary enterprise-wide networks. IDSs will carry out most of their data communication on their own enterprise networks because many of their administrative functions will be internal, and they may not need to join a community-wide network.

There are two schools of thought on the possible interactions of CHINs and IDS networks. One holds that IDSs have no need for CHINs, and that CHINs are a short-term or limited phenomenon that will fade as markets become dominated by two or three competing managed care organizations. Because the IDSs are competitors, they will have no incentive to share information, and thus connectivity between them will not be needed.

The other school of thought says that IDSs need CHINs because even in a managed care environment there will still be out-of-plan referrals, providers with multiple affiliations, and mobility of providers and patients among plans. In order to be totally electronic in processing administrative information, IDSs will need access to a community-wide or regional network infrastructure. Further, even though IDSs will want to keep private their own data on outcomes, utilization, and costs, it is likely that large purchasers of health care (and perhaps regulatory agencies) will insist on seeing at least some of this information on a community-wide basis, and CHINs will offer a mechanism.[36] There is even the view that some IDSs will eventually become CHINs, perhaps setting up subsidiaries to offer CHIN services to their competitors and unaffiliated providers in their communities.[37]

Networking and Public Health

The usefulness of community and regional networks increases if they are also able to interact with public health agencies at the local, state, or federal levels. The Department of Health and Human Services has been tasked by the Administration to act as the lead agency in coordinating federal government activities related to health information systems.[38] Among the long-term goals to be pursued is the creation of a national forum for collaboration on standards development for health information. Health information networks, automated payment systems, and other systems are part of the national information infrastructure (NII) where public- and private-sector activities need to be coordinated.

The Public Health Practice Program Office at the Centers for Disease Control (CDC) is developing an Information Network for Public Health Officials (INPHO) that provides state and local public health officials with access to timely information on disease prevention and health promotion, including: 1) local and national disease and injury rates and associated risk factors and prevention measures; 2) preventive health data, guidelines, regulations, training materials, and emergency notices; and 3) reports of epidemiological investigations. The system will initially employ CDC's personal computer software (WONDER) as well as voice and fax technologies, but will eventually use Internet tools. It will provide an electronic mail service for federal, state, and local public health officials, starting with local area networks and building toward wide area networks. The INPHO system is being pilot-tested in Georgia through a $5.2 million grant from the Robert W. Woodruff Foundation to Emory University in Atlanta, teamed with several other academic and state government organizations in Georgia.

COSTS AND COST-EFFECTIVENESS

System Costs

High system costs often pose a barrier for a business wanting to embrace EDI. Hardware, soft-

[36] F. Bazzoli, "Will CHINs Be Able To Mesh with Enterprise Networks?" *Health Data Management*, March 1995, pp. 47-52.

[37] R.T. Wakerly, "Models of CHIN Ownership," in Wakerly, op cit., footnote 34, pp. 53-71.

[38] A. Gore, Vice President, Washington, DC, memorandum to D. Shalala, Secretary of Health and Human Services, Washington, DC, Mar. 8, 1995.

ware, installation, and staff training are all expensive. If an organization opts to work through an electronic claims company or a VAN, it must pay per-transaction charges. If it creates a direct line to its trading partners, it will incur costs for network setup and telecommunications equipment. Staff will be required to manage the system, adapt it to changing standards, and act as a liaison with new trading partners.

One estimate puts the total average, per-company EDI investment at between $200,000 and $700,000.[39] The lower figure is for a supplier company, while the higher is for a large company seeking to connect all its suppliers. For the health care industry, WEDI estimates implementation costs at $7,500 to $15,000 for individual professionals and $25,000 to $500,000 for institutions.[40] Costs include hardware, software, consulting, and VAN charges. Most companies do not perform a break-even analysis, according to the EDI Group, a firm that studies EDI use generally. Those that do, however, report that they reach the break-even point within two years.[41]

There are relatively weak near-term incentives for some users in the health care industry to assume the high initial costs of EDI. Although there are promises of administrative savings, these will be spread out among most sectors of the industry. Further, it is likely that savings will not be fully realized until all transactions are electronic. A business that has some trading partners using EDI and some using paper has the expense of maintaining both systems. This is often the case in health care at this time.

National Estimates of Administrative Cost Savings

A number of key studies focus on national estimates of potential savings from using information technology for health care administrative functions. These include studies by WEDI, the Tiber Group, Arthur D. Little, Inc. (ADL), HCFA, and Lewin-VHI.[42] The findings of these studies are summarized in table 3-1. It is important to note that *comparisons across studies should be made with caution*: the definitions used for the various administrative transactions vary widely, as do the methodologies for estimating costs and savings. Still, it is instructive to examine the findings from these studies in clarifying possible savings from information technologies in health care.

The studies on national administrative savings project that information technology applications could save in the range of $5 billion to $36 billion per year in total health costs, which translates into approximately 0.5 to 3.6 percent of total national health spending. The Tiber Group study (which was commissioned as part of the WEDI Report) attempted to differentiate the savings per transaction for payers and for providers. It found that the greatest savings for both would be in the areas of claims inquiry and claims submission—which are very information-intensive. With the exception of the ADL report (which included some clinical as well as administrative functions), the magnitude of the projected annual savings was quite similar across studies.

There is some reason to believe that these estimates may be overly optimistic. For example, ex-

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[39] D. M. Ferguson and D. J. Masson, "The State of EDI in the U.S. in 1993," *EDI Forum*, vol. 6, No. 4, 1993, p. 10.

[40] R.L. Schaich, "Health Care Reform Costs and Benefits," *EDI World*, vol. 3, No. 12, December 1993, p. 51.

[41] Ibid.

[42] WEDI estimates and Tiber Group estimates are reported in WEDI, op. cit., footnote 27; Arthur D. Little, Inc., *Telecommunications: Can It Help Solve America's Health Care Problems?* No. 91810-98 (Cambridge, MA: July 1992); U.S. Department of Health and Human Services, Health Care Financing Administration, *White Paper on Financial Implications of Information Technology*, 1991; Lewin-VHI, *Reducing Administrative Costs in a Pluralistic Delivery System*, report prepared for the Healthcare Financial Management Association, Apr. 30, 1993).

TABLE 3-1: Estimates of Cost Savings for Payers, Providers, and Employers Through the Use of Information Technology

Study	Application/function	Claims submission	Enrollment	Payment & remittance	Eligibility	Claims inquiry	Total net savings
Workgroup for Electronic Data Interchange (WEDI)		$45 to$13 1 billion annually	$21 to $43 billion annually	$1 1 to $1 3 billion annually	$25 to $ 49 billion annually	$28 to $ 40 billion annually	$42 billion (over six years)

Key assumptions

1 A comprehensive, standardized Electronic Data Interchange capability is established throughout the health care system according to an aggressive Implementation schedule over the next three years

2 Standard formats will be adhered to very soon

3 Employer automation costs only reflect the costs required to automate the transfer of enrollment data for companies with over 50 employees

4 For enrollment, 171,722 employers with more than 50 employees will save 0.5 to 1.0 FTE or $12,000 to $24,000 per year, minus annual transaction costs of $78 ($1.50 times 52 transactions)

5 For eligibility, there will be an elimination of nearly 6,000 institutions to maintain enrollment or eligibility lists supplied by payers

6 For payment and remittance, on average, there are 15 claims per remittance advice.

7. Implementation schedule assumes costs are amortized over three years
- 30% implementation occurs in year 1
- 70% Implementation occurs in year 2
-100 % Implementation occurs in year 3

Sources: Previous WEDI findings, Health Care Financial Administration reports, A.D. Little report, Lewin-VHI report, proprietary data, and Tiber Group study, which was part of WEDI report

Tiber Group study	$0.73, $1.07	$0.64, $1.10		$0.19, $0	$0.98, $2.05	$2.72, $3.56	$24 billion
Key assumptions		(savings per transaction for insurer, then hospital)					(over 5 years)

1. Startup costs and fixed costs used in the study were assumed to be sufficient for 100% EDI.
2. Surveys were completed by only 14 physicians, nine hospitals, and six payers Therefore, the data are assumed to be externally valid in order to project national savings

3 Broad definitions for the applications (or transactions) were necessary due to definitional issues at many demonstration sites

4 Even though price competition in the computer industry is quite high, costs were held constant for the study

Source: Surveys at each of three demonstration sites.

Arthur D. Little	**$6** billion annually						$36 billion annually
Key assumptions							

1. The $30 billion in savings not due to claims submission will come from electronic management and transportation of patient information, including the use of home health terminals to reduce discussions with providers; reduction in emergency room visits; early intervention: and Improved creation, transport, storage, and retrieval of computer-based patient records

2 Legal issues regarding liability will have been resolved

3 Implementation costs are not included in the economic model

Sources: Data were gathered from available research and pilot studies when available, otherwise determined by panel of experts at Arthur D Little.

(continued)

TABLE 3-1: Estimates of Cost Savings for Payers, Providers, and Employers Through the Use of Information Technology (Cont'd.)

Study	Application/function	Claims submission	Enrollment	Payment & remittance	Eligibility	Claims inquiry	Total net savings
Health Care Financing Administration		$58 billion annually	$04 billion annually	$24 billion annually	$0.8 billion annually	$0.1 billion annually	$436 to $74 billion (over six years)
Key assumptions							
1 For claims subbmission, payers and provld-ers will each save 50 cents per claim for an estimated three billion paper claims		4 Administrative costs assumed to be growing at the rate of total health care expenditures					
2. For eligibility, assumed 75 million transac-tions and savings of $140 per transaction.		5 Each visit, test, or procedure performed by a provider is counted as a separate "claim"					
3 For claims inquiry, assumed provider sav-ings would be one-half as much as payer savings estimated by WEDI							
Source: WEDI report provided most of the information							
Lewin-VHI		$1,9 to $4.5 billion annually					$2.6 to $52 billion net in 1993
Key assumptions							
1 The entire medical bill (all tests and pro-cedures) is counted as one claim.							
2. For claims submission, providers will save $1 30 per claim and payers will save 60 cents per claim							
Sources: Cost estimates from Congressional Budget Office and General Accounting Office, industry sources, including The Medical Group Management Association; calculations by Lewin-VHI experts							

SOURCE. Project HOPE Center for Health Affairs, Bethesda, MD, "Estimating the Cost-Effectiveness of Selected Information Technology Applications," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, May 9, 1995.

perts interviewed by OTA note that the assumption by both WEDI and the Tiber Group that EDI will be rapidly implemented by a high percentage of providers and payers is unrealistic. However, the WEDI Report's other assumptions on savings from specific administrative transactions, which were based on industry surveys and case studies, seem to be more reasonable.[43] Potential savings noted in the ADL report also seem generous for a number of reasons. The report did not include the costs of implementing new systems, for example. The authors defended this omission by pointing to the variability of pricing, and the fact that the cost of implementation would be widely shared with other industry applications. Another problem was that some of the categories of cost savings were vague and the data used to support the claims were not always well justified. Finally, the results include some clinical applications as well as administrative applications, so comparisons with other national estimates are difficult to make.

The HCFA results, which relied heavily on the WEDI methodology, may also be optimistic for reasons noted above. In addition, the report was not explicit about how some of the calculations were made. The Lewin-VHI report was also vague about some of the assumptions underlying their calculations.

Despite limitations, however, it is interesting to note that the studies taken together suggest that information technology applications in health care administration will produce important, but not inordinate, savings to the health care system. In light of some claims made about the potential reduction in administrative costs that would arise from information technology, the actual savings projected appear rather modest. This general prediction seemed to be shared by experts interviewed by OTA. They also emphasized that the fact that existing studies do not show large savings does not diminish the potential importance of technology applications in increasing system efficiencies (which may be difficult to capture in an evaluation) or in improving patient care.

Savings from Reducing Errors and Detecting Fraud

Creating a health care bill or claim is a very complex process, and there are many opportunities for unintentional error or deliberate fraud. An important part of developing the bill is to describe the procedures performed for the patient. This information must be transferred from the patient record to the administrative system and, ultimately, into the bill or claim. Many payers, including HCFA, use one of several diagnostic and procedural coding languages, such as ICD-9-CM, as the basis of their payment formula. Many providers try to capture coding information as close to the source as possible, for example, by listing the code along with the procedure name on paper forms physicians use for ordering tests and procedures, or by having a computer-based system automatically record the code whenever a procedure is ordered by name. When diagnoses and procedures are not captured in coded form (e.g., if they are written in free-hand notes), then trained coders must read through the record to find information to be put in the bill.

The coding systems are far from perfect. Decisions about which code to use are not always clear and can be the subject of negotiation between payer and provider while a complex claim is adjudicated. Misreading, miskeying, and other mistakes can cause bills to have incorrect codes. In addition, some providers deliberately engage in fraudulent practices such as *upcoding* (describing the procedure performed with the code for a more complex one) and *unbundling* (billing for two or more procedures when a single comprehensive code exists that describes the procedure performed) in an attempt to get a higher level of compensation from the payer.

A number of software products have been developed to check claims for inconsistent, erro-

[43] Project HOPE Center for Health Affairs, op. cit., footnote 2.

neous, or suspicious coding. Some payers have their own proprietary systems to check claims before paying.[44] In addition, a number of commercial products are available for payers, providers, or other firms that prepare claims on a provider's behalf. Detecting obvious errors in bills saves providers the trouble and expense of submitting claims that will be rejected; such software is sometimes available in practice management systems and other administrative software for providers.

A recent study by the General Accounting Office (GAO) tested several commercial fraud-detecting software packages on samples of Medicare claims and found them very effective in detecting errors and flagging possible fraud. GAO suggested that use of such software could have saved HCFA about $603 million in 1993 and $640 million in 1994. These savings, amounting to about 1.8 percent of Medicare reimbursements for supplies and services, are in line with the savings reported by private insurers using the same software. GAO also notes that Medicare beneficiaries would have saved money as well—$134 million in 1993 and $142 million in 1994.[45]

Economic Justification of CHINs

No one has demonstrated whether of not CHINs are cost-effective. Those that exist have only been in operation for a few years and their data have not been publicly analyzed. However, the large investments made by vendors suggest that their own proprietary estimates show a profitable future for CHINs. On the other hand, a number of vendors have dropped out of this market already. In addition to the large investments involved, many of them have perceived the possibility, or experienced the reality, of failing to develop community consensus about the role of the CHIN and services that need to be provided. Even if a project is initiated by a vendor rather than a coalition of community groups, it is necessary to have the interest and commitment of a minimum number of potential customers from the relevant user groups; otherwise the project is too risky.[46]

The investment required to build a community network is large. Estimates for WHIN suggest that the partners invested $4 million to $6 million in hardware, software, sales, and operations teams before recouping any costs. Costs for WHIN subscribers depend on their size and the level of service they desire. A hospital might make a one-time investment of $50,000 to $125,000 (depending on its current level of automation, the number of custom interfaces that must be built, etc.). Ongoing costs are determined by an algorithm that includes the number of physicians on staff, number of beds, and annual patient visits. Other ongoing costs include a per-transaction cost for insurance transactions. Physicians' offices pay a $450 installation and training fee, an ongoing charge of $30 per physician per month, and a per-transaction charge for insurance services.[47]

Projected savings from participating in WHIN could be $750,000 to $1.5 million per year for a 300-bed hospital. The actual savings might depend on how effectively the hospital was using information technology and EDI before joining the community network. Before implementing the WHIN, the Aurora Health Care Corp. operated a proprietary network for communicating with physician offices. That system had required a $1 million initial investment and operating costs of $250,000 to $350,000 per year. Aurora estimates

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[44] J. Newall and B. Colbert, "Using Automated Bundling, Unbundling, and Rebundling Processes Before Paying Claims," in *Health Information Networks*, proceedings of a conference sponsored by the Health Care and Insurance Institute, Sept. 28-29, 1993, Philadelphia, PA.

[45] U.S. Congress, General Accounting Office, *Medicare Claims: Commercial Technology Could Save Billions Lost to Billing Abuse*, GAO/IMD-95-135 (Washington, DC: May 1995).

[46] J. Sanders, remarks at *CHINs and CHMISs: Networks for Community Health Information and Management*, meeting of the National Health Policy Forum, Washington, DC, Oct. 25, 1994.

[47] M. Radaj, Vice President, Operations, Wisconsin Health Information Network, personal communication, July 8, 1994.

that participation in WHIN will provide greater functionality for half that cost per year. Annual savings for physicians' practices might be in the $2,500 to $5,000 range.[48] WHIN is currently working with the University of Wisconsin to conduct a cost-effectiveness study.

Cost savings to participants could accrue from a CHIN's ability to: 1) link participants; 2) deliver management information at the point of service; and 3) standardize electronic transactions. Linking participants electronically can reduce the need for telephone calls, travel, postage, and use of delivery services. For example, enabling physicians to check test results, sign attestations, or view images online presumably saves professional time by eliminating some trips to the hospital. Reducing phone calls can be difficult to quantify as a cost savings, but many office administrators have cited it as an immediate and welcome benefit of online systems.

Delivering management information at the point of service can facilitate the process of registering patients, checking their eligibility, and giving them care. Having management information available before treatment begins can reduce the number of rejected claims and other costs of working without complete information. In addition, user software at the provider's location can check the accuracy of entered data (e.g., in claim filing) and put data into a format preferred by the payer—all before it leaves the provider's premises. This could reduce personnel and staff training costs for both providers and payers, and reduce the costs of correcting rejected claims for both providers and payers. Of course, services like these do not necessarily have to be delivered over a community-wide network. A large number of insurance clearinghouses and other electronic medical claims services offer these services directly to providers. The possible advantage of a CHIN is to combine both clinical and insurance information processing in a single system

Community networks offer providers of all sizes the opportunity to move toward more uniform, standardized electronic communication without having the immediate need to change their existing systems. More information can be captured automatically and used in additional ways, which should reduce costs to participants. Use of common interfaces and elimination or standardization of some key entry tasks (such as filing insurance claims) could also reduce personnel and training costs.

POLICY IMPLICATIONS OF ELECTRONIC HEALTH INFORMATION

Among the issues affecting the health care industry's adoption of information technology are: 1) industry fragmentation; 2) complexity of information needs; 3) standards; 4) standard identifiers; 5) an inconsistent legislative and policy environment; and 6) privacy, confidentiality, and security concerns.

Industry Fragmentation[49]

The industries that have implemented electronic commerce most completely have been led by a single industry group devoted to implementing data standards. Examples include the Transportation Data Coordinating Committee that developed EDI standards for the transportation industry in the mid-1970s or the banking industry's National Automated Clearinghouse Association. The health care industry has no single focus for EDI activities. WEDI believes that implementation has been hampered as a result and will not proceed quickly unless a central entity is formed to coordinate implementation and education.[50]

An even more critical factor, however, is the fragmented nature of the health care industry in

[48] Ibid.

[49] This section is based on Canright, op. cit., footnote 9.

[50] Workgroup for Electronic Data Interchange, op. cit., footnote 27, p. 1-9.

general. In most industries where EDI has been successful (e.g., utilities, banking, transportation, and auto manufacturing), a few large organizations—called *hubs* in the language of electronic commerce—made EDI an explicit requirement for continuing a business relationship. Thus, for the smaller *spoke* companies, the decision was not whether to adopt EDI, but how quickly. One health care EDI consultant describes health care in the United States as a $900 billion "cottage industry."[51] There are over 1.2 million health care providers, ranging from single practitioners to 1,000-bed hospitals and more than 3,000 private payers. The effective number of different provider organizations may decline somewhat with the current trend toward hospital mergers, the purchase of clinics and medical practices by integrated delivery systems, and the continuing affiliation of physicians into independent practice associations and other arrangements. But the structure of the health care industry is unlikely to approach the relative simplicity of banking or air transportation. In health care, the industry hubs are providers, and most providers are small organizations without the time, finances, or staff resources to prepare implementation guidelines, set standards, and implement systems. They must rely on the guidance of vendors that provide software, claims processing, and networking services.

HCFA has been the successful organization in moving the health care industry toward EDI because of its financial reach. For many health care organizations, it was HCFA's development of the Medicare Transaction System (MTS) and its incentives to submit Medicare claims electronically that prompted initial interest in EDI. These incentives have included: 1) faster payment for clean claims (14 days for electronic, 27 for paper); 2) electronic funds transfer; and 3) free or at-cost billing software. Private sector payers are unlikely to offer many of these incentives to providers. For example, payers have an incentive to delay payment as long as possible in order to maximize their own use of the funds; they would be unlikely to offer providers quick payment as an incentive to begin an EDI relationship unless it could be clearly demonstrated that EDI reduces their own costs (not the provider's costs or the costs of the system as a whole) enough to offset this advantage. However, because many providers and payers are beginning to use EDI to deal with HCFA, the infrastructure is being created that they can also use to deal with one another.

Complexity of Information Needs

In banking and financial services, most electronic transactions are simple and highly standardized. Consumers and businesses benefit from the ease of using the automated teller machines and credit card transactions made possible by that standardization. Health care payment requires a number of different types of transactions, and often large amounts of data have to be exchanged. In addition, the procedures, information needs, payment arrangements, and authorization procedures for each type of transaction can vary, depending on the characteristics of the payer, patient, patient's employer, and sometimes the diagnosis or procedure involved.[52] This complexity has slowed the diffusion of electronic commerce into the health care arena.

Standards

The key to the functionality and growth of electronic medical payment lies in the establishment of standards. As discussed in chapter 2, standards-setting and acceptance are moving slowly. Current estimates put the number of proprietary claims formats in use at 400—too many even for software to translate between sender and receiver.

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[51] J. J. Moynihan, "More Payers Should Convert to EDI," *Healthcare Financial Management*, vol. 48, No. 5, May 1994, p. 66.

[52] Faulkner and Gray Health Information Center, *Health Care and the Electronic Superhighway: A Provider Perspective on Electronic Data Interchange and Automated Medical Payment* (Washington, DC: Faulkner & Gray, 1992), p. 21.

The standards-setting process is voluntary and compliance with the standards will be voluntary as well. Yet administrative savings may not actually be realized unless standards are more stringent and compliance with them is nearly universal. As mentioned earlier, there are nearly 50 different implementations of the standard UB-92 form, requiring providers and payers with interstate business to use several versions of it. A standard claim form will not truly be standard, for example, as long as each payer can demand additional documentation to accompany it. While payers usually request additional information in an effort to reduce their own costs, the difficulty and expense of maintaining different forms presumably raises costs for the industry as a whole.

Standard Identifiers for Individuals, Providers, and Payers

Interstate electronic commerce for health information would be facilitated by a system of standard identifiers. Because each provider or provider group (as well as payers and other users of health information) maintains its own identification number scheme and assigns its own numbers, patient records are not uniquely identified once they leave the institutions where they have been created. This can create confusion in the multi-institutional sharing of clinical or administrative information. Unique identification can be accomplished by combining several different identifiers—for example, a file number, plus middle initial, plus address—but it is generally agreed that a system of standard identifiers would be more stable over time.

Some argue that the benefits of fully electronic records are more easily obtained if each individual could be uniquely identified. If each person had a universal patient identifier it would be easier to link the health information maintained at different institutions, for example. In addition to identifying patients, health care providers and specific sites of care also need to be identified. While there are a number of recommendations for developing numbering schemes de novo, some industry organizations recommend modifying or expanding existing identification number schemes in order to get unique identifiers in place more quickly.[53]

Universal identifiers are common in some European countries where they are assigned to people at birth. The United States has been slow to adopt a universal numbering system and many groups have actively opposed such a system based on privacy concerns.

The Social Security Number (SSN), or another number based on it, has been recommended for use as the universal patient identifier. Because this numbering system is already in place, some groups argue that it would be the fastest and least costly method of instituting a universal numbering system.[54] The ubiquity and convenience of the SSN make it a tempting candidate for a universal health identifier.

However, privacy advocates have opposed the use of the SSN as a health identifier precisely because it has had so many other uses. The SSN is the key to a lot of nonhealth-related information about a person—including financial, tax, credit, educational, and other information on file with government agencies and private firms. It is very easy, with access to the SSN, to quickly develop detailed dossiers on anyone. In addition, some individuals, primarily infants and noncitizens, do not have SSNs. Some people have multiple SSNs. The system has been in operation for 60 years, and there is a long history of invalid and fraudulently acquired numbers. Because the form of the SSN dates from the precomputer era, it also lacks a *check digit* (an extra digit added to a computer-based number that aids in error detection and correction).

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[53] For example, see American Medical Informatics Association, "Position Paper on Standards for Medical Identifiers, Codes and Messages Needed To Create an Efficient Computer-Stored Medical Record" (Bethesda, MD: Apr. 20, 1993).

[54] Ibid., p. 2.

It can be argued that many of the privacy-based objections to the SSN—fraudulent numbers, linkages to other databases, and so on—will also apply to any new numbering scheme that could be adopted. While there is merit in this argument, there is also the possibility that a new numbering system would be safer because, for example, it would have legal protections from the outset to prevent its use for other purposes.

Alternative schemes for developing unique identifiers have been proposed. Some would include segments of the patient's name, latitude and longitude coordinates of the place of birth, date of birth, and perhaps parts of the SSN. Some systems also involve encrypting the number, or converting it to an alphanumeric identifier, in order to either protect privacy or to make the number shorter and easier to remember.[55]

One system that is now being put into place to identify providers is the National Provider Identifier (NPI), which will be implemented by HCFA in 1996. In its present form, the NPI system is not universal—it will apply only to Medicare participants. It will provide unique identification numbers for physicians, other providers, and the sites where they provide care. In developing the NPI system, HCFA worked with a number of federal, state, and private-sector organizations. The NPI will consist of a seven-character alphanumeric identifier with a one-character check digit. NPI numbers can be encrypted to protect privacy and confidentiality.

By design, there will be no *intelligence* imbedded in the NPI number; that is, analysis of the number itself will not yield useful information about the provider it identifies. Rather, the number points to a location in a database called the *National Provider File* that will contain descriptive data about the provider. Thus, numbers will not have to be reissued when provider characteristics (address, number of locations, or types of specialty) change. The numbering format has the potential to provide 10 million all-numeric identifiers or up to 27 billion alphanumeric identifiers, making it sufficiently large to serve as a national system for identifying all providers, including nonparticipants in Medicare. Should such a national system be desired, authorizing legislation would be needed to allow HCFA to open the system.

HCFA is also in the process of developing a registry and identifier system for payers. This system would identify and maintain information on the payers who offer secondary coverage for Medicare participants. The process of coordinating benefits is complex for Medicare as it is in the private sector. A primary payer, such as Medicare, is often not aware that a patient has secondary coverage, or may not have complete information on the benefits for which the patient is eligible and the rules for calculating reimbursement. Without this information, the primary payer can sometimes pay inappropriately (that is, pay more than the patient is entitled to). In addition, the process of filing a claim with the secondary payer is complex; the provider or patient must often file a separate claim based on remittance information provided by the primary payer. By incorporating a registry of secondary payers and a complete set of rules for coordination of benefits into its Medicare Transaction System, HCFA hopes to be able to more accurately calculate reimbursement based on all the benefits available to a patient. At the same time, it could automatically send a bill to the secondary payer, simplifying the claim process for patients and providers.

Inconsistent Regulatory Environment for Health Information

State government regulations concerning electronic health information and patient records, as well as privacy, vary widely. This creates a difficult environment in which to implement standard-

[55] For example, see P.C. Carpenter et al., "The Universal Patient Identifier: A Discussion and Proposal," *Patient Centered Computing: 17th Annual Symposium on Computer Applications in Medical Care* (New York, NY: McGraw Hill, Inc., 1993).

ized processes. There are four areas in which state legislation and regulation impact on electronic health information. They include laws on: 1) storage media for medical records; 2) use of electronic signatures; 3) privacy and confidentiality of health information; and 4) patient access to health records.

Storage Media for Medical Records

State governments generally have licensing authority over health care providers and require them to maintain medical records. Nearly every state regulates what media are permissible for storing medical records. In many states, the language is reasonably "technology neutral" and the use of catchall phrases such as "other useable forms" or "other appropriate processes" has been taken to mean that computerized record storage is permitted. In some states, however, legislation has served as a barrier to the development of automated patient records by specifying the permitted media (e.g., microfilm or paper) and excluding disks, tapes, and other computerized storage media. Other states require clinicians' signatures in ink on particular forms, implying a paper original to which the signature can be affixed. Some states specifically permit the use of computers for some functions but forbid it for others, thus hindering the development of a complete computer-based record. There are other paradoxes and inconsistencies in legislation as well, with some states permitting electronic signatures for some purposes but requiring retention of a paper or microfilmed record.[56]

Only a few states specifically authorize computerized medical records. Indiana statutes, for example, authorize the use of "computerized records that maintain confidentiality." They specifically state that the recording of hospital medical records by the data-processing system is "an original written record" and authorize the courts to treat information retrieved from such systems as originals for purposes of admissibility into evidence.[57]

Some of the states whose statutes posed barriers to electronic patient records are making progress toward changing the statutes. For example, North Dakota is considering legislation that would make the recording of a medical record on a computerized system the equivalent of a photographic process, thus making printouts and other items retrieved from the system admissible in court.

Recordkeeping rules for nonhospital providers—nursing homes and physicians' offices, for example—are often covered by different state statutes or regulations and can be very different from those that apply to hospitals in the same state. Implementing a complete electronic patient record in a multisite provider organization, that might include hospitals and nursing homes, can be complicated if these requirements differ widely.

The absence of state legislative or regulatory support for electronic patient records does not necessarily mean that providers in that state are forgoing development of information systems or electronic record systems. It does mean, however, that the providers face certain legal risks if they do not maintain the paper record system as well, and they must bear the costs of operating both systems. Currently, most providers are not technologically capable of creating a "complete" electronic record in any case. They maintain a mixed paper and electronic system for practical, as well as regulatory, reasons. The regulatory inconsistencies among states can create difficulties for health care organizations that are attempting to develop common patient record systems for sites in more than one state.

Federal legislation governing business records (which includes medical records) implies that computerized records are permitted (once again

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[56] J. P. Tomes, *Compliance Guide to Electronic Health Records"* (New York, NY: Faulkner and Gray, 1994), pp. 14-19.

[57] Burns Ind. Code Ann. sec. 34-3-15.5-2.

using language about "other processes").[58] In addition, HCFA, which administers the Medicare program, authorizes the use of computerized medical records if they are maintained in a form that can be reproduced legally, and if the system meets Medicare's conditions for participation. These conditions basically state that the system must protect the security of the records and ensure that only the authorized persons are able to sign them. The Department of Health and Human Services, in an effort to encourage the development of computerized patient records, had legislation introduced in the 103d Congress to require providers to maintain outpatient data in electronic form as a condition of participation in Medicare.[59]

Electronic Signatures

Signatures are necessary to attest to the completeness and authenticity of a medical record. Generally, each entry in a record is signed or authenticated by the person responsible for that entry. An electronic record can be signed electronically, and this is permitted in many states; once again, however, electronic signatures are treated differently from state to state. Some states are silent about the specific means or technology to be used for the signature, or they say that industry and professional standards should dictate the form of the signature. This would seem to permit the use of electronic signatures in those states because the Joint Commission on Accreditation of Healthcare Organizations, American Hospital Association, and other industry groups have published guidelines related to electronic signatures. Some states (like Pennsylvania, Alaska, and California) specifically authorize the use of an electronic signature activated by a computer key that is known only to the authorized user.

HCFA accepts electronic signatures on admission data sheets, attestations, and other documents used to reimburse providers treating Medicare patients. Providers must demonstrate that their computer systems meet HCFA guidelines.

Privacy and Confidentiality of Health Information

Both federal and state legislation cover the privacy of patient records. Records held by the federal government are protected under the Privacy Act,[60] which governs federal disclosure of confidential information. At the state level there is a variety of approaches to privacy protection, and a number of states have privacy laws that cover medical information. Other states have sections in their Medical Practice Acts that prohibit physicians from revealing information obtained in confidence from a patient during treatment. The American Medical Association has published standards for hospitals to protect the privacy of patient information. Some courts have enforced these standards under state contract law as implied conditions of the contractual relationship between physicians and patients.

Even among the states that have well-defined laws on the privacy of medical records, few address the flow of information to secondary users, such as insurance payers, researchers, and so forth. Further, because states are so inconsistent in how they deal with electronic information generally, few of them confront issues directly related to protecting privacy in *computerized* patient records. For a more detailed discussion, see the previous OTA report, *Protecting Privacy in Computerized Medical Information.*[61]

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[58] 28 U.S.C. 1732.

[59] Tomes, op. cit., footnote 56, p. 14.

[60] 5 U.S.C. sec. 552a.

[61] 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), pp. 41-45.

Patient Access to Health Records

Because patients have a property right in their records, it seems reasonable that they should be able to inspect or copy them. Access to medical records held by the federal government (e.g., Department of Veterans Affairs or other hospitals operated by the federal government) is governed by the Privacy Act. The Privacy Act requires agencies to establish procedures under which individuals can view or receive copies of their own records. It also authorizes the establishment of special procedures for handling information that might, in the judgment of the agency, have an adverse effect on the individual. These procedures have generally involved designating a third party to examine the records and releasing them to a physician designated by the patient.[62]

For private sector hospitals and other providers, state laws and regulations govern patient access to medical records. Thirty-seven states have statutory provisions for allowing a patient to review and/or copy his or her medical records. In a few additional states, the patient's right to access is not specifically stated, but can be inferred from other language.[63] In addition, some courts have ruled that providers have a common-law duty to allow a patient to access his or her records, absent legislation.[64] In 22 states, the patient may be charged reasonable copying fees, and 19 require that the patient apply for the records in writing. Twelve states permit physicians to deny patient access to a record if something in the record would have an adverse affect on the patient; in most of these cases, however, the record must be released to an attorney, physician, or other representative designated by the patient.[65]

A patient's right of access to information derived from the medical record, but housed in the database of an insurer or other third party, is unclear in many states. Only 14 states have legislation giving patients access to insurance databases and limiting redisclosure of medical information held by nonproviders.[66]

Privacy, Confidentiality, and Security of Health Information

Privacy, confidentiality, and security of electronic data are areas of great concern because of the sensitivity of health information. *Privacy* is essentially the right of an individual to limit access to information regarding that individual. *Confidentiality* is a form of informational privacy characterized by a special relationship between people, such as the relationship between doctor and patient. *Security* refers to technical and organizational procedures that protect electronic information and data-processing systems from unauthorized access, modification, destruction, or misuse.[67]

The appropriate levels of privacy, confidentiality, and security, as well as the techniques for achieving them, may vary depending on the institutional context and the use of the information. Tradeoffs are often necessary. For example, within a single hospital, confidentiality might be best served by allowing a patient's record to be seen

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[62] U.S. Congress, Congressional Research Service, *Access to Medical Records Under Federal Law*, No. 93-708A (Washington, DC: Aug. 3, 1993), p. 16.

[63] U.S. Congress, Congressional Research Service, *Patient Access to Medical Records: A Statutory Survey of the United States*, No. 92-896A (Washington, DC: Nov. 17, 1992), and *Medical Records: State Laws and Regulations Regarding Ownership and Patient Access*, No. 93-519A (Washington, DC: May 20, 1993).

[64] R. S. Dick and E.B. Steen (eds.), *The Computer-Based Patient Record: An Essential Technology for Health Care* (Washington, DC: National Academy Press, 1991), p. 166.

[65] U.S., Congressional Research Service, *Patient Access*, op. cit., footnote 63.

[66] Dick and Steen, op. cit., footnote 64.

[67] L. O. Gostin et al., "Privacy and Security of Personal Information in a New Health Care System," *The Journal of the American Medical Association*, vol. 270, No. 20, Nov. 24, 1993, p. 2487.

only by the attending physician and the nurse assigned to that patient. However, such a policy would affect the quality of patient care—it would unduly inconvenience and slow the work of substitute nurses, consulting physicians, intensive care personnel, or other caregivers who might need the record on short notice. Thus, a balance between confidentiality and convenience must be found. Most hospitals allow fairly broad access to patient records by authorized caregivers, and they usually have security systems to keep track of each access. In some cases, this feature is used regularly to keep caregivers aware that they are accountable for their use of the information system. At one hospital, for example, users are regularly notified on-screen that each instance of access to a patient record is automatically recorded and that patients have the right to see a list of those who looked at their records.[68]

When information moves out of the single provider institution, priorities may change. The EDI industry has focused most of its concern on the security of information. Companies engaged in transmitting business information electronically—financial institutions in particular—have adopted technical solutions to two problems. The first is that information transmitted over phone lines might be read by unauthorized persons. One technique for addressing this is *encryption*. A second problem is that people sending or receiving information may not, in fact, be who they say they are. *Authentication* techniques—the use of passwords, keys, and other automated identifiers—are used to verify the identity of the person sending or receiving information.[69]

Thus far, the EDI industry has a good security record, according to the Workgroup on Electronic Data Interchange (WEDI), which says "there have been no reported incidents of the confidentiality of EDI messages being compromised."[70] Indeed, the risk of data leakage to outside computer hackers can be minimized in an online system. Security measures such as encryption procedures, password access, and audit logs help to discourage data theft. With electronic information, system administrators have more numerous and powerful tools for monitoring and protecting information than they do with paper-based records.[71]

Privacy and confidentiality—the main focus of concern for the health care industry—are proving more difficult to protect. As health care information increasingly moves over electronic networks, it becomes accessible to more people at widely scattered institutions with different policies and procedures in place. The potential for abuse increases accordingly. Unauthorized uses of information by authorized users can be a major problem that is difficult to stop by technological means. Because of a plethora of conflicting state laws regarding confidentiality, it is difficult to establish legally defensible policies on proper access to records; people handling records often have no clear guidelines for acceptable release of information. A 1993 OTA report on privacy and confidentiality of health information notes:

> The present system of protection for health care information offers a patchwork of codes; State laws of varying scope; and Federal laws applicable to only limited kinds of information, or information maintained specifically by the

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[68] C. Safran et al., "Protection of Confidentiality in the Computer-Based Patient Record," *M.D. Computing*, vol. 12, No. 3, 1995.

[69] For further information on network security issues and technologies, see U.S. Congress, Office of Technology Assessment, *Information Security and Privacy in Network Environments*, OTA-TCT-606 (Washington, DC: U.S. Government Printing Office, September 1994) and *Issue Update On Information Security and Privacy in Network Environments*, OTA-BP-TCT-147 (Washington, DC: Government Printing Office, June 1995).

[70] Quoted in Benjamin Wright, "Health Care and Privacy Law in Electronic Commerce," *Health Care Financial Management*, vol. 48, No. 1, January 1994.

[71] Ibid.

> Federal Government. The present legal scheme does not provide consistent, comprehensive protection for privacy in health care information, whether it exists in a paper or computerized environment.[72]

The situation has not changed appreciably since this report was published.

Without uniform privacy and confidentiality laws, it is extremely difficult to expedite the development of interstate health records transfer. Accordingly, WEDI called on Congress to ensure the uniform, confidential treatment of identifiable information in electronic environments. As electronic interstate transfer of medical data increases, policies concerning the access to medical information by secondary users of medical data, the use of medical data for nontreatment purposes, and the redress of privacy violations must be made consistent in all state. Privacy legislation should also address the requirements for informed consent of patients. Patients are often unaware of how their medical information will be used, to whom it may be released, and what rights they may have to access or correct it once it is in the hands of a secondary user.

Whether information is stored in a computer or on a piece of paper, the public fears the abuse of medical information by both authorized and unauthorized parties. In a 1993 health privacy poll, 80 percent of all respondents believed that consumers had lost all control over the circulation and use of health care information.[73] These concerns can lead (and have led) to physicians withholding information from patient records at the patient's request in order to protect his or her privacy.[74] To create an inaccurate or incomplete patient record, even with beneficial intent, could ultimately have serious effects on the patient; in addition, such actions render records less useful for outcomes research and other statistical purposes.

Improved patient education about privacy rights may decrease the lack of control patients feel over the spread of medical information. Until national, uniform privacy legislation is enacted, WEDI suggests steps to protect privacy in its 1992 report.[75] Providers should:

- ensure that the patient has authorized release of health information to an insurer by signing the release contained on the insurance form,
- ensure that they release information in strict compliance with the written release,
- ensure that they have complied with any relevant laws governing disclosure to insurers,
- establish security policies for employees who have access to and process patient health information, and
- establish security protocols for computer systems used to process claims.

The WEDI guidelines were not intended to replace the need for federal legislation or to absolve system operators from responsibility to design and maintain secure computing environments.

Although solutions to the networking problems of privacy, confidentiality, and security remain unclear, the questions they embody do not: What potential benefits of increased access to health care information will materialize, and will they outweigh the reduction in individual privacy that increased access to information inevitably brings? These questions must receive considered answers. "Opportunities for using electronic networks may be lost if there is serious mistrust of their safety."[76]

The concept of *fair information practices* set forth in the federal Privacy Act is fundamental to a number of existing privacy laws and proposed ini-

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[72] Office of Technology Assessment, op. cit., footnote 60, p. 13.

[73] Gostin et al., op. cit., footnote 67.

[74] Office of Technology Assessment, op. cit., footnote 60, p. 6.

[75] Workgroup for Electronic Data Interchange, *1992 Report* (Hartford, CT, and Chicago, IL: September 1992).

[76] Gostin et al., op. cit., footnote 67.

tiatives to protect medical information. Common characteristics are:

1. Records pertain to medical information on individuals.
2. Individuals are given the right to access much of the personal information kept on them.
3. Limits are placed on the disclosure of certain personal information to third parties.
4. Health care personnel are required to request information directly from the individual to whom it pertains, whenever possible.
5. When a government entity requests personal information from an individual, laws require the individual to be notified of the authority for the collection of data, whether the disclosure is mandatory or voluntary.
6. The individual may contest the accuracy, completeness, and timeliness of his or her personal information and request an amendment.
7. Health care personnel must decide whether to amend the information within a fixed time, usually 30 days after receiving a request.
8. The individual whose request for change is denied may file a statement of disagreement, which must be included in the record and disclosed along with it thereafter.
9. The individual can seek review of a denied request.

Protecting Privacy in Computerized Medical Records[77] noted that basing new protection for medical information solely on the Privacy Act and on principles of fair information practices will fail to consider the complexity of today's information environment, with its distributed processing, sophisticated database management systems, computer networks, and widespread use of microcomputers.

> It is apparent that protecting personal information in a computerized environment involves, at a minimum, access to records, security of information flows, and new methods of informing individuals where information is stored, where it has been sent, and how it is being used.[78]

POLICY CONSIDERATIONS FOR CONGRESS

Attempts to improve administrative efficiency by increased use of electronic commerce in health care are an important component of a larger effort to reduce costs, improve quality of care, and improve access. Compared with a paper-based system, electronic information systems do appear to reduce costs for some users. The industry is moving in this direction. Standards development activities are under way.

However, getting started with electronic commerce is expensive. Some organizations have weak financial incentives to make the necessary investments to institute electronic payments, while others are forging ahead without waiting for standards to be set. Some experts interviewed by OTA commented that the complexities of dealing with paper records and paper-based transactions, particularly as health care organizations grow larger and enter new lines of business, are forcing some organizations to implement electronic systems, even if they have no way to measure the actual cost-effectiveness of a particular system. The computer network, like the telephone, is becoming a part of the way business is conducted; a firm simply has to have one to compete in the market, whether it makes economic sense or not.[79]

There may be some savings for the health care system as a whole if electronic medical payments, for example, are implemented on a near-universal scale. However, at current rates of implementation, high levels of use of electronic payments or compliance with standards may not be achieved for some time. The health care industry in the

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[77] Office of Technology Assessment, op. cit., footnote 60.

[78] Ibid., p. 79.

[79] Project HOPE Center for Health Affairs, op. cit., footnote 2.

United States is not organized as a "system" with a central focus or consensus on how to deal with systemwide problems. The different parts of the system have diverse incentives, and efforts to control costs in one area may increase costs in another. However, these shifted costs are so subtle and spread over so many participants in a complex system that they are hard to quantify. For example, a major payer, in an effort to reduce its own costs, may begin to request additional data and documentation (beyond what is on the standard forms) when providers submit large claims. All providers who deal with that payer then incur additional costs to resubmit rejected claims, develop and maintain different versions of the standard form, or provide the additional data with all claims to avoid the problem of deciding when to send it and when not to. Situations like these make it difficult for the industry to establish truly uniform procedures.

The trend toward managed care reduces this diversity of interest to some extent. The percentage of people covered by traditional indemnity insurance in the fee-for-service sector can be expected to decrease, thus reducing the number of transactions between providers and payers as well. Some managed care organizations, like staff model HMOs, will internalize these transactions, and will presumably perform them efficiently out of sheer corporate self-interest. But managed care is taking many forms, including independent practice associations and other arrangements for which transactions will remain external between a network of different provider and payer organizations. For the near future, absent a far-reaching government-imposed restructuring of the system, many private insurers and health care providers will continue to do business as independent firms whose interests do not coincide.

There are three major areas in which government action might be considered: 1) providing leadership in the adoption of standards for electronic medical payments and other transactions and exchanges of health information; 2) establishing a system of unique identifiers for people, providers, and payers; and 3) establishing a more consistent regulatory environment for interstate exchanges of health information.

Standards

The federal government has already played a major role in establishing the current level of standardization. For example, in the area of electronic medical payments, HCFA's commitment to electronic claims-filing and its adoption of EDI standards have caused many providers and private payers to use these technologies. Further steps by HCFA—for example, offering truly expedited payment to providers who file electronically (instead of making delayed payment to those who make paper claims, as is currently the case)—could encourage more providers to make the necessary investments needed to comply. HCFA's early adoption of EDI standards for other forms and transactions could also inspire other payers to make use of them. HCFA's ongoing plans to establish a national payer file and to automate secondary payments should also serve as an example of how to simplify the complex process of coordination of benefits. Thus, one option for federal action is to *continue to influence the standardization of health care information transactions through the federal government's role as a major insurer.*

However, even HCFA's leadership will not ensure universal compliance with standards among all payers and providers, and it is likely that widespread compliance is needed in order to realize noticeable savings. As long as some set of participants does not comply, many others will have to maintain separate systems or multiple versions in order to do business with them. The information involved is very complex, and certain classes of participants—payers, state governments, and others—will continue to create the need for new types of data for their own purposes, but not necessarily those of their trading partners or the system as a whole. If they have either money or licensing authority on their side, their trading partners will have to comply with their demands in addition to the standard.

Given that near-universal compliance seems to be important, but is not being achieved as yet,

Congress may want government to take a more active role in administrative simplification. Thus, a more active approach would be for Congress to consider *requiring the adoption of industry-developed standards for core electronic transactions, including maximum data sets, and setting timetables for their implementation.*

This option suggests the adoption of standards for a small set of core transactions within the near future. It assumes that the transition from a fee-for-service environment to a managed care environment is going to be a gradual one, and that for a number of years it will be worthwhile to make the basic fee-for-service transactions as efficient as possible. This option is also limited in that its aim is not to mandate sweeping requirements for implementing electronic transactions, but rather to focus on a small set of transactions. Core transactions include: claims and billing, payment and remittance advice, eligibility inquiry, enrollment, and coordination of benefits. Standard forms for managed care transactions, such as the encounter report, could also be considered in this group. These are areas where the voluntary standards process is well advanced. Requiring adoption of standards for other transactions might be considered in the future.

The option includes a requirement for *maximum data sets* for each transaction. It will be necessary to obtain consensus from providers and payers about what information is needed for the transactions, and then ensure that participants may not unilaterally increase information requirements that would lead to the proliferation of nonstandard forms.

A requirement for universal compliance with an electronic transaction system would necessarily create problems for some providers and payers, particularly small ones. Clearly not all providers and payers will be able to handle electronic transactions or modify their proprietary systems to meet standards within any given timeframe; however, they should be able to contract with community health information networks, clearinghouses, electronic medical claims services, or other firms who can provide these services for them.

Unfortunately, a government-imposed standards-setting process would require some central focus of authority to set timetables and to ensure compliance. Therefore, a necessary corollary to the option discussed above would be to *charge a government agency with responsibility and authority to set standards and data definitions for administrative transactions in consultation with industry groups, and to manage changes to standards over time; or create an agency or commission for this purpose.*

Establishing a central authority, whether within an existing agency or in a new commission, is also a cost—one that would be shifted from the health care system as a whole to the government. However, it is unlikely that standards and timetables will be adhered to unless someone is in charge.

Possible disadvantages of requiring standardization and creating an authority—for example, locking into a standard too soon—do not appear to be problems for electronic medical payments at this time, at least for core transactions. Industry groups have made progress with standards for the basic core transactions and preliminary versions are available for many. There is a need, however, to ensure that the standards are implemented in the same way so their use is uniform. Industry input, from both payers and providers, is definitely needed for this. Clearly, if the agency or commission attempted to develop standards de novo, many unnecessary costs could be incurred; therefore it would have to work closely with industry groups already in existence. A number of industry groups have voiced support for greater government involvement, including actions to speed the standards-setting process.

Standard Identifiers for Individuals, Providers, and Payers

Consistent with the above options, another area for nationwide action would be to *establish a system of unique identifiers for patients, providers, and payers.*

Controversy continues about the particular system of identifiers to be used for individuals. In the

past, OTA has cautioned against use of the SSN as a national identification number of any kind, largely on privacy grounds. OTA has suggested in earlier work that a new numbering system, with legal protections against misuse built in from the beginning, would be more appropriate. Supporters of the SSN argue, with some merit, that the disadvantages cited for the SSN are bound to afflict any numbering system eventually, even one that is developed from scratch. With modifications, such as a check digit or other additional digits, the SSN may be the fastest and possibly the lowest-cost option for establishing a numbering system.

Identifier systems that meet the needs of both private sector and government users would be most useful. HCFA has made efforts to include a variety of public and private stakeholders in the development of its national provider identifier (NPI). That system, which HCFA proposes to implement for Medicare providers in 1996, has the potential to be expanded into a universal system. Expanding the NPI to include non-Medicare providers would require congressional action to allow HCFA to open up the system and to establish which agency should administer it. Similarly, HCFA's efforts toward developing a payer registry and automating the secondary payment process could serve as the basis for establishing a national, automated coordination-of-benefits system for private payers.

Consistent Regulatory Environment

Some state governments, under the influence of industry associations and other groups, are attempting to change state legislation that limits the development of computer-based patient records. However, the variety of state legislation that affects electronic health information is still bewildering and poses a barrier to the efficient development of interstate electronic commerce in health care. One option is to *encourage the passage of uniform state legislation with regard to privacy and confidentiality, allowable storage media, and standards for health information.* A number of industry groups are already working with legislatures to enact uniform legislation. In addition, the Department of Health and Human Services has recently been tasked by the Administration to take the lead in developing model state privacy laws and model institutional privacy policies for health information. Such leadership by a federal agency may be useful in speeding the adoption of new information laws.

Privacy and confidentiality are particularly important areas in dealing with health information; if there is little confidence that an electronic medical information system will protect them, then providers and patients will be unwilling to use it. If the process of revising legislation on a state-by-state basis is seen as too time-consuming, or not sufficiently effective, then some additional federal intervention may be necessary either to support uniform legislation or to provide federal legislation. In this case, Congress may wish to e*stablish federal legislation and regulation with regard to privacy and confidentiality of medical information, as well as storage media for medical records and electronic data standards for storage and transmission of medical information.* A corollary to this option is to *charge a government agency, or create a committee or commission, to oversee the protection of health care data; to provide ongoing review of privacy issues; to keep abreast of developments in technology, security measures, and information flow; and to advise Congress about privacy matters in the area of health care information.*

The purpose of these options is to create a national environment where electronic commerce and the development of computer-based patient records is not discouraged by local differences in regulation. This would establish a minimum *floor* so that interstate commerce and information exchange can be maintained. There is still a need for considerable research on the computer-based patient record and other kinds of health information. Detailed standards about the computer-based patient record within a particular provider organization cannot be legislated or established by regulation at this time, and, in fact, such regula-

tion may never be desirable. However, minimum standards for the storage and protection of health information, and for its exchange among institutions, may now be in order.

Many violations of security, privacy, or confidentiality are caused by *insiders*—trusted individuals who exceed their authority or put information they are authorized to have to an unauthorized use.[80] Establishing clear and uniform law to protect privacy and confidentiality, along with civil and criminal penalties for violations, would encourage organizations that handle electronic health care information to establish strong internal policies and procedures, which will be as important as technological protections for information. With regard to privacy and confidentiality, an earlier OTA report cited seven provisions to be considered in any federal legislation affecting health information:

1. Define the subject matter of the legislation, *health care information*, to encompass the full range of medical information collected, stored, and transmitted about individuals, not simply the patient record.
2. Define the elements comprising invasion of privacy of health care information and provide criminal and civil sanctions for improper possession, brokering, disclosure, or sale of health care information, with penalties sufficient to deter perpetrators.
3. Establish requirements for informed consent.
4. Establish rules for educating patients about information practices; access to information; amendment, correction, and deletion of information; and creation of databases.
5. Establish protocols for access to information by secondary users, and determine their rights and responsibilities in the information they access.
6. Structure the law to track the information flow, incorporating the ability of computer security systems to monitor and warn of leaks and improper access to information so the law can be applied to the information at the point of abuse, not to one "home" institution.
7. Establish a committee, commission, or panel to oversee privacy in health care information.[81]

These principles will continue to be useful in designing uniform state or federal regulation with regard to health information security, privacy, and confidentiality.

[80] Office of Technology Assessment, op. cit., footnote 69.

[81] Office of Technology Assessment, op. cit., footnote 60, p. 87

Using Information Technology To Improve the Quality of Health Care

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The quality of health care is ultimately judged by the impact of specific health services on the patient's health status.[1] Improving quality involves identifying and using health services that, when properly executed, produce the greatest improvement in health status. The most direct contribution that information technology can make to improving the quality of health care is to provide the clinician with better information about the patient and health problem at hand, and alternative tests and treatments for that problem, preferably at the point of care. This would enable clinicians to choose more effective services more quickly[2] and help them avoid potentially tragic errors.[3]

This chapter discusses the potential for advanced information technologies to improve the quality of health care—as indicated



[1] Institute of Medicine, *Medicare: A Strategy for Quality Assurance,* K.N. Lohr (ed.) (Washington, DC: National Academy Press, 1990), pp. 20-25.

[2] K.L. Coltin and D.B. Aronow, "Quality Assurance and Quality Improvement in the Information Age," *Putting Research to Work in Quality Improvement and Quality Assurance*, M.L. Grady, J. Bernstein, and S. Robinson (eds.), Agency for Health Care Policy and Research, Pub. No. 93-0034 (Rockville, MD: July 1993), pp. 51-54; S.D. Horn and D.S.P. Hopkins, "Introduction," *Clinical Practice Improvement: A New Technology for Developing Cost-Effective Quality Health Care*, S.D. Horn and D.S.P. Hopkins (eds.)(New York, NY: Faulkner & Gray, 1994), pp. 1-5.

[3] L.L. Leape, "Error in Medicine," *Journal of the American Medical Association*, vol. 272, No. 23, Dec. 21, 1994, pp. 1851-1857; L.L. Leape et al., "Systems Analysis of Adverse Drug Events,"*Journal of the American Medical Association*, vol. 274, No.1, July 5, 1995, pp. 35-43; D.W. Bates et al., "Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention," *Journal of the American Medical Association*, vol. 274, No.1, July 5, 1995, pp. 29-34.

by the effectiveness of clinical decisionmaking[4]—and the potential role of the federal government in that process. The most relevant technologies[5] include:

- electronic patient records,
- structured data entry,
- advanced human-computer interface technologies,
- portable computers,
- automated capture of data from diagnostic and monitoring equipment,
- relational databases with online query (keyword search and retrieval),
- knowledge-based computing, and
- computer networks.

This chapter first reviews the *clinical decision support* approach to improving health care, and the ways in which information technology could enhance clinical decisionmaking. It then examines the *performance assessment* approach to improving health care, which involves evaluating specific health services, providers,[6] and insurance plans.[7] Ways in which some of the problems confronting both approaches might be resolved by using information technology are explored. The chapter concludes with a discussion of policy issues and options regarding potential governmental roles in those developments.

CLINICAL DECISION SUPPORT

Clinical decision support can be broadly and simply defined as the use of information to help a clinician diagnose and/or treat a patient's health problem. Two kinds of information are involved: 1) information about the patient; and 2) information about the kind of health problem afflicting the patient and alternative tests and treatments for it. Clinical decision support is by no means a new phenomenon—such information traditionally has been available from several sources. However, those sources have limitations that often diminish their reliability or their accessibility at the point of care.

The time pressures of clinical practice do not allow clinicians to study the patient's entire health history or review the latest clinical knowledge on every nonroutine health problem they encounter. Consequently, one major goal of clinical decision support is to locate needed information and make it available to the clinician in readily usable form at the point of care as *quickly* as possible, and in a manner that minimally interferes with the care process. Moreover, the potentially severe consequences of incorrect clinical decisions for both the patient and the clinician require that the information retrieved be as *accurate* as possible.

Limitations of Traditional Information Sources

Information About the Patient

The specific kinds of information about the patient that are useful in clinical decisionmaking fall into two broad categories:

1. *Health problems*, both current (signs and symptoms, physical findings, diagnostic test results, functional status, etc.) and previous (medical history, including previous services for each health problem); and

[4] This approach focuses on the effectiveness of the health services delivered by providers and insurance plans (see footnotes 6 and 7). The role of the patient in clinical decisionmaking and self-care, and ways in which information technology can enhance that role, were discussed in chapter 1.

[5] See chapter 2 for details on these technologies.

[6] Throughout this chapter, the term *providers* includes both individual clinicians and institutional providers such as hospitals. *Clinicians* include physicians and other licensed practitioners, such as nurses. *Physicians* include allopathic medical doctors, osteopaths, chiropractors, podiatrists, etc. In discussing clinicians who diagnose and treat health problems, this report includes nurse practitioners, physician assistants, and other *physician extenders* who are licensed to prescribe medications.

[7] The term *health insurance plan* here includes traditional indemnity plans and managed care organizations (health maintenance organizations, preferred provider organizations, etc.).

2. *Background*, including demographic traits (age, sex, ethnicity, and socioeconomic status), risky behaviors (substance abuse and hazardous occupations, sports, hobbies, or sexual practices), exposures (occupational and environmental hazards), allergies, and family history.

Information about the patient traditionally has been drawn from the paper-based patient record and direct clinical examination of the patient. Briefly, the major difficulties with the *paper-based patient record*[8] include:

- indecipherable content,
- lack of comprehensiveness,
- lack of completeness,
- inaccuracy,
- inaccessibility,
- lack of uniformity and standards,
- slow and cumbersome transmission,
- lack of security, and
- sheer physical volume.

These problems make it difficult to quickly locate accurate and readily usable information about the patient at the point of care.

Problems with the *clinical examination*[9] include:

- unsystematic methods in obtaining the patient's health history,
- unsystematic methods in observing the patient's signs and symptoms,
- faulty reasoning and inference in using the collected information, and
- the amount of time required to obtain and record all of this information.

These drawbacks jeopardize the completeness and accuracy of new information about the patient's current health problems.

Information About the Health Problem

The most efficient source of information about a specific health problem is *the clinician's own knowledge and experience with similar cases*. Such information can usually be retrieved almost instantaneously from the clinician's memory and can be readily applied to a health problem in terms that the clinician understands. Indeed, between 80 and 90 percent of clinical actions are based on such information.[10] However, it is impossible for clinicians to remember all available information about all of the health problems they are likely to encounter, or all of the alternative tests and treatments for those problems. Even experts on a given health problem are likely to have only selected information on that problem—information that may be unsystematic, unrepresentative, and biased. Most clinicians need to consult other sources of clinical knowledge and experience, at least on occasion.

A clinician may seek the advice of *other clinicians and researchers* who have special knowledge or experience regarding the health problem at hand. However, the patients usually seen by the consultant may differ from the referring clinician's patients in important ways. In addition, any individual clinician's patients may not be typical of all patients with the health problem at hand, and the consultant's knowledge and experience could also be highly selective. Finally, consultants sim-

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[8] Institute of Medicine, *The Computer-Based Patient Record: An Essential Technology for Health Care*, R.S. Dick and E.B. Steen (eds.) (Washington, DC: National Academy Press, 1991), pp. 12-19; P.C. Tang, D. Fafchamps, and E.H. Shortliffe, "Traditional Medical Records as a Source of Clinical Data in the Outpatient Setting," *Proceedings of the Eighteenth Annual Symposium on Computer Applications in Medical Care*, J.G. Ozbolt (ed.) (Philadelphia, PA: Hanley & Belfus, 1994), pp. 575-579; J.C. Wyatt, "Clinical Data Systems, Part 1: Data and Medical Records," *Lancet*, vol. 344, No. 8936, Dec. 3, 1994, pp. 1543-1547. For further discussion of problems with paper-based patient records, see chapter 2.

[9] See C. Selby et al., "Set Up and Run an Objective Structured Clinical Exam," *British Medical Journal*, vol. 310, No. 6988, May 6, 1995, pp. 1187-1190.

[10] B.C. James, "Advances in Computer-Based Patient Records for Health Services Research," presentation at the 12th Annual Meeting of the Association for Health Services Research, Chicago, IL, June 4-6, 1995.

ply may not be available when needed in urgent cases.

A related source of clinical guidance for practitioners is *legal standards of care*, which specify the levels of care provided by the majority of physicians in particular clinical situations. These standards are determined by the courts, largely on the basis of testimony by expert witnesses during malpractice lawsuits. The widely conflicting opinions expressed by different experts in many such contexts illustrate the extent to which legal standards of care can be vague, inconsistent, and incomplete.[11] Extensive variation in practice patterns among clinicians within and across localities has been thoroughly documented. This variation reflects, in part, the lack of consensus regarding the most effective ways to treat most health problems.[12]

To extend the individual knowledge and experience of individual clinicians, institutional providers or multifacility enterprises with large numbers of patients sometimes conduct *local clinical research* on those patients over time. Such efforts can generate information that is useful in those providers' own clinical decisionmaking, as well as for publication. (Providers with fewer patients often conduct such research as well, but the number of cases may be too small to support statistically reliable comparison among treatment groups.) However, local research may be useful only in that setting if the institution's patients or practice patterns are atypical. In any case, extensive local research is not that common, even among large institutions.

Information published in *printed clinical literature* (reference books, textbooks, research studies, and professional periodicals) is another well-established source of information for clinical decisionmaking. However, it can be difficult to locate such information quickly because of inadequate indexing and the problem of keeping paper materials organized. In addition, a considerable amount of time can elapse before new information gets published; and once published, it quickly becomes outdated. Maintaining large amounts of printed information in accurate, up-to-date, and readily accessible form can be expensive.

As with clinician knowledge and experience, clinical literature also may sometimes harbor biases resulting from the use of unsystematic methods in generating the information. Even peer-reviewed research literature is hampered by *publication bias* stemming from the preference of authors, journal editors, and reviewers for statistically significant results supporting specific hypotheses, particularly if those results are perceived as being important.[13] To be considered worthy of publication, articles whose results fail to support an hypothesis must strongly challenge widely held theories and assumptions. On the other hand, published research findings are often widely and uncritically accepted without careful consideration of the soundness of the methodologies used.

Despite decades of clinical and epidemiological research, systematic evidence is still lacking regarding "what works" in diagnosing, treating, and

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[11] U.S. Congress, Office of Technology Assessment, *Defensive Medicine and Medical Malpractice*, OTA-H-602 (Washington, DC: U.S. Government Printing Office, July 1994), pp. 30-31, 164.

[12] H. Krakauer et al., "The Systematic Assessment of Variations in Medical Practices and Their Outcomes," *Public Health Reports*, vol. 110, No. 1, Jan.-Feb., 1995, pp. 2-12; U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work: Searching for Evidence*, OTA-H-608 (Washington, DC: U.S. Government Printing Office, Sept. 1994), pp. 26-34.

[13] K. Dickersin and Y.I. Min, "Publication Bias: The Problem That Won't Go Away," *Doing More Harm Than Good: The Evaluation of Health Care Interventions*, K.S. Warren and F. Mosteller (eds.) (New York, NY: New York Academy of Sciences, 1993); P.J. Easterbrook et al., "Publication Bias in Clinical Research," *Lancet*, vol. 337, No. 8746, Apr. 13, 1991, pp. 867-872.

preventing most health problems—much less which methods are most cost-effective.[14] In addition, even the evidence that does exist is not always put to use in clinical practice. To rephrase an earlier statement, only between 10 and 20 percent of clinical actions are based on published scientific research.[15]

Practice Guidelines and Protocols

Even when solid experiential or research-based evidence is available, human beings are inherently fallible processors of that information.[16] They can track no more than four variables simultaneously, compared with the hundreds of variables that characterize even a single health condition.[17] It is impossible for clinicians to remember all available information about all of the health problems they are likely to encounter, or all of the alternative tests and treatments for those problems, or all relevant characteristics and histories of all of their patients. Moreover, recall is biased toward things that are considered to be more important, that tend to confirm one's prejudices, and that are more recently experienced.[18] Indeed, one researcher has referred to clinical decision support as "uncertainty management."[19]

In an effort to reduce this uncertainty, *clinical practice guidelines*[20] have been developed over the past few decades by numerous medical specialty societies, insurance companies, utilization review organizations, managed care organizations, and government agencies. Guidelines focus on a given health problem or procedure, and are usually developed through a group consensus process among selected clinical experts on that problem or procedure. The intent is to provide broad parameters within which clinicians continue to exercise judgment, rather than to dictate exact steps to follow.[21] Figure 4-1 reproduces an algorithm that depicts a clinical practice guideline for management of patients with heart failure, developed by the federal government's Agency for Health Care Policy and Research (AHCPR). Even when practice guidelines are available, however, evidence suggests that clinicians often forget to follow them, or deviate from them without clear cause, especially in high-stress situations.[22] Research also shows that it is difficult to change clinician behavior simply by providing them with information, even in the form of guidelines.[23]

Formal *clinical protocols* are more rigorous models of the process of care for a given

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[14] U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work*, op. cit., footnote 12; P.J. Neumann and M. Johannesson, "From Principle to Public Policy: Using Cost-Effectiveness Analysis," *Health Affairs*, vol. 13, No. 3, summer 1994, pp. 206-214.

[15] James, op. cit., footnote 10.

[16] C.J. McDonald, "Protocol-Based Computer Reminders, The Quality of Care and the Non-Perfectability of Man," *New England Journal of Medicine*, vol. 295, No. 24, Dec. 9, 1976, pp. 1351-1355; Leape, op. cit., footnote 3.

[17] A.H. Morris, "Protocol Management of Adult Respiratory Distress Syndrome," *New Horizons*, vol. 1, No. 4, Nov. 1993, p. 594.

[18] Ibid., p. 593.

[19] E.H. Shortliffe, "Medical Informatics and Clinical Decision Making: The Science and the Pragmatics," *Medical Decision Making*, vol. 11, No. 4, Oct.-Dec. Supplement, 1991, pp. S2-S4.

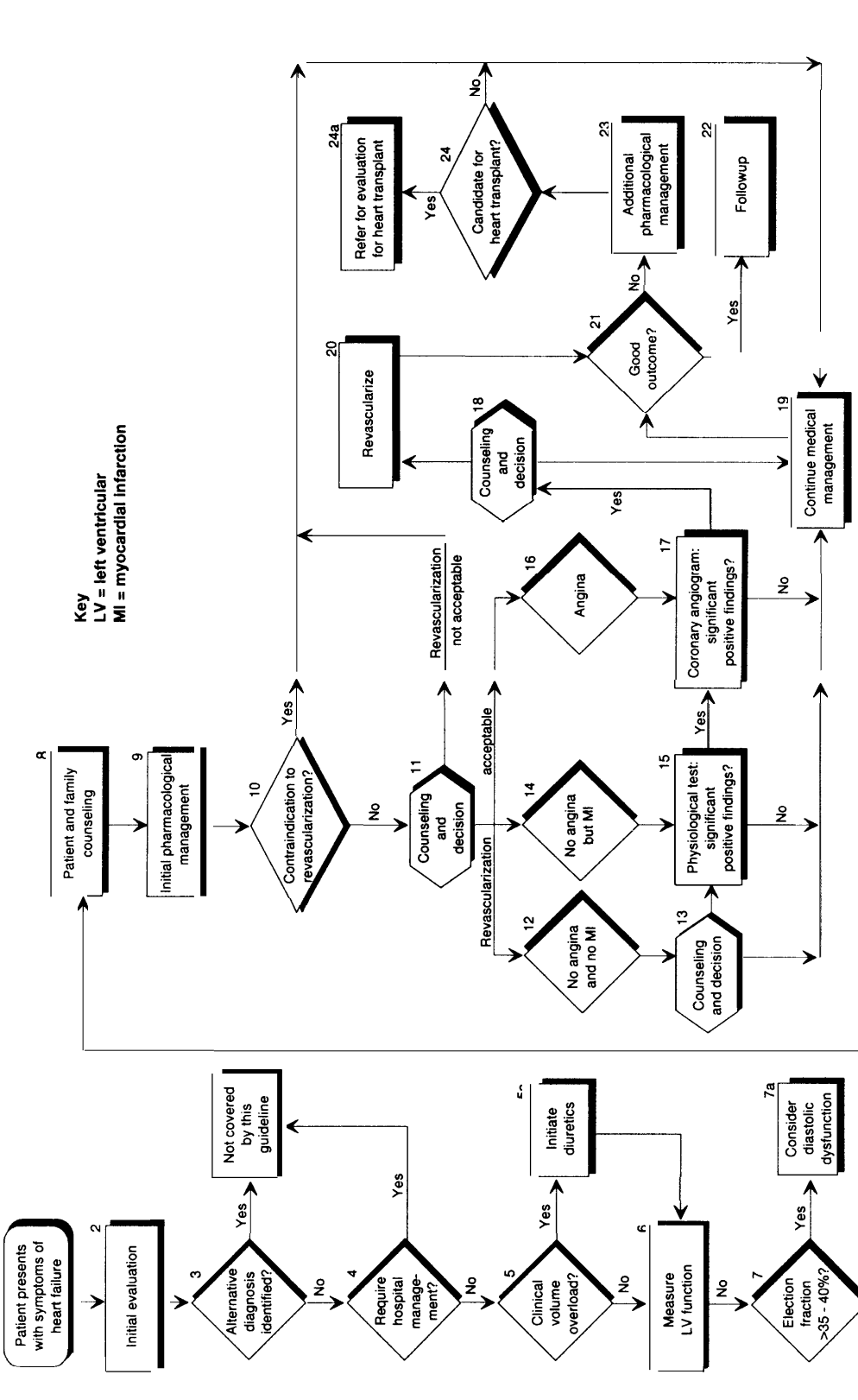
[20] Clinical practice guidelines are sometimes called *practice parameters* or some variation of *clinical paths* or *critical pathways*—terminology adapted from *critical path analysis* in manufacturing and other industries.

[21] U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work*, op. cit., footnote 12, ch. 7.

[22] E. Coiera, "Medical Informatics," *British Medical Journal*, vol. 310, No. 6991, May 27, 1995, p. 1383.

[23] T.H. Lee. et al., "Failure of Information as an Intervention To Modify Clinical Management," *Annals of Internal Medicine*, vol. 122, No. 6, Mar. 15, 1995, p. 436; U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work*, op. cit., footnote 12, ch. 8.

Figure 4-1: Algorithm Depicting a Clinical Practice Guideline for Evaluation and Care of Patients with Heart Failure



SOURCE: Heart Failure Guideline Panel, *Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction,* Clinical Practice Guideline No. 11, AHCPR Pub. No. 94-0612 (Rockville, MD: US. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, June 1994), pp. 114-115.

health problem. They are composed of highly specific steps and decision parameters regarding diagnosis, treatment, or prevention of a problem. The inputs and outputs of a given step can be either deterministic (involving a fixed value or action) or probabilistic (involving a range of possible values or actions). Clinicians may still exercise judgment and override any particular step in a protocol, but having a clear sequence of specific steps to follow can help ensure that none will be inadvertently forgotten or altered.[24]

Many clinicians view practice guidelines and protocols skeptically as being "cookbook medicine,"[25] concocted largely by clinically uninformed researchers and bureaucrats. Some are also concerned that guidelines may be used against clinicians in malpractice suits,[26] although evidence indicates that they are used by both plaintiffs' and defendants' attorneys.[27] Other clinicians criticize guidelines that are based more on judgmental consensus than on scientific evidence. These guidelines are seen as being vague and subjective, lacking in specificity and testability, and based on incomplete and inaccurate information—drawbacks that make it difficult to derive case-specific advice.[28]

For example, nurses at LDS Hospital in Salt Lake City, Utah, found that the AHCPR guideline for treating pressure ulcers was too vague to use in clinical practice. Most importantly, the guideline did not specify the treatment options for various combinations of scores on six components of a measure of risk for developing pressure ulcers. A team of nurses, physicians, and researchers converted the guideline into a more formal clinical protocol by developing exact specifications for those treatment options through an iterative group consensus process and monitoring of patient outcomes.[29] This illustrates how local research can be used to inform the development and refinement of clinical practice guidelines and protocols. It also emphasizes the need for careful testing and screening of these kinds of clinical decision support.

Potential Contributions of Information Technology

The basic question in this area is whether advanced information technologies can 1) improve the accuracy of the information needed in clinical decisionmaking, 2) reduce the amount of time required to retrieve that information, and 3) make that information accessible at the point of care. This section highlights some of the potential contributions these technologies can make to clinical decision support. A later section summarizes some of the limited and mixed evidence bearing on these questions.

Entering and Retrieving Patient Information

The key technology for improving patient information is the electronic patient record that stores comprehensive information on the patient

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[24] Coiera, op. cit., footnote 22.

[25] W.W. Parmley, "Clinical Practice Guidelines: Does the Cookbook Have Enough Recipes?" *Journal of the American Medical Association*, vol. 272, No. 17, Nov. 2, 1994, pp. 1374-1375.

[26] F. Bazzoli, "Computerized Records Will Play a Key Role in the Implementation of Clinical Guidelines," *Health Data Management*, February 1995, p. 32.

[27] A.L. Hyams et al., "Practice Guidelines and Malpractice Litigation: A Two-Way Street," *Annals of Internal Medicine*, vol. 122, No. 6, Mar. 15, 1995, pp. 450-455.

[28] C.J. McDonald and J.M. Overhage, "Guidelines You Can Follow and Can Trust: An Ideal and an Example," *Journal of the American Medical Association*, vol. 271, No. 11, Mar. 16, 1994, pp. 872-873.

[29] S. D. Horn, C. Ashton, and D.M. Tracy, "Prevention and Treatment of Pressure Ulcers by Protocol," *Clinical Practice Improvement: A New Technology for Developing Cost-Effective Quality Health Care*, S.D. Horn and D.S.P. Hopkins (eds.)(New York, NY: Faulkner & Gray, 1994), pp. 253-262; "LDS Nurses Reduce Pressure Ulcer Incidence with Retooled Guidelines," *Report on Medical Guidelines & Outcomes Research*, Feb. 23, 1995, pp. 10-11.

from a variety of sources (clinic, laboratory, pharmacy, etc.).[30] Other technologies for handling patient information operate in conjunction with the electronic patient record. Overall, these technologies could permit *faster, easier, and more accurate collection of information about the patient*.[31] Clinical examination results can be entered by clinicians at or near the point of care, particularly with the aid of portable computers. Structured data entry, such as on-screen forms and menus and prepared blocks of text, can encourage complete data collection and reduce keying errors, particularly when pen-based computing is used rather than keyboards. Automatic date- and time-stamping of entries facilitates documentation and tracking of patient care and outcomes over time.

Some patient data can be captured directly from diagnostic and monitoring equipment, bypassing human data entry altogether. Radiographic images, full-motion videos, and sound recordings can be digitized, stored, and transmitted electronically, often with resolution approaching that of analog technologies. Patient background information and *risk factors*[32] can be entered into computers by patients themselves, again with the aid of structured data entry and advanced human-computer interface technologies. One example of such a system is *HealthQuiz*[33] (see appendix C). Basic demographic traits can be obtained from other computer databases (e.g., insurance eligibility files) through computer networks, again bypassing human data entry.

Using relational databases with online query, information technologies can also permit *faster, easier, and better targeted search and retrieval of previously collected information about the patient*—even at the point of care. Portable computers and advanced human-computer interface technologies can also be helpful here. Electronic storage of digitized radiographic images, full-motion videos, and sound recordings can make them easier to locate, although retrieving them can be slow if the computers, telecommunications equipment, or transmission lines used have insufficient capacity. Increasingly powerful and flexible graphics software and higher resolution displays can offer flexibility in the ways information is organized and displayed to suit the individual needs of clinicians.

Retrieving Information About the Health Problem

Computer and telecommunications networks, in conjunction with online query, portable computers, and advanced human-computer interfaces, can make information about various health problems more readily accessible from either local or remote knowledge bases. Many research libraries provide online access to their computerized catalogs (e.g., the Library of Congress's SCORPIO) and bibliographic databases (e.g., The National Library of Medicine's MEDLINE) that can be queried online. Documents can be ordered electronically (even during an online literature search) from one of the more than 4,000 member libraries of the National Network of Libraries of Medicine. Documents can be shipped in hard-copy form or transmitted electronically via the Internet or fax. Unfortunately, these databases do not cover all of the clinical literature, and it can be difficult to identify all studies of a certain kind, such as randomized controlled trials.[34]

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[30] Although the computer-based patient record is usually conceptualized as being a centralized repository, in reality different components of the record may be stored in separate but seamlessly linked computer systems.

[31] J.C. Wyatt, "Clinical Data Systems, Part 2: Components and Techniques," *Lancet*, vol. 344, No. 8937, Dec. 10, 1994, pp. 1609-1614.

[32] Risk factors are key health problems and background characteristics that can affect the patient's outcome, independent of the specific kinds of services received.

[33] " 'HealthQuiz' Makes Preventive Care Guidelines Easy To Apply," *Report on Medical Guidelines & Outcomes Research*, Jan. 26, 1995, pp. 5-6.

[34] U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work*, op. cit., footnote 12, p. 81.

The National Cancer Institute (NCI) maintains a Physician Data Query (PDQ) system that provides online information via the Internet (CancerNet) and by fax (CancerFax) regarding various cancers, ongoing clinical trials, and individuals and organizations involved in cancer care. The University of Pennsylvania also maintains a multimedia cancer information resource on the Internet called OncoLink. The Centers for Disease Control and Prevention provide online access to the full text of *Morbidity and Mortality Weekly Report*, and has recently launched an online journal called *Emerging Infectious Diseases*. Several biomedical journals are also available online.[35]

Some periodicals, and even complete books and reports, are becoming available on CD-ROMs that can be purchased or obtained through many libraries. (In their current form, however, CD-ROMs cannot be updated, and must be replaced as knowledge changes.) Both CD-ROMs and the Internet permit inclusion of graphics, videos, and sound in textual documents. This helps offset the complaint that it is not only less pleasant to read documents on a video screen than on paper, but actually slower.[36]

Information technology is also making practice guidelines more readily accessible. The National Library of Medicine (NLM) offers online access to practice guidelines developed by AHCPR, and NCI's PDQ system includes information on cancer treatment protocols. Private organizations such as the American Medical Association are also distributing their practice guidelines on CD-ROMs and computer diskettes.

In recent years, an international movement among researchers and clinicians has developed an approach to clinical problem-solving called *evidence-based medicine*.[37] It involves systematic searching and critical appraisal of the research literature to identify findings that can be applied to a clearly defined clinical problem. This approach goes beyond the narrative review articles occasionally published in leading clinical journals. It employs *systematic review* of the literature, in which specific items of information are extracted from each work and compared across works, using structured methods. The most sophisticated form of systematic review is *meta-analysis*, or quantitative synthesis of the statistical results of a number of studies on a given topic.[38] Special journals have been established to summarize and evaluate the vast literature on selected health problems.[39] The Cochrane Collaboration, an international network of researchers, distributes results of systematic reviews of randomized controlled trials—or the most reliable evidence from other sources—on selected health problems (beginning with pregnancy and childbirth) in uncopyrighted form via the Internet, as well as on computer diskettes and CD-ROMs.[40] However, it is unclear how these results will get incorporated systematically into clinical practice guidelines and protocols.[41]

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[35] H.F. Judson, "Structural Transformations of the Sciences and the End of Peer Review," *Journal of the American Medical Association*, vol. 272, No. 2, July 13, 1994, p. 93.

[36] J.C. Wyatt, op. cit., footnote 31, p. 1613.

[37] W. Rosenberg and A. Donald, "Evidence Based Medicine: An Approach to Clinical Problem-Solving," *British Medical Journal*, vol. 310, No. 6987, Apr. 29, 1995, pp. 1122-1126.

[38] U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work*, op. cit., footnote 12, pp. 59-65.

[39] F. Davidoff et al., "Evidence Based Medicine: A New Journal To Help Doctors Identify the Information They Need," *British Medical Journal*, vol. 310, No. 6987, Apr. 29, 1995, pp. 1085-1086.

[40] Cochrane Collaboration, "The Cochrane Collaboration: Preparing, Maintaining, and Disseminating Systematic Reviews of the Effects of Health Care," Oxford, England, brochure, n.d.

[41] J.C. Wyatt, "Clinical Data Systems, Part 3: Development and Evaluation," *Lancet*, vol. 344, No. 8938, Dec. 17, 1994, p. 1687.

The prospect of making information such as research results readily and inexpensively available for online query through the Internet has spawned visions of *electronic (online) publishing*.[42] Not only are certain peer-reviewed journals already available online, but in some disciplines, such as physics, *preprints* containing preliminary results are often distributed over the Internet prior to printed publication.[43] At first glance, this might appear to reduce the problem of publication bias. However, in addition to the fact that much of that bias rests with authors themselves, there are several other concerns about this prospect. Most important is the absence of online screening mechanisms to replace the process of scientific peer review that seeks to ensure the quality of published research.[44] Without such mechanisms for screening documents for scientific rigor as well as relevance to one's interests,[45] the increasing problem of information overload could worsen. Moreover, public access to unrefereed preprints of medical research could lead some people to misuse medications.[46] On the other hand, online access to the full text of commercially published books and journal articles is likely to remain limited until electronic subscription and payment mechanisms become established and issues regarding intellectual property rights and electronic copying are resolved.[47]

Computer-Based Clinical Decision Support Systems

Increasingly, the traditional sources of clinical decision support are being supplemented by *clinical information systems*, mainly at large academic medical centers. The most rudimentary of these are *library systems* or *simple data systems*[48] that merely display information about the patient and/or the health problem to the clinician without offering advice based on analysis of that information. However, some clinical information systems contain *expert systems* or *knowledge-based systems* that do offer advice to the clinician regarding diagnosis, testing, or treatment.[49] The goal of either simple or knowledge-based decision support systems is to provide more complete and accurate information more quickly to the clinician—preferably at the point of care—thereby improving clinical decisionmaking in terms of patient outcome measures. These benefits to the clinician presumably outweigh the added burden of more extensive data collection and entry. Clinical information systems may also contain other applications besides decision support, such as on-

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[42] R.E. LaPorte et al., "The Death of Biomedical Journals," *British Medical Journal*, vol. 310, No. 6991, 1387-1390, May 27, 1995, pp. 1085-1086; Judson, op. cit., footnote 35.

[43] J.P. Kassirer and M. Angell, "The Internet and the *Journal*," *Journal of the American Medical Association*, vol. 332, No. 25, June 22, 1995, p 1709.

[44] Both Judson and LaPorte et al, op. cit., footnote 42, propose an online peer review system in which all readers of a document would comment on it. LaPorte et al. go further in proposing that readers give each document ratings in various categories. These comments and summary ratings would subsequently be attached to the document for other readers to use in screening. One potential problem with this scenario is that readers willing to take time to evaluate all documents that they read might well be a small, self-selected, hence unrepresentative group; and there would be no way to ensure that they were qualified to evaluate the document. Kassirer and Angell discuss the perils of "majority rule" compared to peer review. Op. cit., footnote 43.

[45] LaPorte et al. suggest that software *agents* could be used to select only documents that meet certain user-specified content criteria. Op. cit., footnote 42.

[46] Kassirer and Angell, op. cit., footnote 43.

[47] U.S. Congress, Office of Technology Assessment, *Information Security and Privacy in Network Environments*, OTA-TCT-606 (Washington, DC: U.S. Government Printing Office, September 1994), pp. 96-110.

[48] Wyatt, op. cit., footnote 41.

[49] Wyatt refers to these as *advisory systems*. Ibid.

line order entry, that allows the clinician to submit orders for tests and treatments (including pharmaceuticals).

A knowledge-based system designed for clinical use, sometimes called a *clinical decision support system* (CDSS), usually involves three basic components:[50]

1. *Data on the patient* being diagnosed or treated are either entered into the system manually, captured automatically from diagnostic or monitoring equipment, or drawn from an electronic patient record.
2. A *knowledge base* contains rules and decision algorithms that incorporate knowledge and judgment about the health problem at hand and alternative tests and treatments for it, mainly in the form of "if-then" statements, such as "if the patient's potassium is less than 3.0 mEq/dl and the patient is on digoxin, then warn the clinician to consider potassium supplementation."[51]
3. An *inference engine* combines information from both the patient data and the knowledge base to perform specified tasks, outlined in appendix C.

Some CDSSs—usually those developed more recently—employ probabilistic and adaptive approaches, such as fuzzy logic, Bayesian networks, or neural networks. Others—usually those developed earlier—employ rule-based systems, decision trees, and other deterministic methods, although probabilistic decision nodes are sometimes employed.[52]

Many of the major applications of CDSSs were implemented over the past 15 to 20 years in two pioneer systems:

- the Health Evaluation through Logical Processing (HELP) system developed by Intermountain Health Care (IHC) and its flagship institution, LDS Hospital and the University of Utah in Salt Lake City;[53] and
- the Regenstrief Medical Record System (RMRS), developed by the Regenstrief Institute and Indiana University, initially at Wishard Memorial Hospital in Indianapolis.[54]

Components of both of these systems are marketed commercially: HELP by the 3M Co., with about five installations outside of Utah; and RMRS by Shared Medical Systems, Inc. (SMS), with about 10 installations outside of Indiana. Several other CDSSs, or some of their particular applications, are also commercially available. However, most are implemented by clinical researchers in the form of highly specialized, localized, and experimental systems that vary widely in their levels of development.

Computer-Based Clinical Protocols

The most advanced CDSSs integrate several of the applications outlined in appendix C into formal clinical protocols. Again, some are based on deterministic models, while others employ probabilistic and adaptive approaches. Converting a clinical protocol into computer-based algorithms forces the developer to use unambiguous terminology, examine the logic of all linkages

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[50] See D.P. Connelly and S.T. Bennett, "Expert Systems and the Clinical Laboratory Information System," *Clinics in Laboratory Medicine*, vol. 11, No. 1, March 1991, p. 136.

[51] R.F. Gibson and B. Middleton, "Health Care Information Management Systems To Support CQI," *Clinical Practice Improvement: A New Technology for Developing Cost-Effective Quality Health Care*, S.D. Horn and D.S.P. Hopkins (eds.)(New York, NY: Faulkner & Gray, 1994), p. 109.

[52] R.A. Miller, "Medical Diagnositc Decision Support Systems—Past, Present, and Future," *Journal of the American Medical Informatics Association*, vol. 1, No. 1, Jan./Feb. 1994, pp. 11-16.

[53] See chapter 2 and G.J. Kuperman, R.M. Gardner, and T.A. Pryor, *HELP: A Dynamic Hospital Information System*, Computers and Medicine Series (New York, NY: Springer-Verlag, 1991).

[54] See C.J. McDonald et al., "The Regenstrief Medical Record System: 20 Years of Experience in Hospitals, Clinics, and Neighborhood Health Centers," *M.D. Computing*, vol. 9, No. 4, July/August 1992, pp. 206-217.

among steps, and—in deterministic models—specify exact parameters. It also facilitates refinement and updating of the protocol over time, based on any of the traditional sources of clinical decision support outlined earlier, plus feedback from clinicians who use the protocol—particularly the reasons they document for overriding its recommendations—and from local research on patient outcomes.

Researchers at Intermountain Health Care[55] have developed an approach to quality improvement, called *clinical practice improvement*, that essentially combines computer-based protocols, local research, and the principles of *continuous quality improvement* (CQI).[56] A protocol is developed for a selected health problem (e.g., acute respiratory distress syndrome) based on review of relevant literature, clinician judgment, and retrospective analysis of data from the electronic patient record system. The protocol is refined through discussion and consensus among clinicians, and serves to guide diagnosis and treatment for the selected health problem. In addition, randomized controlled trials of various alternative diagnostic and therapeutic procedures for that problem are conducted, and the protocol is further refined in light of the results of those trials.

Computer-based clinical protocols may also prove valuable in a more indirect way. The full potential of CDSSs is constrained by the limitations of electronic storage devices. Storing complete, full-text information on all possible health problems and alternative tests and treatments for them in a manner that permits rapid retrieval of that information at the point of care is prohibitively expensive. However, by distilling selected elements of full-text information on a particular health problem and its alternative tests and treatments into explicit steps, criteria, and parameters, clinical protocols can greatly reduce storage requirements.

Other Potential Benefits of Information Technology

Both clinical protocol development and local research can benefit from advanced information technologies. Most patients receive care from more than one provider, and within a given provider organization there are usually several separate information systems, often one for each department (inpatient, laboratory, pharmacy, etc.). Electronic patient record systems and computer networks within and across provider organizations can facilitate the tracking of all care and outcomes of individual patients over time. These systems make it easier and more efficient to link the separate records for a given patient across all departments and providers, particularly if a common, unique patient identifier is used in all records. The value of assembling patient data across several departments is illustrated by local research that used the HELP system at LDS Hospital to identify specific causes of adverse drug events[57] and hospital-acquired infections.[58] Computer net-

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[55] S.D. Horn and D.S.P. Hopkins (eds.), *Clinical Practice Improvement: A New Technology for Developing Cost-Effective Quality Health Care* (New York, NY: Faulkner & Gray, 1994).

[56] CQI (also known as *total quality management*, or TQM) was originally developed in the field of manufacturing and was subsequently adapted to health care. See W.E. Deming, *Common Causes and Special Causes of Improvement: Stable System, Out of Crisis* (Cambridge, MA: MIT Center for Advanced Engineering Study, 1986); D.M. Berwick, "Continuous Improvement as an Ideal in Health Care," *New England Journal of Medicine*, vol. 320, No. 1, Jan. 5, 1989, pp. 53-56; Institute of Medicine, *Medicare: A Strategy for Quality Assurance*, K.N. Lohr (ed.) (Washington, DC: National Academy Press, 1990), pp. 58-64; S.B. Kritchevsky and B.P. Simmons, "Continuous Quality Improvement: Concepts and Applications for Physician Care," *Journal of the American Medical Association*, vol. 266, No. 13, Oct. 2, 1991, pp. 1817-1823; Leape, op. cit., footnote 3; Leape et al., op. cit., footnote 3.

[57] R.S. Evans et al., "Preventing Adverse Drug Events in Hospitalized Patients," *The Annals of Pharmacotherapy*, vol. 28, No. 4, April 1994, pp. 523-527.

[58] D.C. Classen et al., "Prophylactic Antibiotics Used To Prevent Surgical Wound Infections," Horn and Hopkins, op. cit., footnote 55, pp. 217-221.

works across provider organizations could also permit wider and faster dissemination of clinical protocols and the results of generalizable local research, particularly to remote sites.

An indirect but important way for advanced information technologies to enhance the quality of health care could be improving the outcomes data used in research on the effectiveness of specific health services. Electronic patient records, structured data entry, advanced human-computer interfaces, portable computers, and automated data capture from diagnostic and monitoring equipment could make the collection of patient data not only faster and easier, but also more complete and accurate. This could permit more valid and reliable measurement of patient risk factors, clinical processes, and outcomes. Records or results for patients with a given health problem but treated in different ways could be pooled across providers, creating very large databases for assessing the effectiveness of specific health services. This would require using health problems, process and outcome measures, and analytical methodologies that were as similar as possible across providers. Research based on these improved data could enhance the medical knowledge on which clinical decision support is based.

From the perspective of physicians, one direct benefit of using advanced information technology in medical practice recently became readily apparent: Two malpractice insurance companies began offering reduced premiums to physicians who use specific commercial electronic patient record systems.[59] This development mainly reflects the improved patient information and documentation of care that electronic patient records offer, compared with paper-based records.

Continuing Problems in Clinical Decision Support

Technology Development

As impressive as their applications are, the usefulness of clinical decision support systems can still be hampered by incomplete, inaccurate, or inaccessible information—problems that advanced information technologies could help overcome. As discussed in chapter 2, however, the capabilities of many of the information technologies employed in CDSSs remain limited and their costs remain high, posing substantial barriers to their widespread use. Several technological advances are needed for faster, easier, and more accurate collection, entry, and retrieval of patient information, and more readily accessible information about the health problem. The needed advances include:

- advanced human-computer interface technologies, particularly voice recognition, for easier and possibly hands-free input and retrieval of information;
- more extensive use of structured data entry, such as on-screen forms and menus and prepared blocks of text, to ensure complete data collection and reduce keying errors;
- smaller, more portable computers that can link into larger computer networks, either through wireless technologies or docking stations;
- improved wireless technologies that minimize such limitations as the restricted range and placement of infrared technologies that use line-of-sight transmission, or the electromagnetic interference generated by radio-wave transmission;

[59] "Malpractice Insurers Offer Discounts for Doctors Using Electronic Records," *Health Data Management*, February 1995, p. 14.

- more efficient methods of filtering and summarizing the enormous quantities of data captured directly from diagnostic and monitoring equipment, such as focusing on abnormal data values and trends;
- higher capacity and more flexible electronic storage devices, such as updatable CD-ROMs;
- higher resolution computer displays;
- more powerful and flexible graphics software;
- improved technologies for capturing and storing digitized radiographic images, full-motion videos, and sound recordings, and faster methods of retrieving such information;
- faster and more flexible methods of online query using relational databases;
- higher capacity telecommunications equipment and transmission lines; and
- more complete coverage of the research literature by online bibliographic databases.

As one researcher put it:

> [Clinicians] need a system that is easy to use: computer terminals must be ubiquitous, system response must be immediate (not seconds), necessary data should always be on-line, accessible, and confidential, and very little training should be required.[60]

In addition, system down time must be at an absolute minimum, and data should be retained for as long as possible without diminishing system response times. Systems that meet all the needs of clinicians may have to be developed in-house rather than adapted from commercial products.[61]

Standards Development

The issues regarding standards development discussed in chapters 2 and 3 apply here as well. However, some additional aspects of these topics and issues that apply to clinical decision support require further discussion.

Messaging standards

At first glance, it might appear that the development of messaging standards for electronic exchange of information among disparate computer systems is less important in clinical decision support than in other health care applications of advanced information technologies, such as electronic claims payment. Clinical decision support is inherently localized—that is, specific to individual providers—whereas electronic commerce involves transactions among providers and between providers and other parties. Nevertheless, most patients receive care from more than one provider and from several departments within a given organization. Thus, messaging standards and common, unique patient and provider identifiers could facilitate patient record linkage through computer networks. (At the same time, standards for protecting patient and provider privacy would need to be developed and enforced—see chapter 3.) Such standards could also encourage wider and faster dissemination of clinical protocols and local research results, and could enable providers with different types of computer systems to access various central repositories of medical knowledge.

Clinical information content

In theory, clinical decision support could also benefit from further development of standards for clinical information *content*—mainly common medical nomenclatures and uniform coding systems for diagnoses, procedures, and test results—to help ensure that all needed information is present and accurate. Some analysts believe the development of a universal clinical nomenclature and coding system is critical to the effective use of information technology to improve the quality of health care.[62] However, developing a truly univer-

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[60] Wyatt, op. cit., footnote 41, p. 1682.

[61] Ibid., p. 1685.

[62] M. Ackerman et al., "Standards for Medical Identifiers, Codes, and Messages Needed To Create an Efficient Computer-Stored Medical Record," *Journal of the American Medical Informatics Association*, vol. 1, No. 1, January./February 1994, pp. 1-7.

sal system is a difficult task, given the wide variation in existing systems and the intensity of institutional commitment to those systems. Indeed, some analysts question whether a truly universal system can *ever* be developed, contending that "terminology evolves in a context of use" that cannot be supplanted.[63] Instead, "vocabularies need to be constructed in a manner that preserves the context of each discipline and ensures translation between disciplines."[64] An alternative to compiling *enumerative* systems that attempt to list all possible terms in advance is a *compositional* approach. Such systems use basic terms as building blocks that can be combined in various ways to form higher level terms tailored to particular applications and specialties.[65]

NLM has already made some progress in this area through the ongoing development of its Unified Medical Language System (UMLS), which is being tested at about 500 sites.[66] (Institutions and individuals receive the software free of charge in exchange for testing it and commenting on it.) Despite its name, UMLS is not in itself a unified clinical language; rather, it is more a means of translating among disparate clinical nomenclatures. Its major purpose is to facilitate the retrieval and integration of biomedical information from disparate machine-readable sources by mapping and interpreting over 200,000 specific concepts across different classification systems, coding systems, and *controlled vocabularies* (in which only one term denotes each concept). The central component of the UMLS is a *Metathesaurus* that essentially links synonyms from disparate vocabularies to a common term.

A separately developed Unified Nursing Language System (UNLS) is being incorporated into the UMLS.[67] A related NLM project is the Integrated Academic Information Management System, which provides grants to academic medical centers for investigating communications and information processing technologies. These technologies are designed to facilitate exchange and interpretation of data among different computer systems, with the ultimate goal of developing integrated health care information systems.[68]

One such effort is the Arden Syntax, a language for encoding and sharing medical knowledge based largely on the HELP and RMRS systems described earlier.[69] The syntax is organized into separate Medical Logic Modules (MLMs) that contain sufficient logic to make a single medical decision, running automatically in conjunction with a program known as an event monitor. The syntax offers the ability to query clinical databases, many of which have been found to be compatible with the syntax. Six institutions are actively using the syntax, and three others are reviewing it. MLMs have been used to generate alerts, interpretations, diagnoses, screening for clinical research, quality assurance functions, and administrative support. However, they have not

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[63] Coiera, op. cit., footnote 22, p. 1384.

[64] P.F. Brennan, "On the Relevance of Discipline to Informatics," *Journal of the American Medical Informatics Association*, vol. 1, No. 2, Mar./Apr. 1994, p. 200.

[65] Coiera, op. cit., footnote 22, p. 1385.

[66] D.A. Lindberg, B.L. Humphreys, and A.T. McCray, "The Unified Medical Language System," *Methods of Information in Medicine*, vol. 32, No. 4, August 1993, pp. 281-291; A.T. McCray, Chief, Cognitive Sciences Branch, National Library of Medicine, personal communication, June 8, 1995.

[67] K.A. McCormick et al., "Toward Standard Classification Schemes for Nursing Language: Recommendations of the American Nurses Association Steering Committee on Databases To Support Clinical Nursing Practice," *Journal of the American Medical Informatics Association*, vol. 1, No. 6, November/December 1994, pp. 421-427.

[68] Coltin and Aronow, op. cit., footnote 2.

[69] Columbia-Presbyterian Medical Center, Arden Syntax home page on the World Wide Web <URL:http://www.cpmc.columbia.edu/arden/>, 1995; T.A. Pryor and G. Hripcsak, "The Arden Syntax for Medical Logic Modules," *International Journal of Clinical Monitoring and Computing*, vol. 10, No. 4, November 1993, pp. 215-224.

been fully validated for clinical use, and not all of the ones developed are in active use. Nonetheless, the Arden Syntax has been adopted as a standard by the American Society for Testing and Materials (ASTM document E 1460).

Effectiveness and Safety of Clinical Decision Support Systems

Effectiveness

Evidence regarding the effectiveness of CDSSs in improving clinical processes and patient outcomes is limited and mixed.[70] One review of the development and evaluation of clinical data systems focused on "simple data systems" that do not offer clinical advice, but rather simply display information on the patient and/or the health problem.[71] It concluded that these systems improve some clinical processes (accuracy of predictions of patient progress, number or types of diagnostic tests ordered, and completeness of data collection), but that there is little evidence of improvement in patient outcomes. Regarding data accuracy, the reviewer noted:

> If the system is not interactive, if data are collected largely for billing or administrative purposes, if coding staff are poorly instructed and trained, and if clinicians are unaware of the system and do not monitor the data, inaccuracy will be the rule. Reasons for data inaccuracy are often organisational, not technical.[72]

Data completeness is improved when the system prompts the clinician or clerk for specific data items. However, it is less clear whether payment incentives improve data completeness, or whether data are more complete when a clinician enters them directly rather than using encounter forms. It is also unclear whether using computers saves clinician time; but even if it doesn't, it will likely improve the quality of data.[73]

A recent review of systematic studies of the impact of CDSSs on clinician behavior and patient outcomes found generally positive effects on clinician behavior, although this effect varied according to the type of application performed by the CDSS.[74] Three of four studies of CDSSs for determining the dose of toxic drugs reported statistically significant improvements in achieving therapeutic levels. Four of six studies of preventive care reminder systems found significant increases in the performance of specific immunizations or screening tests. Seven of nine studies of the impact of CDSSs on active medical care (e.g., adherence to a protocol for management of hypertension) found significant positive effects. On the other hand, only one of five studies of computer-aided diagnosis found a significant improvement in diagnostic accuracy. Moreover, only three of ten studies of the impact of CDSSs on patient outcomes found significant effects favoring the use of a CDSS.

More recent studies also demonstrate the mixed potential of CDSSs. One study found that computer-based alerts of rising creatinine levels in hospitalized patients enabled clinicians to change medications or dosages earlier, thereby decreas-

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[70] Wyatt, op. cit., footnote 41; M.E. Johnston et al., "Effects of Computer-based Clinical Decision Support Systems on Clinician Performance and Patient Outcome: A Critical Appraisal of Research," *Annals of Internal Medicine*, vol. 120, No. 2, Jan. 15, 1994, pp. 135-142; D.M. Rind et al., "Effect of Computer-Based Alerts on the Treatment and Outcomes of Hospitalized Patients," *Archives of Internal Medicine*, vol. 154, No. 13, July 11, 1994, pp. 1511-1517; E.S. Berner et al., "Performance of Four Computer-Based Diagnostic Systems," *New England Journal of Medicine*, vol. 330, No. 25, June 23, 1994, pp. 1792-1796; W.A. Knaus et al., "The SUPPORT Prognostic Model: Objective Estimates of Survival for Seriously Ill Hospitalized Adults," *Annals of Internal Medicine*, vol. 122, No. 3, Feb. 1, 1995, pp. 191-203.

[71] Wyatt, op. cit., footnote 41, p. 1686.

[72] Ibid., p. 1684.

[73] Wyatt, op. cit., footnote 41, pp. 1684-1686.

[74] Johnston et al., op. cit., footnote 70.

ing the risk of serious renal impairment by more than half.[75] The SUPPORT prognostic model (see appendix C) predicted survival as well as did a group of clinicians. However, incorporating the clinicians' subjective estimates as predictors in the model improved both its predictive accuracy and its ability to identify patients with high probabilities of survival or death.[76]

Using data describing 105 actual cases that differed in their degree of diagnostic difficulty, another study evaluated the performance of four general diagnostic CDSSs: Dxplain, Iliad, Meditel, and QMR (see appendix C). The performance of these systems on several measures of diagnostic accuracy was compared to diagnoses determined by group consensus among 10 clinical experts. No single system consistently scored better than the others on all performance measures. A majority of the diagnoses that the systems listed were correct (or closely related to the correct diagnosis), but the correct diagnosis usually did not appear in the top five diagnoses listed by the systems. Moreover, far less than a majority of the diagnoses they listed were considered relevant. On average, they listed less than half of the diagnoses identified by the expert clinicians, but they listed about two additional relevant diagnoses not originally identified by the clinicians. These results emphasize the potential usefulness of CDSSs in reminding clinicians of overlooked alternatives, but also the importance of clinician experience and judgment in interpreting and filtering information.[77]

Safety

CDSSs, particularly computer-based clinical protocols, may reduce inappropriate practice variations and improve patient outcomes. Yet it is possible that the most successful CDSSs could become viewed as rigid sets of rules for diagnosing and/or treating particular health problems. Clinicians might then become overly dependent on them, adhering to the recommended steps without question or independent investigation, and allowing their own knowledge, skill, and judgment to erode as a result.[78] Alternatively, systems that provide too many simultaneous streams of information could cause information overload, prompting clinicians either to focus on certain items and neglect other important tasks, or to shun all such information .[79]

Any of these developments could adversely affect the quality of patient care and undermine the interpersonal aspects of patient care (the "quality of caring").[80] Indeed, there are indications that patients find clinicians less communicative when using computers to enter patient data. Clinicians themselves mainly fear that computers might threaten patient and provider privacy, create legal or ethical problems, increase government control of health care, or rely on out-of-date knowledge.[81]

CDSSs are only as good as the medical knowledge on which they are based. Due to methodological errors in the research underlying a CDSS or to substantive misinterpretation of research results, a CDSS may contain incorrect parameters or decision criteria or may overlook crucial steps in the

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[75] Rind et al., op. cit., footnote 70.

[76] Knaus et al., op. cit., footnote 70.

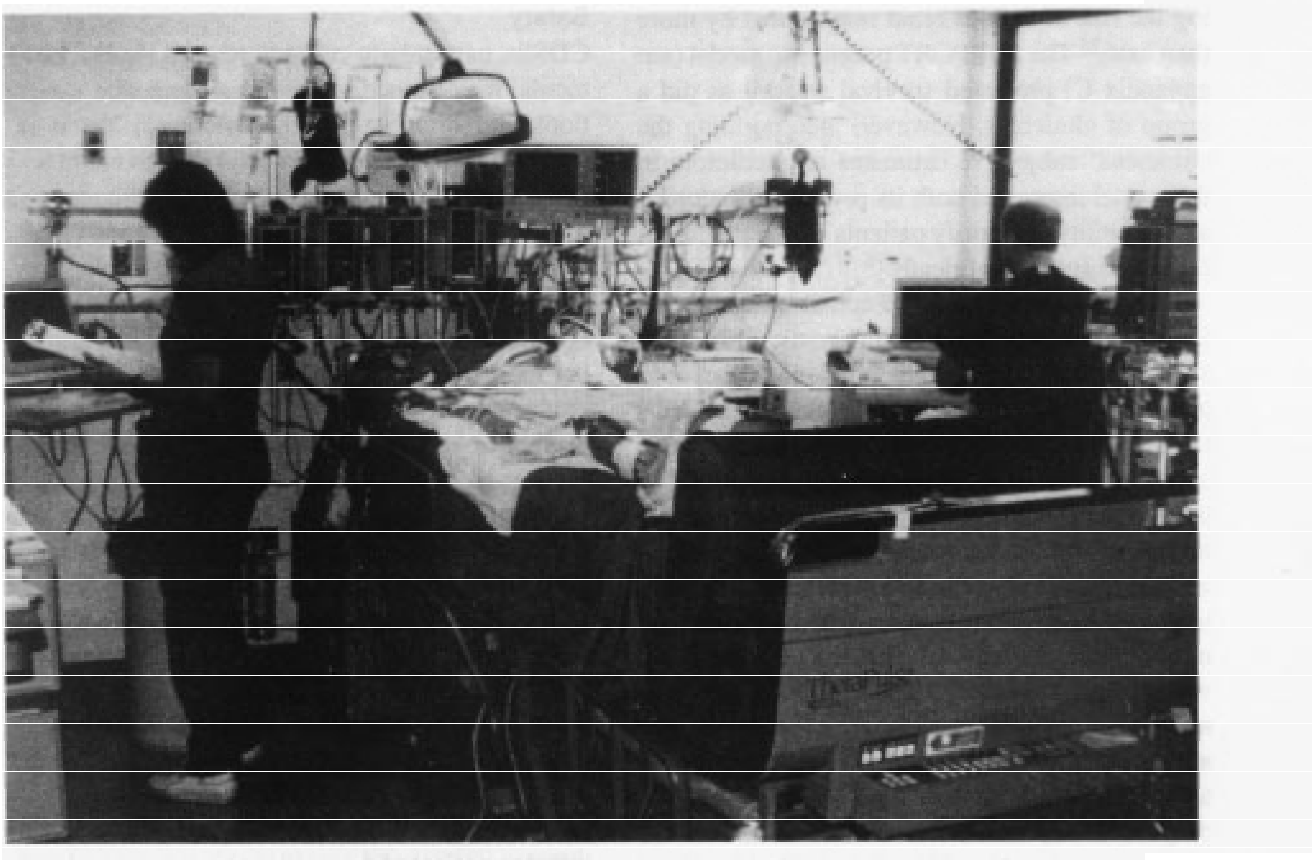
[77] Berner et al., op. cit., footnote 70.

[78] D. DeMoro, Director, Health Care Professions Council, Service Employees International Union Local 250, Oakland, CA, personal communication, Mar. 29, 1995.

[79] D.M. Rind, R. Davis, and C. Safran, "Designing Studies of Computer-Based Alerts and Reminders," *M.D. Computing*, vol. 12, No. 2, Mar.-Apr. 1995, p. 125.

[80] DeMoro, op. cit., footnote 78.

[81] Wyatt, op. cit., footnote 41, p. 1684



A patient in the Intensive Care Unit at IDS Hospital in Salt Lake City Utah, is monitored by computer-controlled devices that help clinicians observe the patient's condition and alert them to unfavorable trends.

diagnosis or treatment of a given health problem. It could thus mislead a clinician into making decisions that harm patients. One observer points out that the vast amounts of information that computers can process at lightning speed can make it virtually impossible for humans to verify that the results are correct. He recommends that:

- clinicians have substantial input into the design and development of a clinical information system,
- the limitations of the system be clearly spelled out to the user, and
- the system itself be designed to explain to the user exactly what it is doing as it is being used.[82]

Assessing Clinical Decision Support Systems

Some analysts have called for rigorous evaluation of the effectiveness and safety of clinical information systems.[83] However, there seems to be little sentiment for mandatory testing and certification of such systems by government authorities. Regardless, CDSSs should be used with caution, and they should be carefully assessed regarding their

[82] M.F. Smith, "Are Clinical Information Systems Safe? Clinicians Should Give More Attention to Possible Failures in Their Computer Systems," *British Medical Journal,* vol. 308, No. 6929, Mar. 5, 1994, p. 612.

[83] Wyatt, op. cit., footnote 41; Rind, Davis, and Safran, op. cit., footnote 79; R. Wall, "Computer Rx: More Harm Than Good?" *Journal of Medical Systems,* vol. 15, Nos. 5/6, December 1991, pp. 321-334; L.I.. Iezzoni, " 'Black Box' Medical Information Systems: A Technology Needing Assessment,'' *Journal of the American Medical Association,* vol. 265, No. 22, June 12, 1991, pp. 3006-3007.

effectiveness and safety—by their developers and users, and perhaps by payers and accrediting bodies, if not by the government. As one researcher put it:

> Clinicians should try to judge the claims of these newcomers in the same cautious way that they would examine claims about a new drug.[84]

As pointed out in chapter 2, the U.S. Food and Drug Administration (FDA) already regulates *medical software* as medical devices. Current policy[85] *exempts* from regulation any software that is either:

1. general in purpose (e.g., database management systems or *library* systems for storing, retrieving, or disseminating health care information);
2. used in education or nonclinical research, or only in the practice of the provider (practitioner or institution) that developed it (i.e., without being disseminated further); or
3. a knowledge-based decision support system that is "intended to involve competent human intervention before any impact on human health occurs (e.g., where clinical judgment and experience can be used to check and interpret a system's output)."[86]

In its definition of research software, the FDA intends to include software that is distributed free of charge in source-code form so that it can be examined by other researchers.[87] (Commercial software must be distributed as object code that is designed to be read only by particular computers, and is thus very difficult for humans to alter.)

In the case of "home-grown" software that is not distributed beyond the originating institution, and if the institution conducts research using federal government funds, then the use of such software on human subjects is regulated by the local Institutional Review Board.[88] There are apparently no restrictions on the development and use of home-grown software in institutions that do not conduct federally sponsored research, or among practitioners in private practice. Yet these systems, too, could mislead clinicians into making decisions that might harm patients. The issue is whether the FDA should review and/or repeal any of the exemptions listed above.

It can be argued that regulation of clinical decisionmaking is not within the FDA's purview, and that other public and private sector mechanisms, such as the malpractice system and managed care, can adequately perform that function. Further, the effectiveness and safety of clinical information systems could be assessed by private sector organizations, such as payers or professional societies. On the other hand, those organizations may not be capable of performing such assessments, or of conducting research on the best methods of doing so.

Assessment of CDSSs can include randomized controlled trials in which the health outcomes of patients treated with the aid of a CDSS are

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[84] Coiera, op. cit., footnote 22, p. 1381.

[85] This policy is based on a draft statement published on Nov. 13, 1989 (see footnote 86) that has yet to be formally implemented. The FDA has used this draft statement as a basis for determining the applicability of the medical device regulations to specific software products on a case-by-case basis. The agency is in the process of developing formal regulations in this area. H. Rudolph, Acting Director, Office of Science and Technology, Center for Devices and Radiological Health, U.S. Food and Drug Administration, personal communication, June 30, 1995.

[86] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation, "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review" (Rockville, MD: Aug. 29, 1991), pp. 37-40.

[87] This new criterion for identifying research software was adopted partly in response to the case involving a radiotherapy dosing product (see chapter 2, footnote 47). Rudolph, op. cit., footnote 85.

[88] Ibid. Each provider institution that conducts research using federal government funds is required to establish an Institutional Review Board, largely to ensure that required procedures regarding treatment of human subjects—mainly informed consent—are followed.

compared with those treated by conventional methods.[89] However, numerous complications can hamper such trials.[90] In particular, implementing a CDSS may engender other changes in practice patterns (e.g., teamwork, consultation, training, and altered role relationships) that are more directly responsible for any observed changes in patient outcomes than is the CDSS itself.

Moreover, random assignment of patients or clinical staff to comparison groups may not be feasible here.[91] If only *patients* are randomized into the comparison groups (with the CDSS being used in one group and not in the other), then clinical staff may carry over CDSS-induced changes in practice patterns from the treatment group to the control group. Yet randomizing *staff* into the comparison groups can disrupt teamwork and alienate one staff group or the other (e.g., new burdens for the treatment-group staff or feelings of exclusion for the control-group staff). Another approach is to randomize entire staff teams or departments, although such clustering requires much larger samples to maintain precision of estimates. This approach is similar to the method of the *firms trial* in clinical research in which patients are randomly assigned to similar (*parallel*) providers who use different treatments, rather than to different groups that receive different treatments from the same provider.[92]

At a minimum, CDSSs appear to help prevent clinicians from neglecting or altering basic steps in specific processes of care. However, it will be a long time before CDSSs cover every contingency in those processes, even for highly specific health problems. Despite the vagaries of clinician experience, memory, and judgment, these will continue to be essential elements of clinical decisionmaking. As randomized controlled trials and other forms of *effectiveness research* increase knowledge regarding which health services truly "work" for a given health problem, *marked* deviations from established standards of practice will become less justifiable. However, there will continue to be room for variation in the judgmental application of those standards to individual patients in particular settings and locations. CDSSs must continue to be viewed as aids to clinician experience and judgment, rather than as substitutes for them; and clinicians must retain the ability to override the recommendations of CDSSs. At the same time, clinicians should also be required to document the reasons for those decisions so that the CDSSs can be improved over time.

PERFORMANCE ASSESSMENT

Comparison to Clinical Decision Support

A less direct approach to improving the quality of health care is assessing the performance of providers and health insurance plans.[93] This approach seeks to:

- evaluate the performance of providers or plans in delivering health services to patients,
- give providers or plans feedback on their performance to help them improve, and
- give performance information to payers, purchasers, and consumers to help them select providers and plans.

Performance measures can focus on several aspects of patient care. Two of the more important ones are: 1) the use of specific services that are considered to be appropriate for a given health

[89] Johnston et al., op. cit., footnote 70; Smith, op. cit., footnote 82; Wall, op. cit., footnote 83; J. Wyatt and D. Spiegelhalter, "Evaluating Medical Expert Systems: What To Test and How?" *Medical Informatics*, vol. 15, No. 3, July-Sept. 1990, pp. 205-217.

[90] Wyatt, op. cit., footnote 41; Rind, Davis, and Safran, op. cit., footnote 79.

[91] Ibid.

[92] U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies That Work*, op. cit., footnote 12, pp. 57-58.

[93] This approach focuses mainly on providers. Even assessing the performance of insurance plans involves, in part, assessing the performance of the providers employed or contracted by those plans.

problem, and 2) patient outcomes of those services, usually measured by adverse events such as deaths, complications, and readmissions. In this respect, the kinds of information needed to assess providers or plans are similar to those needed for clinical decision support: detailed information about individual patients and their health problems, and the specific health services that individual providers (clinicians or institutions) use to diagnose, treat, or prevent those problems. The kinds of technologies required to generate and utilize that information are also similar.

Although, in theory, they should have no bearing on clinical decisionmaking, certain additional factors (beyond those minimally needed for clinical decision support) may also influence clinicians' choices of services and affect patient outcomes.[94] These include the patient's socioeconomic status, social supports (marital status, living arrangements, etc.), and type of health insurance (e.g., indemnity, prepaid, public, or uninsured). These factors need to be considered in assessing provider and plan performance, and perhaps in clinical decision support as well. In addition, the more subjective aspects of the care process, such as patient satisfaction with the health services they receive or with various features of insurance plans, are apparently of greater interest in performance assessment than in clinical decision support—at least at present.

In examining the link between processes and outcomes, performance assessment usually focuses on adverse outcomes that result from services already rendered, thus helping to identify processes that need correcting. In contrast, clinical decision support focuses on selecting services in advance that are likely to maximize favorable outcomes and minimize adverse ones. In both approaches, patient risk factors condition the relationship between processes and outcomes.

Relationship to Other Recent Trends

The performance assessment approach to quality improvement fits with recent trends toward managed care and increased competition among providers and insurance plans.[95] Traditional indemnity insurance and fee-for-service reimbursement are seen as creating incentives for providers to overuse health services in order to maximize income. Thus, one goal of performance assessment is to reduce "unnecessary" services, thereby restraining the escalation of health care costs.

On the other hand, managed care—particularly prepayment for health services—is seen as creating incentives for providers to keep costs lower than the prepayment amount. One way to do this is to reduce the volume and intensity of services delivered to patients. If this leads to underuse of services that are "necessary" for the diagnosis, treatment, or prevention of a given health problem, then patients' health status could be adversely affected. Thus, another goal of performance assessment is to monitor patient outcomes and rates of use of services that are presumed to improve those outcomes.

The performance assessment approach assumes that giving providers feedback on their per-

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[94] J.S. Feinstein, "The Relationship Between Socioeconomic Status and Health: A Review of the Literature," *The Milbank Quarterly*, vol. 71, No. 2, 1993, pp. 279-322; N.E. Adler et al., "Socioeconomic Inequalities in Health: No Easy Solution," *Journal of the American Medical Association*, vol. 269, No. 24, June 23/30, 1993, pp. 3140-3145; H.R. Burstin, S.R. Lipsitz, and T.A. Brennan, "Socioeconomic Status and Risk for Substandard Medical Care," *Journal of the American Medical Association*, vol. 268, No. 17, Nov. 4, 1992, pp. 2383-2387; J. Hadley, E.P. Steinberg, and J. Feder, "Comparison of Uninsured and Privately Insured Hospital Patients: Condition on Admission, Resource Use, and Outcome," *Journal of the American Medical Association*, vol. 265, No. 3, Jan. 16, 1991, pp. 374-379.

[95] See R. Lavizzo-Mourey, "Measuring Quality in Health Care Reform," *Journal of Health Care for the Poor and Underserved*, vol. 5, No. 3, 1994, pp. 202-211; J.E. Sisk and S.A. Glied, "Innovation Under Federal Health Care Reform," *Health Affairs*, vol. 13, No. 3, summer 1994, pp. 82-97; Health Care Quality Alliance, *Quality Considerations: An Analysis of Federal Health Care Reform Plans* (Washington, DC: Health Care Quality Alliance, July 1994); C. Anderson, "Measuring What Works in Health Care," *Science*, vol. 263, No. 25, Feb. 25, 1994, pp. 1080-1082.

formance in terms of patient outcomes encourages them to improve their processes of care by selecting the most effective services for a given health problem. Identification and correction of problems in production processes is one major component of CQI in manufacturing, an approach that was subsequently adapted to the health care industry. More recently, managed care organizations and even pharmaceutical companies have sought to adapt the CQI approach to the management of specific chronic, costly health problems, such as diabetes, asthma, and high blood pressure, across all care settings. In part, this approach, known as *disease management*, involves practice guidelines, outcomes measurement, and feedback to providers and insurance plans.[96] At the same time, employers and health plans have sought to deal with the rising cost of pharmaceuticals through *pharmacy benefit management*, which employs techniques of disease management as well as pharmacy networks, negotiated discounts and rebates, lists of preferred drugs, and online utilization review.[97]

All of these related approaches rest on the following series of assumptions. The most *effective* services also tend to be the most *cost*-effective ones because, even if they cost more to provide, their positive impact on patient health status leads to reduced use and cost of services in the long run. Thus, giving providers feedback on their performance both improves the quality and reduces the cost of health care. In addition, distributing performance information to payers, purchasers, and consumers helps them choose providers that employ the most cost-effective services for a given health problem. Moreover, if sufficient numbers of payers, purchasers, and consumers use only those providers that employ the most cost-effective services, then this forces *all* providers to use those services and to reduce the prices of those services. This increased competition among providers induces further improvements in the quality of health care and reductions in its cost.

Performance Indicator Projects (Report Cards)

In recent years, various groups have sought to develop summary sets of performance indicators commonly called *report cards*.[98] Assessments using such indicators are designed to:

1. help consumers, payers, and self-insured purchasers compare and select among providers;
2. help consumers and purchasers select among insurance plans; or
3. give performance information to accreditation bodies for providers or insurance plans.

They can also be used to provide feedback to providers for quality improvement purposes, and to assist public policy makers in regulating plans and formulating health policy.[99] In addition, providers and insurance plans often tout performance indicator projects or favorable results in their marketing efforts; others respond by trying to make process changes that will improve their scores on performance indicators.[100] However, systematic evidence regarding the impact of performance in-

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[96] K. Terry, "Disease Management: Continuous Health-Care Improvement," *Business and Health*, April 1995, pp. 64-72; G. Anders, "Drug Makers Help Manage Patient Care," *Wall Street Journal*, May 17, 1995, p. B1.

[97] L. Etheredge, *Pharmacy Benefit Management: The Right Rx?* Briefing Paper, Health Insurance Project, The George Washington University, April 1995.

[98] For a critical appraisal of performance indicator projects, see A. Epstein, "Performance Reports on Quality—Prototypes, Problems, and Prospects," *Journal of the American Medical Association*, vol. 333, No. 1, July 6, 1995, pp. 57-61.

[99] U.S. Congress, General Accounting Office, *Health Care Reform: "Report Cards" Are Useful but Significant Issues Need To Be Addressed*, GAO/HEHS-94-219 (Washington, DC: September 1994); J. Mangano, "Report Cards Come of Age," *1995 Medical Quality Management Sourcebook*, K.J. Migdail and M. Youngs (eds.) (New York, NY: Faulkner & Gray, 1994), pp. 1-21.

[100] L. Oberman, "How Do Health Plans Perform?" *American Medical News*, Mar. 20, 1995, pp. 1, 30.

dicator projects on provider or plan behavior is lacking.

Perhaps the earliest and best-known performance indicator project was the effort by HCFA to assess mortality rates among Medicare patients in every hospital in the nation. Reports were released annually to the public beginning in 1986, but were suspended in 1993 due, in part, to criticism of HCFA's methodology,[101] particularly regarding *risk adjustment*.[102] As a supplement to its Peer Review Organization program of quality assurance, HCFA is developing a new set of performance indicators for ambulatory care, known as Developing and Evaluating Methods to Promote Ambulatory Care Quality (DEMPAQ).[103] Another government project is the U.S. Public Health Service's Year 2000 Health Objectives for the Nation, comprised of population-based measures of health promotion and disease prevention, such as infant mortality rates.[104]

In the private sector, the National Committee for Quality Assurance (NCQA) developed the Health Plan Employer Data and Information Set (HEDIS) as part of its oversight of health insurance plans (largely managed care organizations).[105] Box 4-1 summarizes the measures used in HEDIS. Like many performance indicator projects, the HEDIS measures focus on processes of care, that is, utilization of presumably appropriate services among certain groups of plan members, and the accessibility or availability of those services. Of the HEDIS "quality of care" measures, only hospitalization for asthma and low birth weight represent patient outcomes. Moreover, none of the HEDIS measures is adjusted for member or patient risk factors. HCFA is in the process of adapting the HEDIS model to its Medicare and Medicaid programs.[106]

In 1994, NCQA conducted a one-year pilot test of 28 of the HEDIS measures using data from 21 health plans throughout the United States. (The pilot study also included a survey of enrollee satisfaction with health plan performance.) The HEDIS pilot data from each participating plan were audited for reliability and comparability by an independent firm. Each audit involved a review of the overall structure of the plan's data collection and processing procedures; a site visit to the plan by an audit team; verification of the plan's source code and specifications; and validation of the plan's measures and data. The pilot study identified needs for additional quality measures in key clinical areas (e.g., mental health), risk adjustment, field testing, improved standardization of data collection procedures, investment in enhanced clinical information systems, refinement

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[101] U.S. Congress, General Accounting Office, op. cit., footnote 99; S.T. Fleming, L.L. Hicks, and R.C. Bailey, "Interpreting the Health Care Financing Administration's Mortality Statistics," *Medical Care*, vol. 33, No. 2, February 1995, pp. 186-201.

[102] Risk adjustment is statistical control of patient risk factors in the analysis of the utilization and outcomes of health services. The term also refers to control of financial risk factors faced by insurance companies. See L.I. Iezzoni, "Risk Adjustment for Medical Outcome Studies," *Medical Effectiveness Research Data Methods*, M.L. Grady, and H.A. Schwartz (eds.), Agency for Health Care Policy and Research, AHCPR Pub. No. 92-0056 (Rockville, MD: July 1992), pp. 83-97.

[103] Delmarva Foundation for Medical Care, Inc., *Developing and Evaluating Methods to Promote Ambulatory Care Quality, Final Report* (Washington, DC: August 1994), pp. 1-6.

[104] U.S. Department of Health and Human Services, Public Health Service, *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, DHHS Pub. No. (PHS) 91-50212 (Washington, DC: U.S. Government Printing Office, 1991).

[105] National Committee for Quality Assurance, *Health Employer Data and Information Set and Users' Manual, Version 2.0* (Washington, DC: 1993); National Committee for Quality Assurance, *HEDIS 2.5: Updated Specifications for HEDIS 2.0* (Washington, DC: January 1995).

[106] "HCFA, Outside Groups to Adapt HEDIS for Use in Medicare, Medicaid Programs," *BNA's Health Care Policy Report*, Mar. 27, 1995, pp. 479-480.

BOX 4-1—Health Plan Performance Measures Used in the Health Plan and Employer Data and Information Set (HEDIS)[1]

QUALITY OF CARE

Childhood Immunization Rate: Proportion of children who had received specified Immunizations as of their second birthday.

Cholesterol Screening: Proportion of adults aged 40 to 64 who received a cholesterol test during the past five years.

Mammography Screening: Proportion of women aged 52 to 64 who received one or more mammograms during the past two years

Cervical Cancer Screening: Proportion of women aged 21 to **64** who received one or more Pap tests for cervical cancer during the past three years

Low Birthweight: Proportion of all live births that were low birthweight (under 2,500 grams) or very low birthweight (under 1,500 grams) during the past year.

Prenatal Care in First Trimester: Proportion of women with one or more live births during the past year who had one or more prenatal care visits 26 to 44 weeks prior to delivery,

Asthma Inpatient Admission Rate: Proportion of members aged 2 to 19 (or 20 to 39) who had one or more inpatient discharges with a principal diagnosis of asthma within the past year, also, of those members with such discharges, the proportion who had more than one such discharge.

Diabetic Retinal Exam: Proportion of members aged 31 to 64 with diabetes (i.e., who were dispensed insulin or oral hypoglycemics) who received a retinal ophthalmoscopic examination during the past year.

Ambulatory Follow-Up After Hospitalization for Major Affective Disorder: Proportion of members aged 18 to 64 with an Inpatient discharge for major affective disorder during the past year who had one or more ambulatory mental health encounters or day/night treatments within 30 days of discharge.

[1] The listed measures are used in the set of performance measures for health insurance plans known as the Health Plan Employer Data and Information Set (HEDIS), Version 25 HEDIS was developed by the National Committee for Quality Assurance (NCQA) as part of its oversight of managed care plans The categories and titles of the measures are drawn from the NCQA manual, HED/S25 *Updated Specifications for HEDIS 20* (Washington, DC January 1995) The descriptions of the measures are OTA summaries of the detailed specifications presented in that manual. All measures are based on plan members who were continuously enrolled in the plan during the specified time period. *A plan* IS a health insurance plan, a *member* IS a person who is enrolled in the plan

(continued)

of audit procedures, and more research on the kinds of information consumers need. [107]

Another performance indicator project is the Indicator Measurement System (IMSystem) developed by the Joint Commission on Accreditation of Healthcare Organizations, as part of its "Agenda for Change" to adopt specific outcome-oriented measures to support the process of accrediting hospitals and other institutional providers. Implementation of the IMSystem began in 1994, starting with voluntary participation by hospitals that could generate the necessary data. 108 Box 4-2 summarizes the measures used in the IMSystem, which are about equally divided between process and outcome measures.

[107] National Committee for Quality Assurance, *Executive Summary for Report Card Pilot Project* (Washington, DC: 1995), PP. 1-6.

[108] Joint Commission on Accreditation of Healthcare Organizations, *IMSystem General Information* (Oakbrook Terrace, IL: 1994), PP. 3-6.

BOX 4-1—Health Plan Performance Measures Used in the Health Plan and Employer Data and Information Set (HEDIS) (Cont'd.)

OTHER MEASURES[2]

Access to Health Services: The proportion of adult members who had one or more provider visits during the past three years, the proportion of primary care physicians accepting additional members, and average waiting time for a primary care provider appointment.

Member Satisfaction: The proportion of members who are satisfied with the plan, and the percentage of members of who rate the plan as good, very good, or excellent

Membership: Total number of member years, and the proportion of members who disenroll from the plan (including those who die), by type of plan health maintenance organization, preferred provider organization, or point of service/other.

Utilization: Average length of inpatient stay, the number inpatient discharges per 1,000 member years and the number of inpatient days per 1,000 member years.

Finance: Average revenue per member per month, the percentage change in average revenue, the loss ratio (percentage of total premiums devoted to expenses), the number of years in business, net income (revenue minus expenses), and net worth (assets minus liabilities).

Health Plan Management and Activities: The percentage of primary care physicians who are board certified, the percentage of specialist physicians who are board certified, and the percentage of primary care physicians who left the plan

SOURCE: U S Congress, Office of Technology Assessment, 1995, based on National Committee for Quality Assurance, *HEDIS 25 Updated Specifications for HEDIS 20* (Washington DC January 1995)

[2]These are examples of measures listed under categories other than *Quality of Care* in the HEDIS 25 manual

The IMSystem also adjusts for patient risk factors (demographic traits, complicating health problems, etc.) by developing an outcome prediction model for each performance measure. Each model is based on risk factors that contribute significantly to the prediction of that performance measure. Using a given model, each institution's actual sore on the performance measure is compared to its predicted score. [109] Institutions that score "worse" than predicted can then investigate the reasons behind those results. IMSystem reports are available to consumers for $30 per hos - pital. [110]

Performance indicator projects are also being conducted by several managed care organizations. employer coalitions, and state governments, some using the HEDIS model. Examples include: United HealthCare Corp. (a national managed care organization); the Massachusetts Healthcare Purchaser Group (an employer coalition); and the states of California, Florida, New York, and Pennsylvania. [111] Moreover, several legislative proposals for national health reform, including the Clinton Administration's 1994 plan, have contained mandates for the development of such indi -

[109] Ibid., pp. 16-18.

[110] "JCAHO Releases Data, Gets Blasted by AHA and AMA," *Business and Health,* January 1995, p. 16.

[111] U.S. Congress, General Accounting Office, op. cit., footnote 99; S. Vibbert et al. (eds.), *The Medical Outcomes & Guidelines Sourcebook* (New York, NY: Faulkner& Gray, 1994); K.J. Migdail and M. Youngs (eds.), 1995 *Medical Quality Management Sourcebook (New* York, NY. Faulkner & Gray, 1994).

BOX 4-2—Provider Performance Measures Used in the Indicator Measurement System (IMSystem)[1]

Postprocedure Complications (five indicators): Proportion of patients undergoing procedures involving anesthesia administration and an inpatient stay who develop each of the following postprocedure complications within two postprocedure days.

- central nervous system complication,
- peripheral neurological deficit,
- acute myocardial infarction,
- cardiac arrest, and
- Intrahospital mortality.

C-Section: Proportion of deliveries done by Caesarean section.

VBAC: Proportion of patients with a history of previous Caesarean section who deliver by vaginal birth after Caesarean section.

Low Birthweight: Proportion of live births with a blrthweight less than 2,500 grams

Birth Complications: Proportion of live-born Infants with a birthweight greater than 2,500 grams who have one or more of the following complications

- an Apgar score of less than 4 at 5 minutes,
- admission to the neonatal intensive care unit within one day of delivery for longer than 24 hours,
- clinically apparent seizure, or
- significant birth trauma.

Low Birthweight Complication: Proportion of live-born infants with a birthweight greater than 1,000 grams and less than 2,500 grams who have an Apgar score of less than 4 at 5 minutes.

Delayed CABG Recovery: For patients undergoing isolated coronary artery bypass graft (CABG) procedures, the number of days from initial surgery to discharge.

Timely Thrombolytic Therapy: For patients admitted through the emergency department (ED) with a principal discharge diagnosis of acute myocardial infarction (AMI) and receiving thrombolytic therapy, the amount of time from ED arrival to administration of thrombolytic therapy.

CHF Diagnostic Accuracy: Proportion of patients with a principal discharge diagnosis of congestive heart failure who have documented etiology indicating that diagnosis.

Delayed PTCA Recovery: For patients undergoing percutaneous transluminal coronary angioplasty (PTCA), the number of days from procedure to discharge.

CABG Mortality: Proportion of patients undergoing an isolated coronary artery bypass graft who die in the hospital.

PTCA Mortality: Proportion of patients undergoing PTCA who die in the hospital.

AMI Mortality: Proportion of patients with a principal discharge diagnosis of AMI who die in the hospital

Cancer Pathology Reporting: Proportion of patients undergoing resection for primary cancer of the female breast, lung, or colon/rectum for whom a surgical pathology consultation report is present in the medical record.

1 The measure listed are used in the set of performance indicators for hospitals and other institutuonal providers known as the IMSystem (Indicator Measurement System) The IMSystem was developed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for use in JCAHO's procedures for accrediting such providers OTA adapted and abbreviated the titles and descriptions of the measures from specifications presented in the JCAHO manual, IMSystern *Genera/ Informafion* (Chicago, IL Aug. 22, 1994), pp. 8-12

(continued,)

BOX 4-2—Provider Performance Measures Used in the Indicator Measurement System (IMSystem) (Cont'd.)

Tumor Staging: Proportion of patients undergoing resection for primary cancer of the female breast, lung, or colon/rectum who have stage of tumor designated by a managing physician.

Breast Cancer Testing: Proportion of female patients with Stage I or greater primary breast cancer undergoing initial biopsy or resection who have estrogen receptor analysts results in the medical record

Lung Cancer Diagnosis/Staging: Proportion of patients with non-small cell primary lung cancer undergoing thoracotomy who have complete surgical resection of tumor.

Colon/Rectum Cancer Preoperative Evaluation: Proportion of patients undergoing resection for primary cancer of the colon/rectum whose preoperative evaluation by a managing physician included examination of the entire colon.

Trauma Monitoring: Proportion of trauma patients with systolic blood pressure, pulse rate, and respiratory rate documented on arrival in the ED and at least hourly for three hours or until ED disposition, whichever is earner

Head Trauma Monitoring: Proportion of trauma patients with selected intracranial injuries who have a Glasgow coma scale score documented on arrival in the ED and at least hourly for three hours or until ED disposition, whichever is earner.

Airway Management for Comatose Trauma: Proportion of ED comatose trauma patients with selected Intracranial Injuries who are discharged from the ED prior to endotracheal intubation or cricothyrotomy

Timely CT Scans: For patients undergoing computerized tomography (CT) scan of the head, the amount of time from emergency department arrival to initial CT scan.

Timely Neurological Procedures: For patients undergoing selected neurosurgical procedures, the amount of time from emergency department arrival to procedure.

Timely Orthopedic Procedures: For patients undergoing selected orthopedic procedures, the amount of time from emergency department arrival to procedure.

Timely Abdominal Procedures: For trauma patients undergoing selected abdominal surgical procedures, the amount of time from emergency department arrival to procedure.

Preventable Death from Pneumothorax/Hemothorax: Proportion of patients who die in the hospital with a diagnosis of pneumothorax or hemothorax who did not undergo a thoracostomy or thoracotomy.

Preventable Death among Trauma Patients: Proportion of trauma patients with a systolic blood pressure of less than 70 mm Hg within two hours of ED arrival who die in the hospital without undergoing a laparotomy or thoracotomy.

SOURCE: U.S. Congress, Office of Technology Assessment, 1995, based on Joint Commission on Accreditation of Healthcare Organizations, *IMSystem General Information* (Chicago, IL Aug 22, 1994)

caters to be used in assessing all providers and insurance plans. Private, for-profit companies have also entered the market for performance information, producing reports for sale to the general public. A prominent example is a consumer magazine called *Health Pages* that reports on the services and prices of physicians, hospitals, and managed care plans in several cities for $3.95 per issue. [112]

[112] K. Thomas, "*Heal*

In January 1995, a private, for-profit data analysis firm published a performance report on 10 hospitals in Orange County, California, using raw, unadjusted Medicare billing data to measure mortality rates for coronary artery bypass graft surgery. The $10 purchase price of the report was partially subsidized by an undisclosed subscription fee from the study's top-ranking hospital, which used the results in newspaper advertising. While this case prompted some observers to call for regulation of performance measurement methods and reporting—by the industry itself, if not by the government—others expressed confidence that "the market will eventually sort itself out."[113]

Information Technology and Performance Assessment

Advanced information technologies could contribute to performance assessment in health care in two main ways. One is improving the measures and data on which those assessments are based. The second is making the results of those assessments, and the measures and data on which they are based, more readily accessible to payers, purchasers, consumers, and researchers.

By its very nature, performance assessment reviews *past* performance, and thus cannot feasibly employ clinical trials and other forms of prospective analysis. Performance assessment thus employs retrospective analysis that involves either primary data collection or secondary analysis of available administrative data, or both (as with the HEDIS and IMSystem measures). Primary data are collected mainly through: 1) clinician reviews of paper-based patient records, and 2) surveys of patients and providers. Administrative data include hospital discharge abstracts, and health insurance claims or encounter records and enrollment records. Each of these data sources has certain limitations that advanced information technologies might help overcome.

Given current information technologies and analytic methods, tradeoffs exist between primary and secondary data for assessing provider and plan performance. A balance must be sought among several considerations: 1) the clinical detail of the information that can be gathered, 2) the number of patients that can be included, 3) the cost per unit of information gathered, and 4) the amount of time required to obtain and clean the data. Larger numbers of patients enhance the precision of statistical estimates, and clinical detail is essential in statistical control for confounding variables—particularly patient risk factors—that could affect the provider's choice of services or the patient's outcome.

In general, administrative data can cover very large numbers of patients at very low cost to the analyst and can be obtained relatively quickly. (The time and expense of collecting such data have already been absorbed by administrative processes.) However, they can cover only the more *objective* measures of care processes (e.g., the proportion of diabetics receiving an annual retinal examination) and patient outcomes (e.g., the proportion of births with low birth weight). Moreover, administrative data contain very little clinical detail to support process and outcome measures.[114]

In contrast, primary data collection can cover more *subjective* measures (e.g., appropriateness of a procedure, patient satisfaction with the care received, patient self-perception of health status and quality of life, etc.) as well as several of the more objective ones. Moreover, it can obtain rich detail on those measures: clinical detail, in the case of patient record review; and perceptual/attitudinal detail, in the case of surveys. However,

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[113] "Bypass Surgery Report Ignites Uproar Among Calif. Hospitals," *Report on Medical Guidelines & Outcomes Research*, Jan. 26, 1995, pp. 1, 2, and 12.

[114] J.G. Jollis et al., "Discordance of Databases Designed for Claims Payment versus Clinical Information Systems: Implications for Outcomes Research," *Annals of Internal Medicine*, vol. 119, No. 8, Oct. 15, 1993, pp. 844-850.

such data are collected at much greater cost in both time and money; so they are usually gathered on far fewer patients, thereby reducing the precision of statistical estimates. Ideally, all measures would be obtained in complete clinical detail on very large numbers of patients very quickly and at very low cost. This is precisely the vision offered by advanced information technologies.

A major limitation of readily available administrative data is the absence of measures of various confounding factors that may affect a provider's choice of services or a patient's outcome, and thus distort the true effects of the processes of care being evaluated. The most important confounding variables are patient risk factors (demographic traits, complicating health problems, etc.). Failing to adjust adequately for such factors could mislead payers, purchasers, and consumers regarding provider or plan performance,[115] as illustrated by the recent case involving a private report card on hospitals in Orange County, California.

Many of the most important patient risk factors are best measured using detailed clinical data, such as physical findings and diagnostic test results. Computerization of such clinical information should make it easier to obtain and use in performance assessments. One approach would be to require that more clinical information be included in administrative data. In recent years, payers and government agencies have mandated increased numbers of diagnosis and procedure codes and other clinical data elements included in claims and discharge abstracts. This has greatly increased the information burden on providers;[116] yet it still does not yield the kinds of clinical detail required for valid performance assessment. Moreover, accuracy problems in diagnosis and procedure coding render those data suspect.[117]

The more promising approach to providing needed clinical information is to computerize the patient record. Rather than having clinically trained personnel read, interpret, and code the information contained in paper-based patient records, most of the relevant information could be precoded in the electronic patient record and readily extracted for analysis. Alternatively, uncoded information (free text) contained in the electronic patient record could be processed through advanced methods of pattern recognition, such as natural language processing (see chapter 2). The usefulness of these capabilities greatly depends on three other aspects of advanced information technologies: input, storage, and retrieval. That is, to be useful for performance assessment purposes, the information in the electronic patient record must be accurately and easily entered (preferably at the point of care) and extracted (usually at sites other than the point of care, e.g., an analyst's office). Moreover, storage capacities must be adequate to handle the huge quantities of information involved.

As stated earlier, computer networks could make it easier to track the care and outcomes of individual patients by facilitating record linkage across all providers and departments. Networks could also make it easier to share patient data, performance measurement algorithms, and assessment results among providers, payers, purchasers, and researchers to compare the performance of providers or plans. Like assessing the effectiveness of specific health services, such comparisons would require using health problems, process and

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[115] Epstein, op. cit., footnote 98, pp. 58, 60; S. Salem-Schatz et al., "The Case for Case-Mix Adjustment in Practice Profiling: When Good Apples Look Bad," *Journal of the American Medical Association*, vol. 272, No. 11, Sept. 21, 1994, pp. 871-874.

[116] D.R. Longo et al., *Inventory of External Data Demands Placed on Hospitals* (Chicago, IL: The Hospital Research and Educational Trust of the American Hospital Association, 1990).

[117] See L.I. Iezzoni, *Risk Adjustment for Measuring Health Care Outcomes* (Ann Arbor, MI: Health Administration Press, 1994), pp. 142-167; R.A. Bright, J. Avorn, and D.E. Everitt, "Medicaid Data as a Resource for Epidemiologic Studies: Strengths and Limitations," *Journal of Clinical Epidemiology*, vol. 42, No. 10, 1989, pp. 941-943; J. Whittle, "Large Administrative Database Analysis," *Tools for Evaluating Health Technologies: Five Background Papers*, U.S. Congress, Office of Technology Assessment, OTA-BP-H-142 (Washington, DC: U.S. Government Printing Office, February 1995), pp. 33-35.

outcome measures, and analytical methodologies that are as similar as possible across providers. These efforts would also be facilitated by messaging standards for electronic exchange of information among different computer systems, and by methods of translating among disparate clinical nomenclatures and coding systems.

CONCLUSIONS

Summary of Findings

Advanced information technologies—electronic patient records, structured data entry, new human-computer interface technologies, portable computers, automated data capture, relational databases with online query, knowledge-based computing, and computer networks—can potentially improve the quality of health care. They could do so by enhancing clinical decision support and by improving data for assessing the effectiveness of health services and the performance of health care providers and insurance plans. Specifically, they could facilitate:

- faster and easier collection and entry of information about the patient's health problem and background, with portions of that information being:
  - —entered by clinicians at or near the point of care;
  - —captured directly from diagnostic and monitoring equipment (including digitized radiographic images, full-motion videos, and sound recordings); or
  - —entered by the patient prior to care;
- faster, easier, and better targeted search and retrieval (possibly at the point of care) of:
  - —previously collected information about the patient; and
  - —information about the kind of health problem afflicting the patient and alternative tests and treatments for it, drawn from local or remote knowledge bases;
- more flexible organization and display of this information as appropriate for particular clinicians;
- development of computer-based clinical protocols and other forms of CDSSs that apply decision rules and other knowledge-based approaches to information about the patient and the health problem;
- more rigorous construction and analysis of measures of service effectiveness and provider and plan performance; and
- more rapid and widespread dissemination of not only the results of these measures and local clinical research using CDSSs, but also the patient data, measurement algorithms, and CDSSs on which those results are based.

Currently, empirical evidence demonstrating the ability of these technologies to achieve these goals is limited, mixed, or incomplete. Moreover, concerns have been raised about possible adverse effects on the quality of health care arising from these applications, including:

- incorrect parameters or criteria, or omitted or altered steps, in clinical decision support systems that could lead to inappropriate care;
- excessive reliance on clinical decision support systems, which could undermine the ability of clinicians to exercise professional judgment in nonroutine cases and reduce the interpersonal aspects of patient care ("the quality of caring"); and
- the temptation to use readily available administrative data for assessing the effectiveness of specific health services or the performance of providers or insurance plans. If the data are incomplete or inaccurate, the results could be misleading.

Policy Options

The private sector has been largely responsible for the development and application of information technologies in clinical decision support and performance assessment of health care providers and insurance plans. The federal government's role has mainly involved:

- developing information systems and performance measures for its own health insurance and health care delivery programs, most notably Medicare;

- funding of intramural and extramural research and demonstration projects; and
- participating in consensus standards-development processes along with private sector organizations.

All of these activities in both the private and public sectors are likely to continue, with some increasing and others decreasing. In an era of budgetary and regulatory restraints, however, major new government initiatives, such as funding for technology development or mandated regulation of clinical information systems, are unlikely. It can be argued that this is appropriate—in other words, that the federal government should not interfere in private market decisions regarding the selection of new technologies or their applications.

On the other hand, the federal government—specifically HCFA—is responsible for ensuring the quality of health care rendered to Medicare and Medicaid beneficiaries.[118] Recent efforts to move more beneficiaries into managed care have underscored quality concerns, given the expectation that capitation creates an incentive for underservice.[119] Several policy issues regarding the potential impact of information technology on the quality of care delivered to Medicare and Medicaid beneficiaries deserve the attention of federal policymakers.

Effectiveness and Safety

The foremost issue is the extent to which clinical information systems actually change clinical practice patterns and patient outcomes, and whether those changes are beneficial to providers and patients. Empirical research on this issue remains limited, mixed, or incomplete, and more solid evidence regarding these impacts needs to be obtained. If these systems do indeed improve the quality of care, then the next set of issues can be addressed: What are the most efficient means of developing and implementing such systems?

Much of the research supporting the development and evaluation of clinical information systems (including CDSSs) has been conducted by academic institutions and other private sector organizations. Many of these projects have received grant or contract funding from federal executive branch agencies, mainly NLM and AHCPR (or its predecessor, the National Center for Health Services Research, NCHSR). However, there has been little coordination among these privately and publicly funded projects in terms of their methods of evaluating the effectiveness and safety of clinical information systems. The focus of these evaluations should be on the impacts of these systems on clinical practice patterns and patient outcomes. Where possible, these evaluations should be conducted prospectively, including randomized controlled trials.

Given its methodological shortcomings, assessing the performance of providers and insurance plans and disseminating information regarding that performance to various parties may prove to be an ineffective approach to improving the quality of health care.[120] At present, however, there is great demand for performance information in both the public and private sectors; and if such information is going to be produced and used, it should be as valid and reliable as possible. Advanced information technologies—primarily electronic patient records—promise to improve performance assessment by making more information on patients, providers, services, and outcomes more readily available in a more detailed, accurate, and usable form. Most importantly, such information could improve methods of risk adjustment for performance indicators that are based on health care processes and outcomes. Conversely, the development of reliable and valid performance assess-

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[118] The state governments share responsibility for the Medicaid program with the federal government.

[119] Given a fixed payment per plan member, providers may be tempted to minimize the volume and/or intensity of services rendered for each patient.

[120] Epstein, op cit., footnote 98.

ment indicators could improve the application of information technology to health care by identifying the most important data elements to include in electronic patient records.

Like clinical information systems, much of the research and development work on performance assessment and risk adjustment has been conducted by private sector organizations, often with funding from federal agencies, mainly AHCPR (or NCHSR) and HCFA. Working with private sector organizations, HCFA has begun developing the DEMPAQ indicators for ambulatory care among Medicare beneficiaries and adapting the privately developed HEDIS system to the Medicaid managed care population. Nonetheless, there has been little coordination among all of these privately and publicly funded projects on performance assessment and risk adjustment, or between these projects and those evaluating the effectiveness and safety of clinical information systems. The basic issue is whether all of these federal efforts should continue as they are, or whether more or less funding and/or coordination would be appropriate.

OPTION 1a: *Maintain or increase funding for intramural research and extramural grants and contracts to private sector organizations for research and demonstration projects designed to:*

- develop and test the reliability and validity of various methods of measuring and assessing (with risk adjustment) the performance of providers and health plans;
- develop, implement, and evaluate specific systems of risk-adjusted performance indicators;
- evaluate the effectiveness and safety of clinical information systems, including CDSSs.

The FDA could employ the results of the evaluations of clinical information systems in formulating regulations for that class of medical software, and HCFA could adapt the most promising performance assessment systems for use in its Medicare and Medicaid programs—as it is now doing with the Medicaid HEDIS indicators (which are not yet risk-adjusted). This option would maintain the current approach of funding research, development, and evaluation programs through several government agencies, with little coordination among them. It would thus preserve the autonomy in program direction currently enjoyed by the various agencies and the consequent diversity in the types of programs and their results. On the other hand, HCFA would have to: 1) wait for the needed performance assessment systems to be developed and evaluated; and 2) use performance indicators that still may not be truly appropriate for the Medicare or Medicaid populations.

OPTION 1b: *Maintain or increase funding for HCFA to develop and evaluate performance assessment methods and systems suitable for Medicare and Medicaid enrollees, using intramural research and extramural grants and contracts to private sector organizations for research and demonstration projects as needed.*

This is HCFA's current approach in developing the DEMPAQ indicators for ambulatory care among Medicare beneficiaries. Given that HCFA is also adapting privately developed indicators (Medicaid HEDIS), options la and lb are not mutually exclusive. However, option 1 a would be more costly than option lb because, under option 1a, development and evaluation funding would be spread over a broader array of performance assessment systems as well as clinical information systems. From another perspective, more effort could be concentrated on the information needs of the Medicare and Medicaid programs for a given amount of funding. On the other hand, option lb would sacrifice federal direction of evaluations of clinical information systems that could be useful to the FDA in formulating regulations.

OPTION 1c: *Assign the task of coordinating the development and evaluation of performance assessment methods and systems and clinical information systems to a single agency*

This option could be adopted regardless of whether option la, option lb, or both were pursued. The designated agency—such as HCFA or AHCPR—would ensure that all federally funded projects employ rigorous and uniform methods to enhance the soundness and comparability of their

results. In addition, agency personnel would meet with representatives of private sector corporations, foundations, and research organizations that also fund or conduct such projects to discuss the most promising approaches to research, development, and evaluation. This option would require only small additional costs for personnel, travel, and meetings; yet it could greatly increase the value and timeliness of project results. On the other hand, it would diminish the autonomy in program direction currently enjoyed by the various agencies and the consequent diversity in the types of programs and their results.

OPTION 1d: *Reduce funding for development and evaluation of performance assessment methods and systems and clinical information systems, and direct HCFA to employ performance assessment methods and systems developed and evaluated in the private sector with minimal adaptation.*

This option would capitalize on the diverse array of performance assessment methods and systems being developed in the private sector. It would reduce government expenditures, depending on the amount of work needed to adapt privately developed performance assessment systems to the Medicare or Medicaid populations—which in turn would depend on the initial suitability of those systems' indicators. However, to an even greater extent than with option la, HCFA would have to: 1) wait for the needed performance assessment systems to be developed and evaluated in the private sector; and 2) use performance indicators that still may not be truly appropriate for the Medicare or Medicaid populations.

Until more solid evidence is available regarding the effectiveness and safety of existing clinical information systems and the reliability and validity of performance assessment systems, more drastic action—such as mandating the testing and certification of all such systems—is probably not justified. Legal questions regarding who should be held liable in situations in which such systems lead clinicians to make decisions that harm patients are probably best left to the courts to resolve.

Standards and Technology

Assuming that clinical information systems are found to be effective and safe in terms of their impacts on practice patterns and patient outcomes, the next set of issues focuses on the most efficient means of developing and implementing those systems. Three options regarding government involvement in the development of standards and technology that were presented in chapter 2 warrant additional emphasis here. One is continued government participation (along with private sector organizations) in the voluntary, cooperative, public- private process of developing consensus standards for electronic messaging (exchange of information among disparate computer systems). The second is funding and coordinating research to overcome specific technological barriers (e.g., limitations of electronic storage devices). These actions would not only facilitate the development and testing of clinical information systems and performance assessment systems, but would also enhance the clinical knowledge on which they are based.

The third option concerns continuation of funding for NLM to develop the Unified Medical Language System (UMLS). A major problem confronting the UMLS project is that one of the most widely used systems for classifying and coding health care services, called the *Physicians' Current Procedural Terminology, Fourth Edition (CPT-4),* is copyrighted by the American Medical Association (AMA). Thus, the more recent versions of CPT-4 cannot be incorporated into UMLS. [121] Many major payers currently employ CPT-4 for "professional" billing by clinicians and other noninstitutional providers and suppliers, but also use the *International Classification of Dis -*

[121] McCray, op. cit., footnote 66.

eases, Ninth Edition, Clinical Modification (ICD-9-CM), Volume 3 (Procedures), for billing by inpatient hospitals and other institutional providers.

For payment and other purposes, services rendered by a clinician in an inpatient setting must be coded using both of these systems, creating additional costs for providers. For many services, however, the codes in ICD-9-CM cannot be equated ("crosswalked") with those in CPT-4 because of substantial structural differences between the two coding systems.[122] Moreover, both ICD-9-CM (Vol. 3) and CPT-4 have serious technical limitations, such as overlapping and duplicative codes and inconsistent and noncurrent use of terminology. Most importantly, neither has adequate room for expansion, so both are running out of codes as new services are created or different uses of existing services are distinguished. In addition, neither system provides sufficient clinical detail to support the creation of the kinds of databases required to accurately assess patient outcomes using advanced information technologies.[123]

Citing these and other problems, the National Committee on Vital and Health Statistics (NCVHS), an advisory body to the Secretary of Health and Human Services, has recommended the development of a single, unified classification and coding system that covers all health care services rendered by all providers in all settings, and that can be used for multiple purposes (reimbursement, research, etc.).[124] The NCVHS maintained that, although implementing such a system would initially be costly (particularly in the conversion of computer systems, databases, reimbursement systems, and documentation), it would save money in the long run through administrative simplification; more accurate coding and documentation; encouragement of automation and uniform terminology, data collection, and data processing; better monitoring and detection of errors, fraud, and ineffective procedures; and reduced training costs.[125]

Legislation that would have required the development of such a system was introduced in the 103d Congress (H.R. 1255), but was tabled in favor of incorporation into broader health care reform legislation that subsequently did not pass.[126] A survey of users of ICD-9-CM (Vol. 3) and CPT-4 found extensive dissatisfaction with them and widespread support for the concept of a single, unified system. Opposition to this concept was expressed mainly by physicians and representatives of medical organizations.[127] On the other hand, concern has been expressed about the proprietary nature of CPT-4 and the AMA's role in maintaining a system that is widely used for public purposes.[128]

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[122] For example, in CPT-4 the code for total abdominal hysterectomy (58150) includes procedures performed with or without removal of ovaries or fallopian tubes, whereas ICD-9-CM (Vol. 3) has separate codes for total abdominal hysterectomy (68.4) and removal of ovaries and/or tubes (65.3 through 65.6). Thus, the CPT-4 code cannot be used to identify patients who had undergone only a total abdominal hysterectomy (without removal of ovaries or fallopian tubes). See American Medical Association, *Physicians' Current Procedural Terminology, 1994* (Chicago, IL: September 1993), p. 355, and Practice Management Information Corp., *International Classification of Diseases, 9th Revision, Clinical Modification, Fourth Edition, 1993* (Los Angeles, CA: 1993), pp. 935, 937.

[123] Iezzoni, *Risk Adjustment for Measuring Health Care Outcomes,* op. cit., footnote 117, pp. 164-167; Whittle, op. cit., footnote 117; U.S. Department of Health and Human Services, Public Health Service, National Committee on Vital and Health Statistics, *The National Committee on Vital and Health Statistics, 1993* (Washington, DC: May 1994), pp. 8-10, 54-75.

[124] U.S. Department of Health and Human Services, Public Health Service, National Committee on Vital and Health Statistics, op. cit., footnote 123, pp. 54-55.

[125] Ibid., pp. 59-62.

[126] Ibid., p. 56.

[127] Ibid., pp. 56-58.

[128] Ibid., p. 60.

The NCVHS concluded that existing service classification and coding systems "are structurally flawed and wastefully redundant," and that neither ICD-9-CM (Vol. 3) nor CPT-4 "can be 'fixed' without a complete overhaul (that is, creating a new classification)."] 29 Yet in 1994, even HCFA reaffirmed its intention to continue this dual coding system policy in its Medicare and Medicaid programs, despite the substantial barriers this poses to efficient information processing and analysis.[130] Although the agency intends to conduct a pilot study on the feasibility of modifying or replacing ICD-9-CM (Vol. 3), and will remain open to ideas regarding a unified system, HCFA intends to continue its use of CPT-4 and its "cooperative relationship with the AMA."[131]

OPTION 2a: *Provide additional funding for intramural and extramural research on the feasibility of developing a single classification and coding system that could be applied to all health care services performed by all providers in all settings.*

Although this research could be conducted or directed by a single agency (such as NLM, HCFA, or AHCPR), extensive involvement by and cooperation with other agencies, private sector organizations (providers, payers, research associations, and particularly the AMA), and the World Health Organization (WHO) would be essential. If such a classification system were developed, NLM could then incorporate it into UMLS. This research would incur modest additional cost, and would further delay development of a unified service classification and coding system.

OPTION 2b: *Establish a new executive branch program to develop a unified service classification and coding system.*

This option would bypass research on the feasibility of developing such a system (option 2a). Again, the program to develop a new system could be conducted by one or more executive branch agencies, with extensive input from other agencies, private sector organizations, and WHO. This option would also incur larger additional costs than option 2a; however, it could expedite development of the new system. On the other hand, it would be more objectionable to parties that are committed to the current dual coding system policy.

OPTION 2c: *Once a unified service classification and coding system is developed, mandate that all federal agencies that manage health insurance and health care delivery programs use that system in those programs.*

In addition to HCFA, these agencies include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service. Promoting efficient information processing and analysis in these programs would seem warranted, considering the government's enormous investment in them. Given the magnitude of these programs in the health care marketplace, most private payers would probably soon adopt the new unified service classification and coding system, just as they began using the ICD-9-CM system after HCFA implemented it. On the other hand, such a

[129] Ibid., p. 54.

[130] U.S. Deparment Health and Human Services, Public Health Service, National Committee on Vital and Health Statistics, Subcommittee on Medical Classification Systems, Meeting Minutes, Washington, DC, Apr. 18, 1994, pp. 5-7, 9-10, For physician and supplier billing, HCFA actually uses its own system, called the HCFA Common Procedure Coding System (HCPCS), that incorporates CPT-4 but also contains additional codes.

[131] Ibid., p. 5. In another manifestation of this relationship, HCFA and the AMA recently formed the National Uniform Claim committee, "designed to give physicians more of a say in the creation and implementation of standards for electronic claims processing." This move has been harshly criticized by some participants in the existing voluntary, cooperative, public-private process of consensus standards development. "Yet Another Group Prepares To Work on Claims Standards," *Health Data Management*, May 1995, p. 14.

mandatory approach would probably be the most objectionable option to parties that are committed to the current dual coding system policy.

OPTION 2d: *Provide minimal funding for monitoring and facilitating private sector development of a unified service classification and coding system.*

Rather than mandating and/or funding the development of a unified service classification and coding system, Congress could continue to leave the development of such a system to the private sector. Minimal funding could be provided for existing agencies (e.g., NLM) and committees (e.g., NCVHS) to monitor private sector activities and to facilitate those activities—for example, by sponsoring meetings among interested parties. This option would capitalize on the existing voluntary, cooperative, public-private process of developing consensus standards. It would also be the least objectionable option to parties that are committed to the current dual coding system policy, and it would only marginally increase government expenditures. Its major drawback would be the long period of time that would probably be required for the consensus standards-development process to produce the needed system.

Telemedicine: Remote Access to Health Services and Information

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Telemedicine can be broadly defined as the use of information technology to deliver medical services and information from one location to another. Since the 1960s, telecommunication has been used to exchange medical information between sites in both rural and urban areas. One of the earliest applications of telemedicine was at the University of Nebraska where two-way, closed-circuit microwave television was used for psychiatric consultations. Another was in Boston, where a video link was established between a health clinic at Logan Airport and the Massachusetts General Hospital. The National Aeronautics and Space Administration (NASA) also was a pioneer in the 1960s with its satellite support of a telemedicine project, conducted by the National Library of Medicine (NLM), that provided health services to the Appalachian and Rocky Mountain regions and Alaska. In the 1970s, NASA also sponsored the STARPAHC (Space Technology Applied to Rural Papago Advanced Health Care) project, implemented with the Indian Health Service and the Department of Health, Education and Welfare on the Papago Indian Reservation in Arizona.

Early expansion of telemedicine was affected, however, by the cost and limitations of the technology. Recent technological advances—such as fiber optics, integrated services digital networks (ISDN), and compressed video—have eliminated or minimized many of these problems, fostering a resurgence of private- and public-sector interest in the potential of telemedicine to lower costs, improve quality, and increase access to health care, especially for those who live in remote or underserved areas. The technology is not only better; it is also becoming cheaper.



While telemedicine has been practiced for more than 30 years, its current iteration is still in the early stages of development. One

recent journal article remarked that: "Telemedicine is on its way (although it has not yet arrived)."[1] Others believe that telemedicine has now come into its own.

> Having now come of age, telemedicine has the potential of having a greater impact on the future of medicine than any other modality . . . Telemedicine is, in the final analysis, bringing reality to the vision of an enhanced accessibility of medical care and a global network of health care.[2]

It may be a number of years before telemedicine is used widely enough and evaluated sufficiently in terms of its effectiveness and efficiency for definitive statements to be made about its overall value and recommended uses. Like all new technologies, there will be impacts that cannot be anticipated in advance. Rigorous evaluation studies are needed to determine telemedicine's potential benefits, and such research is beginning to take place.

With Congress, the Administration, the health care industry, and consumers all searching for ways to reduce the costs of delivering health care, the potential of telemedicine has been receiving careful scrutiny. A number of bills directly related to telemedicine were introduced in the 103d Congress; so far in the 104th Congress, four bills have been introduced that refer to telemedicine. The Administration's Information Infrastructure Task Force is considering the role that information technology can play in delivering health services more efficiently and effectively as part of the National Information Infrastructure (NII) initiative. A task force subgroup of representatives from federal agencies is addressing the current status and potential of telemedicine. Telemedicine also has important international implications, and organizations like the World Health Organization and the European Commission are exploring its potential as well.

TELEMEDICINE'S POTENTIAL EFFECTS

Parts of the United States that are sparsely populated continue to have difficulty attracting and retaining health professionals, as well as supporting local hospitals and clinics. An earlier OTA report outlined the ongoing problems of delivering adequate, high-quality health care to people who live in rural areas.[3] Since the report was released in 1990, the problems rural residents face in accessing health care have not changed substantially, although there have been some selected improvements. Although access to physicians continues to be limited and rural hospitals continue to close, the financial picture for rural hospitals that remain open has improved somewhat.[4]

One physician, discussing the potential benefits of telemedicine, described the problems facing rural health care this way:

> What do you call a place the size of New York State with almost no medical, surgical, or pediatric subspecialists? . . . Western Kansas. This area has been medically underserved for generations. Subspecialty access has not been the only difficulty. There are also serious problems with the retention of primary care physicians, the provision of nursing education and emergency room coverage, and the financial health of rural hospitals. The primary challenge has been geographic—and until recently there did not seem

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[1] E.A. Franken et al., "Telemedicine and Teleradiology: A Tale of Two Cultures," *Telemedicine Journal*, vol. 1, No. 1, spring 1995, p. 7.

[2] Michael E. DeBakey, "Telemedicine Has Now Come of Age," *Telemedicine Journal*, vol. 1, No. 1, spring 1995, p. 4

[3] U.S. Congress, Office of Technology Assessment, *Health Care in Rural America*, OTA-H-434 (Washington, DC: U.S. Government Printing Office, September 1990).

[4] "Health Care in Rural America," statement of the Office of Technology Assessment at a hearing of the Senate Committee on Agriculture, Nutrition, and Forestry, June 9, 1994.

to be any way adequately to confront the challenge.[5]

There are a number of reasons why isolated areas have difficulty attracting and retaining health care professionals. Medical practice is often more demanding and less lucrative than in larger centers. Providers may also feel isolated from mentors, colleagues, and the information resources necessary to support them personally and professionally. Equipment may be less up to date and facilities less than adequate. Similar problems often plague the delivery of health care to large inner-city populations. Telemedicine is a tool that may help address the problem of provider distribution by improving communication capabilities and providing convenient access to up-to-date information, consultations, and other forms of support.[6]

The use of telecommunications to deliver health services has the potential to reduce costs, improve quality, and improve access to care in rural and other underserved areas of the country. Although the extent of this potential is largely speculative at this time, researchers are beginning to address telemedicine's impacts. According to one researcher:

> . . . telemedicine may be unique in having the potential for introducing low-cost, high-efficiency components that may, under certain conditions, increase access to care while possibly limiting increases in cost by enhancing health outcomes.[7]

If research results prove to be largely positive, telemedicine is likely to become fairly routine over the next 10 to 20 years.[8]

One thing is certain—no single technological solution will work for all communities. Each location is unique, and systems designed to address access problems must be tailored to meet the particular needs and culture of each community, whether rural or urban. As noted in an earlier OTA report, communities are endowed differently with respect to their cultures, locations, landscapes, and natural and human resources, as well as their access to information technologies.[9]

Costs of Delivering Health Care

Determining the costs of delivering medical services is a difficult task under any circumstances. It is even more complicated when dealing with a technical application like telemedicine where so many aspects of its practice are still unknown. Comparing the cost of telemedicine with the delivery of conventional medical services is one approach. However, it is important to keep in mind that, in reality, the practice of telemedicine will assume its own characteristics and may ultimately be quite different from previous models. Another approach might be to compare telemedicine to other ways of increasing access to specialist care (i.e., visiting consultant clinics or satellite clinics).[10] The cost of telemedicine needs to be considered in relation to how it contributes to

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[5] Ace Allen, "Telemedicine in Kansas: Introduction," *Kansas Medicine*, vol. 93, No. 12, December 1992, p. 322.

[6] See Daniel McCarthy, "The Virtual Health Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America," *American Journal of Law & Medicine*, vol. 21, No. 1, 1995.

[7] R.L. Bashshur, "On the Definition and Evaluation of Telemedicine," *Telemedicine Journal*, vol. 1, No. 1, spring 1995, p. 23.

[8] Jim Grigsby et al., "Analysis of Expansion of Access to Care Through Use of Telemedicine, Report 4: Study Summary and Recommendations for Further Research," Center for Health Policy Research, Denver, CO, December 1994, p. 3.2.

[9] U.S. Congress, Office of Technology Assessment, *Rural America at the Crossroads: Networking for the Future*, OTA-TCT-471 (Washington, DC: U.S. Government Printing Office, April 1991), p. 7.

[10] Michael G. Kienzle, Project Director, University of Iowa National Laboratory for the Study of Rural Telemedicine, Iowa City, IA, personal communication, May 10, 1995.

improving the health of the population by preventing disease, treating illness, and ameliorating pain and suffering, and how it compares with alternative systems.[11]

A recent report prepared for the Health Care Financing Administration (HCFA) that included an extensive literature review of telemedicine research found no studies that provided an adequate overview of its cost-effectiveness.[12] Although it is too soon to know whether the use of telecommunications to deliver health care services will actually lower costs, it would seem to have the potential to do so for some participants. For example, telemedicine can eliminate time and wages lost at work and traveling expenses incurred when specialists and/or patients have to travel for consultations. In addition, keeping patients in their own communities can increase local hospital revenues and decrease the cost to patients. The cost of a bed in a community hospital is considerably less than in a large medical center. Costs might also be reduced by staffing hospitals and clinics with allied health professionals, such as nurse practitioners and physician assistants, who would deliver services where there is no resident physician. These providers could be assisted and monitored remotely by physicians using a telecommunications link. In some cases, overall costs might also be lowered using telemedicine if patients are treated sooner when their illnesses are less severe. However, if earlier diagnosis leads to an expensive course of treatment that would otherwise not have been provided, costs could increase.

An earlier OTA report noted that one of the greatest problems rural hospitals face is the outmigration of residents to urban areas for care.[13] Many hospitals in small communities have been forced to close because their bed census dropped so low they became uneconomical to operate. The economic impact on a small community when its hospital closes is enormous. In addition to reducing access to care, such closures have a major impact on employment opportunities. The viability of small hospitals might improve if telemedicine allowed more patients to receive consultative services locally, rather than being referred to large medical centers.

In addition to cost considerations, it is important not to lose sight of the *value* of telemedicine in delivering services or ensuring health care jobs. Communities suffer when people do not receive needed care or become unemployed when a hospital closes because it is no longer economically viable. These societal costs are important, but extremely difficult to measure. As one recent report stated:

> . . . improved access and quality, benefits from preventive care, and rural economic development are difficult to quantify and are likely to be left out of the cost-effectiveness equation. When this occurs, the cost-effectiveness analysis will misrepresent telemedicine's true benefits and lead to sub-optimal decisions on whether and how to invest in these systems.[14]

While telemedicine might reduce costs in certain cases, there is also the potential that costs may increase, at least in the short term. A consultation could represent an additional cost when used for a patient who would not have been seen by a specialist at all without the availability of telemedi-

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[11] For a discussion of cost-benefit analysis and cost-effectiveness analysis, see R.L. Bashshur, "Telemedicine Effects: Cost, Quality and Access," *Journal of Medical Systems*, April 1995.

[12] Jim Grigsby et al., "Analysis of Expansion of Access to Care Through Use of Telemedicine and Mobile Health Services, Report 1: Literature Review and Analytic Framework," December 1993, p. 2.3. The lack of cost-effectiveness data on the use of information technology in health care delivery is not unusual. An OTA contractor report reviewing such studies as they apply to administrative simplification found little in the literature. "Estimating the Cost-Effectiveness of Selected Information Technology Applications," Project HOPE, Center for Health Affairs, unpublished contractor report prepared for the Office of Technology Assessment, March 1995.

[13] U.S. Congress, Office of Technology Assessment, op. cit., footnote 3, p. 12.

[14] Office of Rural Health Policy, Health Resources and Services Administration, Public Health Service, Department of Health and Human Services, *Reaching Rural*, (Washington, DC: 1994), p. 11.

cine.[15] However, the advantage of early diagnosis and treatment using telemedicine may offset later, more expensive episodes, thereby reducing the overall costs of care. Concerns have also been raised about the potential for overutilization or fraud if third-party reimbursement for telemedicine consultations becomes widespread, thus driving up costs. There is also the possibility that telemedicine might lower costs to patients, but increase costs for Medicare because more people are provided access to health care.[16] What is not known is whether real improvements in health status would offset the increase in demand for care, should either occur.[17]



For practitioners in rural or other underserved areas, telemedicine can improve communication capabilities by providing convenient access to consultants, up-to-date information, and other forms of support

■ Access to Health Services

Access to health services is a function of demographic factors such as geography, education, economic status, and age. For patients to have access, there must be health care providers and adequate facilities and services to deliver care. In a June 1994 hearing, the Chair of the Congressional Rural Caucus testified:

> . . . the primary discussion in rural areas about health care reform is not focused on the structure of alliances or the composition of the standard benefits package, but is concerned about the financial stability of the local hospital or recruitment of a new town doctor.[18]

Rural and remote areas face special problems when it comes to delivering health care. For example, the rural population is disproportionately older and poorer. They have more chronic illnesses and more work-related accidents. A large percentage of general physicians are within five years of retirement.[19]

Geography is a critical factor because, traditionally, there has been a shortage of care in areas where medical providers are less likely to want to practice, such as rural and inner city locations.[20] It is difficult to recruit and retain health care providers because this type of practice tends to be less lucrative, fails to provide professional interaction and support, and places high demands on practitioners. Although the number of physicians practicing in rural areas is increasing overall, rural residents continue to be more than twice as likely

[15] Jim Grigsby et al., "Analysis of Expansion of Access to Care Through Use of Telemedicine and Mobile Health Services, Report 2: Case Studies and Current Status of Telemedicine;" May 1994, p. 3.2.

[16] Grigsby er al., Report 4, op. cit., footnote 8, p. 7.6.

[17] R.L. Bashshur, School of Public Health, University of Michigan, personal communication, May 15, 1995.

[18] Congresswoman Jill Long, Chair, Congressional Rural Caucus, testimony before the Senate Committee on Agriculture, Nutrition and Forestry, June 9, 1994.

[19] Ibid.

[20] Ibid.

as the nation as a whole to face shortages of primary care physicians.[21] To help attract and keep physicians, it seems clear that a community's access to health services may increasingly depend on providing practitioners with electronic access to information, continuing medical education, and peer support. This may be particularly true for a new generation of practitioners who are accustomed to using computers in their work.

The availability of telemedicine services may help rural and other underserved communities solve some of their problems in accessing health care by making rural practice more attractive. Online access to information and expert advice may help rural health care professionals overcome their sense of isolation from other colleagues and the lack of access to the up-to-date information they need to practice effectively. Telemedicine services also increase the access of rural physicians to medical specialists and vice versa, providing a two-way educational experience. Teachers in academic medical centers learn about the problems physicians face in a rural practice, which will help them better prepare medical students for the realities of practice. Rural physicians gain in two ways—from the educational experience of interacting with and learning from specialists, and by having access to formal continuing medical education courses.[22] Some people caution, however, that improving telecommunication links should not be viewed as a substitute for improved physician availability in rural areas.[23] Citizens may take the view that they are receiving second-class medical services if the role of telemedicine is perceived as a substitute for a health care provider in their community.

Quality of Care

Experts who assess the quality of conventional medical care use complicated measures of structure, process, and outcome.[24] Structure refers to staff, equipment, and organization; process refers to measures of appropriateness, necessity, and technical quality; and outcome refers to measures of effectiveness, as well as the patient's functional status, health status, and satisfaction and quality of life.

Because telemedicine is an electronic means to deliver care, not a specific medical procedure, it cannot be compared with conventional care in the same way that individual procedures can be measured.[25] Clinical effectiveness has not been demonstrated for all clinical functions using all types of technology. However, a scale of clinical effectiveness can be constructed to differentiate those services that have been assessed from those that are still experimental. Grigsby et al. have suggested one way of demonstrating how the quality of care delivered using telemedicine could be assessed, based on a number of applications. Their report suggests four categories of current telemedicine applications:

1. Applications that are plainly effective.
2. Applications that are likely to be effective, but the implications of implementing them are unclear. They would require further research to understand their effects.

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[21] S.M. Korczyk, "Health Care Needs, Resources and Access in Rural America," a report for the National Rural Electric Cooperative Association (Washington, DC: National Rural Electric Cooperative Association's Retirement, Safety and Insurance Department, spring 1994), p. 14.

[22] For a relevant discussion related to education, see U.S. Congress, Office of Technology Assessment, *Teachers and Technology: Making the Connection*, OTA-EHR-616 (Washington, DC: U.S. Government Printing Office, April 1995).

[23] Korczyk, op. cit., footnote 21, p. 19.

[24] For a more complete discussion of quality assessment, see ch. 4, "Information Technologies and the Quality of Health Care."

[25] Grigsby et al., "Analysis of Expansion of Access to Care Through Use of Telemedicine and Mobile Health Services, Report 3: Telemedicine Policy: Quality Assurance, Utilization Reviews, and Coverage," Center for Health Policy Research, Denver, CO, August 1994, p. 3.3.

3. Applications for which the safety and effectiveness are currently unknown, or for which basic research is required to specify requisite technical parameters.
4. Applications that are entirely experimental, or which anticipate the integration of different existing advanced technologies.[26]

Whether and how telemedicine affects the quality of care delivered has not yet been proven. However, it is possible to speculate that some aspects of the electronic medical encounter might provide better care from the patient perspective. Telemedicine could provide faster, more convenient treatment.[27] The ability to receive the services of a specialist without having to leave one's community also provides better continuity of care. Similarly, allowing a patient to remain in the local hospital with family and friends for support could improve the quality of the experience for the patient and could, in fact, contribute to a faster recovery. These benefits would minimize the disruption of the patient's life and reduce the amount of working time lost. Followup care seems well suited to telemedicine, and might be carried out more effectively and efficiently by electronic means, thereby avoiding the costs of time and travel for an office visit.

For the health care provider, telemedicine can offer tools to assist in providing high-quality services. Having timely, convenient access to the most up-to-date information, continuing medical education programs, decision support systems, and consultations with specialists in large medical centers should increase the provider's options and improve his or her ability to accurately diagnose and effectively treat patients. The development of clinical practice guidelines for telemedicine could enable providers to deliver better care. However, whether or not telemedicine consultations improve the quality of care will only be known when the research has been done to determine patient outcomes.

TELEMEDICINE APPLICATIONS

Telemedicine is broadly defined as the use of information technology to deliver medical services and information from one location to another. However, there are differences of opinion regarding what the definition should include.[28] Most agree that it includes applications in areas such as pathology and radiology, as well as consultations

CLOSE TO HOME JOHN McPHERSON



"Mrs. Nortman just sent in this fax of a rash that she's got on her stomach."

[26] Ibid., p. 3.4.

[27] Norwegian researchers have found that—assessed by criteria for delivering health services in a timely fashion and as *close to* the patient residence as possible-telemedicine maintains a higher level of quality than traditional medical services. U. Holand and S. Pedersen. "'Quality Requirements for Telemedical Services," Telemedicine, *Telektronikk,* vol. 89, No. 1, 1993, p. 52.

[28] For a discussion of telemedicine definitions, see Bashshur, **Op. Ch.,** footnote 7. pp. 20-22.

TABLE 5-1: Summary of Telemedicine Application Categories

- Initial urgent evaluation of patients, triage decisions, and pretransfer arrangements.
- Medical and surgical followup and medication checks.
- Supervision and consultation for primary care encounters in sites where a physician is not available.
- Routine consultations and second opinions based on history, physical exam findings, and available test data.
- Transmission of diagnostic Images.
- Extended diagnostic work-ups or short-term management of self-limited conditions.
- Management of chronic diseases and conditions requiring a specialist not available locally.
- Transmission of medical data.
- Public health, preventive medicine, and patient education

SOURCE: Grigsby et al., "Analysis of Expansion of Access to Care Through Telemedicine, Report 4, Study Summary and Recommendations for Further Research," Center for Health Policy Research, Denver, CO, December 1994, p 43

in specialties such as neurology, dermatology, cardiology, and general medicine. While some consider certain forms of medical education within the definition, others would exclude the use of video to transmit purely didactic classroom lectures where there is no direct interaction between student and teacher. Whatever the definition, telemedicine implies a closer link between the telecommunications infrastructure and the health care system that includes the entire range of teleservices.[79]

Telemedicine can be used for a variety of purposes (see table 5-1).[30] Some applications of telecommunications in the health field have been in use longer than others. Teleradiology, for example, has about 30 years' experience and a literature dating from the early 1970s. Other applications are newer, and as yet have produced few research results. Current telemedicine projects vary with respect to goals, organization, funding, and technology. This diversity is shown in brief descriptions of some current telemedicine programs.

■ Teleconsultations

Medical College of Georgia Telemedicine System

The Telemedicine System was initiated by the Medical College of Georgia (MCG) in November 1991 when it connected with Dodge County Hospital in Eastman, Georgia, 130 miles away. The system's overall goal is to ensure that everyone in the state has immediate access to quality health care.[31] The director envisions a telemedicine network that would spread out from a medical center complex to a number of satellite sites, such as rural hospitals, correctional facilities, and even military bases (see figure 5-1). Although the system is currently used largely for cardiology and neurology consultations, it can be adapted for a variety of specialties, such as dermatology, ophthalmology, or gastroenterology through the use of a variety of camera adapters. In addition to consultations, the system can also be used to guide certain procedures, such as a endoscopy or laparoscopy. MCG's

[29] Birger J. Nymo, "Telemedicine," *Telektronikk,* vol. 89, No. 1, 1993, p. 4.

[30] A recent study prepared for HCFA reported findings on the current status of telemedicine in the United states. Grigsby et al., Report 3, op. cit., footnote 25, pp. 3.1-3.5.

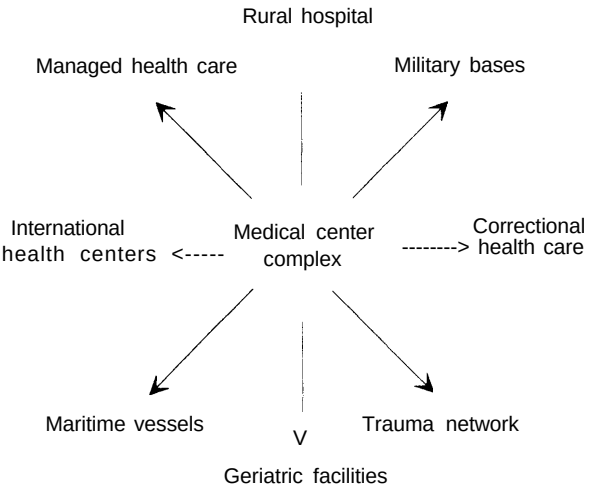
[31] J.H. Sanders and F.J. Tedesco, "Telemedicine: Bringing Medical Care to Isolated Communities," *Journal of the Medical Association of Georgia,* May 1993, pp. 237-241.

system is compatible with multiple types of communication systems—telephone, cable, microwave, and satellite. It is also portable and can be loaded into a van and transported. This is particularly useful for locations that are too small to warrant a system of their own.

The system provides two-way interactive audio/video communications. It has an open architecture and individual components can be replaced and upgraded. Hardware and software are off-the-shelf technologies. The equipment includes a video conferencing console with a codec,[32] personal computer, VCR, electronic stethoscope with an equalizer, a fax machine, CD-ROM, cameras, and monitors. At the remote site, the doctor has a camera that can be attached to any scope (e.g., microscope or otoscope) to project images for the consultant. The CD-ROM provides a medical textbook database, the Scientific American Consult Program, that allows the consulting physician to call up information on a particular diagnosis and send it to the remote physician by fax or modem. The Telemedicine Center, with a grant from the BellSouth Foundation, surveyed physicians who have used the system. Seventy-eight percent felt that their use of the system had been satisfactory to highly satisfactory.

The network has been paid for by the State of Georgia as part of the Georgia statewide communications network. A dedicated T1 communications line is used.[33] There are four channels and a multiplexer. Four to 20 consultations take place each week. A facilitator is available at both sites during the consultation to manage paperwork and videotapes, direct the camera, and operate the equipment (or help the doctor do it). The setup cost for each remote site is from $95,000 to $115,000, and for the MCG hub site from $90,000 to $105,000. These costs include the system, training, and system support (a teleradiology system costs extra).

FIGURE 5-1: A Telemedicine Health Care Network



SOURCE Jay H Sanders, M D Medical College of Georgia (c) 1993

The Telemedicine System is state supported: personnel support is provided by the rural hospitals. The network is being extended statewide. and consists of two tertiary care academic medical centers (MCG and Emory) connected to nine secondary hubs that are comprehensive community hospitals strategically located in a specific health care region of the state. From each of the tertiary and secondary hub sites, there will be three or four spokes going out to primary health care facilities consisting of rural hospitals, correctional facilities, public health facilities. and Area Health Education Center sites. Present initiatives also include interfacing this system with all the distance learning sites in the state so that real-time, interactive preventive and episodic health care can be provided in the classrooms. Plans arc also in place

[32] Codec is an abbreviation for coder/decoder. It is an electronic device that converts an analog electrical signal into a digital form for transmission purposes and decodes it at the receiving end.

[33] A T1 line refers to a digital carrier capable of transmitting 1.544 megabits/second, suitable for high-volume voice, data, or compressed video traffic.

to interface military health care needs with the civilian hospital backbone. Based on the telecommunication infrastructure put into place to support the telemedicine system, a patient at any site can be examined by a physician at any other site. Distance is totally transparent and seamless. MCG also has plans for a demonstration project that will monitor certain patients in their homes, the so-called *electronic house call*, as well as for a desktop telemedicine system for the physicians' offices.

Medicaid and Medicare are currently reimbursing the consultant and the referring physician at Dodge County Hospital, and Medicaid pays the rural hospital a facility fee. This reimbursement was granted by the Medicare carrier (Aetna), and applies only to the original sites in Georgia and not to new ones. Blue Cross/Blue Shield reimburses only the consultant. MCG has estimated that approximately 86 percent of patients who previously would have been transported to MCG now are kept at the remote sites. The daily cost of a hospital bed in a rural area is placed at approximately $800, compared with $1,300 at MCG, and the costs of transportation, increased time away from work, and delay in therapy represent additional expenses.

Physicians in remote areas who use the MCG system for consultations are given credit hours toward meeting their continuing medical education (CME) requirements, which are necessary for license renewals. They do not have to interrupt their practice to attend classroom lectures in a different location. This educational activity becomes directly relevant to their day-to-day practice and more meaningful than a lecture format.

Texas Telemedicine Project

With funding provided by foundations and vendors, the Texas Telemedicine Project began operations in April 1991. It was established as a research project to study viability factors potentially operative in a national health care delivery system. The project uses interactive two-way audio and video to connect sites in Austin with sites in Giddings, a small town with fewer than 4,000 people.[34] The sites in Austin are the Austin State Hospital, the state headquarters of the Texas Youth Commission, the Austin Diagnostic Clinic, and the Texas Telemedicine project office. In Giddings, the Lee Memorial Hospital, a Texas Youth Commission maximum-security unit, the Giddings Regional Dialysis Clinic, and the Community Mental Health Clinic are connected. Each site has a unit with video, audio, and high-speed data transfer channels; ports for a fax and laser printer; and two 20-inch color monitors, two video cameras, two microphones, and a speaker. T1 telecommunication circuits are provided in part by Southwestern Bell, GTE, and LDDS. Economies of scale are produced by scheduled sharing of telecommunication lines.

At night, when emergency triage may be needed for auto accident victims, the system connects the Giddings Hospital with the Austin Diagnostic Clinic. In the morning, the Austin Diagnostic Clinic is connected to the Giddings Dialysis Center to monitor patients coming off and going on dialysis. Management rounds of each site are made electronically by Telemedicine Interactive Consultative Services each day. The Texas Telemedicine Project used a questionnaire for patients and providers to document problems and satisfaction with the system. Results over the first two years documented a 99.35 percent satisfaction rate.

Kansas University Medical Center

Telemedicine in Kansas is a cooperative effort involving the Kansas City and Wichita campuses of the Kansas University Medical Center (KUMC),

[34] Description taken from J. Preston, F.W. Brown, and B. Hartley, "Using Telemedicine To Improve Health Care in Distance Areas," *Hospital and Community Psychiatry,* vol. 43, No. 1, January 1992, pp. 29-30; also J. Preston, Director, Texas Telemedicine Project, personal communication, May 14, 1995.



In 1991, before telemedicine was available, physicians from The University of Kansas Medical Center in Kansas City Kansas, traveled 270 miles to Hays, Kansas, to visit patients.



In 1995, an oncologist at The University of Kansas Medical Center in Kansas City, Kansas, consults with a nurse practitioner at the Hayes Medical Center via an interactive videoconference without leaving the medical center.

the state government, the Northwest Kansas Area Health Education Center, and nine rural hospitals.[35] The system is designed to provide real-time medical consultations involving a patient and practitioner (physician, nurse practitioner, or physician assistant) at the distant end and a specialist at the medical center. Full-motion, compressed two-way video is used, and there are facilities for interfacing imaging equipment, using an electronic stethoscope, for example. Continuing education courses (including courses that provide CME credit for physicians) are offered over the same equipment. The system is currently used 20 to 25 percent for clinical applications, 30 percent for continuing education (nonphysicians), 20 percent continuing medical education (physicians), and 20 to 25 percent for administrative functions.

Teleconsultations are mainly used to determine the need for face-to-face treatment or for regular followup after a face-to-face visit. In 1993, 180 consultations were conducted in 931 hours of total operations (including continuing education and administrative uses). In 1994, there were 189 consultations. KUMC estimates that, while telemedicine does not completely replace the need for transportation, it can eliminate a significant amount of travel for patients and specialists.

Use of T1 telecommunications lines in the State of Kansas network costs $35 per hour for on-peak use and $20 per hour for off-peak; but local access is expensive, especially if the transmission has to cross local access transport area (LATA) boundaries. Hospitals in the telemedicine program are paying between $421 and $1,318 per month for local access to the nearest point-of-presence of the State network. Local access charges for T1 lines are mileage-sensitive.

A telemedicine suite includes one or two 35-inch, 650-line digital monitors, one or two video cameras, graphics stand, slide converter (35mm to video interface), VCRs, microphones, and auscultation equipment (wireless stethoscope). The camera at the distant site can be controlled remotely by the physician at the central site. Any medical imaging equipment that puts out an NTSC (television) signal can be interfaced directly, or a videotape made by that equipment can be played. Radiographic images are transmitted via video camera (use of a digitizing scan-

[35] Description based on site vitie, descriptive material provided; A. Allen, R. Cox, and C. Thomas, "Telemedicine in Kansas,'' *Kansas Medicine*, December 1992, pp. 323-325; and A. Allen, Oncologist Telemedicine Project, University of Kansas, personal communication, July 6, 1995.

ner is far more expensive). All inputs are sent to a codec, which converts analog signals to digital ones for transmission. When purchased, the cost of a basic equipment suite was about $90,000, and now has dropped closer to $50,000.

The State of Kansas permits educational, medical, county government, and other such organizations to connect to the KANS-A-N state-owned digital telephone network. The network does not yet extend to every county, and T1 lines are not yet available for local access in all counties. The telemedicine application usually uses one-quarter of a T1 line (384 kb). Compression to this bandwidth gives some "ghosting" and "tiling" on fast motion, but is acceptable for viewing normal, medically significant motions such as a patient's gait. KUMC's experience is that picture quality for medical images such as ultrasound, computerized axial tomography (CT) scans, magnetic resonance imaging (MRI), or some x-rays is not perceptibly impaired; however, quality is not good enough for a mammogram. Picture quality on fast motion is reportedly better using one-half T1 bandwidth.

The Mayo Clinic

The Mayo Clinic in Rochester, Minnesota, became a major developer of telemedicine in 1987 when it expanded to sites in Scottsdale, Arizona, and Jacksonville, Florida. Today, Mayo uses telemedicine for clinical care, education, and administrative coordination to integrate the three sites. Current projects include the use of satellite communications to deliver consultative care to the Middle East and the use of compressed video and land lines to deliver a wide range of services to affiliated entities within Iowa, Wisconsin, and Minnesota. Mayo Clinic also provides services for the Amman Diagnostic Clinic in Jordan. During 12 weeks in 1994, Mayo joined with the Pine Ridge Indian Reservation and NASA in an experiment to provide professional education and clinical consulting services to professionals at Pine Ridge. Based on questionnaires completed by all the participants, it was determined that the project was both feasible and useful.[36]

Mayo is collaborating with NASA and the Advanced Research Projects Agency (ARPA) on a project to use the Advanced Communications and Technology Satellite (ACTS) to deliver services to small communities in remote environments.[37] In November 1993, Mayo sponsored a telemedicine symposium, and in April 1995 hosted the Second International Conference on the Medical Aspects of Telemedicine and Second Annual Mayo Telemedicine Symposium.

East Carolina University School of Medicine

East Carolina University (ECU) performs telemedicine consultations to the largest prison in North Carolina and two rural hospitals.[38] Physicians see and talk to the patients via the telemedicine link and then diagnose and prescribe medications when necessary. A digital stethoscope, a graphics camera, and a miniature, handheld dermatology camera are used to aid in patient examinations. The working model developed for the prison system is now being expanded to six rural hospitals and a large naval hospital (see figure 5-2). A unique aspect of the ECU program is the hybrid communications network and hardware that have been integrated. With the addition of an asynchronous transfer mode (ATM) network, this will be

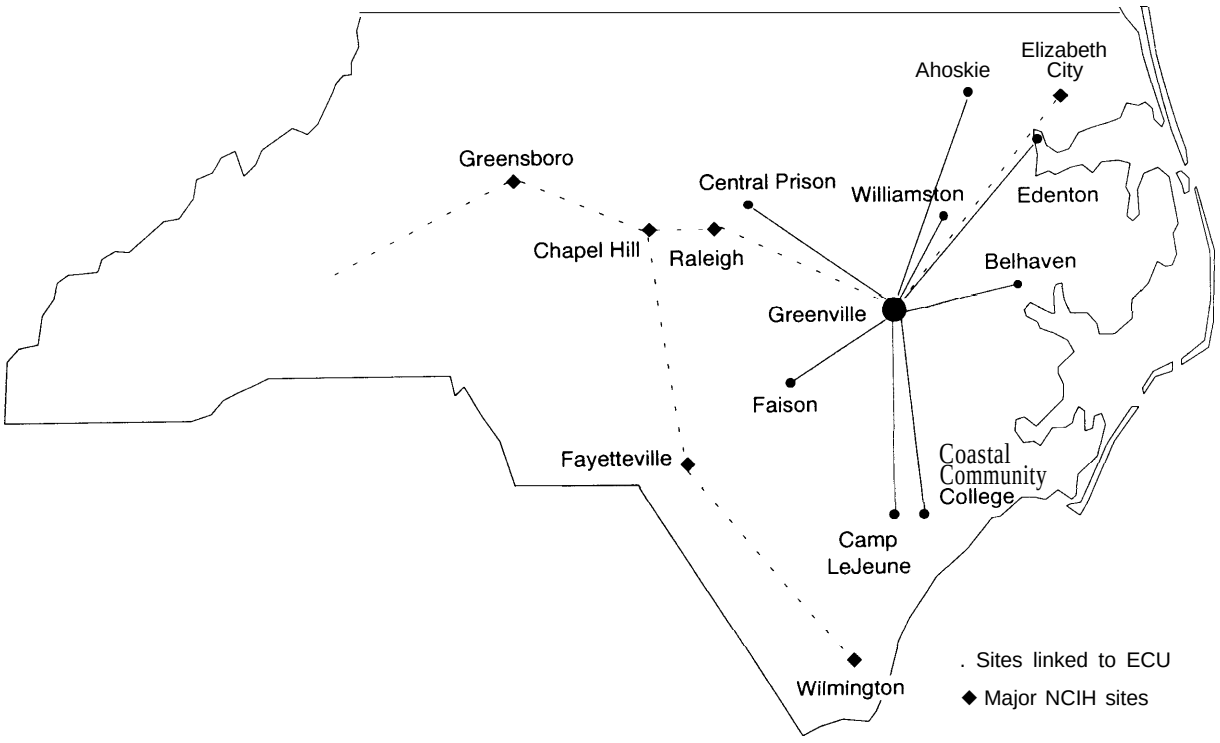
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[36] T.E. Kottke and M.A. Trapp, "The Pine Ridge Indian Reservation/Mayo Clinic/NASA Telemedicine Project: A Feasibility Study," presented at the Second International Conference on the Medical Aspects of Telemedicine and Second Annual Mayo Telemedicine Symposium, Rochester, MN, Apr. 6-9, 1995. See also U.S. Congress, Office of Technology Assessment, *Telecommunications Technology and Native Americans: Opportunities and Challenges*, OTA-ITC-621 (Washington, DC: U.S. Government Printing Office, August 1995).

[37] E.G. Tangalos, Mayo Clinic/Mayo Foundation, Rochester, MN, "Hearing on Telemedicine: An Information Highway To Save Lives," held by the Subcommittee on Investigations and Oversight, Committee on Science, Space, and Technology, U.S. House of Representatives, May 2, 1994, pp. 12-13.

[38] Information from East Carolina University School of Medicine, "Telemedicine," brochure, August 1995; and David Balch, Director, Rural Eastern Carolina Health Network, personal communication, Aug. 15, 1995.

FIGURE 5-2: East Carolina University Telemedicine Network



SOURCE: East Carolina University, Greenville, NC, 1995

the only telemedicine program in the world operating integrated T1 line microwave and ATM links. Current Federal support includes grants from HCFA, the National Telecommunications and Information Administration (NTIA), and the Office of Rural Health Policy (ORHP).

ECU recently conducted a demonstration clinic at a conference in California in which 84 people were seen in three days via a live ATM link to ECU. Conference participants were given the opportunity to have a consulting specialist at ECU listen to their heart beat, examine their ears, look at a skin lesion, or explore some other medical problem of interest. Two-way video, audio, and data were transmitted between the sites.

The Rural Eastern Carolina Health Network (REACH-TV) (consisting of the ECU School of Medicine, Pitt County Memorial Hospital, Eastern AHEC, and the Center for Health Sciences Communication) focuses on telemedicine, teleconferencing/distance learning, and applied research interactive information environments.

RODEO NET Project

The mission of RODEO NET (Rural Options for Development and Educational Opportunities Network) is "to pioneer advances in improving the delivery of human services by connecting people using appropriate communication technolo-

gies."[39] In 1991, the Eastern Oregon Human Services Consortium was awarded a three-year grant of approximately $700,000 by the Rural Health Outreach Grant Program of the Office of Rural Health Policy (Health Resources and Services Administration) for the purpose of demonstrating an innovative model of mental health care in a rural area. RODEO NET uses three networks of Oregon ED-NET, which was created by the State of Oregon in 1989. Network I provides live, interactive one-way video, two-way audio services to 45 "receive" sites in eastern Oregon. Network II provides two-way video, audio, and data services using digitally compressed video technology in 10 studios. COMPASS is a local "dial-up" computer data network that provides a variety of information services. These include user-friendly access to local, national, and international databases and the Internet; government and academic libraries; bulletin boards; electronic mail; and computer-conferencing services.

RODEO NET currently uses all three networks to train mental health providers in eastern Oregon. For example, both professional and paraprofessional staff who work with children and adolescents who have severe emotional disturbances and their families participate in a certificate program to upgrade staff qualifications. Individual training is also provided.

In addition to training, RODEO NET provides crisis response using Network II to enable personnel to access the on-call psychiatrist at the Eastern Oregon Psychiatric Center in Pendleton to help deal with persons suffering extreme emotional or behavioral turmoil. Such a response system often saves the time and money required to transport an individual and keeps that person in the community. RODEO NET provides ongoing clinics for medication management and case consultations on an ongoing or as needed basis, reducing the number of admissions to acute care facilities. Interviews for preadmission, predischarge, and transfers are now accomplished via Network II, and precommitment and psychiatric review board hearings are conducted using interactive TV. The project also plans to work with consumer groups to help them create their own computer networking conferences within the COMPASS system.

Teleradiology and Telepathology

The use of telecommunications to transmit medical images is quite well developed and widespread. A teleradiology system acquires radiographic images at one location and transmits them to one or more remote sites, where they are displayed on an interactive display system and/or converted to hard copy.[40] Transmissions might include CAT scans, MRIs, or x-ray images. CAT scans and MRIs originate in digital form, but a film digitizer must be used to convert conventional radiographs from film to digital form. Teleradiology systems often employ a wide area network.

Teleradiology systems transmit images from one hospital to another, from an imaging center to a hospital, or from an imaging center or hospital to a radiologist's office or home. Each requires different technologies and communication links and each site has different requirements.[41] For example, a radiologist who is on call may review an image in his or her office or at home, but at a later time will also review the original image before making a final diagnosis. In this instance, a lower image resolution, requiring less expensive equipment, may be acceptable. A higher quality image is required if the radiologist is making a final interpretation without seeing the original image, as

[39] Description taken from "RODEO NET Project Summary," Oct. 25, 1993; and Cathy Britain, Program Manager, RODEO NET, personal communication, June 1995.

[40] For an in-depth description of teleradiology, see S. Batnitzky et al., "Teleradiology: An Assessment," *Radiology*, vol. 177, 1990.

[41] S.J. Dwyer, III, et al., "Wide Area Network Strategies for Teleradiology Systems," *RadioGraphics*, vol. 12, No. 3, May 1993, p. 569.

in the case of a request for a second opinion or a hospital that contracts for its radiological interpretations.[42]

In its study for HCFA, the Center for Health Policy Research found that, with some exceptions, radiology using telecommunications is feasible.[43] For providers, training in the use of the equipment appears to be a critical component, particularly learning to manipulate and interpret images using a video image on a monitor. Preliminary research suggests, however, that in most cases radiologists prefer conventional films and view boxes to teleradiology because reading them is less time-consuming and perhaps because they are more familiar with them.[44] The American College of Radiologists is currently evaluating equipment standards and practice parameters.

The field of medical imaging offers one of the most fertile grounds for the application of advanced computer and communications technologies. All-digital systems, known as picture archiving and communications systems (PACS), now offer imaging of sufficient quality for primary diagnosis in radiology, although their high costs are a barrier to diffusion. The University of Virginia operates a PACS system that it plans to hook into two remote sites, at distances of four and 10 miles, using a T1 telecommunications line. Further expansion is planned based on the experience with the two sites.[45]

The use of telecommunications for telepathology is also well established. Because of the need for high-quality imaging, the requirements of pathology call for equipment that is more sophisticated than is required for other telemedicine applications.[46] Early research findings suggest that telemedicine allows frozen sections of tissue specimens to be analyzed accurately.[47] An example of a telepathology program is the Arizona-International Telemedicine Network (AITN), established at the University of Arizona in 1993. Its goals are to provide consultation services, use telepathology in quality assurance programs, participate in research on the development of telepathology systems, and examine the impact of telepathology services on the practice of medicine, including patient outcomes. The network involves five locations in Arizona and one each in Mexico and China.[48]

Home-Based Health Services

In addition to using telecommunications to deliver health services from one medical facility to another, there is also the potential to use it to deliver services to people in their homes.[49] In some ways, electronic "house calls" represent a move back to a health care system that is more home-centered rather than hospital-centered.[50] Using a variety of technologies—including telephone, computers, monitoring devices, and interactive video—telemedicine could reduce or eliminate patient travel, resulting in lower costs for the patient and perhaps making a hospital or clinic visit unnecessary. This could be particularly helpful to people whose mobility is limited or who may not be well enough to travel. The elderly face particu-

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[42] Batnitzky, op. cit., footnote 40, p. 15.

[43] Grigsby et al., Report 1, op. cit., footnote 12, p. 2.13.

[44] Grigsby et al., Report 4, op. cit., 8, p. 2.3.

[45] *Healthcare Telecom Report*, Sept. 12, 1994, pp. 5-6.

[46] Grigsby et al., Report 1, op. cit., footnote 12, p. 2.6.

[47] Grigsby et al., Report 4, op. cit., footnote 8, p. 2.3.

[48] A.K. Bhattacharyya et al., "Case Triage Model for the Practice of Telepathology," *Telemedicine Journal*, vol. 1, No. 1, spring 1995, pp. 9-17.

[49] See also the section on consumer health informatics in ch. 1.

[50] Mary Gardiner Jones, "Electronic House Calls: 21st Century Healthcare Services for Consumers," *Proceedings of the Mayo Telemedicine Symposium*, Oct. 1-3, 1993, p. 39.

lar challenges in meeting their need for services, and advanced telecommunications—particularly two-way video to the home—could ultimately provide them a full range of services.[51]

Home-based telemedicine could be particularly effective for followup care and for monitoring chronic illnesses, such as asthma or diabetes. Monitoring allows preventive measures to be taken before problems get so severe that hospitalization becomes necessary. Telemetry devices at home that connect to a computer—to provide electrocardiograms or blood-pressure readings, for example—could alert the patient's physician that treatment is necessary. Such a system could provide a more cost-effective method of care by reducing medical visits for conditions that are not severe.

Several demonstrations are currently under way related to home delivery of services. For example, in several months, Eastern Carolina University (ECU) will begin home trials for about six patients (initially) for remote cardiac rehabilitation using telephone, cable TV, and telemetry units. Using one-way video and two-way audio, a physician will monitor a patient at home while the patient rides a stationary bicycle. Patients will see the physician on their cable TV and will be able to converse with him or her.[52] This will permit real-time monitoring of their vital signs by the medical center. In addition, ECU and Economic Growth Strategies, Inc., in conjunction with Smart House, has created a health demonstration house. Health House will use interactive communications to provide monitoring, diagnosis, and information products and services.

In collaboration with the Center for Total Access at Fort Gordon and the Georgia Tech Research Institute, the Medical College of Georgia also is planning to place equipment in 25 homes to monitor patients who have frequent hospitalizations or emergency room visits. A similar system will be placed in a large nursing home, and into the home of the nursing home's medical director, to avoid unnecessary admissions to the hospital. The Harvard Community Health Plan in Burlington, Massachusetts, operated a Triage and Education System by placing computer terminals in 150 homes. Patients used the system to get customized health information and guidance based on responses to a questionnaire they completed on the screen. It enabled patients to manage common illnesses or injuries and monitor chronic health conditions. The project was deemed a success, but was discontinued because funds were unavailable to finance it when the demonstration ended.[53]

The Comprehensive Health Enhancement Support System (CHESS) uses an interactive computer system to provide information, social support, and problem-solving tools for people living with AIDS and HIV infection. CHESS was developed at the University of Wisconsin-Madison under a grant from the W.K. Kellogg Foundation. The system provides information, referrals to service providers, patient support in making difficult decisions, and networking with experts and others facing the same concerns. When computers were placed in homes for three to six months, their use was extremely heavy. Subjects who used CHESS reported a significantly higher quality of life in several dimensions, including social support and cognitive functioning. Users also reported significant reductions in some types of health care costs.[54] CHESS has also been used in a study of eight African-American women with breast cancer who lived in impoverished areas of inner-city

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[51] Mary Gardiner Jones, "Meeting the Home Health Care Needs of the Elderly in the 21st Century Through Telecommunications: Report and Recommendations," Consumer Interest Research Institute, Washington, DC, Mar. 10, 1995, p. 6.

[52] *Healthcare Telecom Report*, vol. 2, No. 7, Mar. 28, 1994, p. 1.

[53] Site visit, Harvard Community Health Plan, 1994. Most users liked the system, and HCHP noted a 15 percent increase in the use of self-care to treat health problems, a 14 percent increase in appropriate level of care decisions, and a 5 percent reduction in health center visits.

[54] D.H. Gustafson et al., "The Use and Impact of a Computer-Based Support System for People Living with AIDS and HIV Infection," n.d.

Chicago. It was very well received, extensively used, and produced feelings of acceptance, motivation, understanding, and relief among participants.[55]

Delivering health services directly or providing needed information does not always require the user to have sophisticated equipment. The Connect System at Cleveland State University uses a computer and voice mail system to monitor drug-using pregnant patients, patients in drug treatment, and mothers of newborns. This system is for nonemergencies, and patients access it using a touchtone telephone and a password. It is used to communicate with caregivers, and the computer calls the patient if there is a message waiting. Those without a telephone can call in on a regular basis to collect messages. There is also a Community Health Rap line that will find an expert to answer questions. Telephone Pals will connect patients with others who share a common health condition. Home Monitoring allows a clinician to call a child's parent at regular intervals to ask a series of questions. Answers are sent directly to the clinician, who will contact the parents if there is a need for action. Appointment and medication reminders are also sent. Research showed that sending reminders for immunizations resulted in 82 percent of patients in the experimental group keeping their appointments, compared with 69 percent for the control group. The resulting immunization rates were 68 percent for the experimental group, compared with 45.5 percent for the control group. This is in a community in which only 4 percent graduated high school and 40 percent owned their own telephone (12 percent were both homeless and phoneless).[56]

Other Sites

Telemedicine offers safety, security, and cost advantages in delivering services to correctional facilities. For example, since 1992, the East Carolina University (ECU) School of Medicine has provided consulting services to the Central Prison in Raleigh, North Carolina, a top-security prison.[57] The prison doctor is able to consult via telecommunications with specialists at ECU, thus avoiding the need to transport inmates or bring in specialists. Consultants were reluctant to visit the prison, and the cost of transporting an inmate to the hospital ranged from $700 to $5,000, depending on the amount of security required.

In Texas, the University of Texas Medical Branch at Galveston has seen 40 to 62 patients a week from the prison population in Phase 1 of a program that began in October 1994. Their goal is 100 patients per week by the end of 1995.[58] Patients are usually presented by physician assistants. The Texas prison system is looking at telemedicine as a way to reduce referrals to the state's tertiary care centers, such as the one at Galveston, which are overburdened with inmate referrals. The Medical College of Georgia also is connected to correctional facilities, and inmates who previously needed to be transported for health care can now be treated at the prison using telemedicine.[59]

It seems clear that the delivery of health services using telecommunications is possible in any

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[55] F.M. McTavish et al., "CHESS: An Interactive Computer System for Women with Breast Cancer Piloted with an Under-served Population," n.d.

[56] F. Alemi, Health Administration Program, Cleveland State University, Cleveland, Ohio, personal communication, May 11, 1995.

[57] East Carolina University School of Medicine and the Center for Health Sciences Communication, World Wide Web site home page: <URL: http://www.telemed.med.ecu.edu/>.

[58] R.M. Brecht, "Implementation of Telemedicine Into the Texas Prison System," presented at the Second International Conference on the Medical Aspects of Telemedicine and Second Mayo Telemedicine Symposium, Rochester, MN, Apr. 7, 1995.

[59] J. Sanders, testimony, hearing of the House Committee on Science, Space, and Technology, Subcommittee on Investigations and Oversight, May 2, 1994.

number of settings, including school clinics and nursing homes. In addition to rural areas, experiments are taking place in urban areas as well. An example is at Stanford University in California, where a pilot project is under way to connect an urban clinic serving the poor, a large multispecialty group practice, and a nursing home.[60] Telemedicine's potential to respond in emergency situations, such as natural disasters or military deployments, has already been demonstrated.[61] Decisions concerning potential applications clearly will be based on the usual criteria of how they affect health care costs, access, and quality.

Telemedicine Projects in Other Countries

A number of other countries, particularly those with remote or isolated areas, currently use telecommunications to deliver health services. The characteristics of these programs tend to reflect both the health care and telecommunications policies of the individual country.

For example, in Norway, the health sector has been chosen by the government as one of the main areas for the national plan for information technology.[62] Remote areas and severe winter weather conditions make the delivery of health care difficult. The University Hospital of Tromso, with the support of Norwegian Telecom Research, has been using telemedicine since 1988 for remote diagnosis in Northern Norway for radiology; pathology; dermatology; cardiology; ear, nose and throat; and psychiatry. The system is also used extensively for distance education for physicians and nurses, as well as training in use of the technology. This is a coordinated research and development project with an interdisciplinary research group based in Tromso. Cooperation with institutions and personnel in the regional health service is encouraged. Local research institutions participate and local industry is involved in developing the technology.[63] The telemedicine network is expected eventually to expand to Oslo and additional remote areas of Norway. Plans are also under way to link up with the Mayo Clinic and Johns Hopkins University Hospital in Baltimore, Maryland, for consultations.[64]

In Canada, the oldest and best-known use of telemedicine is at the Memorial University of Newfoundland where its Telemedicine Centre has operated since 1975. The Centre operates a dedicated audio network with 54 sites in health centers and the remainder in community colleges, high schools, university campuses, and government buildings. It provides both health programs (continuing health education, medical data transfer, community health education programs, and health professional meetings) and a wide range of distance education programs and administrative meetings for government and others.[65] Another telemedicine program in Western Canada links Drumheller Regional Health Complex with the University of Calgary and adjoining Foothills Hospital. This program was developed in partnership with Alberta Government Telephones and Calgary-based Hughes Aircraft, which is providing the hardware and software.[66]

South Australia established a Telemedicine Project in June 1991 to examine the potential role of telemedicine in health services delivery. It is a

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[60] Bob Holmes, "Medicine Cruises the Infobahn," *Stanford Medicine*, spring 1995, pp. 20-23.

[61] J.B. Crowther and R. Poropatich, "Telemedicine in the U.S. Army: Case Reports from Somalia and Croatia," *Telemedicine Journal*, vol. 1, No. 1, spring 1995, pp. 73-80.

[62] B.J. Nymo and B. Engum, "Telemedicine To Improve the Quality, Availability and Effectiveness of the Health Service in Rural Regions," paper presented at "Seminar on the Regional Impact of Advanced Telecommunication Services," Kiruna, June 19-21, 1990, p. 1.

[63] Ibid., p. 4.

[64] *Healthcare Telecom Report*, July 18, 1994, p. 8.

[65] Memorial University of Newfoundland, Telemedicine Centre, Information Sheet, 1993.

[66] *Calgary Herald*, "Long-Distance Healing," June 27, 1993, p. A1.

collaborative effort of the Economic Development Authority of South Australia, the South Australian Health Commission, MFP Australia, and Telecom Australia.[67] The project was established between the Royal Adelaide Hospital, South Australia's largest teaching hospital with more than 800 beds and a full range of specialist services, and South Australia's largest country hospital in Whyalla, situated 400 kilometres northwest of Adelaide. The Whyalla Hospital has 150 beds, services a town of 27,000 people, and has a limited range of specialist services. From September 1992 to June 1993, a total of 190 telemedicine sessions were held, divided between education, clinical, administration, and demonstration and training sessions. A study of the project reported that clinical use was most successful for psychiatry, dermatology, and geriatric assessment. Postgraduate medical education and administrative education were also very successful. The project proved less successful for physiotherapy, occupational therapy, speech pathology, and dentistry. The study also concluded that telemedicine services will be most successful where they complement and enhance existing health services.

TELEMEDICINE ISSUES

Like all applications of new technologies, there are barriers to widespread diffusion of telemedicine.[68] Some of the problems are related to the technology, but most can be attributed to other factors.

Reimbursement for Services

A critical issue for telemedicine is whether and how it will be reimbursed by Medicare/Medicaid and other third-party payers. In rural areas, up to 40 percent of physicians' patient base consists of Medicare/Medicaid patients.[69] As one congressman testified at a 1994 hearing on rural health care:

> Telemedicine is particularly important to rural health delivery systems. . . However, without the assurance of payment for telemedicine services, the full potential of telemedical technology will never be realized. . . This administrative roadblock prevents the development and expansion of these systems in rural America.[70]

HCFA, the federal agency responsible for Medicare/Medicaid reimbursement of services, has been under pressure to reimburse for services delivered using telemedicine, and is considering what its policy should be. Traditionally, physicians have not been reimbursed for consultations using telecommunications (i.e., the telephone). Current rules for reimbursement require face-to-face contact (defined as in the same room) between physician and patient. Services that do not involve direct interaction with the patient, such as teleradiology, telepathology, or EKG testing, are also reimbursed;[71] however, consultations in which there is interaction between patient and consultant using videoconferencing are not.[72] Aetna, the Medicare carrier in Georgia, currently covers telemedicine consults at the Dodge County Hospital, part of the Medical College of Georgia's telemedicine system. This policy does not apply to new sites in Georgia.

To assist HCFA in its decisionmaking, the agency commissioned a study of the primary factors to consider in any reimbursement policy. The researchers outlined three principal consider-

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[67] "South Australian Pilot Telemedicine Project," Project Team Evaluation Report, November 1993, p. 2.

[68] For a discussion of barriers to implementation, see J.H. Sanders and R.L. Bashshur, "Challenges to the Implementation of Telemedicine," *Telemedicine Journal*, vol. 1, No. 2, summer 1995.

[69] *BNA's Health Care Policy Report*, vol. 2, Feb. 28, 1994, p. 418.

[70] Pat Roberts, (R-KS), hearing before the Committee on Ways and Means, Subcommittee on Health, House of Representatives, U.S. Congress, Feb. 7, 1994.

[71] Office of Rural Health Policy, op. cit., footnote 14, p. 6.

[72] Ibid.

ations: 1) the adequacy of the technology, 2) medical effectiveness, and 3) the appropriateness of the applications.[73] The report concluded that it would be reasonable to proceed with reimbursement for some telemedicine services—those that are widely accepted as effective; those that are probably effective, but with unknown effects on the health care system (with some restrictions placed on reimbursement); and applications that require basic research (evaluated for reimbursement on a case-by-case basis).[74] Coverage might also be restricted to certain geographic areas, institutions, or applications. In addition to this recently completed project, HCFA is currently supporting several demonstration projects that will help in its decision process. The agency also has funded a telemedicine evaluation project, to be conducted by researchers at the University of Michigan, and a data collection project at the Telemedicine Research Center in Portland, Oregon.

At a May 1994 hearing on "Telemedicine: An Information Highway To Save Lives," a HCFA official testified:

> Because of our limited experience with delivery of telemedical services in the real world, we would like to proceed with caution. However, I can say with confidence, that through the use of pilot projects undertaken by both the Government and private industry, we will be able to learn the best approach to provide effective and efficient health care services for our beneficiaries. HCFA envisions accessible health care being provided through the use of telemedicine and other emerging technologies but it must be based on solid data so that the quality of health care provided is not compromised.[75]

It is unlikely that HCFA will move ahead without a clearer understanding of all the issues. Research currently under way should address some of the questions that the agency would want answered before proposing a uniform reimbursement policy for telemedicine. In the meantime, some experiments could be tried that would further the decisionmaking process, particularly with respect to costs. HCFA is currently seeking a Medicare waiver from the Office of Management and Budget that would allow the agency to provide reimbursement for physician services rendered via telemedicine for pilot projects in Iowa, Georgia, West Virginia, and North Carolina.

HCFA will continue to be concerned about telemedicine's safety and effectiveness, quality of care, practice standards, and the impact on physician distribution. However, the agency will also be concerned about any increase in Medicare spending that could result from reimbursement for telemedicine services. At a time when reductions in the growth of Medicare are being proposed, there will be reluctance to initiate policies that could increase costs by increasing access to services.

Lack of Research/Experience

Another barrier to telemedicine is the lack of research demonstrating its safety and efficacy, clinical utility, and cost-effectiveness. This is a problem for potential users, payers, and policymakers. No one knows for certain which medical conditions are best suited to the use of telemedicine. For example, believing that the "hands-on" experience is critical for initial patient examinations, some providers feel that telemedicine works better for followup care than for an initial visit. Clearly, some procedures are better suited to the use of interactive video than others in terms of the patient's comfort level. Research on patient satisfaction with telemedicine is limited, but results indicate that in general they like it.

Early experiments in telemedicine were terminated before they produced answers concerning its cost, impact on access, and effects on quality of

[73] Grigsby et al., Report 1, op. cit., footnote 12, p. i.

[74] Grigsby et al., Report 4, op. cit., footnote 8, p. 5.1

[75] Helen L. Smits, Deputy Administrator, Health Care Financing Administration, statement at a hearing at the National Institutes of Health before the Committee on Science, Space and Technology, U.S. House of Representatives, May 2, 1994, p. 13.

care.[76] Those projects did not end because they failed to achieve their objectives. Instead, the reasons included: 1) lack of familiarity and limited experience with the systems, 2) lack of institutional commitments to sustain them when outside funding ran out, 3) lack of incentives for physicians to use the systems, 4) limitations of the technology, and 5) poor system planning and design.[77]

In its request for proposals for an exploratory evaluation of telemedicine, the Office of Rural Health Policy listed four primary objectives:

1. to determine the current status of telemedicine in rural health with respect to the number and types of systems in operation, levels of technology employed, types of specialty services provided, utilization of services, costs, and patient and provider acceptance;
2. to explore the effects of telemedicine on access to care, practitioner isolation, and the development of health care networks;
3. to explore the organizational factors (at facility, network, community, and state levels) that aid or impede the successful development and implementation of telemedicine systems; and
4. to develop, test, and refine data collection instruments that may be used in subsequent evaluation efforts.[78]

The results of this exploratory evaluation and other research under way should lay the groundwork for future research projects designed to answer the many questions concerning the effectiveness of telemedicine. Evaluation tools will clarify what telemedicine technologies are most appropriate and which health care services are best suited to remote consultation.[79] The National Library of Medicine, with some support also from HCFA and the Department of Veterans Affairs, is currently sponsoring a study by the Institute of Medicine that will try to establish clear evaluation criteria by which the appropriateness, effectiveness, acceptability, and other aspects of telemedicine might be rigorously measured and assessed. (See also appendix D.)

Several organizations have formed to promote and coordinate telemedicine research activities and share research strategies. Examples are the National Consortium for Telemedicine Evaluation (see box 5-1) and the Clinical Telemedicine Cooperative Group (see box 5-2). The American Telemedicine Association also promotes research as part of a comprehensive agenda for telemedicine.

Telecommunications Infrastructure

The technology exists to provide a wide variety of telemedicine services over regular telephone lines. For example, the teledermatology program at the Oregon Health Sciences University (supported by NLM's High Performance Computing and Communications initiative) uses still images over standard phone lines to transmit skin images. In many rural areas, however, the telecommunications infrastructure does not provide a medical facility with sufficient bandwidth to carry the necessary signals for interactive video telecon-

[76] Bashshur, op. cit., footnote 11.

[77] Ibid., p. 6.

[78] Office of Rural Health Policy, Health Resources and Services Administration, Public Health Service, Department of Health & Human Services, Request for Proposal No. HRSA 240-OA-22(4) for "Exploratory Evaluation of the Rural Application of Telemedicine," 1995, p. 9.

[79] D.A. Perednia, "Evaluating the Use of Telemedicine for Mental Health Applications," June 1994, pp. 8-9.

BOX 5-1: National Consortium for Telemedicine Evaluation

The National Consortium for Telemedicine Evaluation (NCTE) was organized in 1993 at the University of Michigan, School of Public Health, Department of Health Management and Policy for the purpose of conducting multistate, multisite evaluation of telemedicine systems The evaluation IS focused on accessibility, cost, and quality, The consortium serves two specific objectives: 1) to assist in the evaluation of individual telemedicine programs/projects as prototype systems of care involving specific configurations of technology (high end, low end), manpower (MD and non-MD providers), organization (organized and unorganized, Integrated networks), and clinical applications (specific diagnostic services, full service, full-time service) To date, participants in the Consortium include NASA, Medical College of Georgia, University of West Virginia, MD-TM University of Kentucky, Louisiana Health Care Authority, and Mid-Nebraska Telemedicine System, The Consortium is developing detailed methodologies for telemedicine evaluation, including sample design and data collection protocols

SOURCE: National Consortium for Telemedicine Evaluation, Department of Health Management and Policy School of Pubic Health, University of Michigan, Ann Arbor, MI

sultations.[80] The cost of the telecommunications links required for telemedicine represents a major barrier to its broader use. Often new lines must be laid and new tariffs developed. If a single facility has to absorb the full costs of the transmission services. the costs may be prohibitive. In addition to laying a new line for broadband service, it may also be necessary for the communications carrier to install a digital switch to ensure that the quality of the compressed video signals is acceptable.

Boundaries were established after the breakup of AT&T that made telephone calls placed outside the local access transport area much cheaper than those placed within the same service area.[81] The high cost of connectivity between local and long-distance carriers is a difficult hurdle for telemedicine systems to overcome.[82] To lower transmission costs, some have suggested that an *essential service rate* be set for local governments, hospitals, and educational facilities that would provide a basic level of service at guaranteed prices that are not based on distance.[83] In some cases, cooperative efforts among telemedicine providers, state agencies, and telephone companies have resulted in negotiated rates that are more affordable for the providers .84 Implementing telemedicine projects generally is easier in states like Pennsylvania, North Carolina. Georgia, Kansas, and Iowa where statewide networks already exist. As the number of statewide networks increases,

[80] For an in-depth discussion of the rural communication infrastructure, see U.S. Congress, Office of Technology Assessment, op. cit., footnote 9. For further discussion of the communication infrastructure, see U.S. Congress, Office of Technology Assessment. *Critical Connections." Communication for the Future,* OTA-CIT-407 (Washington, DC: U.S. Government Printing Office, January 1990). For a description of broadband network technology, see U.S. Congress, Office of Technology Assessment, *Advanced Network Technology,* OTA-BP-TCT-101 (Washington. DC: U.S. Government Printing Office, June 1993), ch. 3. For an in-depth discussion of the role wireless technologies will play in the emerging Nil, see U.S. Congress, Office of Technology Assessment, *Wireless Technologies and the National Information Infrastructure,* OTA-ITC-622 (Washington, DC: U.S. Government Printing Office, July 1995).

[81] Office of Rural Health Policy, op. cit., footnote 14, pp. 4-5. The report cited the example of the Texas MedNet Project, whose 1992 monthly transmission costs were $27 per mile within the same local telephone service area, and $5 per mile between service areas.

[82] E.G. Tangalos, '"Telemedicine Outcomes: What We Know and What We Don't," paper presented at the Rural Telemedicine Workshop. Office of Rural Health Policy, Washington, DC, Nov. 3-5, 1993, p. 4.

[83] Office of Rural Health Policy, op. cit., footnote 14, P. 17.

[84] Dena S. Puskin and Jay H. Sanders, "Telemedicine Infrastructure Development, ''. *Journal of Medical Systems,* vol. 19, No. 2, 1995, p. 2.

BOX 5-2: Clinical Telemedicine Cooperative Group Organized by the Telemedicine Research Center (TRC) Oregon Health Sciences University

The Clinical Telemedicine Cooperative Group (CTCG) is a not-for-profit, independent medical research corporation with offices in Portland, Oregon, and Kansas City, Kansas CTCG members share common telemedicine research protocols, data collection instruments, and testing methodologies, By coordinating research efforts, members are able to perform statistically valid telemedicine research faster, and at a lower cost, than would otherwise be possible, Expertise in computer systems, research design, imaging, statistical analysis, engineering, and specific medical expertise is available to CTCG members through TRC staff and affiliates The CTCG network is based on successful community-based research cooperatives---models that demonstrate the advantages and validity of large-scale, multicentered trials in clinical research. Pilot funding for the CTCG was provided by the Health Care Financing Administration.

SOURCES: D.A. Perednia, "Telemedicine System Evaluation and a Collaborative Model for Multi-centered Research,*Journal of Medical Systems,* vol. 19, No 3, 1995, and J Kadel, Member Information Coordinator, CTCG, Oregon Health Sciences University, Portland, OR personal communication, July 11, 1994

more and more uses will be found for telemedicine in both rural and urban areas.

In rural areas, hospitals, schools, government, and other community groups can aggregate demand and share a network to help spread the system costs. This can only be accomplished, however, when residents are involved in planning and developing a system and have a sense of ownership in it. In an earlier study, OTA suggested that Rural Area Networks would allow rural communities to customize networks to their own needs, while achieving economies of scale and scope[85] (see figure 5-3). By sharing in the creation of such a network, rural communities would be able to enjoy some of the benefits of their urban counterparts. A system of "bandwidth on demand", in which users pay only for the time they use on the system, would greatly reduce the costs of telemedicine and obviate the need for a dedicated communications line. Such service could be provided using an advanced switching technology such as asynchronous transfer mode, which can support many different kinds of services. To ensure that systems are interoperable, technology standards will be essential for communication providers.[86] Many of these issues are currently being addressed in the context of the Administration's NII initiative, particularly by members of the Information Infrastructure Task Force (IITF).

Delivering health care to the home is increasingly important for people who need convalescent or chronic care. A public network that can provide two-way video, high speed data transfer, and graphics is required before a wide range of health services can be delivered directly to the home. Some telephone companies are beginning to respond to this recognized need by devising strategies to implement such advanced services, and home services are figuring prominently in NII discussions.

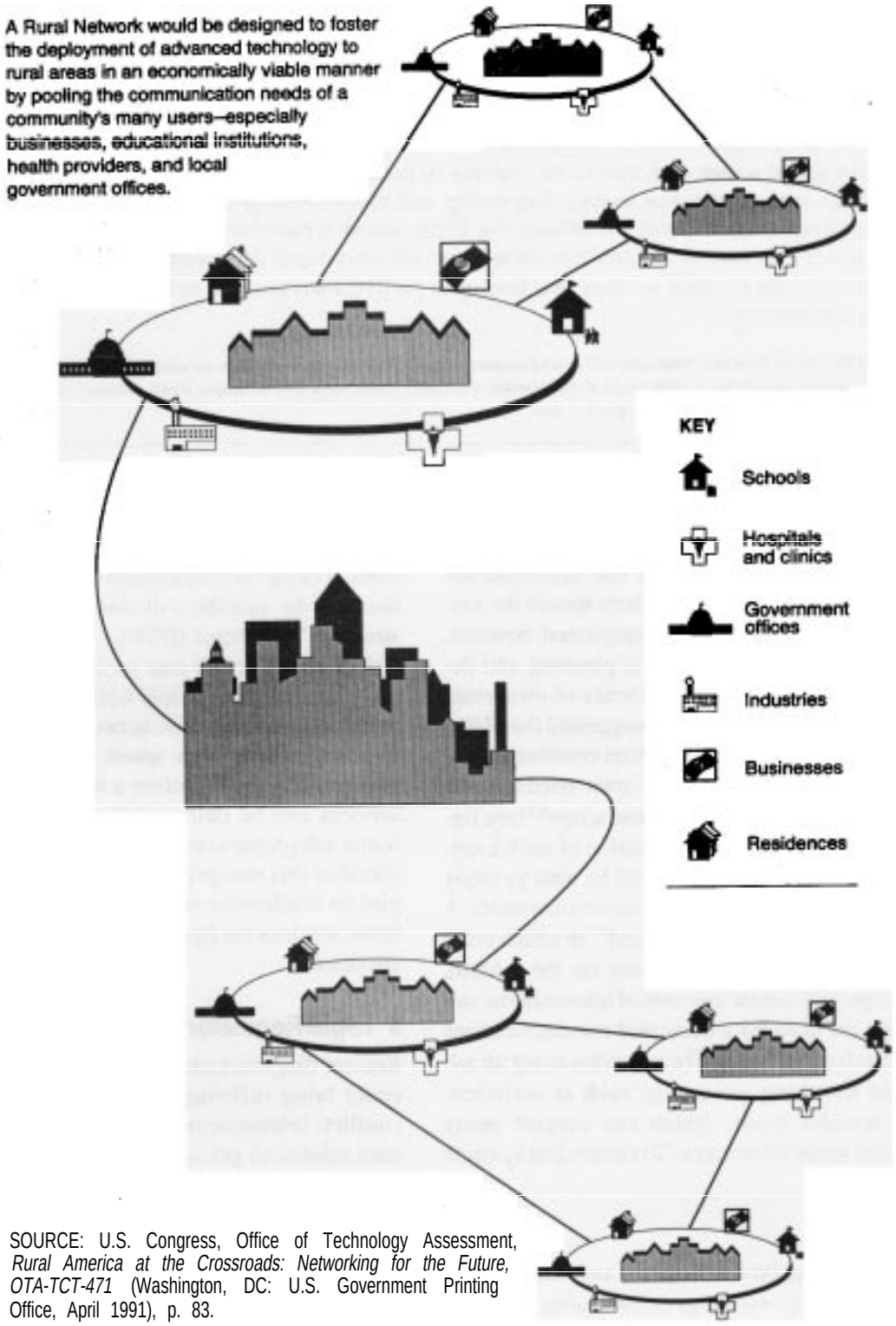
▮ Legal/Regulatory

Remote diagnosis and treatment across state lines could bring differing laws and regulations into conflict. Telemedicine raises a number of legal issues related to privacy/confidentiality, licensing

[85]U.S. Congress, Office of Technology Assessment, op. cit.. footnote 9, p. 59.

[86]For discussions of technology standards, see chs. 1 and 2. See also U.S. Congress, Office of Technology Assessment, *Global Standards: Building Blocks for the Future,* TCT-512 (Washington, DC: U.S. Government Printing Office, March 1992).

FIGURE 5-3: Rural Area Networks



SOURCE: U.S. Congress, Office of Technology Assessment, *Rural America at the Crossroads: Networking for the Future, OTA-TCT-471* (Washington, DC: U.S. Government Printing Office, April 1991), p. 83.

and credentialing, and liability that could represent significant barriers to its broader diffusion.

Privacy and Confidentiality

Privacy in health care information has been protected in two ways: 1) in the historical ethical obligations of the health care provider to maintain the confidentiality of medical information, and 2) in a legal right to privacy, both generally and specifically, in health information. *Confidentiality* involves control over who has access to information. Other terms frequently used in privacy protection discussions are integrity and security. *Integrity* assures that information and programs are changed only in a specified and authorized manner, that computer resources operate correctly, and that the data in them are not subject to unauthorized changes. A system meeting standards for access allows authorized users access to information resources on an ongoing basis.[87] *Security* refers to the framework within which an organization establishes needed levels of information security to achieve, among other things, the confidentiality goals.[88]

The use of telecommunications to deliver medical care may pose additional risks to the privacy of patients and their records. For example, the creation of a videotape of a consultation might pose a new privacy threat for the patient unless appropriate safeguards to control access to it are built into the process. The issue of who has access to this information will need to be considered and resolved in advance. Depending on the nature of the examination, the patient may also have privacy concerns in terms of who is actually present in each location during the consultation. Nonmedical personnel, such as a technician or facilitator, may be needed to assist in the consultation.

If a videotaped consultation becomes part of the patient's medical record, it would be treated like other videotaped information on the patient (e.g., an angiographic procedure, for example). In these cases, the usual privacy laws would apply. State laws governing the transmission and retrieval of patient medical records vary, and officials are concerned about user verification and access, authentication, security, and data integrity.

A previous OTA study found that the present system of protecting health care information offers a patchwork of codes; state laws of varying scope; and federal laws applicable to only limited kinds of information, or information maintained specifically by the federal government.[89] The present legal scheme does not provide consistent, comprehensive protection for privacy in health care information, whether it exists in a paper or computerized environment. Clearly the privacy implications for telemedicine will continue to receive careful scrutiny. Vice President Gore has recently asked the Department of Health and Human Services (DHHS) to develop model institu- tional privacy policies and model state laws for health information in the context of the NII.[90] This activity is to be coordinated with the activities of the IITF in the privacy area.

Physician Licensing

Physicians must be licensed by the states in which they practice. Telecommunication facilitates consultations without respect to state borders and could conceivably require consultants to be licensed in a number of states. This would be impractical and is likely to constrain the broader diffusion of telemedicine programs. In July 1994, the State of Kansas passed legislation requiring

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[87] C.P. Pfleeger, *Security in Computing* (Englewood Cliffs, NJ: Prentice Hall, Inc. 1989), pp. 5-6.

[88] Ibid., p. 90.

[89] 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), pp. 12-13.

[90] Vice President Al Gore, memorandum to Donna Shalala, Secretary of Health and Human Services, Mar. 8, 1995.

that out-of-state physicians who provide consultations using telemedicine be licensed in Kansas.

The licensing problem for telemedicine could be addressed by the implementation of national licensing standards or the classification of physicians practicing telemedicine as consulting physicians, thereby circumventing state rules. For a start, such a national license could be provided to physicians who provide consultations to *underserved* populations. A precedent exists for physicians serving in the military, the Department of Veterans Affairs, the Indian Health Service, and the Public Health Service.[91] Another way to address the problem of licensing is to place the overall responsibility for the patient's care in the hands of the referring physician and view a consultant in a different state as making recommendations only. A novel approach unique to telemedicine would be to consider that the patient is being "transported" electronically to the consultant, thus obviating the need for the specialist to be licensed in the patient's home state.[92]

The issue of credentialing arises with telemedicine in terms of the use of consultants. In the Medical College of Georgia program, the Joint Commission on Accreditation of Hospitals (JCAHO) has determined that hospital credentials are not a problem for the consulting physician as long as all physician orders are written by the referring physician. The Federation of Boards of State Medical Examiners has established a task force to deal with the problem of providing interstate telehealth care, while preserving state licensure, credentialing, and monitoring of health care professionals.[93]

Liability

The liability implications of telemedicine are unclear. At least two aspects of telemedicine could pose liability problems. One is the fact that, in a remote consultation, the specialist does not perform a hands-on examination, which could be regarded as delivering less than adequate care. The second aspect is that the use of compressed video, in which repetitious information is eliminated as the data are converted from analog to digital and back, may raise the issue of diagnosing with less than complete information.[94] On the other hand, telemedicine may, in fact, decrease the threat of malpractice suits by providing better recordkeeping and databases, and the fact that taping the consultations will automatically provide proof of the encounter. Tapes could also help to prove the innocence of providers who are falsely accused.

Consulting physicians could reduce their liability by adhering to practice guidelines for various telemedicine applications. Such guidelines would need to be established by national health professional associations.[95] Another way of limiting liability would be to protect physicians and medical centers that provide telemedicine consultations to the underserved under the doctrine of *sovereign immunity*, which might take the form of a cap on economic damages or some other hold-harmless protection.[96] Liability considerations for telemedicine must, of course, be viewed in the context of ensuring the patient adequate recourse in cases of actual negligence.

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[91] Sanders and Bashshur, op. cit., footnote 68.

[92] Ibid.

[93] J. Preston, M.D., President, American Telemedicine Association, personal communication, May 14, 1995.

[94] Office of Rural Health Policy, op. cit., footnote 14, pp. 8-9.

[95] Ibid., p. 9.

[96] Ibid.

Development Costs/Financing

The costs of developing a telemedicine project can be high. These costs include telecommunication charges, equipment costs, technical support, training, and administrative support. Many small communities operating on their own will be unable to afford these costs. Telemedicine lends itself to cost-sharing as a way of financing projects as well as assembling the expertise necessary to make it successful. For example, the Medical College of Georgia project is a partnership that includes private industry, the state government, the Governor's office, academia, and, most importantly, the primary health care facilities. There are many other examples of groups working together to share the expense of building a system. Within communities, systems that are too costly for health applications alone can be shared with educational, local government, social, and community services to make the investment feasible.

One suggestion for small rural health care facilities is to lease a system for three to five years. The revenue generated by the anticipated increase in bed census and ambulatory care activity could be used to offset the leasing costs. Some facilities may still need government support in the form of a loan for start-up purposes before they could assume the costs of leasing a system.[97]

Technological and Implementation Issues

In implementing a telemedicine project, it is important to first define its objectives, and then select the appropriate technology to meet those needs.[98] The focus should be on how telemedicine can contribute to better clinical decisionmaking and patient care. Depending on what the project is designed to achieve, the technology might range from a touchtone telephone to a sophisticated multimedia system. This points to the need for careful planning in advance and a clear understanding of the project goals. Experience suggests the need for a flexible, open system that can easily be adapted to advances in technology. The complexity and sophistication of the technology selected will depend on what it is required to do. Transmission speed, image resolution, storage capacity, mobility, and ease of use are important considerations.

Those who will be using the system must be involved in its design from the beginning. Once implemented, onsite technical assistance is necessary to ensure that any technological problems can be immediately addressed and rectified. It is important that the system be conveniently located so providers can access it easily. Adequate training must be provided, and the presence of a facilitator will ensure that consultations run smoothly. As desktop multimedia telemedicine platforms become available to place in the health care provider's office, issues of cost, location, convenience, and the operational and maintenance difficulties of telemedicine will diminish significantly.

One of the barriers to telemedicine is the lack of technical standards. To achieve an integrated network of providers, the ability to interconnect using uniform standards will be essential. (Technical standards are discussed in detail in chapter 2.)

Earlier telemedicine demonstration projects often did not survive when funding ended. Some also ceased to function when individuals who had spearheaded the projects left. Some recent federal grants made for telemedicine demonstration projects are building in safeguards to ensure that projects have the ability to continue beyond the pilot stage. Some researchers suggest that relying on any government funding can be a potential impediment to implementation. Administrators will need to be convinced that telemedicine consultations will provide the possibility of generating

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[97] J.H. Sanders, "Telemedicine: Challenges to Implementation," paper presented at the Rural Telemedicine Workshop sponsored by the Office of Rural Health Policy, Nov. 3-5, 1993, p. 9.

[98] D.S. Puskin, "Telecommunications in Rural America: Opportunities and Challenges for the Health Care System," *Annals of the New York Academy of Sciences,* vol. 670, Dec. 17, 1992, pp. 71-72.

revenue to cover their costs. Assuming reimbursement is available for services delivered using telemedicine, a telemedicine system should only be initiated if the economics can support its operation.[99]

Human Infrastructure

While issues related to technology are important and often get most of the attention, it is also apparent that organizational, management, and human factors also play a critical role in implementing a telemedicine system. As one telemedicine user points out:

> In the final analysis, it will be the human component at each end of the system—not the technology—that will determine whether it is successful or not.[100]

A family physician who worked in a hospital that had installed a little-used teleradiology system commented that "the personnel part of the equation is far more complex and difficult than the technology part of the equation."[101] For example, the nature of the relationship between the referring and consulting physicians may be a key factor in whether or not a system is fully used. Existing referral relationships between providers may need to be altered when telemedicine is introduced, which could cause some dislocations and affect its use.[102]

How well the system is organized, managed, and maintained, as well as whether or not it is conveniently located, will help to determine its rate of use. Several telemedicine programs have reported that scheduling can be a major problem. Because time is an important factor to busy professionals, they are likely to be more responsive to using telemedicine if scheduling is efficient and convenient. This problem may be resolved when the telemedicine technology eventually reaches the physician's desktop.

Resistance to change is often a problem when new technologies are introduced. Health care professionals are no exception, and many will not be interested in or willing to participate in telemedicine. Some will feel threatened by the introduction of technology into their practice. However, as one telemedicine pioneer put it:

> Telemedicine does not replace the physician or relegate him to a less important role. Telemedicine depends upon him and his special abilities, and it offers him a new way to practice medicine. Through an interactive telemedicine system, the fundamental doctor-patient relationship not only can be preserved, but potentially augmented, enhanced and more critically focused.[103]

Nevertheless, telemedicine will change the way providers practice. Some practitioners will miss the hands-on aspects of examining a patient that has been such an integral part of their medical training and experience.[104] Some may also have concerns about the quality of the image or the ability to make an accurate diagnosis based on the available equipment.[105]

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[99] J.H. Sanders, Professor of Medicine, Medical College of Georgia, personal communication, May 1995.

[100] Office of Rural Health Policy, op. cit., footnote 14, p. 13.

[101] Tom Dean, quoted in "Is Telemedicine the Answer to Rural Health's Problems?" *Rural Health News*, vol. 1, No. 2, spring 1994, p. 9.

[102] P. Whitten and T. Franken, "A Survey of Rural Primary Care Practitioners' Attitudes and Perceptions of Telemedicine," abstract book, Second International Conference on the Medical Aspects of Telemedicine and Second Annual Mayo Telemedicine Symposium, April 1995, p. 6.

[103] K.T. Bird, "Telemedicine: Concept and Practice," in R.L. Bashshur, P.A. Armstrong, and Z.I. Youssef (eds.), *Telemedicine: Explorations in the Use of Telecommunications in Health Care* (Springfield, IL: Charles C. Thomas, 1975), p. 90.

[104] Researchers at the Georgia Institute of Technology are working on a project to design a glove that could be worn by the consultant that would mimic the hands-on experience.

[105] Grigsby et al., Report 4, op. cit., footnote 8, p. 7.2.

BOX 5-3: American Telemedicine Association

The American Telemedicine Association (ATA) was incorporated in 1993 to promote professional, ethical, and equitable Improvement in health care delivery through telecommunications technology and to enhance broad-based community telecommunications applications. The Association will: 1) promote telemedical research and education; 2) assist in the development of telemedical policy and standards, 3) provide education to public and professional organizations; **4)** interact with worldwide communication systems, 5) serve as a clearinghouse for telemedical information and services; and 6) support local health care system initiatives in telemedicine, especially in medically underserved areas, In November 1994, the Board of Directors adopted a set of telemedicine policy priorities focused on practice guidelines, privacy, liability, reimbursement, medical licensure, national disasters, technology development, the national telecommunications Infrastructure, research and demonstrations, and interactive distance learning.

ATA affords a structured forum for clinicians, technologists, research bodies, and public policy institutions. It has provided leadership in consumer advocacy for reimbursement, provided an emergency response structure that Incorporated guidance from those at the site in a recent national disaster, stimulated educational and political action with organized medicine, Initiated research and teaching recommendations for medical schools by national medical leaders, and provided testimony before Congress,

SOURCES: American Telemedicine Association information sheet, n d , American Telemedicine Association Policy Priorties, November 1994 and Jane Preston President, American Telemedicine Association, personal communication, May 14, 1995

TELEMEDICINE POLICY OPTIONS

There is ongoing activity and interest in telemedicine at the federal level in both the executive and legislative branches. A community of people interested in telemedicine—including representatives from federal agencies, Congress, telemedicine users, researchers, and vendors—meet in a variety of forums. Hearings have been held, seminars have been conducted, and demonstrations of telemedicine have been provided. At the same time, the number of organizations, conferences, newsletters, and journals related to telemedicine is rapidly proliferating, and online information and discussion groups have helped to inform people about its potential (see appendix E).

Responsibility for telemedicine policy is shared among federal, state, and local lawmakers, and many of the decisions affecting the diffusion of telemedicine are influenced largely by the private sector. Groups such as the American Telemedicine Association have provided leadership in consumer advocacy for reimbursement, stimulated educational and political action with organized medicine, initiated research and teaching recommendations for medical schools, and testified before Congress (see box 5-3). Federal efforts to reform both health care and telecommunications, each traveling its separate path, will have an impact on telemedicine's progress. As noted by one telecommunications expert:

> . . . Telemedicine barely rated a blip on the radar screen when Congress debated new telecommunications legislation last year. This omission is all the more remarkable in [that] . . . the other major legislative initiative in the 103d Congress was improving Americans' access to health care while simultaneously controlling health care costs . . . Congress dealt with communications in one hearing room and health care in another [and] failed to connect the two together. [106]

[106] Newton W. Minow, Director, The Annenberg Washington Program, "Telecommunications, Medicine and the Public Interest," speech given at the Second International Conference on the Medical Aspects of Telemedicine and Second Annual Mayo Telemedicine Symposium, Rochester, MN, Apr. 8, 1995.

Aspects of telecommunications reform related to universal service, health care, and tariffs are relevant to telemedicine. Health care reform initiatives center on reducing costs and improving access and quality. These goals reflect the trends toward managed care, new competitive strategies on the part of health care providers, and the move toward outpatient care and away from large inpatient facilities.

Federal telecommunications policymakers involved in reform initiatives have an important role to play in ensuring that proposed legislation supports the delivery of health care using telecommunications. The Snowe-Rockefeller amendment to the Telecommunications Competition and Deregulation Act of 1995, S. 652, supports access to the NII for schools, libraries, and rural health care providers. Section 253 of the Act on Universal Service calls for actions that will benefit consumers in rural and high-cost telecommunication areas. In Congress, both the House/Senate Ad Hoc Committee on Telemedicine and Health Care Informatics and the Congressional Rural Caucus continue to explore the potential of telemedicine to meet the needs of their constituents. A telemedicine conference held at Airlie House in Virginia, in August 1994, was requested by the Ad Hoc Committee, and a report was recently released that sets out a policy agenda for telemedicine over the next several years.[107]

Telemedicine is considered an integral part of the Administration's NII planning efforts. A key player is the Information Infrastructure Task Force, a forum where both telecommunications and health care needs converge. Telemedicine is being addressed by a task force subgroup, and considerable progress has already been made toward formulating telemedicine strategies. The National Telecommunications and Information Administration is helping to fund telemedicine demonstration projects through its Telecommunications and Information Infrastructure Assistance Program. The National Information Infrastructure Testbed, a nonprofit consortium, has provided telemedicine demonstrations as part of its goal of advancing the NII (see box 5-4). Along with NII activities, federal agencies such as the Office of Rural Health Policy, the Rural Utilities Service, the National Library of Medicine, the Department of Defense, the Department of Veterans Affairs, the Agency for Health Care Policy and Research, and the Health Care Financing Administration support telemedicine in various ways (see appendix D).

Telemedicine is likely to proceed with or without federal support. However, federal government support will be required to guarantee that telemedicine benefits those who need it most—people living in rural locations, inner city areas, and Native American communities that the private sector is likely to bypass for more lucrative areas. In a time of fiscal constraints, any federal funding provided will need to be carefully monitored to ensure it is being used wisely. If Congress wishes to encourage the diffusion of telemedicine, it can have the most impact in the areas of research funding and reimbursement for telemedicine services. The two are closely connected, in that formulating a reimbursement policy is dependent on obtaining satisfactory answers to many of the questions raised about telemedicine.

Federal Funding for Telemedicine Research

One option for Congress is to continue to provide funding for telemedicine demonstration and evaluation projects. Telemedicine research currently under way is critical to answering many of the questions about its efficacy and effectiveness. Proposed funding cutbacks could adversely affect these efforts, many of which are just getting started. Requiring matching funds or other con-

[107] Bashshur et al. (eds.), *Working Conference on Telemedicine Policy for the NII*, sponsored by the Health Information and Application Working Group of the IITF Committee on Applications and Technology and the Senate/House Ad Hoc Steering Committee on Telemedicine and Health Care Informatics, coordinated by the Center for Public Service Communications (Washington, DC: May 1995).

BOX 5-4: National Information Infrastructure Testbed

The National Information Infrastructure Testbed (NIIT) is a nonprofit consortium of over 50 members formed by industry with participation by academic institutions and government agencies to accelerate the development of a National Information Infrastructure (Nil) Members participate in a series of application-focused demonstration projects designed to assess the technological, operational, and policy issues associated with creating an NII. NIIT's Healthcare Working Group consists of organizations such as AT&T, Hewlett-Packard, Hughes Aircraft Co , Jet Propulsion Laboratory, Lawrence Livermore National Laboratory, Network Systems Corp., Pacific Bell, Polaroid Corp., Sandia National Laboratories, SunOptics Communications, University of Southern California (USC) Medical Center, the USC-Advanced Biotechnical Consortium, and WilTel. In September 1994, the NIIT presented a nationwide demonstration via satellite to congressional and Administration staff in Washington, DC The demonstration was based on a simulated medical emergency using teleconsultation, 3-D Imaging, and real-time collaboration in the diagnosis and treatment of a patient.[1]

SOURCE: Background materials provided by the National Information Infrastructure Testbed, Sept. 20, 1994

[1] Background materials provided by the National Information Infrastructure Testbed, Sept. 20, 1994

tributions from those applying for federal grants is one way of leveraging investments in telemedicine projects. This mechanism necessitates a major investment and commitment on the part of the grantees, which helps ensure that projects will continue after federal funding ceases. Innovative approaches to funding should be considered wherever possible to get the most out of scarce financial resources.

Until recently, there was little or no coordination of telemedicine activities among federal agencies. Mechanisms are now in place through the telemedicine working group of the Administration's Information Infrastructure Task Force to monitor and coordinate federal support of telemedicine, which is essential in the current climate of budget cutbacks and fiscal constraint. Representatives of federal agencies have been meeting regularly for over a year in an effort to share information and begin to coordinate telemedicine funding activities.

Current federal funding for telemedicine is heavily weighted toward rural communities. Because telemedicine could provide a partial solution to the severe problems faced by some inner-c it y health care providers, this also would be a fertile area for federal support, perhaps in cooperation with private sector organizations. Funding for telemedicine demonstrations in other areas, such as public health or geriatrics, could also provide valuable information to Congress and the Administration about its potential value in improving health care delivery.

Fostering Cooperative Strategies

To reduce the cost barriers of implementing telemedicine, *Congress could provide incentives to encourage cooperative efforts and consortia.* In many small communities, it makes economic sense for groups to share the costs of implementing, operating, and maintaining a telecommunications network. For example, schools, medical clinics, libraries, social service agencies, and others who would benefit from improved information services may need to join forces to share the costs of a system. Federal funding could be designed to encourage and reward such cooperative efforts.

The U.S. military and NASA have been leaders in research related to telemedicine applications. The military has devised ways to use telecommunications to deliver health care to remote areas, whether for battlefield or peacekeeping opera-

BOX 5-5: Telemedicine Information Exchange

The Telemedine *Information Exchange* (TIE) was launched in February 1995 by the Telemedicine Research Center (TRC) at the Oregon Health Sciences University in Portland, Oregon Begun with demonstration funding from the Health Care Financing Administration and several private corporations, TIE provides a comprehensive telemedicine clearinghouse that is easy to use, easily accessible, comprehensive, and continuously maintained TIE uses available health care Information resources, and currently benefits those directly or indirectly affected by telemedicine, including health care providers, individuals, community and economic development leaders, and rural-based corporations The databases include complete bibliographic Information, listing of active telemedicine programs, legislative and funding information, upcoming meetings, and relevant product and services. Updated weekly, TIE is available to users online, 24 hours-per-day, through use of computer modems, toll-free 800 number services in the continental United States (1 -800 -555 -5 TIE), and the Internet System via World Wide Web Client Access <URL http//tie.telemed.org/ >

SOURCE: D. A. Perednia, Oregon Health Sciences University, personal communication, May 9, 1995

(ions. In some cases, the military is cooperating with civilian health care personnel to deliver telemedicine services. For example, Eisenhower Medical Center is working with the Medical College of Georgia to develop the "electronic housecall." In addition, the Army's health care system in Georgia will utilize the civilian telemedicine infrastructure. Walter Reed Army Medical Center works with North and South Carolina in collaborative telemedicine projects. In a pilot project, the Naval Hospital at Camp Lejeune will link East Carolina University using asynchronous transfer mode technology, focusing on emergency care and teleradiology.[108] The military and the Department of Veterans Affairs have health facilities throughout the country, and could be encouraged to cooperate with local civilian groups in setting up a telemedicine system. Wherever possible, cooperative efforts could be fostered to spread the federal expertise as broadly as possible and take advantage of economies of scale and scope.

■ Disseminating Research Results

In many cases, the people who might benefit most from telemedicine applications know very little about them. The recent increase in seminars and meetings on the subject, especialy those that offer continuing medical education credits and research presentations, is beginning to fill some of the knowledge gap. Online databases are also helpful in spreading information about telemedicine. However, as government-supported research results become available, it is important that agencies disseminate these as widely as possible to providers in rural and other underserved areas. The electronic clearinghouse concept would be a useful vehicle to educate potential users, although in many cases those with the greatest need to know may not have the means to access electronic databases.

Congress might wish to ensure that mechanisms exist to widely disseminate research results and other information about telemedicine. This could be done by a federal agency within DHHS, such as the National Library of Medicine or the Office of Rural Health Policy.

One of the original goals of the IITF's telemedicine working group was to prepare an online database of federal telemedicine projects. When this is complete, and if it is kept current, it should pro-

[108] From East Carolina University School of Medicine World Wide Web home page <URL:http://www.telemed.med.EDU/>.

vide information that will track federal spending on telemedicine. An electronic clearinghouse of information concerning telemedicine would greatly facilitate the sharing of all types of information related to telemedicine. A viable alternative to a federal clearinghouse would provide support for a private-sector group, such as the Telemedicine Information Exchange (TIE) network operated by the Telemedicine Research Center at the Oregon Health Sciences University (see box 5-5). This option would avoid duplication of effort, although a database of federal activities might still be desirable. The major problem with any online database is keeping it up to date. Sufficient staff and financial support would be required to do this, whether in the public or private sectors.

Reimbursing for Telemedicine Services

Because the data that would support a uniform reimbursement policy for telemedicine consultations are not yet available, HCFA is moving slowly and deliberately in accumulating the necessary information on which to base a sound decision. This seems a prudent strategy. Experimenting with reimbursement in certain demonstration sites will provide valuable insights that will eventually enable the agency to craft a careful policy based on actual results. *Congress may wish to ensure that adequate funding is provided to support those experiments.* As the results of these experiments become available, *Congress may wish to provide oversight and conduct hearings* to determine if further action is required.

Appendix A: Workshop Participants

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Appendix C Applications of Clinical Decision Support Systems[1]

C

Clinical Decision Support Systems (CDSSs)—at least those whose effectiveness has been evaluated—perform one or more of the following functions: diagnosis, drug dose determination, preventive care reminders, and active (diagnostic or therapeutic) care advice.[1] These applications and some recent examples —including ones whose effectiveness has *not* been evaluated—are discussed in the following sections. With most of these systems, clinicians do not interact directly with the computer; rather, staff personnel input the needed data on the patient and provide the clinician with computer-printed reports.[2]

COMPUTER-AIDED DIAGNOSIS

These systems are designed to assist the clinician in determining the patient's exact diagnosis or the condition underlying his/her presenting health problem. The systems take as input the patient's signs and symptoms, physical findings, test results, and background information, and then report one or more possible diagnoses that match that combination of characteristics. The patient data must ordinarily be manually key-entered in a particular format required by the system. Rather than attempting to cover all diagnoses, most systems focus on specific health problems.

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[1] Johnston et al., op. cit., footnote 1. Connelly and Bennett propose a similar scheme for classifying the functions of knowledge-based systems that have clinical laboratory applications: classify (e.g., diagnosis), predict (e.g., adverse events), plan (i.e., recommend specific actions), monitor (including alerts, reminders, and process control/scheduling), facilitate (make a human task easier), and convey (present data, conclusions, etc.). D.P. Connelly and S.T. Bennett, "Expert Systems and the Clinical Laboratory Information System," *Clinics in Laboratory Medicine*, vol. 11, No. 1, March 1991, pp. 136-138.

[2] Johnston et al., op. cit., footnote 1, p. 137.

However, several systems, including Dxplain,[3] Iliad,[4] Meditel,[5] and QMR,[6] are designed to address the entire field of internal medicine. They employ either deterministic or probabilistic/adaptive algorithms to produce a list of possible diagnoses, ranked in order of likelihood.[7]

DRUG DOSE DETERMINATION

These systems are designed to assist the clinician in determining the proper dosage of a specific drug for a particular kind of patient.[8] Some evidence suggests that clinicians have a particularly difficult time calculating drug dosages.[9] Again, data on the patient is usually entered manually in a format required by the system. (The patient's diagnosis is usually assumed by the system, based on the drug being used.) The algorithms in the knowledge base then ascertain the proper dosage of the drug in question, either as an exact quantity or as a permissible range. One example of such a system generates estimates for dosing of aminophylline for acute asthma cases presenting in the emergency room.[10] Commercial programs have also been developed for dosing of selected drugs based on patient-specific characteristics and measured drug concentrations.[11]

PREVENTIVE CARE REMINDERS

These systems are designed to remind the clinician to administer a particular preventive service when the patient reaches a certain stage in the process of care for a given health problem (e.g., retinal examination for diabetics), or simply a certain stage of life (e.g., immunization). Unlike computer-aided diagnosis and drug-dose determination, which are usually designed to provide a single report in response to a specific set of data on a given patient, a preventive care reminder system requires repeated input of data on the patient over time. This includes not only the patient's diagnoses and other clinical characteristics, but also the treatments and tests administered and when they were administered. To the extent that the set of rules for generating reminders represents a model of the disease process for which a preventive service is to be administered, they constitute a type of formal clinical protocol.

The protocol specifies exactly what preventive treatments should be performed at each stage in the process of care for the health problem at hand, based either on the amount of time that has elapsed since the previous stage (e.g., a previous treatment or test) or on data values measuring the patient's

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[3] Massachusetts General Hospital, Boston, MA.

[4] Applied Informatics, Salt Lake City, UT.

[5] Meditel, Devon, PA.

[6] CAMDAT, Pittsburgh, PA.

[7] E.S. Berner et al., "Performance of Four Computer-Based Diagnostic Systems," *New England Journal of Medicine*, vol. 330, No. 25, June 23, 1994, pp. 1792-1796; R.A. Miller, "Medical Diagnostic Decision Support Systems—Past, Present, and Future," *Journal of the American Medical Informatics Association*, vol. 1, No. 1, January/February 1994, pp. 8-27.

[8] R.W. Jelliffe et al., "Adaptive Control of Drug Dosage Regimens: Basic Foundations, Relevant Issues, and Clinical Examples," *International Journal of Biomedical Computing*, vol. 36, No. 1-2, June 1994, pp. 1-23.

[9] S. Rolfe and N.J.N. Harper, "Ability of Hospital Doctors To Calculate Drug Doses," *British Medical Journal*, vol. 310, No. 6988, May 6, 1995, pp. 1173-1174.

[10] E.R. Gonzales et al., "Computer-Assisted Optimization of Aminophylline Therapy in the Emergency Department," *American Journal of Emergency Medicine*, vol. 7, No. 4, July 1989, pp. 395-401.

[11] Dasta et al., op. cit., footnote 1.

condition at that point in time. The Regenstrief Medical Record System at Indiana University[12] was apparently the first CDSS to develop a comprehensive set of preventive care reminders, for example, to administer influenza vaccinations.[13] More specialized examples include two systems that provide reminders to perform blood pressure measurement and cervical cancer screening, respectively.[14] The HealthQuiz program elicits background information and risk factors from patients, then compares their answers to detailed preventive care guidelines, flags problems, and recommends appropriate interventions.[15]

ACTIVE-CARE ADVICE

These systems are designed to assist the clinician in performing diagnostic or therapeutic procedures (including pharmaceutical treatments) when the patient reaches certain stages in the process of care for a given health problem, again often modeled in a formal clinical protocol. An active-care advisory system requires repeated input of data on the patient's health problems, tests, and treatments over time. The protocol specifies exactly what diagnostic and therapeutic procedures should be performed at each stage in the process of care for the health problem at hand. This type of computer-based clinical advice can take six basic forms:

1. *Treatment recommendations* (including pharmaceuticals) appropriate for the health problem at hand, for example, the MYCIN program that provides diagnostic and treatment advice for patients with meningitis,[16] and the *antibiotic consultant* component of the Health Evaluation through Logical Processing (HELP) system at LDS Hospital in Salt Lake City, Utah, that recommends appropriate antibiotics in light of the patient's characteristics and specific infection, drawn from an electronic medical record.[17]
2. *Reminders* to the clinician to perform specific diagnostic or therapeutic procedures at certain stages in the process of caring for the health problem at hand, such as adult respiratory distress syndrome in the HELP system.[18]
3. *Alerts* to the clinician regarding potential adverse events, for example, worsening of the patient's condition, based on feedback of abnormal test results.[19]
4. *Feedback* (including alerts) regarding orders that the clinician entered for the patient, including:

- possibly inappropriate treatments, given the patient's complicating health problems and/or

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[12] C.J. McDonald et al., "The Regenstrief Medical Record System: 20 Years of Experience in Hospitals, Clinics, and Neighborhood Health Centers," *M.D. Computing*, vol. 9, No. 4, July/August 1992, pp. 206-217.

[13] C.J. McDonald, S.L. Hui, and W.M. Tierney, "Effects of Computer Reminders for Influenza Vaccinations on Morbidity During Influenza Epidemics." *MD Computing*, vol. 9, No. 5, September-October 1992, pp. 304-312.

[14] I. McDowell, C. Newell, and W. Rosser, "A Randomized Trial of Computerized Reminders for Blood Pressure Screening in Primary Care," *Medical Care*, vol. 27, No. 3, March 1989, pp. 297-305; I. McDowell, C. Newell, and W. Rosser, "Computerized Reminders To Encourage Cervical Screening in Family Practice," *Journal of Family Practice*, vol. 28, No. 4, April 1989, pp. 420-424.

[15] "'HealthQuiz' Makes Preventive Care Guidelines Easy To Apply," *Report on Medical Guidelines & Outcomes Research*, Jan. 26, 1995, pp. 5-6.

[16] E.H. Shortliffe, "Computer Programs To Support Clinical Decision Making," *Journal of the American Medical Association*, vol. 258, No. 1, July 3, 1987, pp. 61-66.

[17] R.S. Evans, D.C. Classen, and S.L. Pestotnik, "Improving Empiric Antibiotic Selection Using Computer Decision Support," *Archives of Internal Medicine*, vol. 154, No. 8, Apr. 25, 1994, pp. 878-884.

[18] A.H. Morris, "Protocol Management of Adult Respiratory Distress Syndrome," *New Horizons*, vol. 1, No. 4, November 1993, pp. 593-602.

[19] K.E. Tate, R.M. Gardner, and L.K. Weaver, "A Computerized Laboratory Alerting System," *M.D. Computing*, vol. 7, No. 5, September-October 1990, pp. 296-301; D.M. Rind et al., "Effect of Computer-Based Alerts on the Treatment and Outcomes of Hospitalized Patients," *Archives of Internal Medicine*, vol. 154, No. 13, July 11, 1994, pp. 1511-1517.

background characteristics (even if the treatment would otherwise be appropriate for the health problem at hand), for example, alerts regarding drug allergies in the order-entry system at Brigham and Women's Hospital in Boston;[20]
- possibly inappropriate treatments regardless of the patient's health problems or characteristics, for example, commercial programs to detect drug-drug and drug-nutrient interactions;[21]
- likely conflict or redundancy between a chosen test and others already ordered for the patient;[22]
- likely results of a test ordered for the patient; if the probability of an abnormal result is low, the clinician can reconsider whether the test is really worth performing;[23]
- results of previous tests on the patient that are like the one being ordered, so the clinician may reconsider whether the test really needs to be repeated;[24]
- the cost of a test or treatment ordered for the patient, so the clinician can reconsider whether it is really worth performing;[25] and
- tests or treatments that would be less costly than the one ordered, but equally effective in treating the health problem at hand.[26]

5. *Prompts* to the clinician for decisions regarding testing or treatment options, or for entry of information on the patient's health problems or background, as in the drug order-entry system at Brigham and Women's Hospital.[27]
6. *Prognoses* of intensive care unit patients based on such predictors as severity of illness (using vital signs and other physical measures) and physiological reserve (age and complicating health problems) in the Acute Physiology and Comprehensive Health Evaluation (APACHE) system.[28] APACHE is also used as a method of measuring severity of illness and risk-adjusting outcome measures.[29] An expanded prognostic model known as SUPPORT (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments) is designed to predict survival to 180 days (rather than to discharge) and includes patients who are not severely ill.[30]

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[20] R. F. Gibson and B. Middleton, "Health Care Information Management Systems To Support CQI," *Clinical Practice Improvement: A New Technology for Developing Cost-Effective Quality Health Care*, S.D. Horn and D.S.P. Hopkins (eds.) (New York, NY: Faulkner & Gray, 1994), pp. 116-117.

[21] T.I. Poirer and R. Giudici, "Evaluation of Drug Interaction Microcomputer Software: Comparative Study," *Hospital Pharmacy*, vol. 26, No. 1, January 1991, pp. 30-37; T.I. Poirer and R. Giudici, "Evaluation of Drug-Food/Nutrient Interactions Microcomputer Software Programs," *Hospital Pharmacy*, vol. 26, No. 6, June 1991, pp. 533-540.

[22] Connelly and Bennett, op. cit., footnote 2.

[23] W.M. Tierney et al., "Computer Predictions of Abnormal Test Results: Effects on Outpatient Testing," *Journal of the American Medical Association*, vol. 259, No. 8, Feb. 26, 1988, pp. 1194-1198.

[24] W.M. Tierney et al., "Computerized Display of Past Test Results: Effect on Outpatient Testing," *Annals of Internal Medicine*, vol. 107, No. 4, October 1987, pp. 569-574.

[25] W.M. Tierney, M.E. Miller, and C.J. McDonald, "The Effect on Test Ordering of Informing Physicians of the Charges for Outpatient Diagnostic Tests," *New England Journal of Medicine*, vol. 322, No. 21, May 24, 1990, pp. 1499-1504.

[26] W.M. Tierney et al., "Physician Inpatient Order Writing on Microcomputer Workstations: Effects on Resource Utilization," *Journal of the American Medical Association*, vol. 269, No. 3, Jan. 20, 1993, pp. 379-383.

[27] Gibson and Middleton, op. cit., footnote 21.

[28] W.A. Knaus, D.P. Wagner, and J. Lynn, "Short-Term Mortality Predictions for Critically Ill Adults: Science and Ethics, *Science*, vol. 254, No. 5030, Oct. 18, 1991, pp. 389-394; J.E. Zimmerman, W.A. Knaus, and M. Seneff, "Outcome Prediction in Intensive Care," *Intensive Care Rounds*, No. 10125 (Abingdon, England: The Medicine Group (Education), Ltd., January 1993).

[29] L.I. Iezzoni, "Risk Adjustment for Medical Outcome Studies," *Medical Effectiveness Research Data Methods*, M.L. Grady and H.A. Schwartz (eds.), Agency for Health Care Policy and Research, AHCPR Pub. No. 92-0056 (Rockville, MD: July 1992), pp. 83-97.

[30] W.A. Knaus et al., "The SUPPORT Prognostic Model: Objective Estimates of Survival for Seriously Ill Hospitalized Adults," *Annals of Internal Medicine*, vol. 122, No. 3, Feb. 1, 1995, pp. 191-203.

Appendix D Executive Branch Telemedicine Activities

D

In September 1993, the Clinton Administration published its *Agenda for Action* report, outlining its vision of the National Information Infrastructure (NII) and specific actions the government would take.[1] By Executive Order 12864, the President appointed the Information Infrastructure Task Force (IITF), under the direction of the Secretary of Commerce. The IITF is comprised of high-level representatives of the federal agencies that play a role in developing and applying information and telecommunications technologies, including independent agencies and commissions such as the Federal Communications Commission. The President also appointed the Advisory Council on the NII, which broadly represents the key constituencies affected by the NII (business, labor, academia, public interest groups, and state and local governments).[2]

The IITF's Committee on Applications and Technology coordinates efforts to develop, demonstrate, and promote applications of the NII and develops and recommends technology strategy and policy to accelerate its implementation. One of the subgroups of the Health Information and Applications Working Group is responsible for telemedicine. The purpose of the telemedicine subgroup is to promote the efficient, effective use of telemedicine in the delivery of health care services through the coordination of federal resources and policies. In August 1994, the IITF Health In-

[1]Information Infrastructure Task Force, "The National Information Infrastructure: Agenda for Action," National Telecommunications and Information Administration, Washington, DC, Sept. 15, 1993.

[2]NII Principles and Actions: A Checklist of the Clinton Administration's Progress, September 1993-94, September 1994, p. 3.

formation and Applications Working Group convened a meeting of experts to devise a policy strategy for telemedicine. In April 1995, a report of the conference's conclusions and recommendations was released.[3]

In March 1995, Vice President Al Gore requested the Department of Health and Human Services (DHHS) to lead an interagency effort to address and resolve major policy issues involved in the NII and the health sector.[4] This effort is to be coordinated with the ongoing work of the Information Infrastructure Task Force. With respect to telemedicine, DHHS was asked to prepare a report on current telemedicine projects, the range of potential telemedicine applications, and public and private actions to promote telemedicine and to remove existing barriers to its use.

The federal government has funded a number of pilot projects in telemedicine over the past 30 years. There is currently a good deal of interest in and funding for both demonstration projects and evaluation projects, although proposed budget cutbacks could have a significant negative effect on funding for telemedicine projects . A sample of executive branch telemedicine activities is provided below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The *Office of Rural Health Policy* (ORHP), in the Health Resources and Services Administration, has been involved in telemedicine for more than 5 years, mainly providing grant funding for demonstration projects. These have included Texas Tech University (in cooperation with the Health Care Financing Administration and the Assistant Secretary for Planning and Evaluation), West Virginia University's Robert C. Byrd Health Sciences Center in Morgantown, and RODEO NET in Oregon (described in chapter 5). ORHP sponsored a workshop in November 1993 to explore major telemedicine policy issues and the role of telemedicine systems in rural health care network development. Conference deliberations resulted in the publication of the report, *Reaching Rural*.[5]

In November 1994, ORHP awarded three-year grants totaling $4.5 million to support 11 telemedicine projects in 10 states. These were awarded under the Rural Telemedicine Grant Program, and will demonstrate the use of telemedicine as part of rural health network development and provide a baseline of information for conducting a systematic evaluation of telemedicine systems serving rural areas. Cost participation was required on the part of grantees. In addition, continuation funding of $800,000 was granted to the Robert C. Byrd Health Sciences Center telemedicine pilot project in West Virginia. In the fall of 1994, ORHP also awarded a grant for an 18-month evaluation of telemedicine projects.

The *Health Care Financing Administration (HCFA*) is a key player in telemedicine in terms of developing policies for Medicare and Medicaid reimbursement of telemedicine services. The agency has supported several research projects in telemedicine, most notably at Texas Tech University (with the Assistant Secretary for Planning and Evaluation and ORHP) and Iowa Methodist Hospital in Des Moines. HCFA also supported the University of Colorado's Center for Health Policy Research in a study to develop a framework for

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[3]*Report of the Working Conference on Telemedicine Policy for the NII,* sponsored by the Health Information and Application Working Group of the IITF Committee on Applications and Technology and the Senate/House Ad Hoc Steering Committee on Telemedicine and Health Care Informatics, April 1995.

[4]Vice President Al Gore, memorandum to Donna Shalala, Secretary of Health and Human Services, Washington, DC, Mar. 8, 1995.

[5]*Reaching Rural*, Office of Rural Health Policy, Health Resources and Services Administration, Public Health Service, Department of Health and Human Services, 1994.

evaluating various types of telemedicine.[6] In the summer of 1994, new grants were awarded as part of a congressionally supported research and demonstration program. HCFA provided startup funding for the Clinical Telemedicine Cooperative Group, an ad hoc alliance to share common telemedicine research protocols and testing methodologies; it also provided some startup funding for the Telemedicine Information Exchange(TIE), a database established at the Telemedicine Research Center, Oregon Health Sciences University. HCFA is also providing some of the support for the Institute of Medicine's study of evaluation criteria for telemedicine.

The National Library of Medicine (NLM), through the High Performance Computing and Communications Program (HPCC), funds applications research in a number of areas, including telemedicine. For example, the National Laboratory for the Study of Rural Telemedicine at the University of Iowa has recently received a three-year grant of $7.3 million to test the use of Iowa's fiberoptic network to link medical facilities and libraries at the University to hospitals, clinics, and perhaps doctors' offices, throughout the state. Oregon Health Sciences University, University of Pittsburgh, and West Virginia University also received funding for telemedicine projects from the HPCC Health Care Awards. NLM is the principal funder of an Institute of Medicine study under way on criteria for evaluation of telemedicine projects. NLM has also compiled a telemedicine bibliography containing more than 1,600 citations that is also available on the Internet.[7]

The *Agency for Health Care Policy and Research (AHCPR*) helped to support the development of telemetry (transmitting electrocardiograms and vital signs), and telemedicine (including the early NASA STARPAHC project on the Papago Indian Reservation in Arizona). It has also provided support for meetings on telemedicine.

DEPARTMENT OF AGRICULTURE

The *Rural Utilities Service (RUS*) (formerly the Rural Electrification Administration) sponsors the Distance Learning and Medical Link Grant Program, which demonstrates the ability of rural communities to utilize existing or proposed telecommunications systems to achieve sustainable, cost-effective distance learning or medical-link networks. Implemented in fiscal year 1993, a total of $20 million in funding has been committed to a total of 61 projects. Approximately 20 of these are primarily medical links and a majority have some health-related aspects. For fiscal year 1995, a total of $7.5 million is available to fund $75 million in applications from about 250 applicants.[8] For Medical Link Projects, RUS funds equipment used in physician consultation, teleradiology, and educating rural health care providers. Some of the equipment includes teleradiology workstations, x-ray scanners, and digital microscopes, as well as distance-learning equipment such as encoding and decoding devices, specialized cameras and video monitors, video switchers, microphone mixers, computers, and local area networking equipment.

DEPARTMENT OF COMMERCE

In October 1994, the *National Telecommunications and Information Administration* (NTIA), through its Telecommunications and Information

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[6]The Center for Health Policy Research, Denver, CO, produced four reports for HCFA. Jim Grigsby et al., *Analysis of Expansion of Access to Care Through Use of Telemedicine and Mobile Health Services: 1) Literature Review and Analytic Framework*, December 1993; 2) *Telemedicine Policy: Quality Assurance, Utilization Review, and Coverage*, August 1994; 3) *Study Summary and Recommendations for Further Research*, December 1994; and 4) *Telemedicine Policy: Coverage and Payment*, February 1995.

[7]"Telemedicine: Past, Present, and Future, January 1966 through March 1995," Current Bibliographies in Medicine, CBM No. 95-4, National Library of Medicine, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD. Internet access through FTP to nlmpubs.nlm.nih.gov and login as anonymous.

[8]J.R. Binder, Director, Rural Development Assistance Staff, Rural Utilities Service, personal communication, May 10, 1995.

Infrastructure Assistance Program (TIIAP), awarded more than $24 million for fiscal year 1994 to support the development of the NII. A total of 14 of 92 grants were for planning and demonstration projects that are designed to develop, demonstrate, and promote applications of information technology that will educate, restrain health care costs, improve quality, and increase access to health care with the potential for widescale deployment and interconnection over NII networks. Grantees were required to provide matching funds.

DEPARTMENT OF DEFENSE (DOD)

The Medical Research and Materiel Command, Fort Detrick, is conducting several telemedicine and teleradiology projects in cooperation with other branches of the military and various universities. The Walter Reed Army Medical Center (WRAMC) has successfully employed telemedicine in Somalia, Croatia, Macedonia, and Haiti. WRAMC is also working with several southern states to develop peacetime clinic and hospital consultation procedures. The Center has also taken the lead with the Uniformed Services University of the Health Sciences in establishing a military telemedicine initiative to provide retrospective and prospective evaluations of the various projects.

The Medical Diagnostic Imaging Support (MDIS) system, developed by DOD based on the commercial Picture Archiving and Communication System (PACs), is employed in several teleradiology networks that use satellites as well as land lines to connect military treatment facilities with each other and with ambulatory clinics and university medical centers throughout the world. These projects include the Hilltop Plan (based on four central sites in the United States and Korea), the AKAMAI project (linking Tripler Army Medical Center in Hawaii with several sites around the Pacific Rim), and Project Daybreak (linking several remote sites in Korea with Tripler as well as the central site in Seoul). Future plans envision integration of MDIS with other health care information systems, including computer-assisted diagnosis programs, multimedia devices, and reference databases.

Other branches of the military are also using a variety of telemedicine systems to better meet their needs to deliver health care to their members in a variety of settings. The Tri-Service Telemedicine Testbed Project, established in September 1994, provides a plan for guiding the Testbed Project and integrating telemedicine technologies into the Military Health Services System. This action also implemented the National Digital Telemedicine Testbed initiative of the DOD National Performance Review. In July 1995, the Army Medical and Materiel Development Command and the ISIS Center, Georgetown University Medical Center, co-sponsored a meeting to develop approaches for DOD technology assessment and evaluation of telemedicine.[9]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

NASA has had a long-term involvement in telemedicine activities. The agency is interested in telemedicine for medical care in space for future long-duration space platforms and to minimize risk to astronauts. NASA was involved in the early STARPAHC Program, as well as the Spacebridge to Armenia, which provided consultations via satellite to a disaster area in 1988. NASA was recently involved in a joint effort with Russia, the Spacebridge to Moscow, to link several U.S. medical centers with a hospital in Moscow. The agency also participated with the Mayo Clinic in a telemedicine feasibility study with the Pine Ridge Indian Reservation in 1994. In September 1994, NASA joined with the Uniformed Services University of the Health Sciences in sponsoring the Second International Conference on Teleme-

[9]The Chestertown Roundtable, "Developing Approaches for DOD Technology Assessment and Evaluation of Telemedicine," Chestertown, MD, July 30-August 1, 1995.

dicine: Remote Health Care and Disaster Response.[10]

DEPARTMENT OF VETERANS AFFAIRS (VA)

The VA is testing the use of its electronic mail systems for teleconsultation. This system handles text, images, voice, scanned documents, electrocardiogram signals, and patients' reports. Using the VA's wide area network, this capability will allow consultations between physicians at different VA locations. The Birmingham (AL) VAMC plans to purchase videoconferencing equipment for all VA medical centers in Alabama. This equipment will be placed in the treatment areas of the hospitals. Physicians will be able to consult with specialists prior to transporting patients for specialty care, including discussing x-rays and other pertinent medical data. The patient will also be able to participate in these discussions, if feasible and medically advisable. It is believed that this will greatly reduce the number of patients needing to be transported for care, and will also serve as an education tool for physicians. Also, the Tuscaloosa VAMC has transmitted radiology images to the Birmingham VAMC for reading by the radiologist in residence. The VA is also a supporter of the Institute of Medicine study of evaluation criteria for telemedicine.

[10]The conference proceedings are published in three special issues of the *Journal of Medical Systems*, vol. 19, No. 1, February 1995; vol. 19, No. 2, April 1995; and vol. 19, No. 3, June 1995.

Appendix E Electronic Health Information Sources

E

An enormous amount of health information is now available in electronic form. Until recently, most of these resources were accessible through dial-up bulletin board systems or, if the files resided on a computer connected to the Internet, through a number of different means of transferring copies of the files from the source computer to a remote user's computer. Recently, however, a new graphical interface to the Internet, known as the World Wide Web (WWW), has made it possible to rapidly retrieve, arrange, and display on *web pages* the contents of files—rather than just their names—and for users to transfer from resource to resource along a virtually endless web of *hyperlinks* with the click of a mouse button.

This appendix briefly surveys some of the audio, visual, textual, and hypertextual health information available on the WWW. The Uniform Resource Locator (URL) that accompanies each electronic resource identifies its location and filename and the appropriate method for accessing the files. The URLs are used by web browser software, such as Netscape Navigator,[1] Mosaic,[2] or Lynx,[3] to locate and retrieve the files. This list of web sites represents only a sample of the wide variety of free health information that is available on the WWW.

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[1] Netscape Communications Corp., <URL: http://home.netscape.com/ >. URLs listed in this appendix are accurate as of the date of publication but will change over time. The indices mentioned in the last section of the appendix should be consulted for updated access information.

[2] National Center for Supercomputer Applications, <URL: http://www.ncsa.uiuc.edu >.

[3] W3 Consortium, <URL: http://www.w3.org/hypertext/WWW/Lynx/Status.html >.

CONSUMER AND PATIENT INFORMATION

University health clinics are a rich source of information for consumers and patients. Sites such as *Healthwise*[4] at Columbia University, the *HEALTHLINE Server*[5] at the University of Montana, and the *HealthInfo Gopher*[6] at Rice University offer multimedia educational materials, advice columns, mailing lists, and other resources addressing preventive medicine, nutrition, AIDS, sports medicine, drug and alcohol abuse, women's health, sexuality, and other general health information topics. Abstracts and summaries of articles about health issues from newspapers and the popular press are collected at sites such as *Biomedicine and Health in the News*[7] and *Health and Medicine in the News.*[8] The Iowa Health Book at *The Virtual Hospital*[9] has patient information, such as a guide for helping a child cope with visiting a family member hospitalized in an intensive care unit. The *TALARIA Hypermedia Clinical Practice Guidelines for Cancer Pain*[10] and the *PharmInfoNet DrugDB*[11] (a descriptive database of pharmaceuticals and their effects, organized according to generic and trade names) are two other examples of resources available throughout the web that may help consumers understand complex medical care. In addition, the web indices summarized at the end of this appendix contain subscription information for a huge variety of e-mail mailing lists and Usenet discussion groups concerning specific diseases and health conditions.

RESOURCES FOR HEALTH PROFESSIONALS

Numerous web pages contain information and hyperlinks designed for specific health professionals. *Nightingale*,[12] *NP Web*,[13] *Physician's Guide to the Internet*,[14] and the *Interactive Medical Student Lounge*[15] are sites designed respectively for nurses, nurse practitioners, physicians, and medical students. Sites such as the *Emergency Medicine and Primary Care Home Page*[16] provide resources and discussion forums for specialized health disciplines, and reference sites such as the *CHORUS Collaborative Hypertext of Radiology*[17] contain quick reference materials. Cumulative indices of research literature from over 20 different subject areas in biomedicine are maintained at *Current Bibliographies in Medicine*.[18] A variety of sites are devoted to medical education. Some, such as the *University of California at San*

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[4] Columbia University Health Service, Health Education and Wellness Program, <URL: http://www.cc.columbia.edu/cu/healthwise/ >.

[5] University of Montana Student Health Services, <URL: http://healthline.umt.edu:700/ >.

[6] Rice University Student Health Service, <URL: gopher://riceinfo.rice.edu/11/Safety/HealthInfo >.

[7] University of Connecticut Health Center, Lyman Maynard Stowe Library, <URL: gopher://inform.uchc.edu/11gopher_root%3a%5b_data04._data0401%5d >.

[8] University of Minnesota, <URL: gopher://lenti.med.umn.edu:71/11/news/citations >.

[9] University of Iowa College of Medicine, Department of Radiology, Electric Differential Multimedia Laboratory, <URL: http://indy.radiology.uiowa.edu/VirtualHospital.html >

[10] University of Washington, Department of Statistics, <URL: http://www.stat.washington.edu/TALARIA/TALARIA.html >.

[11] Pharmaceutical Information Associates, Ltd., <URL: http://pharminfo.com/drugdb/db_mnu.html >.

[12] University of Tennessee at Knoxville, College of Nursing, <URL: http://nightingale.con.utk.edu:70/0/homepage.html >.

[13] University of New Hampshire, Department of Nursing, <URL: http://unhinfo.unh.edu/unh/acad/health/nursing/index.html >.

[14] NetRep Explorist, <URL: http://www.netrep.com/global/biz/pgi/pgi.html >.

[15] University of Kansas, <URL: http://falcon.cc.ukans.edu:80/~nsween/ >.

[16] Emergency Medicine Bulletin Board System, <URL: http://www.njnet.com/~embbs/ >.

[17] Medical College of Wisconsin, <URL: http://chorus.rad.mcw.edu/chorus.html >.

[18] National Library of Medicine, <URL: ftp://nlmpubs.nlm.nih.gov/bibs/cbm/ >.

Francisco Primary Care Teaching Module[19] and *The Interactive Patient,*[20] are designed for medical students and residents, and others—including the *University of Washington Radiology Webserver,*[21] the *Interesting Case Conference,*[22] and *MedEd*[23]—offer practice in diagnosis or continuing medical education courses. *MedSearch America*[24] is an electronic bank of job listings for health professionals.

MEDICAL IMAGES

As web browsers capable of displaying photographic images and video clips have been developed, the World Wide Web has become an ideal medium for distributing medical images for instructional and historical purposes. The *Visible Human Project*[25] documents human anatomy in a series of magnetic resonance, photographic, and computerized tomography images of cross-sections of a human body at one millimeter intervals; the *Visible Embryo Project*[26] is a related compilation of images illustrating human developmental embryology. The *GE Three Dimensional Medical Reconstruction*[27] page includes animated "fly-throughs" of heart arteries, the lungs, and the brain, and a simulation of a baby delivery. A compendium of brain images is found at the *Whole Brain Atlas*.[28] The *Medical Illustrator's Home Page*[29] serves as a contact point for medical illustrators, publishers, authors, and medical schools. Nearly 60,000 historical images from the archives of the National Library of Medicine are found in *OnLine Images from the History of Medicine*.[30] An index of other medical imaging resources is found at *Medical Imaging on the Web.*[31]

TELEMEDICINE AND RURAL MEDICINE

Information about distance medicine, telemedicine, and rural medicine can be found at the *Telemedicine Information Exchange,*[32] *Telemedicine Resources,*[33] *REACH-TV,*[34] and *RuralNet*.[35]

HEALTH POLICY AND GOVERNMENT

Many government agencies maintain WWW sites with information for both health care professionals and health care consumers. The web site at the

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[19] Stanford University and the University of California at San Francisco, Divisions of General Internal Medicine, <URL: http://www-med.Stanford.EDU/MedCenter/MedSchool/DGIM/Teaching/Modules-index.html >.

[20] Marshall University School of Medicine, <URL: http://medicus.marshall.edu/medicus.htm >.

[21] University of Washington, Department of Radiology, <URL: http://www.rad.washington.edu/ >.

[22] Massachusetts General Hospital, Department of Emergency Medicine, <URL: http://emergency.mgh.harvard.edu/wicc.htm >.

[23] Loyola University (Chicago) Medical Education Network, <URL: http://www.meddean.luc.edu/lumen/MedEd/Medpage.html >.

[24] MedSearch America, <URL: gopher://gopher.medsearch.com:9001/1 >.

[25] National Library of Medicine, <URL: http://www.nlm.nih.gov/extramural_research.dir/visible_human.html >.

[26] National Museum of Health and Medicine, Human Developmental Anatomy Center <URL: http://bubba.afip.mil/ >.

[27] General Electric Corporate Research and Development, <URL: http://www.ge.com/crd/ivl/three_dim_medical.html >.

[28] Harvard Medical School, <URL: http://www.med.harvard.edu/AANLIB/home.html >.

[29] Mednexus, <URL: http://www.mednexus.com/med_illustrator/index.html >.

[30] National Library of Medicine, <URL: http://www.nlm.nih.gov/hmd.dir/oli.dir/ >.

[31] Center for Advanced Studies, Research, and Development in Sardinia, <URL: http://www.crs4.it/~france/MEDICAL/institutions.html >.

[32] Telemedicine Research Center, <URL: http://tie.telemed.org/ >.

[33] University of Washington, Image Computing Systems Laboratory, <URL: http://icsl.ee.washington.edu/~cabralje/tmresources.html >.

[34] East Carolina University School of Medicine, Center for Health Sciences Communication, <URL: http://www.telemed.med.ecu.edu/telemenu.htm >.

[35] Marshall University School of Medicine, <URL: http://ruralnet.mu.wvnet.edu/ >.

Health Care Financing Administration[36] contains information about Medicare and Medicaid, and the web site at the Department of Health and Human Services[37] guides consumers to a wide variety of health information available through agencies such as the Food and Drug Administration[38] and the National Institute on Aging.[39] *The Health Services/Technology Assessment Text*[40] includes the full text of clinical practice guidelines, quick-reference guides for clinicians, and consumer brochures developed with the support of the Agency for Health Care Policy and Research. The Centers for Disease Control and Prevention[41] and the Public Health Service[42] maintain WWW sites with information about communicable diseases, epidemics, and population-based health care. Many institutions, such as the World Health Organization,[43] maintain web sites with information on international health issues. A useful index to governmental health information resources is found at the *National Health Information Center.*[44]

STANDARDS

Two useful web resources dedicated to the various technical standards discussed throughout this report are the *MSDS Healthcare Standards Home Page*[45] and the *Gateway to Standards Organizations.*[46]

PROFESSIONAL ORGANIZATIONS AND JOURNALS

Many professional societies including the American Medical Informatics Association,[47] the American Psychological Society,[48] and the International Society of Nephrology[49] maintain web pages with membership information and news about society activities and publications. Peer-reviewed academic journals are beginning to appear online, including *The Digital Journal of Ophthalmology*[50] and *The Journal of Medical Imaging*,[51] as well as government publications such as the *Morbidity and Mortality Weekly Report.*[52]

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[36] Health Care Financing Administration, <URL: http://www.ssa.gov/hcfa/hcfahp2.html >.

[37] Department of Health and Human Services, <URL: http://www.os.dhhs.gov/ >.

[38] U.S. Food and Drug Administration, <URL: http://www.fda.gov/fdahomepage.html >.

[39] National Institute on Aging, <URL: gopher://gopher.os.dhhs.gov/1/dhhs/aoa/aoa/agepages >.

[40] National Library of Medicine, <URL: http://text.nlm.nih.gov/ >.

[41] Centers for Disease Control and Prevention, <URL: http://www.cdc.gov/ >.

[42] Public Health Service, <URL: http://phs.os.dhhs.gov/phs/phs.html >.

[43] World Health Organization, <URL: http://www.who.ch/programmes/WHOProgrammes.html >.

[44] National Health Information Center, <URL: http://nhic-nt.health.org/ >.

[45] Duke University Medical Center Information Systems, <URL: http://www.mcis.duke.edu:80/standards/ >.

[46] United Technologies National Standards System Network, <URL: http://hsdwww.res.utc.com/std/gateway/orgindex.html >.

[47] American Medical Informatics Association, <URL: http://amia2.amia.org/ >.

[48] American Psychological Society, <URL: http://psych.hanover.edu/APS/ >

[49] International Society of Nephrology—Renal Pathology Society, <URL: http://synapse.uah.ualberta.ca/synapse/000p0035.htm >.

[50] Massachusetts Eye and Ear Infirmary, Department of Ophthalmology, <URL: http://www.meei.harvard.edu/meei/DJOhome.html >.

[51] Johns Hopkins University, School of Medicine, Department of Radiology and the William H. Welch Medical Library, <URL: http://jmi.gdb.org/JMI/ejourn.html >.

[52] Centers for Disease Control and Prevention, <URL: http://www.crawford.com/cdc/mmwr/mmwr.html >.

INDICES

The World Wide Web resources listed above are only a small fraction of the existing sites, and new sites are being developed at a very rapid pace. Several sites maintain current catalogs of health information resources on the Internet. The index sites include *Medical Matrix*,[53] *IHPNet*,[54] *Hospital Web*,[55] *The Whole Internet Catalog: Health and Medicine*,[56] *MedWeb*,[57] and the *Yahoo! Medicine List*.[58]

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[53] Internet Working Group of the American Medical Informatics Association, <URL: http://kuhttp.cc.ukans.edu/cwis/units/medcntr/Lee/HOMEPAGE.HTML >.

[54] International Network for Interfaith Health Practices, <URL: http://www.interaccess.com/ihpnet/health.html >.

[55] Massachusetts General Hospital, Department of Neurology, <URL: http://dem0nmac.mgh.harvard.edu/hospitalweb.html >.

[56] Global Network Navigator, <URL: http://nearnet.gnn.com/gnn/wic/med.toc.html >.

[57] Emory University Health Sciences Center Library, <URL: http://www.cc.emory.edu/WHSCL/medweb.html#toc2 >.

[58] Yahoo! Corp., <URL: http://www.yahoo.com/Health/ >.

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Appendix G Abbreviations and Glossary

G

ACTS
Advanced Communications and Technology Satellite

Administrative data
Data used in the administration of public programs or agencies or private businesses. In health, examples of administrative data are hospital discharge abstracts and health insurance claims and enrollment records.

Administrative simplification
Efforts to reduce the cost and complexity of health care through increased standardization and automation of health care providers' and insurers' administrative activities.

Admission/discharge record (or discharge abstract)
A synopsis of a patient record containing basic identifying and financial information about a patient, along with clinical information, including the admitting and final diagnosis and a summary of procedures performed.

Affordances
Behaviors and actions that are allowed or enabled by a specific technology.

AHCPR
Agency for Health Care Policy and Research

AITN
Arizona-International Telemedicine Network

AMA
American Medical Association

AMI
Acute myocardial infarction

ANSI
American National Standards Institute

Arden Syntax
A computer language for encoding and sharing medical knowledge in discrete modules.

ARPA
Advanced Research Projects Agency, DOD

Artificial neural network
A linked network of simple software-based processors, analogous to a biological neural network, that can be trained as an ensemble to respond consistently to a set of numerical input stimuli.

ASC (Accredited Standards Committee)
A committee chartered by ANSI to work on standards in a particular area of commerce. For example, ASC X12 is the committee working on standards for the insurance industry, including health.

ASTM
American Society for Testing and Materials

Asymmetric encryption
An encryption scheme in which information intended for an individual is encoded with his/her well-known, public encryption key, but may only be decoded with his/her private key (generated from a guarded password).

ATM (asynchronous transfer mode)
A fast networking protocol based on small, uniform packets. ATM communications are suitable for continuous transfer of large amounts of data, including video streams.

ATP (Advanced Technology Program)
A Commerce Department program that funds cooperative development and validation of enabling technologies, including computer and information technologies.

Authenticator
A device that provides an internally stored or calculated response to verify a user's identity when logging onto a computer. Only authorized users are likely to both know a unique piece of information (the password) and be in possession of a unique piece of equipment (the authenticator).

Automated data collection
Direct transfer of physiological data from monitoring instruments to a bedside display system or a computer-based patient record.

Backbone
A high-capacity communications channel that carries data accumulated from smaller branches of a computer or telecommunications network.

Bandwidth
The amount of information an electronic connection can carry per unit of time, usually expressed in bits per second.

Biometric identifier
A retinal pattern, fingerprint, or other anatomical feature that can be used by a computer program (along with appropriate interface equipment) to positively identify a user.

C-section
Caesarean section

CABG
Coronary artery bypass graft

Capitation
A method of paying for health care based on a set fee per member (of the health care plan) per unit of time.

CAT scan
Computerized axial tomography scan

CBA (cost-benefit analysis)
A comparison of the net costs of an intervention with the net savings.

CD-ROM
Compact disk, read-only memory

CDSS
Clinical decision support system

CEA (cost-effectiveness analysis)
A structured, comparative evaluation of two or more health care interventions.

CHESS (Comprehensive Health Enhancement Support System)
An interactive computer system developed at the University of Wisconsin that provides information, social support, and problem-solving tools for people living with AIDS and HIV infection.

CHF
Congestive heart failure

CHI (consumer health informatics)
The study, development, and implementation of computer and telecommunications applications and interfaces designed to be used by health consumers.

CHIN (community health information network)
Electronic systems that facilitate community-wide exchange of clinical and administrative information among providers, payers, banks, pharmacies, public health agencies, employers, and other participants in the health care system.

CHMIS (community health management information system)
An electronic system similar to a CHIN that has an explicit emphasis on building a data repository for use in assessing the performance of health care providers and insurance plans.

Clinical decision support
The use of information to help a clinician diagnose and/or treat a patient's health problem, including information about the patient and information about the kind of health problem afflicting the patient and alternative tests and treatments for it.

Clinical information system
Hospital-based information system designed to collect and organize data related to the care given to a patient, rather than administrative data.

Clinical practice guideline
An outline of broad parameters for the diagnosis, treatment, prevention, or rehabilitation of a particular health problem.

Clinical protocol
A rigorous, detailed model of the process of care for a particular health problem.

CME
Continuing medical education

Cochrane Collaboration
An international network of researchers that distributes results of systematic reviews of randomized controlled trials—or the most reliable evidence form other sources—on selected health problems.

Codec
1) In telemedicine, an abbreviation for *coder/decoder*, an electronic device that converts an analog electrical signal into a digital form for transmission purposes and decodes it the receiving end. 2) In computer-based video technology, an abbreviation for *compressor/decompressor*, the software that reduces the size of digitized video frames.

Coding standard
A system for assigning alphanumeric codes to specific words, concepts, or actions for the purpose of standardizing messages between computers or organizations.

COMPASS
A local dial-up computer data network in Oregon that provides a variety of information services.

Computer-based patient record
A compilation in digital form of all the clinical and administrative information related to the care of a single individual.

Confounding variable
A factor other than the health service in question that may influence the outcome of that service.

Consensus standard
A non-proprietary technological standard developed through an open, participative process under the aegis of a standards development organization.

Coordination of benefits
The determination of primary payer, that is, the payer whose coverage is applied first. A secondary payer reimburses, subject to the terms of its contract, that portion of a claim unpaid by the primary payer.

CPR
Computer-based patient record

CPT-4 (Current Procedural Terminology, Fourth Edition)
A classification and coding system for health services maintained by the AMA that is used in billing by clinicians and other noninstitutional providers.

CQI (Continuous Quality Improvement)
A method of analyzing and improving processes for manufacturing products or delivering services to meet customer needs and expectations.

CSN (Community Services Network)
A project in Washington, DC, that uses communication and computer technologies to support and coordinate health and human services at the community level.

Data distillation
An informal label for the process of deriving meaning from raw data.

Data repository
The component of an information system that accepts, files, and stores data from a variety of sources.

DDE
Direct data entry

Decision support
See Clinical decision support.

Demand management
A method of controlling health care costs by controlling access to health care services.

DEMPAQ (Developing and Evaluating Methods to Promote Ambulatory Care Quality)
A set of performance indicators for ambulatory care providers that is being developed by HCFA for its Medicare program.

DHHS
Department of Health and Human Services

DICOM (Digital Imaging and Communications in Medicine)
A standard for communications among medical imaging devices.

Discharge abstract
See Admission/discharge record.

Disease management
A method of managing the care of a specific health problem (usually a chronic and costly disease) that employs the principles of continuous quality improvement, including the use of clinical practice guidelines, outcomes measurement, and feedback to providers and insurance plans.

DOD
Department of Defense

DRG (Diagnosis Related Group)
A class of health problems derived from sets of diagnosis and procedure codes and used by HCFA to determine reimbursement for treatments.

DS-0, DS-1, DS-3
Digital telecommunications channels capable of transmitting 64 kilobits, 1.544 megabits, and 45 megabits per second, respectively. The higher capacity connections are suitable for high-volume voice, data, or compressed video traffic.

DSP (digital signal processor)
A special-purpose computer processor customized to make rapid calculations associated with audio or video data streams.

ECU
East Carolina University

ED-NET
A statewide network created by the State of Oregon in 1989 that offers a full range of services for those who have a need to communicate.

EDI (electronic data interchange)
The application-to-application interchange of business data between organizations using a standard data format.

Electronic mailing lists
Free, subscription-based, electronic mail communications on the Internet or commercial online services focused on defined topics.

Encoder
Decision support systems used to facilitate accurate assignment of codes for clinical procedures.

Fault-tolerant computer systems
Reliable computer systems incorporating redundant processors, disk drives, and power supplies to ensure almost full-time operation of a critical information network.

FDA
Food and Drug Administration

Firewall
Computer hardware and software that block unauthorized communications between an institution's computer network and external networks.

Firms trial
A form of randomized controlled trial in which patients are randomly assigned to similar ("parallel") providers who use different health services, rather than to different groups that receive different services from the same provider.

Frame relay
A fast networking protocol in which data are packaged in variable-length frames for shuttling between computer networks.

Functional imaging
Medical imaging modalities that portray the function (such as oxygen uptake) as well as the morphology of anatomical features.

Grouper
Software used to deduce DRGs from sets of diagnosis and procedure codes, or to analyze the grouping decisions of medical coders for consistency and thoroughness.

Handwriting recognition
Conversion of script or block lettering to computer-based text.

HCFA
Health Care Financing Administration

HEDIS (Health Plan and Employer Data Set)
A set of performance indicators for managed care plans, developed by NCQA.

HELP (Health Evaluation through Logical Processing)
A clinical information system at LDS Hospital in Salt Lake City, Utah.

HISPP (Healthcare Informatics Standards Planning Panel)
A body created by ANSI to coordinate standards development efforts among the various standards bodies in health care.

HL7 (Health Level 7)
An application-level interface specification for transmitting health-related data transactions, generally used within a single institution.

HMO
Health maintenance organization

HOST
Healthcare Open Systems and Trials consortium

HPCC (High Performance Computing and Communications)
An advanced technology program involving several agencies of the federal government, including NLM and NIST.

Human capital approach
A valuation technique used in cost-benefit analysis that assigns a monetary value to a human life based on an estimate of the individual's projected future earnings.

ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification)
A classification and coding system for health problems and services, maintained by NCHS and HCFA, and used for billing by inpatient hospitals and other institutional providers.

IDS (integrated delivery system)
An organized system of health care providers spanning a range of health care services.

IEEE
Institute of Electrical and Electronics Engineers

IHC (Intermountain Health Care)
A provider organization based in Utah.

IITF
Information Infrastructure Task Force

IMSystem (Indicator Measurement System)
A set of performance indicators for inpatient hospitals and other institutional providers maintained by JCAHO.

Inference engine
A computer routine that coordinates the activities of a knowledge- or rule-based decision support system.

IPA (independent practice association)
An organization that contracts with a managed care plan to deliver health services at a single capitation rate.

ISDN (integrated services digital network)
A digital telephony protocol.

JCAHO
Joint Commission on Accreditation of Healthcare Organizations

JPEG (Joint Photographic Experts Group)
A standard for compression of static images.

Knowledge-based system
A decision support system based on automated, systematized application of sets of rules or heuristics for analysis of raw data.

KUMC
Kansas University Medical Center

LAN (local area network)
Communications lines linking a localized group of computers, printers, and servers.

Laser optical card
A plastic device the size of a credit card that can hold large amounts of digital data. Typically, the data cannot be altered once they are written to the card.

LATA (Local Access Transport Area)
A geographic region used to define telephone areas.

LOINC (Laboratory Observation Identifier Names and Codes)
A set of universal names and codes for identifying laboratory test results in order to facilitate the exchange and pooling of clinical laboratory results.

Magnetic stripe card
A plastic card with a magnetic strip on the back that can store about 250 characters, mainly for identification and verification of eligibility for insurance benefits.

Managed care (or managed health care)
A vaguely defined term referring to various systems of health care delivery that attempt to manage the cost, quality, and accessibility of health care.

Managed care organization
An organization, such as an HMO or PPO, that uses one or more techniques of managed care.

MCG
Medical College of Georgia

Messaging standard
A standard governing the structure of electronic messages between computers.

Meta-analysis
Quantitative synthesis of the statistical results of numerous studies on a given topic.

MIB (Medical Information Bus)
A hardware and software standard (IEEE P1073) that enables standardized connections between medical monitoring devices and clinical information systems.

MLM (Medical Logic Module)
A component of the Arden Syntax.

MPEG (Motion Picture Experts Group)
A video compression standard.

MRI
Magnetic resonance imaging

Multiplexing
Combination of many low-capacity communications channels into one high-capacity communications channel by interleaving the various channels in discrete time or frequency slices.

NASA
National Aeronautics and Space Administration

NCHS
National Center for Health Statistics

NCHSR
National Center for Health Services Research

NCI
National Cancer Institute

NCQA
National Committee for Quality Assurance

NCVHS
National Committee on Vital and Health Statistics

NII
National Information Infrastructure

NIST
National Institute for Standards and Technology

NLM
National Library of Medicine

NTIA
National Telecommunications and Information Administration

NUBC
National Uniform Billing Committee

OCR (optical character recognition)
Automated scanning and conversion of printed characters to computer-based text.

OLAP (on-line analytical processing)
A database architecture that supports querying of complex, multidimensional databases.

ORHP
Office of Rural Health Policy

PACS (Picture Archiving and Communications System)
A computer-based system of storing and retrieving radiographic and other images in digital form.

Patient record
The repository of information about an individual patient, usually stored on paper, but more recently in electronic form in a computer system.

Payer
Insurance company, self-insured employer, administrator, or other entity responsible for paying for an individual's health care.

PBM (pharmacy benefit management)
A method of managing pharmaceutical benefits for insurers and employers that uses disease management, pharmacy networks, negotiated discounts and rebates, lists of preferred drugs, and online utilization review. Also, an organization (pharmacy benefit manager) that performs PBM services.

PBX (private branch exchange)
A institution's internal phone system, which may include voice messaging capabilities.

PC
Personal computer

PC card or PCMCIA card
A credit card-sized computer peripheral or peripheral interface used with portable and desktop computers.

PDA (personal digital assistant)
A handheld computer, usually with no keyboard, that is used for communications or data collection and analysis.

PDQ (Physician Data Query)
A system of online (Internet) information regarding various cancers, ongoing clinical trials, and individuals and organizations involved in cancer care, maintained by NCI.

Pixel
The smallest displayable area on a computer screen.

PPO
Preferred provider organization

Primary data
Data collected directly from individuals (e.g., survey, observation) or documents (e.g., medical record review).

Privacy Act
The Federal Privacy Act of 1974 (5 U.S.C. Section 552a, 1988), which protects individuals from nonconsensual disclosure of confidential information by government agencies.

Proprietary standard
A technological standard developed by a single vendor or vendor group. The standard's specifications may be publicized or held confidential.

Prospective research
Research in which patients are observed as they receive health services.

Provider (or health care provider)
Any person (physician, nurse, etc.) or institution (hospital, nursing home, etc.) that provides health services to patients.

PTCA
Percutaneous transluminal coronary angioplasty

Purchaser
An organization (usually a large employer) that purchases health insurance (usually for its own employees).

Quality assessment
Measurement and evaluation of the quality of health services delivered to patients, usually focusing on the processes and outcomes of those services.

RAID (redundant array of independent disks)
Multiple computer disks configured as a single disk to provide either data redundancy or enhanced access speed.

Randomized controlled trial
A form of prospective research in which patients are randomly assigned to groups that receive different health services and are then observed for differences in outcome.

RBOC (Regional Bell Operating Company)
A regional telephone company resulting from the divestiture of the Bell System in the 1980s.

Relational database
A collection of computer-based information that is organized or accessed according to relationships between data items.

Reliability
The reproducibility of a measure, or the extent to which the measure yields similar results each time it is used on similar samples, or the extent to which its components yield similar results for the same or similar samples.

Report card
A summary set of indicators of the performance of health care providers or insurance plans in delivering health services to patients.

Retrospective research
Research in which patients are observed after they have received health services

Risk adjustment
Statistical control of patient risk factors in the analysis of the utilization and outcomes of health services; also, control of financial risk factors faced by insurance companies.

Risk factors
Key health problems and background characteristics that can affect the patient's outcome, independent of the specific kinds of services received.

RMRS (Regenstrief Medical Record System)
A clinical information system at the Regenstrief Institute, Indiana University, Indianapolis, Indiana.

RODEO NET
Rural Options for Development and Educational Opportunities Network

Rule-based expert system
A decision support system based on large numbers of heuristics, or rules of thumb, derived from analysis of action patterns of experts or from published literature.

Run-length encoding
A data compression scheme in which extended series of repetitive data are replaced by the first item in the series and a token indicating the length of the data run.

RUS
Rural Utilities Service (formerly the Rural Electrification Administration)

Secondary data
Data originally collected for one purpose (e.g., program administration) and then analyzed for a different purpose (usually research or evaluation).

Shared decision support systems
Designed to inform patient/provider decisions regarding prevention, diagnosis, management, and treatment.

Smart card
A plastic device the size of a credit card with an embedded computer processor and memory.

SMS (Shared Medical Systems)
A vendor of hospital information services and products.

SNOMED (Systematized Nomenclature of Medicine)
A system for classifying and coding health problems, symptoms, and services.

Social interface
A human-computer interface design approach in which users interact with representations of physical objects or, in some cases, anthropomorphic agents displayed by their computer.

Speech recognition
Automated conversion of spoken words into computer-based text. Some speech recognition systems recognize only one person's voice; others are speaker-independent but recognize a more limited vocabulary. They may recognize continuous speech or, more commonly, require that slight pauses be inserted between words.

SSN
Social Security number

STARPAHC
Space Technology Applied to Rural Papago Advanced Health Care, a 1970s cooperative telemedicine project supported by NASA, the Indian Health Service, and the Papago people.

Statistical control
Control of confounding variables in retrospective research, either by classifying patients into groups that are homogeneous with respect to those variables, or by adjusting for the variation in the outcome variable that is accounted for by those confounding variables.

Structured data entry
A data collection technique that constrains the language and format of clinical descriptions for the purpose of ensuring uniform, unambiguous, interchangeable messages.

Symmetric encryption
Encryption of a message with a key derived from a password that must be known by both the sending and receiving parties.

Systematic review
Extraction of specific items of information from numerous research works on a given topic and comparison of those items across those works using structured methods.

Tl, T3
See DS-1, DS-3.

Tablet computer
A computer with an integrated display and digitizer, rather than a keyboard. Also known as a clipboard or pentop computer.

TCP/IP (Transmission Control Protocol/Internet Protocol)
A communications protocol governing data exchanged on the Internet.

Telemedicine
The use of information technology to deliver medical services and information from one location to another.

UMLS (Unified Medical Language System)
A computer-based system for translating among disparate clinical nomenclatures, maintained by the National Library of Medicine (NLM).

UNLS (Unified Nursing Language System)
A system similar to the Unified Medical Language System (UMLS) that focuses on nursing services.

Validity
The extent to which an observed situation reflects the true situation. Internal validity is the extent to which the results of a study reflect the true relationship between an intervention and an outcome. External validity is the extent to which the results of a study may be generalized to other settings, etc.

VAN (value added network)
A data communication network that provides services beyond normal transmission, such as error correction or message storage and forwarding.

WEDI
Workgroup for Electronic Data Interchange

WHIN
Wisconsin Health Information Network

WHO
World Health Organization

WIC (Women, Infants and Children)
A special supplemental food program administered by the U.S. Department of Agriculture.

Willingness-to-pay approach
A valuation approach used in cost-benefit analysis that assigns monetary value to human life by considering how much individuals are willing to pay for a reduction in the risk of death or illness.

SOURCES Some definitions adapted from P.R. Kongstvedt, *Essentials of Managed Care* (Gaithersburg, MD Aspen Publishers, 1995) *Health Care and the Electron/c Superhighway A Provider Perspective on Electronic Data Interchange and Automated Medical Payment,* Research Report No. 92-3 (Faulkner and Gray Washington, DC, 1992)

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