Using Information Technology To Improve the Quality of Health Care

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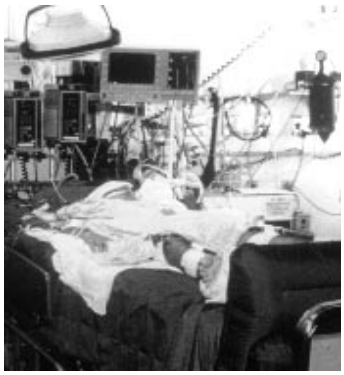
The quality of health care is ultimately judged by the impact of specific health services on the patient's health status.[1] Improving quality involves identifying and using health services that, when properly executed, produce the greatest improvement in health status. The most direct contribution that 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.

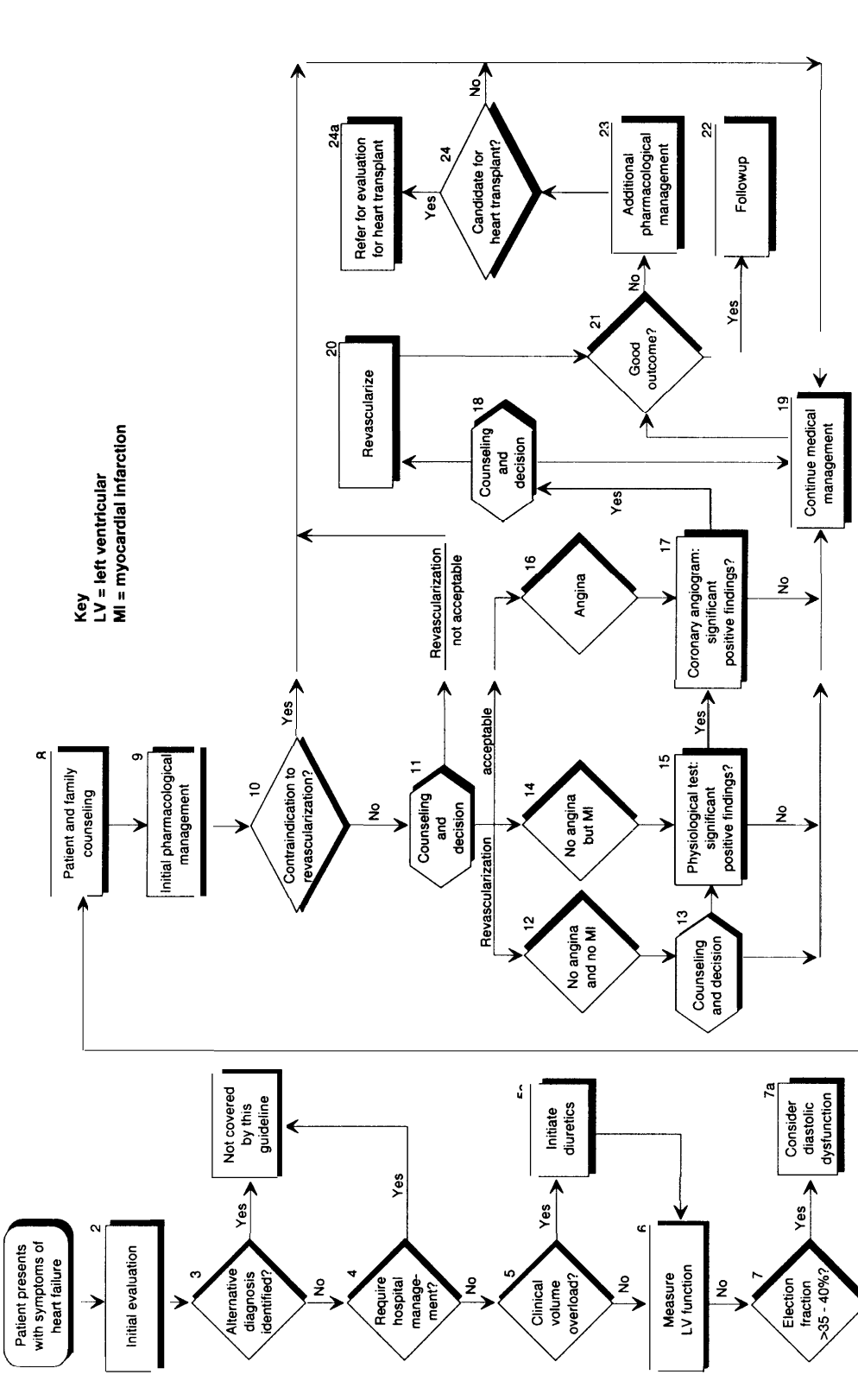
[20] Clinical practice guidelines are sometimes called *practice parameters* or some variation of *clinical paths* or *critical pathways*—terminology adapted from *critical path analysis* in manufacturing and other industries.

[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.

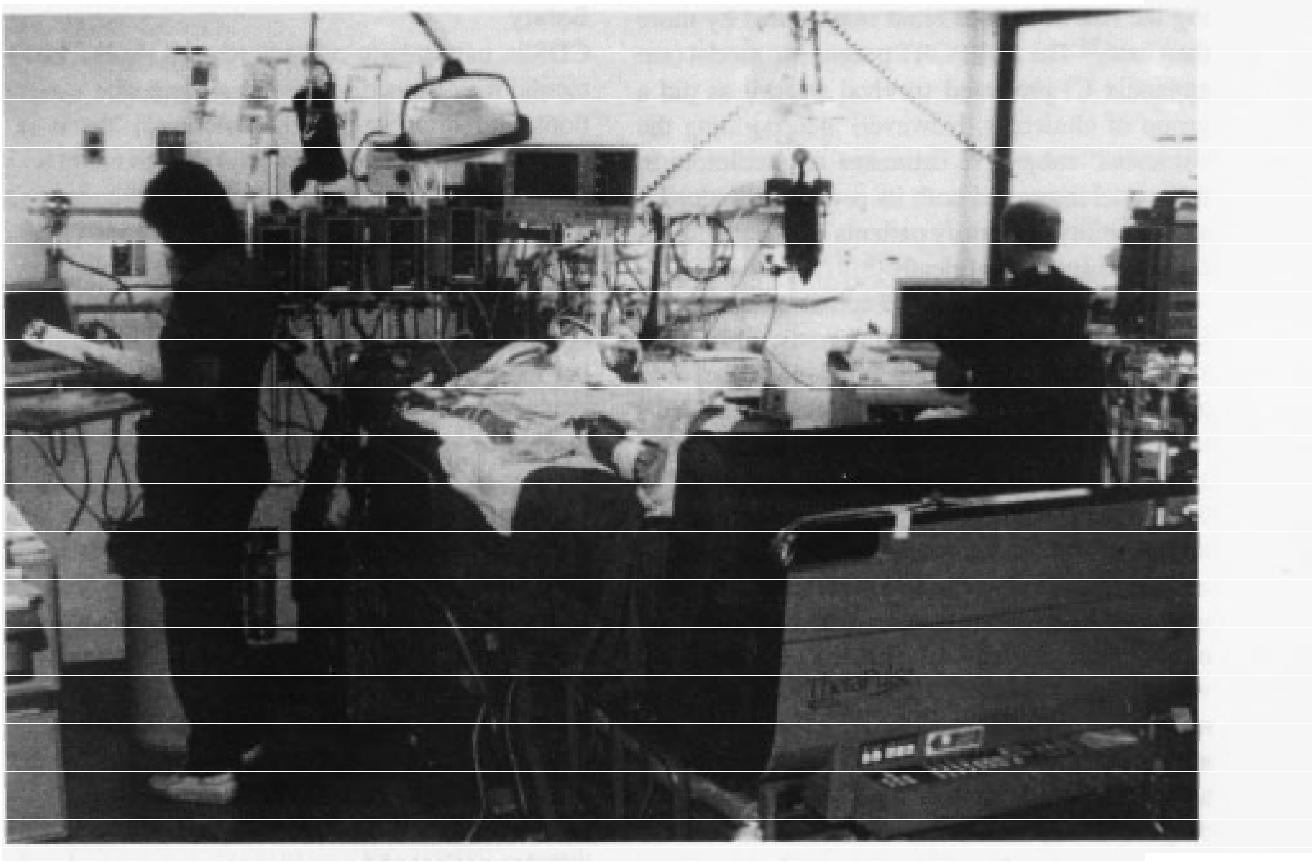
[77] Berner et al., op. cit., footnote 70.

[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.