Medical Informatics

Use of Medical Informatics to Implement and Develop Clinical Practice Guidelines

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Clinical practice guidelines have enormous potential to improve the quality of and accountability in health care. Making the most of this potential should become easier as guideline developers integrate guidelines within information systems and electronic medical records. A major barrier to such integration is the lack of computing infrastructure in many clinical settings. To successfully implement guidelines in information systems, developers must create more specific recommendations than those that have been required for traditional guidelines. Using reusable software components to create guidelines can make the development of protocols faster and less expensive. In addition, using decision models to produce guidelines enables developers to structure guideline problems systematically, to prioritize information acquisition, to develop site-specific guidelines, and to evaluate the cost-effectiveness of the explicit incorporation of patient preferences into guideline recommendations. Ongoing research provides a foundation for the use of guideline development tools that can help developers tailor guidelines appropriately to their practice settings. This article explores how medical informatics can help clinicians find, use, and create practice guidelines.

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What have you done for me lately?

JANET JACKSON[1]

Imagine that you are in your office seeing Mr James for a routine visit. Mr James is 62 years old and has diabetes and ischemic heart disease, which is manifested by mild congestive heart failure and occasional angina. He had a myocardial infarction 3 years ago. Through his employer, Mr James enrolled with Acme Health Care, a managed-care health insurance plan that requires Mr James to choose a primary-care provider. Acme Health Care advertises heavily in your area and emphasizes its focus on preventive medicine and state-of-the-art care. As part of its quality-assurance program, Acme audits primary-care doctors to determine whether they adhere to certain benchmarks for the care of certain conditions. Knowing this, you decide to investigate whether there are clinical practice guidelines to ensure that you have not overlooked any intervention that Mr James might need. What steps should you take to proceed?

First, identify Mr James's major medical problems: diabetes, ischemic heart disease, congestive heart failure, angina, and a need for preventive care. The next step could involve performing a literature search to identify the appropriate guidelines. Medline, the National Library of Medicine's bibliographic database, is a good place to start, although it does not index all guidelines. Begin the search by using the keywords "practice guidelines" and "diabetes mellitus" (in June 1997, this search returned 137 citations). To narrow the options, add searches for the terms "ischemic heart disease," "congestive heart failure," "angina," and "preventive care" (these searches yielded 9, 49, 27, and 103 citations, respectively). It can be discouraging if, along with the many resulting citations that are irrelevant, the citations that *are* relevant refer to journals that are not easily accessible. In addition, Acme Health Care may appear to have its own set of guidelines. What if the contracts your office has with over 10 other health care plans all use different guidelines? Would you have to treat each patient with a different guideline based on who insures the patient?

Clinical practice guidelines have the potential to improve the quality of and accountability in health care.[2–9] Although early studies suggested that implementing guidelines does not affect physicians' behavior,[10] more recent reports indicates that implementing guidelines influences the health care process (in most

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instances) and health outcomes.[11] The recent fierce public debates about guidelines regarding when to screen women for breast cancer,[12] when to screen asymptomatic adults for high cholesterol,[13–17] and how to treat low-back pain[18,19] reflect the growing influence of guidelines on clinical policies and reimbursement decisions. But finding and using guidelines in practice can be difficult and frustrating. In addition, the process of developing guidelines is challenging and expensive.[2–9]

This article, which is part of a series on medical informatics,[20] explores how to use medical informatics to find, develop, and implement practice guidelines. Medical informatics is the study of biomedical information and its use in decision making,[20,21] and it includes a variety of topics: electronic medical records; hospital information systems; bioinformatics (investigation of computer science questions related to molecular biology); telemedicine; database design; decision support; digital imaging and storage; decision analysis; and cost-effectiveness analysis. Guidelines play an important role in medical informatics because their development and use identifies and synthesizes (often with computational techniques) evidence about the outcomes of interventions, a compact representation of the derived policies, and (it is hoped) the delivery of this compiled knowledge to a clinician at just the moment that he or she needs it. Each of these tasks, while fitting within the domain of medical informatics, poses significant research challenges. In addition, once a clinician has a guideline in hand, he or she must decide whether and how to apply it to a patient—the opportunity to use electronically stored patient-specific data to trigger and inform a guidelines use could thus arise.

The first section of this article examines resources currently available to help clinicians locate guidelines. In the sections following, I describe how informatics tools can help to develop and implement guidelines. The final section summarizes current research challenges for guidelines and information systems and outlines potential developments that may make guideline use more convenient and practical.

Finding Practice Guidelines

How could a physician find guidelines to help care for Mr James? A Medline search would certainly identify several relevant guidelines; Medline, however, has two drawbacks. First, to appear in a Medline search, a guideline must either be published in an indexed journal or be specially indexed for inclusion in Medline. Although many guidelines are published in indexed journals, many others are not. A second limitation of Medline is that it does not usually make the text of the guidelines available.

The World Wide Web offers an alternative to Medline. There is a substantial number of guideline resources on the Web that continue to evolve rapidly. The selected websites listed in Table 1 provide access to hundreds of guidelines that often include full text and graphics. Many of the websites are maintained by academic, governmental, or professional organizations. Certain websites are simply directories; for example, the site maintained by the Canadian Medical Association lists over 200 guidelines with links to further information about the guidelines. Some sites serve as directories to other directories, which themselves list many guidelines. This is the case with Medical Matrix: its websites provide links to the guidelines developed by the Agency for Health Care Policy and Research, the National Institutes of Health, and the American College of Cardiology, among others. The American College of Cardiology site is an example of a website developed by a professional organization. Certain websites, such as that of the Guideline Appraisal Project, represent the activities of ongoing research projects that study the development, dissemination, and evaluation of guidelines. As Table 1 shows, a site may use hypermedia (involving text, graphics, pictures, movies, and sound) to represent guidelines and related material. Computer-based representations enable guideline developers to produce an interactive interface[22] to present recommendations that are based on patient-specific information.[23]

Can these Web resources help physicians find guidelines for their patients? In the case of Mr James, a review of sites yields guidelines on ischemic heart disease, congestive heart failure, angina, diabetes, and preventive care that may apply to his overall care (Table 2). Some of these guidelines were available on Medline; others were not. The full text of each of these guidelines is available on the Web, which makes it possible for a physician to download the guidelines and print them directly in the office. Thus, Web-based resources can provide help for guideline identification beyond that available in Medline.

Given the guidelines in Table 2, what do you do with Mr James? The first problem to note is that a relatively cursory investigation found only 15 guidelines that apply to Mr James; a more thorough search would most likely double (or even triple) that number. To find the most appropriate guidelines, you would need to read each of them to see whether they apply to Mr James, whether you agree with the guideline recommendations, and whether the Acme Health Care plan authorizes the recommended interventions. These steps can be complicated and time-consuming. As I discuss in the next section, however, there is a better way—at least in certain situations. An additional concern is that anyone can develop a guideline, and virtually anyone can put a guideline on the Web. Users must therefore take special care to evaluate the quality and source of Web-based guidelines. One way to do so is to limit the use of Web-based guidelines to those developed by known and trusted organizations.

The resources on the Web may make it easier to identify and obtain appropriate guidelines than do paper-based methods. Computer-based representations of guidelines can have audio tracks, still pictures, movies, and interactive formats not possible on printed material.

TABLE 1.—*Selected Guideline Resources Available on the World Wide Web*

Organization/Web Site	*Description of the Site*	*URL*
U.S. National Library of Medicine, Health Services Technology Assessment Text	Provides access to guidelines by AHCPR, NIH, and US Preventive Services Task Force, among others; search capability	http://text.nlm.nih.gov/
Medical Matrix, Healthtel Corporation	Provides links to a database of resources that can assist in patient care; the websites are reviewed by an editorial board composed of members of the Internet Working Group of the American Medical Informatics Association	http://www.medmatrix.org/SPages/Practice_Guidelines.stm
McMaster University, Guidelines Appraisal Project (GAP) homepage	Appraises, summarizes, and disseminates information about practice guidelines	http://hiru.mcmaster.ca/cpg/default.htm
Canadian Medical Association	Offers links to over 200 guidelines, indexed by discipline, title, and developer	http://www.cma.ca/cpgs/
Alberta Medical Association	Features a catalog of guidelines, indexed by discipline (e.g., dermatology)	http://www.amda.ab.ca/cpgs/ catbody.htm
Talaria Website/Madigan Consulting	Shows a hypermedia implementation of the AHCPR cancer pain-management guideline, with associated resources	http://WWW.Stat.Washington.edu/TALARIA/TALARIA.html
American College of Physicians	Has a search capability for guidelines published in the Annals of Internal Medicine	http://www.acponline.org/journals/annals/pastiss.htm
Radiologic Society of North America	Offers links to many guidelines indexed by developer	http://www.rsna.org/practice/guidelin/guidelin.html
American College Cardiology (ACC)	Provides ACC/AHA guidelines on management of heart disease	http://www.acc.org/all/clinical/guidelines/index.html
American Heart Association (AHA)	Features scientific statements about heart disease and stroke	http://www.americanheart.org/pubs/scipub/statements/
Centers for Disease Control (CDC)	Offers prevention and travel guidelines from the CDC	http://www.cdc.gov/
American Association of Clinical Endocrinologists (AACE)	Provides access to AACE clinical guidelines about endocrine disease	http://www.aace.com/guidelines/index.html
All Saints Healthcare System, Inc., Health Sciences Library	Has links to practice guidelines on a variety of current topics	http://www.execpc.com/~vbudzisz/practg.html
Decision Sciences Group, Harvard University	Shows interactive implementation of National Cholesterol Education Project guidelines	http://dsg.harvard.edu/public/guidelines/cholesterol/chlintun.html

These resources can indeed make finding guidelines easier, although clinicians are still faced with the problem of how to use them.

Putting Practice Guidelines into Practice

Mr. Jones's example highlights the problem that a physician must not only find, but determine how to use, the many guidelines that could apply to a single patient. When a patient has multiple medical problems, this task could easily become preposterous. A preferred approach would be to make the guideline to come to you, rather than have to find the guideline yourself. How would this be possible?

The best approach is to integrate the clinical guidelines with a hospital information system or an electronic medical record. Both electronic reminder systems[24–31] and more complex guidelines that are integrated with an information system[32–34] increase physicians' compliance with the intended intervention. A report by Safran and colleagues provides an example. They studied the use of computer-based guidelines that were integrated into an electronic medical record for the care of patients with human immunodeficiency virus (HIV).[32] The computer-based system alerted health care professionals when a patient's status changed to the point at which prompt action was warranted, and it issued reminders when a clinical intervention was necessary, but not urgent. The investigators divided clinicians into two groups: intervention and control. The computer-based system generated alerts and reminders for both groups but simply stored them for the control group. The investigators studied the length of time from the generation of an alert or reminder to the clinician's performance of an appropriate intervention. In the intervention group, the median response time to alerts was 11 days. In the control group, which did not receive alerts or reminders, it was 52 days The median response time to reminders was 114 days in the intervention group; in the control group, it was more than 500 days. The substantial difference in

TABLE 2.—*Guidelines that Might Apply to Mr James*

Organization	*Guideline*	*URL*	*Text Availability*
American Heart Association	When to Start Cholesterol-Lowering Therapy in Patients with Coronary Heart Disease	http://www.americanheart.org/pubs/scipub/statements/1997/ 039702.html	Web, Medline
American Heart Association	Summary of the Scientific Conference on the Efficacy of Hypocholesterolemic Dietary Interventions	http://www.americanheart.org/pubs/scipub/statements/1996/ 1203.html	Web, Medline
American Heart Association	Statement on Exercise: Benefits and Recommendations for Physical Activity Programs for All Americans	http://www.americanheart.org/ pubs/scipub/statements/1996/ 0815_exp.html	Web, Medline
American Heart Association	Guidelines for the Evaluation and Management of Heart Failure	http://www.americanheart.org/ pubs/scipub/statements/1995/ 21955555.html	Web, Medline
Therapeutics Initiative, University of British Columbia	Medical Management of Ischemic Heart Disease: The Optimal Use of Nitrates	http://www.interchg.ubc.ca/jauca/pages/letter6.html	Web
American College of Cardiology	Exercise Testing	http://www.acc.org/all/clinical/ guidelines/index.html	Web, Medline
American College of Cardiology	Evaluation and Management of Heart Failure	http://www.acc.org/all/clinical/ guidelines/index.html	Web, Medline
Agency for Health Care Policy and Research	Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction	http://text.nlm.nih.gov/	Web, Medline
The American Association of Clinical Endocrinologists	Diabetes Guidelines	http://www.aace.com/guidelines/index.html	Web
American College of Physicians	Guidelines for Risk Stratification After Myocardial Infarction	http://www.acponline.org/journals/annals/01apr97/ppmi.htm	Web, Medline
U.S. Preventive Services Task Force	Screening for Colorectal Cancer	http://text.nlm.nih.gov/	Web, related article in Medline (Gastroenterology UI: 97054357)
U.S. Preventive Services Task Force	Screening for Hypertension	http://text.nlm.nih.gov/	Web
U.S. Preventive Services Task Force	Screening for High Blood Cholesterol	http://text.nlm.nih.gov/	Web, related article in Medline (Am Fam Phys UI: 90144431)
U.S. Preventive Services Task Force	Diet and Exercise Counseling	http://text.nlm.nih.gov/	Web
U.S. Preventive Services Task Force	Screening for Problem Drinking	http://text.nlm.nih.gov/	Web

the response times indicates how guidelines that are merged with routine clinical care can greatly affect the process of health care.

The study by Safran and colleagues demonstrates an advantage of computer-based implementations of guidelines. With traditional guideline implementation, the provider must determine, for each patient, whether the guideline recommendations apply. This determination consists of noting if the conditions that should lead to an intervention are met: Is this woman over age 50? Has she had a mammogram within 12 months? Is this patient's CD4 lymphocyte count less than 200 cells/mm^3? Is the patient receiving PCP prophylaxis? When a computer-based guideline is integrated into a hospital information system or electronic medical record, the computer system answers questions such as these by evaluating the necessary conditions from databases of patient information (for example, laboratory test results). Computers are superb at this task; physicians are not, in part because the relevant patient data often are not available.[35–37]

Three recent reviews have summarized over 100 randomized trials of computer-based reminders, guidelines, and information systems.[35–37] These overviews suggest four findings[35]: computer-based reminders for preventive services increase compliance with guidelines for most interventions (such as vaccinations, breast cancer screening, colorectal cancer screening, and cardiovascular risk reduction), but not for all (cervical cancer screening and other preventive services); computer-based reminders usually, but not always, improve physicians' compliance with guidelines for the care of active medical problems (such as hypertension or diabetes); there are few studies that evaluate the effect of computer-based systems on patient outcomes; and there are virtually no studies that address the cost-effectiveness of

computer-based guideline implementation. The three studies provide strong evidence that computer-based reminders and guideline implementations do, in fact, result in the intended changes in provider behavior. Evaluations of the effect of these systems on patient outcomes, rather than on the process of care, are more difficult and more expensive to perform.[35,38] Such studies are clearly needed, however, because changes in the process of health care do not necessarily result in improved patient outcomes.

If computer-based reminders and guideline implementations are useful, why are most health care professionals using paper-based systems? There are two main reasons. First, a computing infrastructure to support computer-based guidelines is not in place. Without an electronic medical record and the associated databases of patient information, comprehensive computer-based implementations of guidelines are not feasible, at least in outpatient situations. Hospital information systems often are comprehensive, but—with some notable exceptions—few have been designed to incorporate guidelines.[32,39,40] The current computing infrastructure in medicine is comparable to that in the airline industry before computer-based reservation systems or to that in banking before the use of computer-based financial transactions.

The second reason that most health care professionals are still using paper-based systems is that there are substantial technical challenges to the comprehensive implementation of computer-based guidelines. Implementing guidelines in electronic medical records requires developers to design guidelines more carefully than they have in the past.[41,42] Tierney and colleagues tried to implement the Agency for Health Care Policy and Research guideline for the treatment of heart failure[43] in an electronic medical record and made five observations: the guideline definition of heart failure relied on an echocardiographic criterion, ejection fraction, that was not routinely reported at their institution; the algorithm branch points were not defined clearly enough to enable computer-based implementation; the branch and decision points relied on evidence (such as symptoms, findings on physical examination, or laboratory data) that was not readily available; the guideline did not consider comorbid conditions or concurrent drug therapy; and there was little discussion of patient follow-up.[41]

These types of problems most often occur because language that clinicians are able to interpret without difficulty is not precise enough for a computer. For example, Tierney and colleagues[43] note that an algorithm warns against using angiotensin-converting enzyme (ACE) inhibitors in patients who have a "history of adverse reactions or intolerance"—a warning that immediately leads to the questions, What constitutes an adverse reaction? and What is the definition of intolerance? Guideline developers must define the recommendations in terms that are specific and in a way that allows the recommendations to be programmed into the information system. Thus, for a computer system to be able to identify an adverse reaction, the developers must specify what constitutes an adverse reaction (for example, the presence of persistent cough or a rise in serum creatinine levels above 2.0 mg per dL [180 μmol per liter]), and the information system must have access to necessary data (such as clinical history and laboratory test information).

Guideline implementation poses many technical challenges for the developers of information systems.[37] Although a full discussion of these challenges is beyond the scope of this paper, they include the difficulty of capturing the required clinical data (such as the history of a cough in a patient treated with ACE-inhibiting drugs); the lack of standards for the development of medical vocabularies and knowledge bases; the requirement for confidentiality of patient records and information; the uncertainty about the legal liability of a system that makes (or erroneously does not make) clinical recommendations; and the difficulty posed by evaluation of the cost effectiveness of such expensive clinical information systems. Developers have made progress in many of these areas,[39] but substantial research challenges remain.

Developing Practice Guidelines

Suppose that, instead of just wanting to find and use guidelines for Mr James's care, you have been asked by Acme Health Care to help develop guidelines that would promote high-quality, cost-effective care for Mr James and patients like him. What is the best way to proceed? One method would be to convene a local panel of experts and try to reach a consensus regarding the best practices for each of Mr James's medical problems. This approach, perhaps the most common and traditional method for guideline development, is the fastest and least expensive way to develop original guidelines. But what if, in our example, the director of quality assurance at Acme Health Care has stated that they only accept guidelines based on "thorough review of the scientific literature"? Developing evidence-based guidelines requires doing more than seeking expert consensus; it calls for the review of perhaps thousands of studies—a far larger task than most physicians are able to undertake. For example, the guidelines developed by the AHCPR required about two years of work and substantial resources. Alternatively, currently available guidelines could be reviewed and adapted for use with Acme Health Care—an approach that many institutions have adopted.

The task of producing guidelines for Acme Health Care illustrates many challenges in guideline development. First, the evolution from consensus-based guidelines to evidence-based guidelines[4–9,44] means that guideline development now requires more time, resources, and specialized expertise than in the past. Review and synthesis of the literature may require expertise in meta-analysis, decision analysis, clinical epidemiology, and cost-effectiveness analysis. Thus, guidelines are likely to be developed by large organiza-

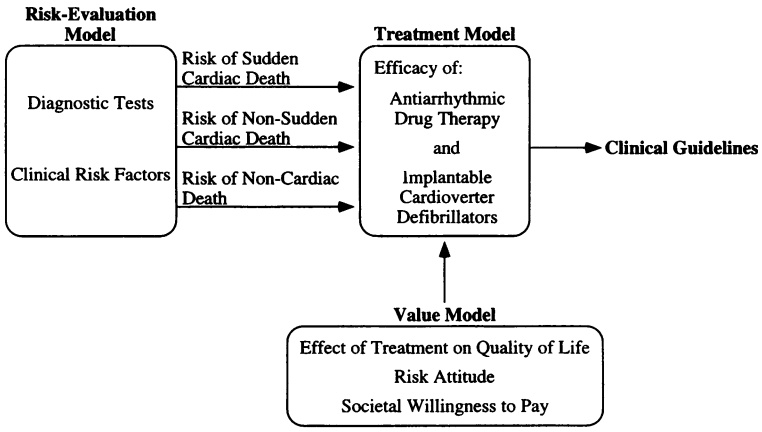

Figure 1.—The figure is a schematic diagram of the decision model developed in the Cardiac Arrhythmia and Risk of Death Patient Outcome Research Team project.

tions that have substantial resources. Second, because guidelines will be used in local practice environments that may differ substantially from one another, guidelines often must be tailored for use in individual practice settings.[45–47] Third, Acme Health Care (and other health care organizations) needs a mechanism for keeping its guidelines up to date. In areas of medicine that change rapidly, such as therapy for HIV disease, guideline recommendations may become obsolete (or even be considered harmful) in two years or sooner. Research in medical informatics has begun to address these, and other, challenges.

Reusable Software for Protocol-Based Care

One approach to the problems inherent in guideline development is to design reusable software tools that enable developers to rapidly create guidelines or protocols. A 10-year research program at Stanford University led by Musen and colleagues has developed a computer system known as EON that provides such tools.[48–53] These investigators have designed software components that perform a variety of functions. The components generate patient-specific treatment plans from protocol specifications; they process patient-specific data to infer concepts about the time intervals for treatment; they perform time-oriented queries on a time-oriented patient database (for example, "Has a patient had anemia during the period in which he was treated with zidovudine?"); and they facilitate the acquisition and maintenance of protocol or guideline knowledge so processing is efficient for both clinical experts and computers. The researchers used EON to implement a computer-based medical record system that offers advice regarding the care of patients who have HIV disease,[54] and they recently demonstrated the rapid development of a prototype application to support care for patients who have breast cancer. The tools developed in this project have the potential to make the development of protocols faster and less expensive. They would enable developers to reuse software components and build protocols using graphical tools that are linked to knowledge bases and that contain information about specific diseases and treatments.

Decision Models as an Aid to Guideline Development

A second promising area of research involves the creation of analytic tools to help develop guideline recommendations. *Decision models* are created as formal representations of decision problems and include the alternative treatments or tests, the probability of intervening chance events, and the value of health and economic outcomes.[55–57] Decision models enable developers to structure guideline problems systematically,[58] to prioritize information acquisition,[59] to develop site-specific guidelines,[45] and to evaluate the cost-effectiveness of the explicit incorporation of patient preferences.[60]

An example of how decision models can provide the foundation for guideline development is the Cardiac Arrhythmia and Risk of Death Patient Outcome Research Team project, a five-year multi-institutional project designed to assess the effects of strategies to prevent sudden cardiac death on length of life, quality of life, and costs.[61,62] This project developed a decision model that assesses the cost-effectiveness of using the implantable cardioverter defibrillator (ICD), compared with drug therapy, to prevent sudden cardiac death. As shown schematically in Figure 1, the treatment model uses information about the risk of death from various causes, the efficacy of therapy, and patient preferences to assess the effectiveness and cost-effectiveness of alternative therapies. The resulting estimates provide a scientific foundation for the development of guidelines. (A detailed explanation of this model, with evidence tables that summarize the pertinent literature, is available on the Web at http://www-smi.stanford.edu/projects/scd/. This site is designed to enable clinicians, policymakers, and guideline developers to examine the assumptions, evidence, and model structure used to evaluate strategies to prevent sudden cardiac death.

In addition, a recently developed method enables users at remote sites to access the model to perform analyses via the Web.[63] Thus, a guideline developer at a remote site can change model inputs to reflect local circumstances and can determine whether such changes warrant the development of different guideline recommendations. If they do, the developer can create a site-specific guideline. The ability to disseminate a decision model (or to have it used remotely over the Web) would provide local developers with a tool to evaluate the need for such guidelines; previous analyses indicate that the development of site-specific guidelines can be noticeably advantageous.[45] Thus, as shown in Figure 2, a centrally located guideline resource, such as a professional organization or a governmental agency, could develop both a guideline and a decision model and disseminate each to potential users. The users could then modify the guideline using the decision model as an aid.

To facilitate the development of such site-specific guidelines, Sanders and colleagues are designing a computer-based tool that automatically generates annotated clinical algorithms from decision models (Figure 3). Because the system uses a decision model to create the algorithm, it will be useful for only the subset of guidelines that are based on decision models. A decision model, however, does not contain all of the information needed to develop an annotated algorithm. The system therefore prompts the developer of the decision model to supply additional information—such as the objective of the guideline, the intended target population, the assumptions underlying the decision model, and the relevant clinical definitions. By denoting the perspective of the underlying decision model, the system also highlights the important distinction between guidelines developed from the perspective of society, of a health plan, or of individual patients. Such a distinction is particularly important if a guideline is based on a cost-effectiveness analysis.

Looking Ahead

Will medical informatics make developing, finding, and using guidelines easier? Innovative use of the World Wide Web should continue to improve the accessibility of guidelines. Guideline use should become easier as developers integrate guidelines within information systems and electronic medical records. Well-integrated systems eventually should make the problem of finding guidelines a historical footnote. Integrated systems will determine for each patient the guidelines that apply and then prompt the clinician. Figure 4 shows a hypothetical system that has noted potentially applicable guideline-based interventions for Mr James; the system enables the clinician to reject or accept the recommendations. For example, if a clinician believed that the recommendation of using an ACE-inhibiting drug was appropriate, he or she would check the "agree" checkbox, which would lead to a menu calling for the choice of a specific drug and dose. The system would then electronically send the prescription to the pharmacy. Such a system would also have hyperlinks to explanations of the guideline recommendations, the guidelines themselves, and associated relevant studies. The goal of this system is to provide information that physicians need to care for patients—when the physician needs the information—and decrease the time it takes to process and act on that information.

What must happen before such systems can become available? An informatics infrastructure—comprehensive electronic medical records or information systems—must become widely available. Medical vocabularies must become sufficiently standardized, to ensure that an information system can understand the meaning of and relationships between medical terms. Guideline developers must produce guidelines that are precise enough in their recommendations to be encoded in information systems. The developers of integrated guideline systems must choose the guidelines that the system uses, which is a potentially formidable task. The system, based on patient-specific data, would need to dynamically determine which of the possibly relevant guidelines are most appropriate for a specific patient. Such a system would have to include methods to prioritize guideline recom-

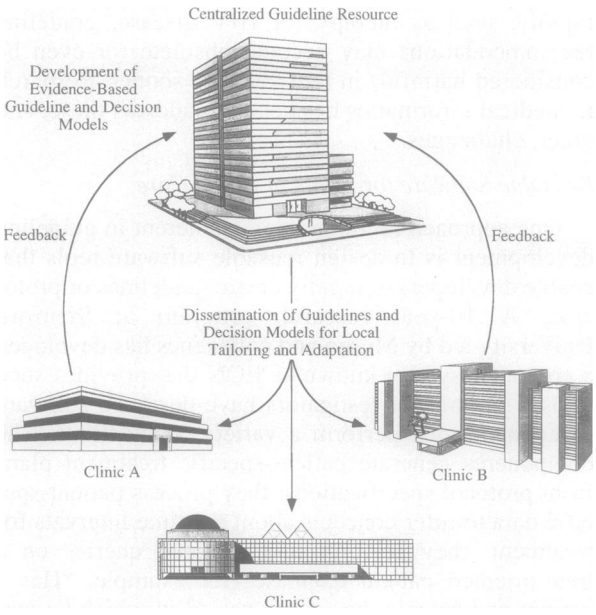

Figure 2.—The figure provides a schematic diagram of an approach to the development of site-specific clinical guidelines. A centralized guideline development resource, with necessary expertise in evidence synthesis, develops a decision model and guideline and disseminates both to local sites (Clinics A, B, and C). The local sites use site-specific information about their patient populations and practice settings, in conjunction with the decision model, to evaluate whether the guideline recommendations require modification at each site. The local sites provide feedback to the centralized guideline development center on the success of implementation, the modifications that were needed for local implementation, and the effect of guideline implementation on health and economic outcomes.

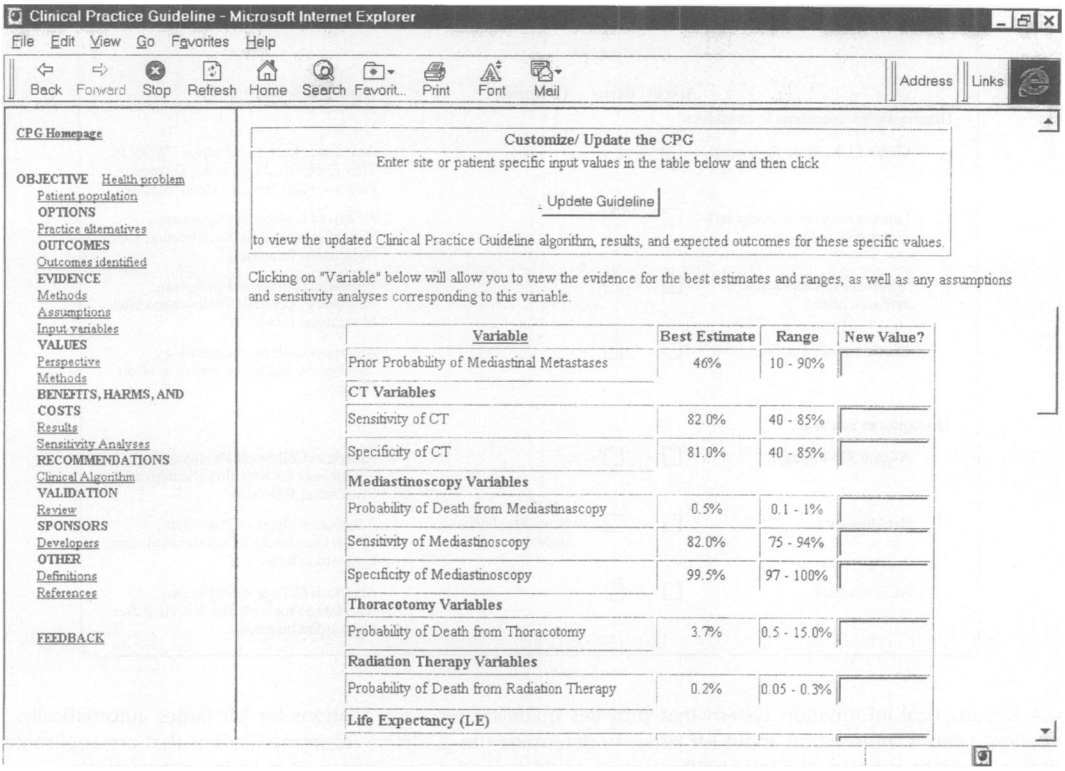

Figure 3.—This figure illustrates the computer interface of a Web-based system for tailoring clinical practice guidelines (CPGs) for local clinical settings. This system, under development at Stanford University, enables a guideline developer at a remote site to access a decision model and change the value of input variables. The figure shows a screen used to update a guideline for staging non–small cell lung cancer. The local developer can change the value of input variables for the previous probability of mediastinal metastases and the sensitivity and specificity of computed tomography (CT) or mediastinoscopy, among others.

mendations and, potentially, reconcile those that conflict. Institutions that use these systems will likely require the development of policies that address not only the monitoring of compliance with guidelines, but the effect of noncompliance on the clinician's liability. Although these challenges are substantial, systems that exist today have already solved many of these problems.

Informatics tools for developing guidelines should become more widespread and more useful. A promising model for guideline development is to use a centralized resource (such as a professional organization, a government agency, or a managed-care group) to develop guidelines; this resource, in turn, would provide tools to help users modify the guidelines appropriately for their practice settings, organizational requirements, and patient populations. A centralized resource may be useful because expertise in evidence synthesis is expensive and scarce. Such expertise alone is not enough; developers at a centralized resource may not be adequately informed about the varied clinical settings in which the guideline will be implemented. A substantial challenge for investigators will be to develop, based on current research tools, aids to guideline development that are practical and that help users tailor guidelines to their practice settings.

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REFERENCES

1. Harris J, III, Lewis T, Jackson J. What have you done for me lately?, *available on* Control (compact disc). A&M Records, CD3905/DX923; 1986

2.Field MJ, Lohr KN. Clinical practice guidelines: directions for a new program. Institute of Medicine (Ed). Washington, D.C.: National Academy Press, 1990, p 160

3.Field MJ, Lohr KN. Guidelines for clinical practice: from development to use. Institute of Medicine (Ed). Washington, D.C: National Academy Press, 1992

4.Eddy DM. The challenge. JAMA 1990; 263:287–290

5.Eddy DM. Clinical decision making—from theory to practice: anatomy of a decision. JAMA 1990; 263:441–443

6. Eddy DM. Clinical decision making—from theory to practice: practice policies—what are they? JAMA 1990; 263:877–880

7. Eddy DM. Practice policies: where do they come from? JAMA 1990; 263:1265–1275

8. Eddy DM. Clinical decision making—from theory to practice: designing a practice policy— standards, guidelines, and options. JAMA 1990; 263:3077–3084

9. Eddy DM. Clinical decision making—from theory to practice: guidelines for policy statements—the explicit approach. JAMA 1990; 263:2239–2243

10. Lomas J, Anderson GM, Domnick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. N Engl J Med 1989; 321:1306–1311

11. Grimshaw J, Russell I. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet 1993; 342:1317–1322

12. Fletcher SW. Whither scientific deliberation in health policy recommendations? Alice in Wonderland of breast-cancer screening. N Engl J Med 1997; 336:1180–1183. Editorial

Active medical problems for Mr. James: diabetes, angina, congestive heart failure, history of myocardial infarction, preventive care

	Accept	Reject	Comment	Guideline Source
Diagnostic intervensions to consider:				
Check LDL, HDL cholesterol	☐	☐		American Heart Association, "When to Start Cholesterol Lowering Therapy in Patients with Coronary Heart Disease"
Echocardiogram to assess left-ventricular function	☐	☐		American College of Physicians, "Guidelines for Risk Stratification after Myocardial Infarction"
Noninvasive stress test to assess ischemia	☐	☐		American College of Physicians, "Guidelines for Risk Stratification after Myocardial Infarction"
Check thyroid function	☐	☐		American College of Cardiology, "Evaluation and Management of Heart Failure"
Therapies to consider:				
Aspirin 325 mg/day	☐	☐		American College of Physicians, "Guidelines for Risk Stratification after Myocardial Infarction"
Beta-blockers	☐	☐	Note: Mr. James has diabetes	American College of Physicians, "Guidelines for Risk Stratification after Myocardial Infarction"
ACE-inhibitor	☐	☐		American College of Physicians, "Guidelines for Risk Stratification after Myocardial Infarction"

Figure 4.—A hypothetical information system that provides guideline recommendations for Mr James automatically. This system would use patient-specific information about Mr James to determine the guideline recommendations that are applicable. If the clinician accepted a recommendation, the information system could order the appropriate intervention automatically.

13. Garber AM, Browner WS, Hulley SB. Cholesterol screening in asymptomatic adults, revisited. Ann Intern Med 1996; 124:518–531

14. American College of Physicians. Guidelines for using serum cholesterol, high-density lipoprotein cholesterol, and triglyceride levels as screening tests for preventing coronary heart disease in adults. Ann Intern Med 1996; 124:515–517

15. Davidoff F. Evangelists and snails redux: the case of cholesterol screening. Ann Intern Med 1996; 124:513–514

16. Garber AM, Browner WS. Cholesterol screening guidelines: consensus, evidence, and common sense. Circulation 1997; 95:1642–1645

17. LaRosa JC, Pearson TA. Cholesterol screening guidelines: consensus, evidence, and the departure from common sense. Circulation 1997; 95:1651–1653

18. Bigos SJ, Bowyer O, Braen G, Brown K, Deyo R, Haldeman S, et al. Acute Low Back Problems in Adults. Clinical Practice Guideline No 14; AHCPR Publication No. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services; December 1994

19. Deyo RA, Psaty BM, Simon G, Wagner EH, Omenn GS. The messenger under attack—intimidation of researchers by special-interest groups. N Engl J Med 1997; 336:1176–1180

20. Altman R. Ten grand challenges for medical informatics. West J Med. 1997; 166:118–122

21. Shortliffe E, Perreault L, Fagan L, Wiederhold G (Eds). Medical Informatics: Computer Applications in Health Care. Reading, MA: Addison-Wesley, 1990

22. Liem EB, Obeid JS, Shareck EP, Sato L, Greenes RA. Representation of clinical practice guidelines through an interactive World Wide Web interface. Proc Annu Symp Comput Appl Med Care 1995: 223-227

23. Abendroth TW, Greenes RA. Computer presentation of clinical algorithms. MD Comput 1989; 6:295–299

24. McDonald CJ, Hui SL, Smith DM, Tierney WM, Cohen SJ, Weinberger M, et al. Reminders to physicians from an introspective computer medical record: a two-year randomized trial. Ann Intern Med 1984; 100:130–138

25. McDonald CJ. Protocol-based computer reminders: the quality of care and the non-perfectibility of man. N Engl J Med 1976; 295:1351–1355

26. McDonald CJ, Hui SL, Tierney WM. Effect of computer reminders for influenza vaccination on morbidity during influenza epidemics. MD Comput 1992; 9:304–312

27. Rind DM, Safran C, Phillips RS, Wang Q, Calkins DR, Delbanco TL, et al. Effect of computer-based alerts on the treatment and outcomes of hospitalized patients. Arch Intern Med 1994; 154:1511–1517

28. Fordham D, McPhee SJ, Adair J, Rodnick JE, Detmer WM. The cancer prevention reminder system. MD Comput 1990; 7:289–294

29. Ornstein SM, Garr DR, Jenkins RG, Rust PF, Arnon A. Computer-generated physician and patient reminders: tools to improve population adherence to selected preventive services. J Fam Pract 1991; 32:82–90

30. Frame PS. Can computerized reminder systems have an impact on preventive services in practice? J Gen Intern Med 1990; 5(Suppl):S112–S115

31. Harris RP, O'Malley MS, Fletcher SW, Knight BP. Prompting physicians for preventive procedures: a five-year study of manual and computer reminders. Am J Prev Med 1990; 6:145–52

32. Safran C, Rind DM, Davis RB, Ives D, Sands DZ, Currier J, et al. Guidelines for management of HIV infection with computer-based patient's record. Lancet 1995; 346:341–346

33. Lobach DF, Hammond WE. Development and evaluation of a computer-assisted management protocol (CAMP): improved compliance with care guidelines for diabetes mellitus. Proc Annu Symp Comput Appl Med Care 1994:787–791

34. Henderson SE, Crapo RO, East TD, Morris AH, Wallace CJ, Gardner RM. Computerized clinical protocols in an intensive care unit: How well are they followed? Proc Annu Symp Comput Appl Med Care 1990; 1:284–288

35. Johnston ME, Langton KB, Haynes B, Mathieu A. Effects of computer-based clinical decision support systems on clinician performance and patient outcome: a critical appraisal of research. Ann Intern Med 1994; 120:135–142

36. Balas EA, Austin SM, Mitchell JA, Ewigman BG, Bopp KD, Brown GD. The clinical value of computerized information services: a review of 98 randomized clinical trials. Arch Fam Med 1996; 5:271–278

37. Shea S, DuMouchel W, Bahamonde L. A meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting. J Am Med Inform Assoc 1996; 3:399–409

38. Rotman BL, Sullivan AN, McDonald T, Brown BW, DeSmedt P, Goodnature D, et al. A randomized controlled trial of a computer-based physician workstation in an outpatient setting: implementation barriers to outcome evaluation. J Am Med Inform Assoc 1996; 3:340–348

39. Doyle E. Is there a computer in the house? At Utah's LDS Hospital, information systems help call the shots. ACP Observer. (Philadelphia, PA) June 1997; pp 1,16, 17

40. Haug PJ, Gardner RM, Tate KE, Evans RS, East TD, Kuperman G, et al. Decision support in medicine: examples from the HELP system. Comp Biomed Res 1994; 27:396–418

41. Tierney WM, Overhage JM, Takesue BY, Harris LE, Murray MD, Vargo DL, et al. Computerizing guidelines to improve care and patient outcomes: the example of heart failure. J Am Med Inform Assoc 1995; 2:316–322

42. Miller PL, Frawley SJ. Trade-offs in producing patient-specific recommendations from a computer-based clinical guideline: a case study. J Am Med Inform Assoc 1995; 2:238–242

43. Konstam MA, Dracup K, Baker DW, Bottorff MB, Brooks NH, Dacey RA, et al. Heart Failure: Evaluation and Care of Patients With Left-Ventricular Systolic Dysfunction. Clinical Practice Guideline No 11; AHCPR Publication No. 94-

0612. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services; June 1994

44. Owens DK. Patient preferences and the development of practice guidelines. Spine 1998;(in press)

45. Owens DK, Nease RF, Jr. A normative analytic framework for development of practice guidelines for specific clinical populations. Med Decis Making 1997; 17:409–426

46. Fridsma DB, Gennari JH, Musen MA. Making generic guidelines site-specific. Proc AMIA Annu Fall Symp. 1996:597–601

47. Fridsma DB, Gennari JH, Musen MA. Customizing work processes for organization models. SMI-96-0645. Stanford, CA: Section on Medical Informatics, School of Medicine, Stanford University. September 1996

48. Musen MA, Tu SW, Das AK, Shahar Y. EON: A component-based approach to automation of protocol-directed therapy. J Am Med Inform Assoc 1996; 3:367–388

49. Tu SW, Kahn MG, Musen MA, Ferguson JC, Shortliffe EH, Fagan LM. Episodic skeletal-plan refinement on temporal data. Commun Assoc Comput Machinery 1989; 32:1439–1455

50. Tu SW, Eriksson H, Gennari JH, Shahar Y, Musen MA. Ontology-based configuration of problem-solving methods and generation of knowledge-acquisition tools: Application of PROTÉGÉ-II to protocol-based decision support. Artif Intell Med 1995; 7:257–289

51. Shahar Y, Musen MA. Knowledge-based temporal abstraction in clinical domains. Artif Intell Med 1996; 8:267-298

52. Das AK, Tu SW, Purcell G, Musen MA. An extended SQL for temporal data management in clinical decision-support systems. Proc Annu Symp Comput Appl Med Care 1992; 1:128-32

53. Das AK, Musen MA. A temporal query system for protocol-directed decision support. Methods Inf Med 1994; 33:358–370

54. Musen MA, Carlson CW, Fagan LM, Deresinski SC, Shortliffe EH. T-HELPER: Automated support for community-based clinical research. Proc Annu Symp Comput Appl Med Care 1992; 1:719–723

55. Owens DK, Sox HC. Medical decision making: probabilistic medical reasoning. *In* Shortliffe EH, Perreault LE, Fagan LM, Wiederhold G (Eds): Medical Informatics: Computer Applications in Medicine. Reading, Massachusetts: Addison-Wesley, 1990, pp 70–116

56. Owens DK, Nease RF, Jr, Shachter R. Representation and analysis of medical decision problems with influence diagrams. Med Decis Making 1997; 17:241–262

57. Nease RF, Jr, Owens DK. Using influence diagrams to structure medical decisions. Med Decis Making 1997; 17:263–275

58. Owens DK, Nease RF, Jr. Development of outcome-based practice guidelines: a method for structuring problems and synthesizing evidence. Jt Comm J Qual Improv 1993; 19:248–263

59. Owens DK, Nease RF, Jr. A model-based approach for prioritizing information acquisition during guideline development [abstract]. Med Decis Making 1991; 11:330

60. Nease RF, Jr, Owens DK. A method for estimating the cost-effectiveness of incorporating patient preferences into practice guidelines. Med Decis Making 1994; 14:382–392

61. Owens DK, Sanders GD, Harris RA, McDonald KM, Heidenreich PA, Dembitzer AD, et al. Cost-effectiveness of implantable cardioverter defibrillators relative to amiodarone for prevention of sudden cardiac death. Ann Intern Med 1997; 126:1–12

62. Sanders GD, Harris RA, Hlatky MA, Owens DK. Prevention of sudden cardiac death: a probabilistic model for decision support. Proc Annu Symp Comput Appl Med Care 1995; 1:258–262

63. Sanders GD, Hagerty CG, Sonnenberg FA, Hlatky MA, Owens DK. Distributed dynamic decision support using a Web-based interface for prevention of sudden cardiac death. Med Decis Making 1997; 17:524 (abstract)