Practice Guidelines: A New Reality in Medicine

III. Impact on Patient Care

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Practice guidelines are being introduced throughout medicine, but expectations about their impact on patient care depend on whether one is a clinician, patient, payer, administrator, or politician. Proponents hope that guidelines will enhance the knowledge, attitudes, and behavior of practitioners and will optimize health outcomes, costs, and malpractice decisions, but scientific evidence of these effects is limited. There are also concerns that guidelines could harm patient care. Clinicians worry that guidelines will promote "cookbook medicine," decrease their autonomy and income, and increase medicolegal liability. A particular concern relates to the expansion of enforcement programs that require clinicians to follow guidelines or face financial or other penalties. Guidelines can rarely define optimal care with certainty, due to poor science, imperfect analytic processes, and differences in patients. Recommendations are often worded in highly specific language that achieves clarity at the expense of scientific validity. Rigid enforcement of such guidelines could harm patients, interfere with the individualization of care, increase costs, and promote unfair judgments against clinicians who deviate from them for good reasons. A model that links the intensity of enforcement to the scientific and clinical quality of guidelines is proposed.

Clinical practice guidelines, which outline the proper care of medical conditions and performance of clinical procedures, are increasingly common in medicine. They are being developed throughout the health care industry to reduce inappropriate care and help control rising costs. They are also part of the health care reform legislation introduced by the Clinton administration.1 This article is the third of a three-part series addressing the role of practice guidelines in patient care. Part I summarized the types of groups that are issuing practice guidelines, including federal and state government; medical specialty societies; academic medical centers; managed care organizations; and other groups. Part II3 discussed the methods by which practice guidelines are developed.

This article explores the potential impact of practice guidelines on patient care. Views differ on whether practice guidelines are good or bad for medicine and whether the current national investment in guideline development is justified.4 This article examines the potential impact of practice guidelines on quality of care and the different expectations that are held by clinicians, patients, payers, and policymakers regarding what guidelines will achieve. The article also addresses the proper uses of practice guidelines and the potential benefits and harms of enforcing practitioner compliance with recommendations.

THE EFFECTIVENESS OF PRACTICE GUIDELINES

Differing Expectations

Attitudes about whether practice guidelines are good or bad for medicine depend largely on how one defines "good" and "bad" and on who in the health care system is judging success. What is sought from practice guidelines often differs if one is a clinician, patient,
Figure 1. The “mechanism of action” of practice guidelines. Guidelines achieve outcomes (eg, improved patient health, decreased costs) through the intermediate steps of changing practitioner knowledge, attitudes, and behavior.

<table>
<thead>
<tr>
<th>Category</th>
<th>Benefits</th>
</tr>
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<tbody>
<tr>
<td>Knowledge</td>
<td>Enhanced medical education (medical school, residency, continuing medical education); illustration of how to perform critical appraisal of evidence; definition of research agenda for future effectiveness studies</td>
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<tr>
<td>Attitudes</td>
<td>Acceptance of new “standard of care”; enhanced credibility of technologies, specialty, health conditions*</td>
</tr>
<tr>
<td>Behavior</td>
<td>Increased compliance with recommended practices; decreased practice variations*</td>
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<tr>
<td>Outcomes</td>
<td>Improved clinical outcomes (eg, morbidity, mortality), decreased costs,* enhanced value of health care; increased reimbursement for services*; decreased medicolegal liability*</td>
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*Benefits sought predominantly by specific parties, such as clinicians (increased reimbursement, decreased medicolegal liability), specialty societies (increased recognition for field), payers (decreased costs), and policymakers (decreased practice variations).

Payer, politician, administrator, or malpractice attorney. Although everyone wants practice guidelines to improve the quality of care, only patients care exclusively about clinical outcomes. Clinicians seek improvements in clinical outcomes but also want to limit impositions on autonomy, income, and medicolegal liability. Insurers, employers, public agencies, and other payers want practice guidelines to reduce costs and practice variations. Legislators and politicians want guidelines to decrease public expenditures, and administrators of hospitals and other health care organizations want them to optimize efficiency and risk management. Utilization reviewers want practice guidelines to help identify inappropriate care. Malpractice attorneys want guidelines to help prove negligence.

These differences in expectations mean that it is virtually impossible to develop guidelines that satisfy all parties. It also means that guidelines developed by one party to meet its needs may not be transferable to other entities within the health care system. Thus, it is not surprising that groups with different agendas find it necessary to develop guidelines on the same topic. Guidelines developed by a payer to determine coverage policy based on economic concerns (eg, cost-effectiveness) may recommend different practices than would guidelines on the same topic developed by a physician organization. Guidelines developed by a specialty society with concerns about income-generating procedures performed by its members may differ from those of a multidisciplinary panel representing many specialties.

Although the goal of improving the quality of patient care is sought by all parties, different measures are often used to judge clinical benefit. The “mechanism of action” by which improved patient care is achieved occurs in steps (Figure 1), and each of these steps has been cited by various parties as evidence of clinical benefit. Thus, guidelines have been considered effective if they improve knowledge, making clinicians aware of the recommendations; attitudes, getting clinicians to agree with and accept the recommendations as a new “standard of care”; behavior, getting clinicians to change practice patterns to conform with the guidelines; and outcomes, improving patient health, controlling costs, etc. Although there is universal agreement that improved health outcomes (eg, morbidity, mortality) are the best measure of success, many parties are willing to consider guidelines a success if they achieve only intermediate outcomes (eg, changing physician behavior, reducing practice variations). Commonly cited measures of success in these four categories are listed in the Table.

Scientific Evidence

There is only limited evidence that practice guidelines can achieve these outcomes. As a source of medical information, guidelines can be viewed as a form of continuing medical education. Studies of continuing medical education have shown that disseminating information, by itself, is often ineffective unless it is coupled with other interventions, such as feedback, audit, or training. Most of these studies, however, examined forms of continuing medical education other than practice guidelines. Studies that have examined practice guidelines in particular as the primary intervention (uncoupled with feedback, training, or other interventions) include the following.

Knowledge. Surveys have shown that about 60% of physicians are aware of national guidelines 1 year after their release. Familiarity with guidelines can be enhanced by aggressive dissemination strategies. In Canada, guidelines on cesarean section were disseminated by mail to obstetricians in the Society of Obstetricians and Gynecologists and were published in medical journals, the society bulletin, and the lay press. In a survey 2 years after their release, Lomas et al found that 87% of obstetricians were familiar with the guidelines. A test administered 1 year after release yielded an overall score of 67% correct; only 3% of the respondents could correctly identify the major recommendations.

In a British study, Fowler et al mailed guidelines on smoking cessation counseling to all general practitioners in the British Medical Association. Of the 3420 respondents, 51% reported having received the mailing, 28% reported having read it, and only...
9% were able to name one of the three practices promoted by the guidelines. Sadowsky and Kunzel\textsuperscript{16} found that dentists who were mailed a laminated placard with American Heart Association guidelines on antibiotic prophylaxis had significantly better performance on five of six vignette cases than did the controls who received no mailing.

Attitudes. There is little direct evidence that clinician acceptance of recommendations can be improved by the distribution of guidelines. Stange et al\textsuperscript{16} found that physicians disagreed with about 12% of published guidelines on preventive services, regardless of whether they were familiar with them before the survey. Hill et al\textsuperscript{23} found that only 6% of physicians who were aware of hypertension guidelines referred to them "very often." Nearly 40% indicated that the extent to which they based their care on the guidelines was "very little" or "not at all." More than two thirds of their hypertension treatment practices were congruent with the recommendations before the guidelines were released, and the results did not change significantly after the release. Similarly, Lomas et al\textsuperscript{17} reported that about 85% of Canadian obstetricians agreed with the guidelines on cesarean section before and after their release.

Behavior. Observational studies have shown that physicians often fail to follow published recommendations. Most of this evidence comes from preventive medicine, where studies have shown consistent discrepancies between physician practices and published guidelines.\textsuperscript{20} For example, despite well-known recommendations for annual screening mammography, McPhee et al\textsuperscript{21} found that only 13% of patients at a university internal medicine practice underwent mammography during the study year. A National Cancer Institute study found that 14% to 42% of women who had never had a screening mammogram cited the physician's failure to recommend the test as the reason for the oversight.\textsuperscript{22}

Similar findings have been reported for guidelines on other topics. One year after the 1977 release of American Heart Association guidelines on antibiotic prophylaxis, Retchin et al\textsuperscript{23} found that only 37% of eligible patients had evidence of prophylaxis in their records. Brooks\textsuperscript{24} found that only 15% of dentists followed the guidelines. Five years after the release of American Academy of Pediatrics guidelines on the treatment of acute diarrhea, Bezerra et al\textsuperscript{25} found that only 2% of surveyed physicians followed recommendations to rehydrate patients rapidly in 4 to 6 hours. Nearly 70% followed the recommendation to begin with a dilute formula.

Ford et al\textsuperscript{26} examined medical records at 17 sites that participated in the National Cancer Institute Community Hospital Oncology Program, which distributed guidelines developed by community experts. Although the guidelines emphasized the importance of staging, staging was recorded in only 67% of charts of patients with lung cancer and in 33% of charts of patients with breast cancer. Radiation therapy consultation, which the guidelines also recommended, was ordered for 50% of patients with lung cancer and 27% of patients with breast cancer.

Some observational studies have compared practice patterns before and after the release of guidelines. In the Canadian study by Lomas et al,\textsuperscript{17} 33% of obstetricians and hospitals reported that they had changed their practices as a result of the guidelines, but independent hospital delivery data showed that cesarean section rates were actually 15% to 49% higher than self-reported rates. The overall national trend in cesarean section rates did not appear to change after the release of the guideline. In the United States, Gleich\textsuperscript{27} reported that cesarean section rates had actually increased in the 5 years after the release of the 1980 National Institutes of Health consensus conference guidelines.

Some studies have observed a partial effect from practice guidelines. The Medicare program reported a decline in the frequency of pacemaker implants after its adoption in 1985 of American College of Cardiology guidelines.\textsuperscript{28} Webb et al\textsuperscript{29} observed improved compliance among pediatricians after the release of locally developed guidelines for status asthmaticus. Kosecoff et al\textsuperscript{30} examined the medical records of 2770 patients at 10 hospitals in Washington State, before and after the release of National Institutes of Health consensus conference statements. They examined compliance with 11 recommendations from four consensus statements on breast cancer, cesarean childbirth, and coronary artery bypass surgery. The study found that compliance with the 11 recommendations 1 year after the conferences (57%) did not differ significantly from rates before the conferences (52% to 57%). Compliance with three recommendations did improve significantly. Observational studies in Europe reported that distribution of guidelines was followed by a decrease in unnecessary roentgenograms in Britain\textsuperscript{31-32} and intravenous albumin therapy for hypovolemia in France.\textsuperscript{33}

Intervention studies have produced mixed results in attempts to use guidelines to change practice behavior. Schectman et al\textsuperscript{34} circulated a one-page guideline on thyroid hormone testing to 30 clinicians at a health maintenance organization. Compliance with the recommendations increased from 35% to 67% within 6 months of circulating the guideline. Wachtel and O'Sullivan\textsuperscript{35} invited 161 physicians at a teaching hospital to help develop guidelines. In the next year, the 79 participating physicians generated 21% to 34% fewer test charges than in the preceding year, but the 82 nonparticipating physicians also had a 14% to 30% reduction in charges for the same tests. Marton et al\textsuperscript{36} randomly assigned 57 medical residents to four groups, which included one group that received a manual with guidelines on cost-effective use of laboratory tests. This group generated significantly fewer charges for hospital tests than controls, but the decrease in test use was not statistically significant. A British randomized, controlled trial found that distribution of guidelines on the evaluation of infertility resulted in improved sexual history taking and physical ex-
aminations of infertile couples. A program that distributed guidelines on antibiotic selection to physicians in western Tennessee did not find a change in prescribing practices when compared with rates of physicians in eastern Tennessee, who received no intervention.

Outcomes

Health Outcomes. There is currently little direct evidence that distributing practice guidelines can improve clinical outcomes. Barboni et al reported that relapses of bronchospasm in patients previously treated and discharged from an emergency department fell from 36% to 13% after the distribution of practice guidelines. In an ongoing study, the Minnesota Clinical Comparison and Assessment Project, about 70 hospitals are collaborating to collect outcome data on the effectiveness of using locally adapted guidelines. This is part of a larger iterative process to assess whether feedback of outcome data enables clinicians to modify practice behavior, improve the quality of the guidelines, and enhance patient outcomes. Studies funded by the Agency for Health Care Policy and Research are currently under way to collect outcome data on the effectiveness of practice guidelines.

Costs. Some clinical studies have reported economic benefits from practice guidelines. Marton et al found that average laboratory charges were $21.30 per visit for patients of medical residents who received guidelines on laboratory use and $31.10 per visit for patients of residents who received no intervention. Finkler and Schwartzben found that a guideline for pediatric emergency room and walk-in patients resulted in a substantial savings when measured against average costs but only a very small decrease in the marginal cost of care. A modeling study, however, found that recently developed pressure ulcer guidelines would neither increase nor decrease costs. Burns et al found that locally developed guidelines on peptic ulcer disease reduced costs for a health plan through the prescription of less expensive medications ($93,000), fewer endoscopic procedures ($10,000), and less frequent hospitalizations ($47,000).

Although information about cost effects in clinical research is limited, news reports suggest that payers are finding economic benefits from practice guidelines. In one report, implementation of a computerized system that uses guidelines to precertify procedures cost a Blue Cross/Blue Shield Association plan $103,804 for the software but generated $265,280 in savings by denying "inappropriate" procedures. Using the same computer system, a partnership of 17 insurers covering 4.6 million persons recently reported saving $1 to $13 for every dollar invested in the service ("Medical second-guessing in advance," New York Times. February 24, 1991:Sect 3:12). The adoption of guidelines by a Kentucky health system lowered average charges for cholecystectomy at one hospital from $4474 per case in 1989 to $3712 per case in 1990; average charges per case of diabetic ketoacidosis at a children's hospital fell from $4074 to $2552 in the same year.

Malpractice Claims. There is indirect evidence that guidelines can reduce the incidence of malpractice claims. Claims for hypoxic injuries in Massachusetts fell dramatically in 1988 after insured anesthesiologists agreed to follow guidelines for intraoperative monitoring. Although factors other than the guidelines may have accounted for this trend, the insurance company lowered malpractice premiums by 20%. Because of changes in risk classification, the average anesthesiologist's premium for an occurrence policy that provides $1 million/$3 million coverage fell from $19,414 in 1987 to $13,870 in 1990 (The Internist. May 1990:10). Nationwide, the proportion of anesthesia claims accounting for malpractice settlement costs fell from 12% to 3% (JAMA. 1992;267:1575). It is unclear whether this success is generalizable to other clinical practices.

In summary, current evidence suggests that the publication of practice guidelines can improve the knowledge of clinicians and may modify their attitudes, but there is inconclusive evidence that guidelines alone can change practice behavior or outcomes. Eisenberg and Williams argued that changes in physician behavior require interventions beyond education, such as peer review and feedback, administrative changes, participation, penalties, or rewards. It is therefore not surprising that studies have shown that simply distributing guidelines does not achieve significant results. In further support of this construct, a growing number of studies are confirming that coupling guidelines with reminders, feedback, audits, training, or computer systems can produce significant improvements in practice behavior and clinical outcomes. Clinical outcomes achieved through this approach to guideline implementation include improved health for patients with diabetes mellitus, decreased anticoagulant-related bleeding, lower cesarean section rates, improved antibiotic therapy, and shortened stays in the hospital and intensive care unit.

Potential Harms

The potential benefits of practice guidelines must be balanced against their potential adverse effects. Different concerns have been voiced by clinicians, patients, payers, and other groups. Clinicians have worried that guidelines will promote "cookbook medicine" (see below). Some argue that the effort to eliminate practice variations, which helped fuel current interest in guidelines (see part I), may promote an unhealthy uniformity in medicine that does not respect differences in patient populations and practice settings. Concerns have been expressed about currency: guidelines often appear in print 1 to 3 years after the original literature review, and immediate updating is necessary to keep them current. In Sweden, a 15-year practice guideline program was abandoned, in part because it could not keep pace with rapid medical advances.
Some clinicians view practice guidelines as a potential threat to their autonomy and income.71 Eddy72 observed that "whoever controls practice policies controls medicine." Clinicians worry that guidelines may interfere with their practice; that they may include unreasonable recommendations prepared by nonclinicians who are unfamiliar with patient care; that evidence-based guidelines, which are meant to inform clinicians about the science base for clinical practices, may be used by payers as a basis for denying coverage73; that guidelines will be tied inappropriately to credentialing and hospital privileges74; and that guidelines will be misused as evidence in malpractice cases.69,75-77 Some physicians worry that their specialty will be threatened by the guidelines of another group. Guidelines are used increasingly by disciplines engaged in "turf wars" to defend the right to perform and bill for procedures.78-81

Medical educators have expressed concern that early exposure to practice guidelines in medical school and residency training may discourage young physicians from acquiring skills in clinical reasoning and from independently thinking through the logic of therapeutic choices.82 Researchers have argued that guidelines may discourage innovation65; funding agencies may be reluctant to award grants for studies of treatments that receive unfavorable reviews in guidelines because of lack of evidence.

Patients, payers, and politicians also have concerns about practice guidelines. Patients are disappointed when guidelines block access to desired services, providers, or coverage.83 Guidelines designed to optimize outcomes for society may not meet the needs of individuals,84 especially if guidelines become an instrument of rationing.85 Payers and politicians worry that guidelines may fail to reduce costs. By promoting services that are currently underutilized, guidelines may even increase costs.4,86

Groups concerned about liability costs, although inspired by the success of the American Society of Anesthesiologists standards (see above), doubt whether guidelines can reduce malpractice claims in other areas of medicine.75

**HOW SHOULD GUIDELINES BE USED? EDUCATION VS ENFORCEMENT**

Given these potential benefits and harms, how should guidelines be used? Historically, the purpose of practice guidelines has been educational. As implied by the term, guidelines are intended to offer guidance, to share information with clinicians to help them decide how best to care for patients. As noted above, however, studies have shown that distributing practice guidelines to physicians does not, by itself, change behavior. Clinicians generally do not act on the information without further incentives.

**Enforcement Policies**

Proponents who are eager to modify the behavior of clinicians have argued that strategies should be adopted to promote or force compliance with recommendations by threatening financial or punitive actions. This has led to enforcement programs, in which clinicians who do not follow guidelines risk losing reimbursement for services,87,88 precertification for procedures,89 and favorable malpractice insurance.90 Others have proposed more punitive approaches, in which clinicians who do not follow guidelines would risk undergoing medical review and face difficulties in obtaining licensure, specialty recertification, and hospital privileges.88 A physician's compliance with guidelines might be considered in hiring decisions or in selecting preferred providers for health plans.87,88 As part of national health care reform, practice guidelines might be imposed by a national health board or by purchasing cooperatives participating in managed competition.80 Other aggressive enforcement strategies have recently been adopted in quality assessment, state legislation, and malpractice insurance programs.

**State Legislation.** New Jersey, New York, and Massachusetts require anesthesiologists to follow guidelines on intraoperative monitoring,48 and Massachusetts law requires compliance for anesthesia licensure.90 Laws in Massachusetts and Nevada require physicians treating patients receiving workers' compensation to follow practice guidelines. The Massachusetts law considers deviation from the guidelines "an inadequate or unreasonable provision of health care services," and physicians who do not comply can be fined or reported to the board of medicine.90 New York is considering legislation that would require chart audits to verify compliance with guidelines before physicians could be recredentialed ("NY examining guidelines for physician recredentialing." Medical Outcomes and Guidelines Alert. September 30, 1993;1:3).

**Risk Management.** Negligence can be defined on the basis of a departure from published recommendations.11 Some malpractice insurers are mandating compliance with guidelines as a condition of coverage or are threatening surcharges or cancellation if a claim results from not following guidelines.80 A 5-year tort reform experiment
in Maine (Maine Liability Demonstration Project) permits physicians in four specialties who participate in the program (more than half of eligible physicians in Maine) and who follow specified guidelines to use compliance as an affirmative defense that cannot be challenged by expert testimony.100

Do Guidelines Define Optimal Care?

These enforcement policies would not be a problem if there were complete certainty that the recommendations promised optimal care for all patients. The reality is that such certainty is rarely justified. There are several reasons for this.

First, science cannot define optimal care with certainty. Few practices in medicine are supported by well-designed studies with definitive results, and the majority either have little scientific support or are based on studies with important design limitations. Typical studies leave unanswered questions about the statistical or clinical significance of results, internal validity, and the generalizability of results to conditions outside the study setting. Although existing research is often adequate to suggest clinical practices that are probably beneficial, it is impossible to be certain that practice guidelines based on this evidence are right and that alternative approaches are wrong.

Second, the process of analyzing evidence and opinion is imperfect. Methods for synthesizing data and gathering expert opinion (see part II of this series) attempt to maximize objectivity and to capture the wisdom of leading experts, but this does not guarantee that the recommendations define optimal care.4 To the extent that they are based on imperfect syntheses of the data (eg, flawed meta-analysis or decision analytic models), evidence-based recommendations can be misguided.101 To the extent that they are based on expert opinion, guidelines can advocate what experts think is beneficial, not what is proved.102 Unintended biases may also cloud the analytic process.103,104 Guidelines issued by a particular specialty or organization may lack objectivity if they recommend a procedure that provides income, reimbursement, or recognition for its members.105 The wording of many guidelines has been “toned down” to palliate outspoken panel members or to obtain the endorsement of the sponsoring organization. Guidelines developed by payers may be based on criteria that are not disclosed for proprietary reasons and that emphasize cost control over clinical benefit.106

Third, patients are not uniform. What is best for patients as a whole, as defined in guidelines, may not be appropriate for a given individual.107 The patient’s medical history, comorbid illnesses, and personal circumstances may mean that the individual is better served by options other than those advocated in the guideline. Due to biologic variation, patients respond differently to the same treatments, and thus standardized approaches often need to be tailored to achieve the best outcomes. Even if outcomes are constant across individuals, differences in patient preferences may mean that what is desirable for one is not desirable for another.108 These subtle differences between patients, which are well known to clinicians,109 often cannot be anticipated when practice guidelines are written.

The Language of Recommendations

These limitations of practice guidelines are not a problem, as long as they are communicated honestly in the wording of the recommendations and rationale. Honest uncertainty is communicated in the rationale by stating clearly which parts of the recommendations are based on science, and the quality of the evidence; and which recommendations are based on opinion, and how that opinion was gathered.3,110 The wording of recommendations should also present honestly the group’s uncertainty about what defines optimal care. Inflexible language about which practices are “right” and “wrong” is appropriate only if there is definitive scientific evidence, the group’s analytic process is unassailable, and the conclusions apply to all patients. Such statements qualify as “standards” rather than “guidelines.”111 Since this level of certainty is rarely present, flexible language is preferred to allow clinicians who disagree with the interpretation of the evidence or who must accommodate the needs of individual patients to make choices other than those advocated in the guideline.

“Wordsmithing,” the process of making subtle changes in language, assumes enormous importance in properly capturing this uncertainty. The statement, “patients should be monitored for 2 hours after surgery,” which may be based on opinion rather than data, does not clarify the rationale for the recommendation. The use of the word “should,” rather than “may,” implies that failure to monitor is inappropriate. The specification of “2 hours” implies that there is evidence that a shorter duration achieves poorer results. If there is any uncertainty about these assumptions, clinicians would have legitimate reasons for monitoring differently, but the wording of this recommendation would mislabel their actions as “inappropriate.”

In practice, many groups fail to consider these issues, and authors of practice guidelines often overstate the confidence with which they define proper care. Recommendations based on opinion have a tendency to be worded with unjustified intensity, because the authors typically feel strongly about the issue. Guideline developers are often under pressure to be as specific as possible. Inexperienced clinicians appreciate clear instructions on how to perform procedures, and clarity has therefore been cited as a key attribute of “good” practice guidelines.9,112,113 But clarity also serves the needs of those who judge physicians. Utilization reviewers, malpractice attorneys, and others who judge quality seek specifics in guidelines to help label “inappropriate” care.

This pressure to be as specific as possible can lead guideline developers to use scientifically insupportable rigid statements and inflexible language in the interest of clarity. Rather than
stating, "patients with frequent angina should be treated," a group may arbitrarily decide to state, "patients with two or more episodes of angina in the past month should be treated" to achieve greater specificity. If there is only opinion and no evidence to support this definition of frequency, the specific language may harm physicians with legitimate reasons for defining frequent angina differently (eg, three or four episodes, increased duration or intensity of pain, electrocardiographic changes).

The Consequences of Enforcement

The fact that practice guidelines do not always recommend optimal care and that their wording may misstate scientific certainty would be a relatively benign problem if guidelines were presented only as information for clinicians. Clinicians would be free to judge quality independently and to ignore poorly written guidelines. However, the limitations of practice guidelines take on enormous importance when enforcement programs, such as those mentioned earlier, require practitioners to follow recommendations or face penalties. There are several reasons for concern about forced compliance.

First, the quality of patient care could be adversely affected. If the guidelines reflect imprecise models of appropriateness, due to imperfect science, the biases of the panel, or improper wording, enforcement could mandate unnecessary services or block access to needed services that the guidelines have mislabeled as "unnecessary."114

Second, enforcement could interfere with the individualization of care. This is the essence of the clinician's fear of "cookbook medicine," simplistic algorithms that fail to recognize the complexity of medical decisions and the need for individual clinical judgment. Enforcement also interferes with the modification of care to accommodate patient preferences, thereby forcing patients to accept the preferences of an expert panel over their own.

Third, enforcement could harm practitioners. Clinicians with legitimate reasons for differing with guidelines could be labeled unfairly as "inappropriate."115 They could face unnecessary inconvenience in filing reports to defend their choices,116 lost income for denied payments, increased insurance premiums, delayed approval for procedures, and legal costs to defend claims of negligence.82

Fourth, enforcement could increase the cost of care. Tests, drugs, and procedures recommended in practice guidelines by biased groups despite inadequate evidence of effectiveness already represent a major source of unnecessary expenditures. Programs that enforce compliance without considering the validity of the guidelines could set off an even greater increase in outlays.

A Rational Model for Guideline Enforcement

Despite these concerns, enforcement of practice guidelines is needed in the proper circumstances. Given its powerful ability to achieve results and the proved limitations of simple educational strategies to change practice behavior, it would seem inappropriate not to enforce guidelines if clinicians are providing improper care. It is essential, however, that enforcement be restricted to those guidelines that are known with certainty to define optimal care. In such cases, in which the evidence is clear, rigid guidelines are indicated, compliance should be expected, and enforcement programs are justified. In cases where optimal care is less certain, however, implementation policies need to leave room for legitimate differences of opinion.

The obvious solution to this problem is to limit enforcement to guidelines that meet scientific and clinical standards of quality. There is early evidence, however, that policymakers are not using this approach; many are instead using either no criteria or economic criteria in choosing guidelines to enforce, presumably assuming that such guidelines are good for patients. A guideline's ability to reduce costs and practice variations is often the first consideration of payers, managed care organizations, and state governments in choosing which guidelines to enforce. News reports have named managed care groups that are under pressure by large employers to use guidelines to reduce costs by 10% to 30% (Business and Health. August 1992:22-27). Guidelines that are being enforced for risk management are often designed to minimize malpractice claims, and thus the recommendations may reflect legal more than scientific evidence.75 One such program states that guidelines should be based on "whether adherence to the proposed standard could have avoided the adverse outcome or prevented a claim from being filed."117

These misapplications of guideline enforcement suggest the need for a more sophisticated approach for deciding which guidelines to enforce. Figure 2 proposes a model that would link the intensity of enforcement to the scientific and clinical quality of the practice guidelines. ("Scientific and clinical quality" refers to the quality of the review of scientific evidence and expert opinion, the scientific appropriateness of the recommendations, and the feasibility of the guidelines in practice; it does not refer to the ability of guidelines to reduce costs, practice variations, or malpractice claims.) Under this model, high-quality guidelines that define optimal care with certainty would be suitable for enforcement, and less intensive interventions would be considered inappropriate. For example, it would be reasonable to require physicians to follow recommendations to evaluate palpable breast masses, to administer antibiotics rapidly for meningococcal meningitis, and to advise patients to stop smoking.

Conversely, a guideline with weak scientific and clinical quality would be suitable only for simple dissemination (eg, publication, meeting presentations), and any pressure on clinicians to follow the guideline would be considered inappropriate. For example, guidelines that recommend lumbar punctures for all children with febrile seizures, based on a panel's informal consensus that "it may provide..."
to guidelines, which gives clinicians the freedom to use that information as they wish, is most likely to maximize benefit and minimize harm.

The potential adverse effects of guidelines can also be minimized by the disclosure of the methods by which they were developed. This allows clinicians, policymakers, and others to make informed choices about the quality of the guidelines and how they should properly be used in public policy. This information will be of increasing importance with the anticipated emergence of multiple, discrepant guidelines on the same topic, because it will provide readers a substantive basis for judging the rationale for the recommendations.

All parties will be better served by enhancing the quality of practice guidelines. There is a need to refine current methods for evidence-based guideline development and to introduce new models for local involvement of the clinicians who must implement them. Medical sociologists and administrators have emphasized that local involvement is essential for guidelines to be accepted as new practice norms and as criteria for measuring quality. There is also a growing role for patient involvement in guideline development to provide the perspective of consumers and greater sensitivity to patient preferences.

More sophisticated approaches for disseminating guidelines are also needed. Most guidelines are simply published in medical journals. The most expansive guideline distribution program is that of the Agency for Health Care Policy and Research, which, by 1992, had distributed more than 1.5 million copies of its guidelines through a combination of media coverage, press conferences, bulk mailings to relevant organizations, and publication of a toll-free telephone number for reprint requests. However, given the limited evidence that such interventions are effective, future efforts should move beyond simple distribution programs to embrace the principles of educational outreach and social influence theory. These approaches are based on research in social psychology, which suggests that physicians are more likely to change practices when they perceive new norms for professional behavior than when they simply receive new information. Techniques such as "academic detailing" build on these principles by targeting local opinion leaders and respected organizations; distributing carefully designed professional brochures, wall charts, and other media; and providing ongoing reinforcement to promote compliance. The effectiveness of these methods is currently being evaluated in studies funded by the Agency for Health Care Policy and Research. One such study using a multicenter, randomized, controlled trial design reported dramatic improvements in compliance with transfusion guidelines. Recent demonstration projects of Area Health Education Centers in Arkansas have shown that outreach methods (academic detailing, computer systems, multimedia exposure) improved compliance with asthma guidelines.

The most important question is whether practice guidelines will improve the health of patients. Evaluation studies and databases for monitoring outcomes are critical to determine whether guidelines achieve these effects and whether different methods for guideline development and implementation influence their effectiveness. Studies that will begin to provide this information are currently under way, and the results will shed new light in the coming years on whether practice guidelines achieve the results that so many hope for.

Perhaps the most longstanding contribution of practice guidelines will be in setting research priorities. The key pieces of evidence that groups find lacking to make recommendations on clinical practices and that force decisions on the basis of opinion are probably the best targets for future outcome research. If guidelines are used in this manner to expand knowledge and decrease uncertainty about what works in medicine, their contribution to the quality of health care will be truly meaningful.
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