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Report to Congressional Requesters

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PRACTICE GUIDELINES

The Experience of Medical Specialty Societies

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Program Evaluation and
Methodology Division

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The Honorable George J. Mitchell
Majority Leader
United States Senate

The Honorable John Glenn
Chairman, Committee on
Governmental Affairs
United States Senate

The Honorable David Pryor
Chairman, Special Committee
on Aging
United States Senate

The Honorable John Heinz
Ranking Minority Member
Special Committee on Aging
United States Senate

In an effort to improve the quality, appropriateness, and effectiveness of health care services and access to such services, the Congress established the Agency for Health Care Policy and Research (AHCPR) in December 1989. Many of the functions assigned to the AHCPR had been under the purview of the National Center for Health Services Research. However, one important new function was given to the Agency: its administrator was to arrange for the development of clinical practice guidelines.

Practice guidelines for medicine are not new. For many years, some medical specialty societies have published forms of guidance as educational tools. Physicians affiliated with individual hospitals or hospital groups have also initiated guidelines, as have insurance companies and peer review organizations that exert influence on medical practice through payment or care-review determinations.

In response to your request that we examine methods for the development of guidelines, we reviewed the experience of medical specialty societies that have developed them. We contacted 35 societies that were identified by the American Medical Association or the Council of Medical Specialty Societies as possessing or developing guidelines and inquired of each whether their guidelines met the following definition:

"guidance—by whatever name—that aids practicing physicians and others in the medical community (and consumers, if included) in day-to-day decisions by describing the degree of appropriateness and the relative effectiveness of alternate approaches to detecting, diagnosing, and/or managing selected health conditions."

Twenty-seven societies responded that they possessed or were developing such guidelines, and they agreed to participate in our study. (Appendix IV lists the organizations that provided information to us.) Our interviews with representatives from these societies were structured to obtain information on

- why guidelines were developed,
- what kinds of guidelines were developed (scope, types of recommendations, types of products),
- the methodology used to develop guidelines,
- who was involved in developing guidelines,
- how guidelines were disseminated,
- what provisions existed for updating guidelines, and
- how much effort was required to produce guidelines.

The society representatives' responses to these questions are provided in appendix II. Even a cursory review of those responses is sufficient to establish that there is no uniformity when it comes to developing practice guidelines. Medical societies vary in

- the reasons why they develop guidelines (to improve quality, to guard against intrusions by others);
- the types of guidelines they produce (ranging from a 3-page quality assessment tool to a book with recommendations on whether, when, and how to treat a host of medical conditions);
- the focus of their guidelines (procedures, diagnoses);
- the persons they involve in development (most use physician members, but some include nonmembers or seek the advice of nonphysicians); and even
- the words they use to refer to guidelines ("practice parameters," "clinical policies," "preferred practice patterns").

In the course of our interviews, we also asked society representatives for their views on what characteristics guidelines should have, how guideline development should proceed, and how to maximize compliance with the guidelines and evaluate their impact. Appendix III presents the responses of the representatives on these issues, which are best characterized as varied.

- Some stated that guidelines should always be definitive, whereas others indicated that guidelines should reflect uncertainty when it is appropriate.
- Some suggested disclaimers to avoid adverse legal consequences, whereas others believed disclaimers were unnecessary.
- While a little more than half of the spokespersons reported that their society members favored guidelines, others mentioned the reservations, wariness, and resignation of some members.

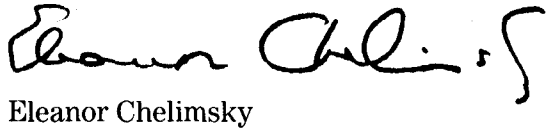
The variability evidenced both in how guideline development has proceeded in the past and in the opinions about how it should proceed in the future means that we can present no behaviors as ideal for adoption in guideline development efforts. Furthermore, the absence of evaluative studies either on the ways in which medical practice guidelines have been developed or on the impacts of guidelines limits our ability to make recommendations on the most efficient or effective mechanisms for guideline development or the best features of completed guidelines. What we can say is that the Agency's position is a challenging one in that

- it will be conducting its work in an area where many of the interested parties (medical specialty societies) have already adopted different approaches; and
- the range of opinions about how guideline development should proceed will result in opposition by some physicians to any approach the Agency adopts.

We conducted our interviews in the winter of 1990 and performed our work in accordance with generally accepted government auditing standards. Because our work focused on the activities of medical specialty societies and did not attempt to evaluate how the AHCPR has developed practice guidelines, we have not sent a draft of this report to the Agency for its comments.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after the date of the report. At that time, we will send copies to the Department of Health and Human Services, the Agency for Health Care Policy and Research, and other interested parties upon request.

If you have any questions or would like additional information, please call me at (202) 275-1854 or Robert L. York, Acting Director for Program Evaluation in Human Services Areas, at (202) 275-5885. Other major contributors to this report are listed in appendix V.



Eleanor Chelimsky
Assistant Comptroller General

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Abbreviations

AHCPR	Agency for Health Care Policy and Research
AMA	American Medical Association
CMSS	Council of Medical Specialty Societies

Introduction

Background

The U.S. Congress, in an effort to enhance the quality, appropriateness, and effectiveness of health care services and access to such services, passed legislation in December 1989 establishing the Agency for Health Care Policy and Research (AHCPR). The new agency, a successor to the National Center for Health Services Research, is charged with many of the same functions as its predecessor. Its role differs, however, in one major respect. Specifically, the legislation (P.L. 101-239) requires that the administrator of AHCPR "arrange for the development and periodic review and updating of clinically relevant guidelines." It further requires that guidelines for no less than three clinical treatments or conditions be completed under the AHCPR's direction by no later than January 1, 1991.

Although the congressional call for guidelines at first seems a radical departure from traditional policy, it is very much in line with a series of recent developments. Both the Institute of Medicine (of the National Academy of Sciences) and the American Medical Association (AMA) support the development of guidelines.[1] In fact, some medical practice guidelines already exist. A variety of groups, such as hospitals, pharmacists, and insurance companies already have developed guidelines in an effort to reduce unnecessary or inappropriate care, malpractice premiums and awards, as well as costs.

Historically, intensive efforts at guideline development in the United States have been made by medical specialty societies. (One society is currently employing a guideline that is a revised version of one that was first written in 1938.) Furthermore, within the past 2 years, many medical specialty societies nationwide have initiated or accelerated efforts to provide medical practice guidelines. The magnitude of this effort is attested to by the fact that at the time of data collection for this study, 96 different guidelines were being developed by those specialty societies with whom we spoke.

Objective, Scope, and Methodology

This report is one product in a larger effort mounted in response to a request from Senators Mitchell, Glenn, Pryor, and Heinz, in their respective roles as Majority Leader; Chairman, Committee on Governmental Affairs; and Chairman and Ranking Minority Member of the Special Committee on Aging. They asked us to examine the steps that need to be

[1]Both organizations have issued reports on guidelines. The AMA issued Attributes to Guide the Development of Practice Parameters in January 1990. The Institute issued Clinical Practice Guidelines: Directions for a New Program late in 1990. The terminology used to refer to guidelines differs in the two reports, and for purposes of clarity, we will use the term "guidelines" throughout this report.

taken to make effective practice guidelines a reality. The objective of this first study is to examine how guidelines have been developed in the past, so as to use that experience to inform future guideline development. Specifically, we describe the methods employed by medical specialty societies in their development efforts and the lessons learned from those experiences. Toward that end, we report both the unique approaches and the commonalities among specialty societies in guideline development.

After we reviewed the literature on medical practice guidelines, we met with staff from the American Medical Association and Council of Medical Specialty Societies (CMSS) for an overview of the current status of practice guideline development. They indicated that medical specialty societies have been the primary developers of guidelines and identified 35 societies that have worked on them. We sent a letter describing our study to each of those societies. The letter presented the following working definition of a guideline:

> "guidance—by whatever name—that aids practicing physicians and others in the medical community (and consumers, if included) in day-to-day decisions by describing the degree of appropriateness and the relative effectiveness of alternate approaches to detecting, diagnosing, and/or managing selected health conditions."

We asked if their guidelines met our definition and whether representatives of the societies would be willing to share their experiences with us. Twenty-seven societies responded that they had or were developing such guidelines, and they agreed to participate in our study. (Appendix IV lists the organizations that provided information to us.)

During our initial interviews, we found that there was such diversity of motivations, approaches, and views about guidelines among societies that any attempt to characterize the universe of experiences through contact with only a sample of societies would be inappropriate. Therefore, we decided to conduct interviews with designated representatives of all societies that expressed a willingness to meet with us. In most cases, we met with one or two representatives; in one case, eight persons attended for the society. In two instances, one representative described the activities of two societies.

In addition to conducting formal interviews with society and medical association representatives, we reviewed testimony presented in 1989 by federal officials, medical organization leaders, and physician experts

during hearings on proposed health care legislation. Finally, we identified and analyzed the salient characteristics of guideline examples provided to us by 20 societies that have completed guidelines.

To help ensure that our interviews contributed to an accurate and useful study, we first sent outlines of topics to be discussed so that participants had the opportunity to prepare thoughtful and complete responses. We assured them that we would not attribute information in our report to specific organizations or individuals. Finally, upon completion of the interviews, we sent copies of interview write-ups to each individual or set of individuals with whom we met, asking them to review and annotate them if they wished to correct or add information. Twenty-four organizations took the opportunity to confirm the information in our write-ups by returning them to us with a representative's signature. In some cases, additional or updated information was added or changes were made.

Because our time and resources were limited, we did not obtain information from other sectors with an interest in practice guidelines—sectors such as payers and quality assurance or utilization review groups. It was beyond the scope of our work to evaluate either the ways in which guidelines have been developed or the results of those efforts because of the length of time over which guidelines have been developed, the extreme variability of the development process, and the lack of evaluative data from development efforts. Our study is thus limited to describing guideline efforts that have already been undertaken, reporting medical societies' views of the lessons they have learned, and distilling this information for use in the present federal initiative to develop clinical practice guidelines.

Experiences With Guideline Development

Introduction

No two medical specialty societies with whom we spoke have produced similar guidelines for similar reasons in a similar fashion. This appendix shows the broad range of these societies' experiences. Included are descriptions of the variety of guidelines we saw, why societies developed guidelines, who was involved, and how guidelines were developed and disseminated. The appendix concludes with information on medical specialty societies' plans for updating guidelines and the magnitude of effort involved in producing guidelines.

Kinds of Products

Guideline types vary greatly, from a 3-page quality assurance tool to a book with recommendations for whether, when, and how to treat a host of medical conditions. There is no consistent correlation between the size of a society or the length of its experience with guideline development and the characteristics of its products. Some comparatively small societies, less experienced with guidelines, produced comprehensive and innovative products.

Societies designed guidelines with different audiences, and sometimes no specific audience, in mind. Some society representatives said the potential audience influenced the form and substance of their products. One society, for example, produced a set of different products on one topic to make the guideline readily useful to several types of users. Another expected to switch from diagnosis-based to procedure-based guidelines to make them useful to health care reviewers, but felt that some of the guidelines' utility to physicians thereby would be sacrificed.[1]

Other ways in which the guidelines varied were whether

- the purpose and intended audience were stated;
- the methodology used to develop the guideline was provided;
- a listing and description of the backgrounds of the developers was included;
- the products included information on patient outcomes and risks; and
- gaps in knowledge or needed areas of research were identified.

[1]Guidelines for care of breast cancer are diagnosis-based; mammography guidelines are procedure-based. Of the 24 products we reviewed, 7 were diagnosis-based, 15 were procedure-based, and 2 were both.

Types of Recommendations

Most of the guidelines we reviewed had recommendations that specific action be taken in a given clinical situation. Several guidelines, however, indicated what could, might, or should not be done in response to a clinical problem. And some even concluded that there was insufficient evidence to offer any prescription for action.

The variation in how definitive the recommendations were was reflected in the terms the societies used to characterize those recommendations. For example, one society used the terms "rule" and "guideline" to distinguish between a required action reflecting principles of good practice (rule) and an action that should be considered but may or may not be performed depending on the patient, circumstances, or other factors (guideline). Under a rule, it is advised that deviation be justified in writing, whereas failure to follow a guideline is not implied to be improper.

Other terms used to distinguish between levels of recommendations were "standard, guideline, and practice option," where

- "standard" means that the consequences of an intervention are sufficiently well known to permit meaningful decisions, and there is virtual unanimity about the desirability of the intervention and about the proper use of the intervention;
- "guideline" means that outcomes are well enough understood to permit meaningful decisions about proper uses of an intervention, and an appreciable, but nonunanimous, majority of physicians and informed patients share preferences regarding the intervention; and
- "practice option" is used when either outcomes are not known, or a significant proportion of physicians or patients feel the intervention is not worth the benefit, or the preferences of informed patients are not known or are evenly divided.

Finally, one society categorizes its recommendations into Classes I, II, and III, with each class used respectively to designate situations where there is

- general agreement that an approach is appropriate,
- legitimate disagreement among experts, or
- agreement that an approach is inappropriate.

Reasons for Guidelines

Medical specialty societies formulate guidelines for a variety of reasons. The two primary ones we were told during the course of our interviews

were to improve quality of care or, most commonly, to defend against a variety of forces outside their specialties.

Improve Quality of Care

Representatives of several societies emphasized that while their organizations have many reasons for guideline development at this time, their primary motive is to improve quality of care. They see guidelines as educational tools for physicians and patients—tools that can help reduce uncertainty and clarify controversial and unproven areas of medicine. Among their views on the ways in which guidelines can lead to improvements in care were the following:

- Guidelines can help physicians monitor their own profession by presenting a standard for dealing with poor performance (that is, unskilled, hazardous care given by incompetent or less trained, less experienced physicians, or by physicians who work in, but are not specialists in, a specialty).
- Guidelines can help to elevate the quality of care provided by all physicians.
- Guidelines can help reduce waste and abuse, while they promote both cost-effectiveness and quality of care.

One medical organization official pointed out what he sees as a dichotomy: the types of guidelines that would help elevate the quality of care by all physicians would not necessarily meet the needs of third-party payers, who seek lines of demarcation for payment or denial of medical charges. One society has attempted to treat that issue by creating several products for one medical condition: quality assurance, risk management, and reimbursement applications as well as physician guidelines.

Defend Against Forces Outside of Specialties

The most commonly stated reason specialty societies are currently developing guidelines is to help defend against forces outside their specialties. Among the views expressed by society representatives are the following:

- Physicians want to help determine, and reduce the variability in, review and payment criteria so as to defend against unmerited payment denial. They are concerned that groups such as the federal government, insurance companies, payment review organizations, utilization and quality assurance reviewers, and health maintenance organizations may impose inappropriate guidelines.

- Physicians want to counter or preempt guidelines, developed by other specialty societies, that they believe are inappropriate or that negatively affect their society's members.
- Physicians want to reduce the need to practice defensive medicine, deter inappropriate litigation, and reduce malpractice awards and insurance premiums.

Guideline Developers

Societies are more similar to each other with regard to who develops guidelines and reviews them before publication than they are in other aspects of producing guidelines. Most involve academicians and clinicians from within their societies; some include others outside their membership.

Committees Usually Develop Guidelines

Guidelines generally have been created by committees. Although the size of committees has varied from 2 to 20 members, the majority have included from 6 to 10 members. In five societies, individuals drafted guidelines, which were then reviewed by committees and others.

Committees were usually composed of a mix of academicians and clinicians who were members of the originating society. Some societies included physicians in other medical societies that also deal with a condition or employ a procedure. (For example, in one case, each of three sister societies had a representative on the others' guideline committees.) Nonphysician medical personnel, such as nurses, and nonmedical personnel, such as writer-editors, methodologists, and group facilitators also served on some committees. One society worked with an insurer, and four have issued guidelines jointly with other societies or are planning to do so.

Most Had Several Guideline Reviews

Most societies had multiple reviews of draft guidelines by such bodies as other guideline development groups, guideline oversight committees, boards of directors, and executive boards. In two cases, the entire society membership received drafts for comment.

Persons outside the originating society were more commonly asked to review rather than help develop guidelines. Several societies sent drafts to executive boards of other societies that had an interest in the topics. In one instance, however, the society saw less need to go outside its membership, since specialized knowledge could be drawn from among its many members who are certified in more than one specialty.

Processes for Guideline Development

Some medical specialty societies benefited from the past experience and guidance of others; however, most laboriously evolved their own processes for guideline development. Society representatives said that AMA and CMSS meetings on guidelines were helpful, and nine societies have either engaged a well-known guidelines consultant or adapted features of his outcomes-based methodology to their processes. Initial practice guideline efforts, however, were usually lengthy, as methodologies evolved.

Literature Review and Consensus

In some cases, guidelines were based solely on the literature or solely on opinion. The majority of guideline development processes, however, included literature review and consensus among development committee members (and, sometimes, outside experts) about the strength of clinical evidence for an intervention. Some guideline developers received direct input from clinicians in the field.

Multiple Steps in the Process

Guideline developers typically (1) identified and prioritized guideline topics, (2) reviewed scientific literature (3) formed consensus, (4) drafted guidelines, (5) sent drafts for review and comment, (6) revised drafts, (7) obtained approval, and (8) printed and disseminated the products.

Many variations to that basic approach occurred. In one instance, a committee chairman developed guideline methodology and prepared drafts. In other cases, topics were suggested by society or committee members. One society placed notices in its own and other medical publications soliciting input early in the process. Sometimes there was no literature review: guidelines were based only on consensus. In some cases, experts served on committees; in others, they advised committees. Some guidelines were based on literature review alone; some were researched and written by one person, with subsequent review by others. In other cases, whole committees brainstormed and produced drafts. Two societies engaged consultants to help committee members with group process development and group dynamics. Three societies asked persons in the field to test draft guidelines.

Internal review involved from one to five layers, with final approval in almost all cases by the societies' governing boards. Societies that obtained extensive input and review, and based their guidelines on literature review as well as on expert opinion and consensus, believe their

processes yielded guidelines with high validity and credibility that were accepted by physicians.

Incorporating Outcomes of Care

Outcomes management has been described as the "technology of patient experience designed to help patients, payers, and providers make rational medical-care related choices based on better insight into the effect of these choices in the patient's life."[2] Some guideline developers believe it is valuable to integrate information about the outcomes of medical care into their societies' guidelines.

Several of our sources indicated, however, that there is a dearth of outcome information. In the absence of such information, some societies estimated outcomes, used results of controlled clinical trials when they were available, or relied on their own knowledge of outcomes and patient preferences. Many representatives said they see a need for their societies to incorporate outcomes information into guidelines, but find the cost of developing such information prohibitive. They suggested that other organizations, such as the federal government, conduct or fund outcomes research. Some have sought grants and are conducting joint outcome studies with other organizations.

Not everyone agreed that outcomes research is necessary. One representative stated that in her society's area of specialization enough studies have already been published about which medical approaches work. Another noted that published outcome data are those achieved by the very best physicians getting the very best results and do not represent the circumstances and work of average physicians. He described his society's method of obtaining these data from community physicians, against whose outcomes other community physicians will be able to compare theirs.

Finally, one society initially plans to describe estimated outcomes and will strive to develop the capacity within 3 to 5 years to use formal methods to determine outcomes. A society spokesman speculated that research may show that some choices are rational for individuals, but not for the society as a whole.

[2]Paul M. Ellwood, M.D., "Shattuck Lecture—Outcomes Management—A Technology of Patient Experience," New England Journal of Medicine, 318:23, p. 1,551.

Dissemination of Guidelines

Twenty of the societies we contacted had completed guidelines. In most cases, guidelines were disseminated to all society members at low cost through existing, sometimes multiple, vehicles. Eight societies published (or plan to publish) guidelines in, or attached to, their professional journals. Guidelines were also included in or with other society publications (for example, newsletters), were published in other societies' journals, or were mailed separately. Some societies publicized the information that guidelines were available on request, either free or at a cost. Some issued press releases indicating the existence of guidelines. One set of guidelines was published by a medical publisher and placed in medical bookstores. Several societies used multiple dissemination mechanisms.

Nearly all societies sent guidelines to all their members. Guidelines appearing in society journals, of course, reach all subscribers, as well as others who may read them in libraries and elsewhere. In other cases, societies mailed guidelines to other societies; to the Department of Health and Human Services and the Health Care Financing Administration; to deans of medical schools; and to individuals and groups, such as payers and medical care reviewers, that had expressed interest in guidelines. The press releases may reach the general public, and representatives of one society spoke of adapting its guidelines for health care consumers.

Provisions for Updating

Society and medical association representatives expressed the need to ensure that guidelines remain relevant, given the dynamic nature of medicine. Most societies have considered scheduling periodic review and updating of existing guidelines, although not all have begun yet, nor have all developed formal plans for doing so.

Schedules for review and updating are diverse: seven societies plan to review guidelines yearly; another will do so every 10 years, or more frequently if it becomes apparent that changes are needed. One society has stated that each guideline will expire after 3 years and must be rewritten unless it was revised in the meantime. Others will keep alert to changes in medicine that signal a need to revise guidelines.

Not all societies have determined who will review and update guidelines. In some cases, the groups that wrote the guidelines will review them; in other cases, the guideline development committees in place at the time of review will do so.

The Effort Required to Produce Guidelines

Society representatives reported that shaping and launching guideline development programs was time consuming. While some societies produced guidelines in as little as 3 months and one effort took 5 years, more typically development took 1 to 3 years.[3]

Of those societies that provided estimates, costs ranged from $5,000 to $130,000 per guideline or set of guidelines, excluding volunteer time. For $100,000, one society produced a guideline package that included quality assurance, risk management, and reimbursement applications with its physician guidelines.

Some societies budget for guidelines; one has set aside $500,000 over an unspecified time, with $180,000 earmarked for the first year. Other societies budget yearly amounts. Some smaller societies are devoting larger amounts of money to guideline development than are larger societies. For example, one society spending approximately $75,000 per year has 4,500 members; the one that has committed $500,000 ($180,000 for the first year) has 5,000 members; one society forecasting $218,000 for guideline development in 1990 has 15,000 members; and one committing $100,000 a year has approximately 66,000 members.

Several society representatives spoke of the value of the time physicians contribute to guideline development and the burden that volunteering places on those physicians. While in nearly all cases societies pay at least a portion of physicians' expenses, almost all physicians donate their time. One 3,000-member society is unable to furnish any funds to its guideline development program. It estimates that over a 2-year period, its physician volunteers donated a total of more than $500,000 in time, in addition to paying their own travel and meeting costs.

[3]Several society representatives speculated that future efforts will require less time since they now have criteria and methodologies.

Suggestions Provided and Issues Raised by Society and Association Representatives

Introduction

The experience of medical specialty societies with guideline development renders their views especially important to those about to embark on the process themselves. Presented below are the comments of society representatives about desirable characteristics of guidelines, factors they believe helpful to guideline development, and their thoughts on achieving compliance with and measuring the impact of guidelines. The appendix concludes by listing some questions and concerns expressed by society representatives about guideline development.

Varied Characteristics of Guidelines

In appendix II, we described components of existing guidelines. Medical association and specialty society representatives correspondingly offered a variety of views and suggestions—sometimes conflicting—about what they considered to be characteristics of good guidelines (for example, how recommendations should be framed and how guidelines should be designed to avoid legal pitfalls). Spokespersons also provided suggestions about disclosing the bases, methodologies, and targets of guidelines.

Guideline Recommendations

As noted earlier, medical specialty societies approached guideline recommendations in different ways. Whereas some were quite definitive, others developed guidelines for areas of uncertainty or conflict regarding appropriate practice. Suggestions by society representatives for framing recommendations ranged from advice that they be quite prescriptive (that is, do this, do not do that) to advice that they be explicitly neutral when necessary or that they state that there is legitimate disagreement over the best course of action.

Legal Considerations

In the view of some societies, guidelines should be developed to minimize possible adverse legal consequences. Some suggest using disclaimers to emphasize that the societies neither endorse particular interventions nor present the guidelines as the only acceptable approaches. One society's lawyers cautioned guideline developers to avoid using such words as "always," "never," and "standards." Another society believes it unnecessary to attach disclaimers, noting that topics should be chosen and guidelines formed with sufficient scientific rigor that the society can stand behind its products without qualification.

Society representatives advised that guidelines be flexible enough to avoid unreasonable restraints of trade. They stated that overly restrictive guidelines could present resource or technology requirements that might unjustly preclude some physicians from practicing.

Public Disclosure

Medical societies differed greatly in the extent to which they disclosed how guidelines were formed and who developed them. Proponents of disclosure suggested that information be provided on

- the intended users of the guidelines;
- the methodology used to develop them, including the evidence used to reach conclusions (e.g., literature, efficacy and outcomes information, consensus);
- areas of variation, ambiguity, and controversy, including issues about which there was a lack of unanimity;
- areas where additional research is needed because of gaps in knowledge; and
- resources needed to implement the guidelines.

Perceived Factors for Successful Development and Dissemination Process

Medical specialty society spokespersons shared many suggestions they believe would be helpful to the guideline development and dissemination process. For example, they offered suggestions on who should be involved, how to increase the efficiency and effectiveness of the process, and how to address and reduce the magnitude of effort required.

Who Should Be Involved?

Society representatives emphasized the need for vigorous guideline development committee leaders who are skilled at facilitating group processes. They recommended engaging recognized, respected panel members from various parts of the country—members who are enthusiastic and dedicated to completing the job of guideline development. They emphasized the value of including persons who represent both sides of an issue, but also cautioned that persons involved with development be neither rigid nor overly ideologic. One spokesperson also stated the importance of demonstrating the independence of the committee developing the guidelines. This avoids creating the appearance that the committee is driven by the federal government or proponents of special interest groups.

Some persons recommended including on committees representatives, as appropriate, from outside the originating society, such as persons from other subspecialties or specialties, nurses, hospital representatives, insurers, clinicians and academicians, consumers, and third-party payers. Society spokespersons recommended using consultants to help develop background material, build consensus, and help limit the negative influences of dominant committee members. They emphasized the value of good editorial and administrative staff. Finally, they emphasized the value of involving all members of the originating society in providing initial input and reviewing and commenting on drafts.

How to Increase Effectiveness

As society representatives described their experiences with guideline development and dissemination, they spoke of pitfalls they experienced, or those they identified and avoided, and described lessons they had learned. Without recounting their stories or how they reached their conclusions, we list their suggestions for what can be done to promote strong development and dissemination processes.

General Suggestions

General suggestions were to

- Ensure that guidelines are credible and useful.
- Offer guidelines, rather than seeming to impose them.
- Avoid politicizing guideline development.
- Allow for technology dissemination and attainment of competence before developing guidelines for a new technology.
- Link education and review tools to avoid replication of work by separate development groups.

Scope and Methodology

Suggestions about the scope and methodology for guidelines were to

- Specify, at the start of the process, the scope of all guidelines the society ultimately intends to undertake. (For example, the society will develop guidelines for 20 conditions, which account for 95 percent of all treatment costs for that specialty.)
- Make the scope of current work manageable.
- Define what should be done during the process and the methodology that will be followed; allow for evolution of the methodology if needed.
- Let society members know what is being done and how; involve the members.
- Focus on quality of care, "letting the chips fall where they may" in regard to cost. (Depending on what practice they are describing, guidelines may have positive, negative, or neutral effects on costs.)

- Incorporate ideas from other societies' development efforts.
- Conduct comprehensive literature searches.
- Hold face-to-face committee meetings.
- Recognize differences with other specialties and groups.
- Avoid duplicating the efforts of related societies.
- Use a small number of people to write the initial draft of the product.
- Have a thorough review process, incorporating review comments.
- Document the criteria and methodology.
- Keep everything "above board": allow everyone to "shoot at" the guidelines; publish guidelines in a scientific journal, allowing everyone to dispute guidelines through letters to the editor.
- Avoid disseminating guidelines through vehicles that may be discarded, such as newsletters.
- Avoid sending guidelines through bulk mail; this type of mail is not forwarded.
- Set expiration dates for products, at which time they are to be reevaluated for relevance.

How to Manage the Resources

Guideline developers offered suggestions and issued several caveats about managing the resources required to produce guidelines. They stated the importance of having the commitment of the organization, along with funds needed for guideline development. They pointed to the need to develop realistic estimates of the time, effort, and money that will be required. They emphasized that societies should explain at the start the extent of commitment and time that will be required of the volunteers who will work on guideline development.

Some suggested that face-to-face meeting costs be reduced through such technologies as conference calls, mail, and word processing. Another suggestion was that guideline development meetings be combined with other society meetings. Finally, one representative suggested that societies develop fund-raising programs to support guideline development.

Making Guidelines Work

For guidelines to have an impact, either physicians must be receptive to them or mechanisms must be developed to achieve compliance. Presented below are the medical society representatives' views on the related issues of receptivity and compliance. It is important to note that societies see themselves as educational arms of the medical profession, with no direct role in promoting compliance.

Receptivity

While a little more than half of the society and medical association spokespersons reported that physicians predominantly favored guidelines for the reasons discussed in appendix II, representatives spoke of reservations, wariness, resignation, or in three cases, negativism. Opinions and concerns included the following.

Guidelines Are Not Needed or Wanted

- Physicians already practice good medicine and do not need any help. Information is in textbooks, and existing material is adequate. To say that guidelines are needed implies that physicians are not practicing the best medicine.
- Guidelines will eliminate autonomy.
- Guidelines might not be effective.
- Some physicians are opposed to any kinds of rules or regulations.

Guidelines Are Difficult to Formulate

- Guidelines could be improperly written by people who do not understand medicine and who will try to "massage numbers" instead of assessing actual patient outcomes and satisfaction.
- Guidelines cannot incorporate the many different thought processes used in making diagnoses.
- Guidelines would be too limiting and, thus, may be harmful to patients if a "cookbook" approach to medicine is adopted.
- If guidelines are too explicit, physicians will not think about what they are doing.

Medical Services Will Be Reduced

- Government and third-party payers will be motivated by cost, not quality.
- They will use guidelines to limit the scope of interventions.

Guidelines May Have Other Negative Impacts

- Academicians may create guidelines with unrealistic expectations of available resources (for example, requiring facilities or equipment to which some physicians may not have access). Such guidelines could prevent some physicians from practicing.
- Guidelines could be used to establish criteria that might be applied unreasonably against physicians in litigation.

As we have seen, those medical specialty societies participating in our study are producing guidelines despite the opposition or misgivings of some members. One society's representatives said that initial fears about guidelines were allayed by informing and involving all members in

the development process. Another representative said that in order to promote receptivity, her society's development committee is taking great care to produce a high-quality, credible initial set of guidelines.

Achieving Compliance

Medical society representatives emphasized that their societies are educational, not policing, organizations. Persons we spoke with said that while some behavioral change can be expected from physicians who embrace guidelines because of a desire to practice good medicine, compliance will likely be achieved primarily through the influence of

- residency training programs,
- physician licensing and certifying boards,
- third-party payers,
- health care regulators,
- peer review and quality assurance organizations,
- society self-assessment programs,
- courts and arbitrators, and
- disciplinary boards.

Assessing Impact

Public Law 101-239 provides that the AHCPR "shall conduct and support evaluations" of the extent to which guidelines developed through the Agency's program have an effect on the clinical practice of medicine. Exactly how such evaluations should proceed is not clear. The AMA, in a report on practice guidelines, argues that

> "While better patient care is the primary benefit that is expected to result from parameters, there are strong indications that the development and implementation of parameters will facilitate benefits in other areas, such as the improved use of resources, reductions in liability exposure, and improvement of review criteria."[1]

As this statement makes clear, there are many areas that can be influenced by guidelines. Thus, evaluations that restrict themselves to one outcome (for example, mortality statistics) will necessarily provide a limited picture of the true impact of any guideline.

Persons from four societies indicated interest in, or plans to conduct, surveys to assess the impact of guidelines developed by their societies. Others spoke of the need for such studies, but said that their societies

[1]"Practice Parameters," Report EE of the American Medical Association Board of Trustees, adopted by the House of Delegates of the AMA, Dec. 1989.

lacked the funds, and therefore studies are not planned. Representatives suggested alternative organizations as potential sponsors of impact studies: the federal government, consumer groups, hospital quality assurance or other review groups, and insurers.

Questions and Concerns Raised by Specialty Societies

Since there is no uniform definition, a basic question is, "What are guidelines?" The following questions about guidelines were also raised by society representatives.

Questions About Guideline Development

- How can guidelines be sufficiently definitive without inhibiting valuable innovation either directly or indirectly through the health payment system?
- How can guideline development groups put controversy about medical approaches to rest, without becoming bogged down by debate in the process?
- How does a medical society include persons and groups outside its organization in the development process and still produce guidelines in a reasonable length of time and at reasonable cost?
- How can societies with broad scopes of practice best approach guideline development? It is comparatively easy for those societies with limited scopes; for others—such as one society that has 1,600 procedures that it may perform—the task can be quite daunting.

Cross-Specialty Concerns

In appendix II, we noted that some medical societies involve others in guideline development, and some issue joint guidelines. Coordination thus occurs for specific topics; however, society representatives point to a need for an effective, objective clearinghouse to orchestrate guideline development nationwide. They indicated that such an organization is needed to coordinate, integrate, avoid duplication, and achieve a degree of standardization of effort among societies. As one person stated, such leadership would help prevent societies from developing guidelines in a vacuum.

Several society representatives spoke of cross-specialty conflicts. One society published guidelines in 1989 to counter the negative impacts on its members of decisions by liability insurers based on the more limiting guidelines published by another society. Other persons spoke of past or potential disagreements with other societies. In some cases, societies see

a need to monitor guideline activities of other organizations to try to counter or preempt guidelines that could adversely affect their members.

Representatives spoke of the need, ultimately, to address a broader concern: how leadership will be determined for disease conditions that span several specialties. For example, which physician should lead the potential team of family physician, internist, surgeon, radiation oncologist, and medical oncologist that might diagnose, treat, and follow a breast cancer patient? Society representatives indicated that cross-specialty concerns are difficult to address, but they are important to ensuring that guidelines promote high-quality patient care.

Medical Organizations Participating in This Study

American Academy of Allergy and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology
American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery, Inc.
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association of Electrodiagnostic Medicine
American Association of Neurological Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Preventive Medicine
American College of Radiology
American College of Rheumatology
American Medical Association
American Society of Anesthesiologists
American Society of Clinical Pathologists
American Society of Dermatologic Surgeons
American Society for Gastrointestinal Endoscopy
American Society of Plastic and Reconstructive Surgeons
American Society for Surgery of the Hand
American Urological Association, Inc.
Council of Medical Specialty Societies
Society of Nuclear Medicine

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