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How physicians can help create useful clinical practice guidelines

ARE CLINICAL PRACTICE GUIDELINES useful, or just a passing fad? Many diverse groups have published guidelines recently, from the federal government, to specialty societies, to individual hospitals. On one hand, guidelines can be an opportunity to standardize disease management, enhance interaction among health care staff, and improve outcomes, including reduced costs.

On the other hand, physicians may resist, actively or passively, when guidelines are developed and imposed by outside forces solely intent on reducing costs. For example, insurers and HMOs often question physicians about a prescription choice for a specific patient, including with their inquiry a recommendation based on a clinical guideline or a treatment algorithm. Physicians tend to view such interventions with suspicion.

Nonetheless, physician resistance to clinical practice guidelines has been sometimes overstated. Fear of the effect of guidelines on litigation does exist, but in actuality, guidelines have been more of a help to physicians than a hindrance in malpractice litigation to date.

As a result of our experience formulating and assessing guidelines for the Cleveland Clinic, we have developed a team-based strategy to create guidelines that physicians will accept and use. Although it is still unclear whether clinical practice guidelines will become a universal clinical tool, we have observed that effective guidelines can be written if the development team:

- Includes representatives of all groups affected
- Designates a physician "champion" to promote implementation of the guideline
- Relies on both published evidence and clinical judgment
- Plans for adequate resources for implementation, data collection and tracking, feedback, and follow-up.

WHAT IS A GUIDELINE?

A variety of policy statements, care paths, and protocols are loosely referred to as guidelines, but the term "guideline" should be used more precisely. "Guideline" indicates a course to follow that in clinical practice tends to be broad and flexible. It should not be equated with "policy," because a policy is binding and typically requires a specific corrective or disciplinary intervention for nonadherence. Clinical practice guidelines are also different from practice protocols, or pathways, which delineate a step-by-step approach to delivering care in a specific setting or for a specific condition.[1]

Guidelines can be useful if they are done right

The format, length, and language, as well as the planning and implementation methods, vary greatly. The final document should be concise yet include key references, tables, algorithms, or other aids when applicable.[2]

Guidelines developed by the federal Agency for Health Care Policy Research (AHCPR) are the result of exhaustive research and consensus among generalists, specialists, consumer advocates, epidemiologists, and other health care planners.[3] Guidelines developed by professional societies tend to be global. Those developed by pharmaceutical companies and payers are more direct and often target resource allocation.

WHICH CONDITIONS REQUIRE GUIDELINES?

The first step in the guideline development process is to choose the condition for which

the guideline is to be developed. Factors involved in selecting the condition include:

- The frequency the condition is encountered by the clinicians who will apply the guideline
- The costs of treating the condition
- The variability of its management.

For example, a clinical practice guideline for a disease that requires vast resources would not be worthwhile if the disease is rarely encountered in practice by the groups who will apply the guideline.

The utility of guidelines that address only a part of a disease management process is debatable. For example, Erickson et al[4] found that the American College of Rheumatology's guideline for monitoring hepatotoxicity in patients receiving methotrexate is useful for physicians caring for patients with rheumatoid arthritis. However, only a minority of physicians (ie, rheumatologists) actually use methotrexate to treat rheumatoid arthritis, limiting the overall usefulness of this guideline.

WHO SHOULD DEVELOP GUIDELINES?

In writing a guideline, all interested groups have to be included

All the disciplines that have a role in applying the guidelines should be represented on the development committee. Physicians (both generalists and subspecialists), nurses, pharmacists, and allied health professionals all have a place, as do administrators, statisticians, epidemiologists, and consumers.

Member selection should be based on the pattern of practice. For example, although gastroenterologists and general surgeons are logical candidates for a team studying gastrointestinal bleeding, most patients with gastrointestinal bleeding present to the emergency service and to general internists. Therefore, emergency physicians and general internists should be included, and a "champion" should be designated to lead the effort.

WRITING THE GUIDELINE

The success of a clinical practice guideline depends on a clear objective, modest goals, good support systems, accurate data collection and tracking, and, most importantly, regular feedback of results to clinicians.[5]

What is the purpose?

The first task of the development team is to agree on an objective. Guidelines are written to improve treatment outcomes, to decrease variability in treatment, to reduce inappropriate care, and to reduce costs. The latter two reasons are valid and should be acknowledged and stated at the outset, but should never be the *primary* goals. Although cost-saving issues must be considered, these discussions should be left to the end of the guideline development process. Optimal patient care must come first.

Fortunately, streamlining and standardizing the process of care often cuts costs and improves care, although a guideline should show that the recommendations are worth any expected harms and costs (eg, any diagnoses missed as a result of not performing certain tests).[6]

For example, when a community hospital implemented a guideline for laboratory testing in patients with diarrhea, it found that eliminating the availability of certain culture techniques resulted in significant cost savings without adversely affecting patient care.[7] At another hospital, a program to identify postoperative complications in the elderly by using a "dynamic guideline" and by providing feedback to surgeons and patients before the approval of elective surgery resulted in a statistically significant drop in hospital length of stay and fewer postoperative complications.[8] Other studies have also shown that guidelines can reduce inappropriate antibiotic use[9] and reduce hospital length of stay in patients with chest pain.[10]

What evidence should be used?

Guidelines should be based on evidence of effectiveness. Whether developed locally or nationally, guidelines should be a combination of research evidence, expert opinion, and clinical experience.[11] Proof of evidence is gathered from published literature, but variations in methods and definitions of outcomes make it difficult to establish definitive evidence in all cases. Therefore, the evidence presented in clinical practice guidelines should be rated so that confidence is not misplaced.[12,13]

Localizing "global" statements

A number of "global" and regional guidelines

have been published by different organizations: AHCPR, the US Preventive Services Task Force, insurance companies, pharmaceutical companies, HMOs, and national professional societies. However, "local" guidelines should be developed. Gates[14] describes a process in which a hospital developed and implemented guidelines on cesarean section and vaginal births after cesarean section. The project was based on a national guideline and implemented as part of a state program. Gates illustrates the importance of analyzing the process for a specific hospital. As he says, "think globally and act locally."

HMOs may also find it necessary to apply a national guideline to local needs. Before a guideline on depression developed by AHCPR was adopted at Kaiser Permanente North West region, the guideline was translated into a user-oriented document, resulting in recommendations addressed mainly from a primary care perspective and in a clinical decision-oriented approach.[15]

KEYS TO IMPLEMENTING A GUIDELINE

As difficult as it is to develop a guideline, implementing it is even more difficult.[2,16] No matter how good a guideline is, it remains a dead letter if nobody follows it.

Barriers to implementation include resistance to change, inability to conform to a common goal, concern over the potential for additional work, and fear of intrusion into clinical decision-making. Some physicians perceive practice guidelines as "cookbook" medicine or regimented medical care.

Merely publishing the guideline in a journal is not effective, and physicians pay limited attention to exhortations from administrators or regulators. Direct physician education is necessary to implement any practice guideline.[17]

Guidelines need a champion

Successful adoption of a guideline requires the empowerment of one or more advocates or "champions."[18] The physician members of the guideline committee cannot rest once the document is written: they need to go out and promote it. The education can take the form of meetings, seminars, discussions,[19,20] and an intervention technique called "academic detailing," modeled on the methods of pharmaceutical sales representatives.[21,22]

Soumerai et al[23] found that small and large group discussions and informed consultations conducted by peers resulted in a significant increase in the use of aspirin and beta blockers after acute MI. However, intervention methods are not always successful. Goldberg et al[24] found that academic detailing and continuous quality improvement programs on compliance with guidelines for the treatment of depression and hypertension were generally ineffective.

Include quality indicators

To get clinicians to accept and follow the guideline and to provide feedback on the guideline's effectiveness, relevant and measurable quality indicators must be built in. Quality indicators can measure either the consistency or the outcome of care, but most health care professionals prefer indicators that measure both.[25] Furthermore, it is important to determine capacity to integrate data collection into daily practice.

KEEPING GUIDELINES UP-TO-DATE

The committee must go out and promote their guideline

Because of the rapid change in medical therapy and technology, those championing a guideline have the additional task of updating it. The degree and the frequency of updates depend on the condition and on the impact of new tests or treatments as they become available. The enactment of a guideline is itself a kind of clinical trial, potentially producing results that can and should be measured.

GUIDELINES AND MALPRACTICE LITIGATION

Many health care providers worry that practice guidelines may lead to increased litigation if they are represented as standards of care.[26,27] For this reason, guidelines should be accompanied by a statement indicating that they do not represent standards of care but are general recommendations, and that they should not replace physician judgment. Strict recommendations about tests or treatment dosage should be avoided or placed in a con-

text that allows flexibility in special circumstances.

These worries may be ill-founded, however. If physicians and hospitals agree on a set of guidelines and use them appropriately, litigation may actually decrease. A few states have introduced or encouraged the use of clinical practice guidelines in litigation usually as a defense for physicians, in an effort to decrease the cost of "defensive medicine." Some believe that adherence to guidelines could reduce defensive medicine costs by 25% over 5 years.[28]

In Maine in 1993, four medical specialties (anesthesia, emergency medicine, obstetrics and gynecology, and radiology) participated in a demonstration project in which practice guidelines were developed by consensus and were introduced as a defense against malpractice. Physicians were able to refer to guidelines to defend themselves, but the plaintiff was not permitted to use physician failure to adhere to a guideline as an argument unless the guideline had already been introduced in the physician's defense.[29]

Guidelines are rarely cited in court cases

In fact, clinical practice guidelines are rarely used in malpractice suits. A review of litigation files of two insurance companies showed that only 17 of 259 claims involved practice guidelines. The only physician or patient factor associated was the length of the physician-patient relationship; physicians who had a longer relationship with a patient were more likely than other physicians to be the subject of a claim involving a guideline.[29]

The same study surveyed 960 malpractice attorneys, who reported that guidelines are likely to be used as inculpatory evidence in 54% of cases, as exculpatory in 23%, and disputed in 23%. Attorneys who tended to use guidelines were those for whom medical malpractice occupied more than 50% of their practice.[30]

In a related report, Hyams et al[31] reviewed court records from 1988 to 1994 and found 28 cases in which guidelines were used successfully in litigation. In 22 cases, the guidelines were inculpatory and in 6, exculpatory. At present, it appears that procedural rules have favored defendant providers in the use of guidelines as standards of care rather than plaintiffs.[27]

CONCLUSIONS

Are clinical practice guidelines useful? If they are viewed as an opportunity for healthcare providers to establish common goals and to agree on an approach to disease management, then guidelines can indeed be relevant by improving exchange among healthcare givers and improving health outcomes.[32,33] On the other hand, clinical practice guidelines may be useless or detrimental if they are imposed on healthcare providers, if they are designed only to reduce costs, and if they are viewed with suspicion and resisted actively or passively.

Are clinical practice guidelines a passing fad? Such a fate is certainly possible. Direct involvement by healthcare providers, clear goals, reliance on solid evidence when available, and on clinical judgment and expertise when it is not are the best ways to promote the effectiveness of clinical practice guidelines.

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