



# CLINICAL PRACTICE GUIDELINES

*Medicine . . . is mobile, and many of us get breathless not so much by trying to keep up with medical progress as by trying to avoid being run over by it.*

—Roger I. Lee (1958)<sup>1</sup>

**R**oger Lee's observation on the runaway nature of medical progress is even truer today. Currently, the National Library of Medicine processes more than 33,000 articles each month. D. T. Durack comments that the growth of medical knowledge can be measured by the weight of medical textbooks and the numbers being produced.<sup>2</sup> The increasing complexity and rapid growth of medical science and technology have been major stimuli for the development of clinical practice guidelines as providers, payers, and regulators attempt to assess current practices and integrate new knowledge and technology.

Most health policy analysts cite three factors as providing today's impetus for guideline development:

- Practice pattern variations
- Concern with inappropriateness of care
- High healthcare costs

Uncertainties about the extent of inappropriate and unnecessary care have arisen from studies that began to appear in the late 1970s examining practice variations and discrepancies. Studies on the use of cardiac pacemakers, carotid endarterec-

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## *The Agency For Health Care Policy And Research Fosters the Development Of Evidence- Based Guidelines*

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tomy, coronary artery bypass surgery, coronary angiography, and upper gastrointestinal endoscopy support the belief that medical practices vary widely and should be made more uniform.

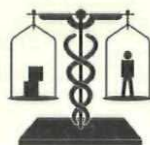
**Summary** As medical technology increases rapidly and becomes more complex, clinical practice guidelines can help healthcare providers assess current practices and integrate technological advances. Through the Agency for Health Care Policy and Research (AHCPR), the federal government has begun to facilitate the development of clinical practice guidelines.

Expert or contract panels, authorized by the AHCPR, develop guidelines on specific clinical conditions. The AHCPR guideline methodology is designed to produce evidence-based guidelines that are valid, clinically applicable, and clinically flexible.

Each panel spends a year or more developing the guideline, beginning with an extensive literature search and review. The panel prepares evidence tables, statistically analyzes aggregate data (where appropriate), conducts harm and benefit analyses, and prepares health policy analyses (or cost-impact studies).

During this process, the panel holds an open forum to solicit comments on the guideline topic. After this public discussion, the panel prepares a final draft of the guideline. Several hundred individuals review the guideline.

Some policymakers believe clinical practice guidelines can lead to better healthcare outcomes. Guidelines can provide information in a useful format for clinicians to use at the bedside or the point of decision making in patient care. Guidelines also provide information that can be used in continuing education and professional education programs.



For example, the small-area variation analyses of John E. Wennberg showed substantial differences in per capita utilization and costs for a variety of procedures and practices across hospital market areas, even after adjustment for differences in patient age and sex.<sup>3</sup> Wennberg found a sixfold difference in hysterectomy and prostatectomy rates among communities in New England.<sup>4</sup> And another study revealed twice as many carotid endarterectomies and half as many coronary bypass procedures per capita in Boston, compared with New Haven, CT.<sup>5</sup> (See **Box** on p. 36.)

Although in many cases these studies did not provide direct evidence for inappropriate, overused, or underused practices, they certainly documented the need for a careful examination of the appropriateness and the quality of the outcomes.

#### **PARTICIPANTS IN GUIDELINE DEVELOPMENT**

The medical profession has led the way in developing practice parameters. The first guideline was published by the American Academy of Pediatrics in 1938. Currently, more than 1,300 guidelines are in the process of being published or are already in print. More than 50 physician organizations; public agencies; and private researchers, payers, providers, and other groups are involved in practice guideline development. In addition, allied health professionals and private payers are beginning to participate in the efforts of the Agency for Health Care Policy and Research (AHCPR).

In response to the economic and healthcare forces that generated private-sector guideline development, the federal government has also joined the fray. The AHCPR was created through the Omnibus Budget Reconciliation Act of 1989. This legislation mandated establishment of the AHCPR, through the Office of the Forum for Quality and Effectiveness in Health Care, to help develop clinical practice guidelines, standards of quality, performance measures, and medical review criteria.

#### **AHCPR'S PERSPECTIVE**

The AHCPR defines clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."<sup>6</sup> This definition is based on the belief that clinically sound, evidence-based guidelines could improve quality of care. Additional research

demonstrates that high-quality care, delivered efficiently, also reduces healthcare costs.<sup>7</sup>

The Institute of Medicine has cited five major purposes for guidelines<sup>8</sup>:

- Assisting patients' and practitioners' clinical decision making
- Educating individuals or groups
- Assessing and ensuring the quality of care
- Allocating healthcare resources
- Reducing the risk of legal liability for negligent care

#### **THE PROCESS**

The Office of the Forum for Quality and Effectiveness in Health Care is authorized to lead guideline panels by convening expert panels or contracting with private and not-for-profit groups. These two mechanisms have been used since 1990. The guideline is thus a product of a private-sector panel of experts, supported by the AHCPR.

The AHCPR guideline development process used by the expert or contract panels is a rigorous, evidence-based methodology. Analysis of relevant literature involves a variety of processes, ranging from consensus of experts (when the literature evidence is insufficient) to meta-analysis of explicit evidence. In addition, analysis of claims data and private-sector data bases helps to describe current practice and provides baseline information on each guideline's health policy impact.

Previously, most guidelines issued by specialty societies, federal agencies, and task forces have been consensus guidelines, developed by a convened group of experts.<sup>9</sup> Today, many professional organizations are using more rigorous guideline development methods involving extensive review of existing literature and analysis of data with conclusions on explicit evidence. Significant enhancements of guideline quality, credibility, and applicability are the goals of evidence-based guidelines, which link recommendations on the quality of the underlying evidence to outcomes.<sup>10</sup> The AHCPR guideline methodology is designed to produce evidence-based guidelines that are valid, clinically applicable, and clinically flexible.

The process begins when the AHCPR selects topics using several criteria. Guideline topics must relate to:

- Clinical conditions with high resource utilization
- A significant number of affected individuals

The increasing complexity and rapid growth of medical science and technology have been major stimuli for the development of clinical practice guidelines.



## CLINICAL PRACTICE GUIDELINE TOPICS

- Management of Functional Impairment Due to Cataract in the Adult
- Diagnosis and Treatment of Benign Prostatic Hyperplasia
- Acute Pain Management: Operative or Medical Procedures and Trauma
  - Management of Cancer-related Pain
  - Diagnosis and Treatment of Depressed Outpatients in Primary Care Settings
- Sickle Cell Disease
- Prediction, Prevention, and Early Intervention of Pressure Ulcers
- Treatment of Pressure Ulcers in Adults
- Urinary Incontinence in Adults
- Initial Evaluation and Early Treatment of the HIV Infected Individual
- Low Back Problems
- Development of Quality Determinants of Mammography
- Otitis Media in Children
- Heart Failure: Outpatient Care of Symptomatic and Asymptomatic Patients with Left Ventricular Systolic Dysfunction
  - Post Stroke Rehabilitation
  - Screening for Alzheimer's and Related Dementias
  - Cardiac Rehabilitation
  - Chest Pain Due to Unstable Angina

- Significant variations in practice patterns for the condition

Selected topics are those believed to have enough available data on outcomes for evidence-based guidelines to be developed. Currently, 18 guidelines are under development or revision (see **Box**, above).

Expert panels for each topic complete the guideline development. AHCPR seeks nominations for panel members through *Federal Register* announcements and through direct mailings to private and professional organizations or individuals. Panels, which average 15 members, are multidisciplinary and always include consumer representatives.

Each expert panel spends a year or more developing the clinical practice guidelines. They begin with an extensive literature search and review of 5,000 to 100,000 relevant articles. The panel prepares evidence tables (summaries of all relevant data, risks, and harms), statistically analyzes aggregate data (where appropriate), conducts harm and benefit analyses, and prepares health policy analyses before it develops the evidence-based recommendations that become the clinical practice guideline.

During the process, each panel holds an open

Many professional societies have recommended the guidelines as course content for residency programs and credentialing.

forum to solicit comments on the guideline topic. Each open forum is announced in the *Federal Register*, and the AHCPR sends announcements to hundreds of professional organizations, industry, insider groups, consumer groups, academic centers, and other groups and persons.

After this public discussion, the panel prepares a final draft of the guideline. This draft is circulated widely to clinicians, researchers, and consumers. Several hundred individuals may review the guideline at this stage. In addition, clinicians are asked to test the guideline with patients in their practice. After this peer and pilot review, revisions are made and occasionally sent for additional peer review before the final version is submitted to the AHCPR. The guideline is then updated to incorporate new literature evidence, new products, and experience or feedback from the guidelines' utilization.

### PRODUCTS AND PERSPECTIVES

The clinical practice guidelines are designed to be useful to researchers, providers, and consumers. This is why AHCPR includes the extensive literature review and data analyses in the "Guideline Report," which usually is several hundred pages. The "Clinical Practice Guideline" (the clinician's overview) usually runs about 100 pages. In addition, a shorter "Quick Reference Guide" is intended to be the guideline's practical form. An important part of each guideline is the "Consumer Guide," prepared in English and in Spanish, to assist consumers in making informed healthcare decisions.

Primary care providers are the guidelines' principal audience. To ensure the guidelines' broad dissemination, AHCPR has established a clearinghouse. (To order guideline products or to obtain further information on their availability, call the AHCPR clearinghouse toll-free at 800-358-9295, or write to AHCPR Publications Clearinghouse, PO Box 8547, Silver Spring, MD 20907.) The clearinghouse will soon Fax press releases that highlight each guideline's major findings.

Persons interested may soon be able to access guidelines (with full-text retrieval) from the National Library of Medicine, CD-ROM versions, and computerized documentation systems that prompt clinicians to document practice based on guideline recommendations. Also, AHCPR supports evaluation studies on computerized applications of guidelines for documentation, decision making, continuous quality



improvement, healthcare provider behavior change, and a determination of whether outcomes have changed as a result of guideline usage.

AHCPR has released three clinical practice guidelines to date: "Urinary Incontinence in Adults," "Prediction, Prevention, and Early Intervention of Pressure Ulcers," and "Acute Pain Management: Operative or Medical Procedures and Trauma."

The urinary incontinence panel concluded that most patients with urinary incontinence, which affects approximately 10 million Americans at an estimated annual cost of \$10 billion (based on 1987 dollars), can be successfully treated. The guideline addresses appropriate diagnosis for this underdiagnosed and underreported condition. It also includes recommendations for treatment, including behavioral, pharmacological, and surgical approaches.

The pressure ulcer guideline panel concluded that most pressure ulcers can be prevented and recommended steps to attain that goal.

The pain management panel's literature search clearly revealed that pain is significantly undertreated. The guideline recommends tools for pain assessment and pharmacological and nonpharmacological methods of pain control. It also discusses pain control for specific operative sites and for specific types of management and includes a formal, institutional approach to management of acute pain.

#### **GUIDELINE APPLICATION**

Some policymakers believe clinical practice guidelines can lead to better healthcare outcomes. Evidence that these goals can be realized includes the basic intraoperative monitoring practice parameters of the American Society of Anesthesiologists, which reduced patients' injuries from oxygen deficiencies and reduced liability premiums of the professionals who used the parameters.<sup>11</sup> After the introduction of American College of Cardiology practice parameters on appropriate use of pacemakers in 1983, the use of pacemakers declined 25 percent during the following year.<sup>12</sup> Over a four-year period the total Medicare savings from this decrease amounted to \$750 million dollars.<sup>13</sup> Numerous other examples of practice parameters' positive impact on quality and cost exist.<sup>14</sup>

The AHCPR has authorized a work group to establish a methodology for developing medical review criteria, standards of quality, and perfor-

mance measures from clinical practice guidelines (see **Box**, p. 34).

#### **GUIDELINE IMPLICATIONS**

The guidelines have many implications for practice, education, administration, and research. Their major benefit is they provide information in a useful format for clinicians to use at the bedside or the point of decision making in patient care. The AHCPR and professional associations are disseminating guidelines to as many individuals as possible. To date, more than 1.5 million guidelines have been released in the first six months of their availability. Feedback from clinicians and consumers will help the panels update the guidelines.

Guidelines provide information that can be used in continuing education and professional education programs. Professional organizations have endorsed the guidelines. Many professional societies have also recommended the guidelines as course content for residency programs and credentialing.

States and hospitals have used the first three guidelines released to help formulate health policy. One state's governor's commission has implemented guideline recommendations to determine patient admission policies for nursing homes. Other states are demonstrating the usefulness of guidelines in protecting physicians from malpractice litigation.

Identification of research deficits has resulted from each expert panel's work and has made significant contributions to helping to define the direction and content of future research. Despite the extensive literature that exists in some (but not all) of the guideline topics, each of the panels has uncovered some basic science, applied science, health policy, and other issues that need further research. In addition to these questions, the expert panels have consistently identified research deficits in the areas of patient preference, patient satisfaction, compliance with treatment, costs, and access.

#### **POSITIVE IMPACT**

The AHCPR guidelines use a rigorous process of development for products that are intended to improve the quality of healthcare delivery. These clinical practice guidelines differ from previous initiatives in that they are evidence based and involve multidisciplinary groups. Other differences are that the AHCPR guidelines feature a health policy impact study, engage the private

During the guideline development process, each panel holds an open forum to solicit comments from professional organizations, insider groups, and others on the guideline topic.



sector in the open forum and peer review processes, and are written for both healthcare providers and consumers.

The AHCPR believes that clinical practice guidelines will have a positive impact on the quality and effectiveness of healthcare in this country through information analyzed, synthesized, and provided to practitioners, patients, and researchers. New guidelines are expected to be released by the end of 1992 and throughout 1993. □

#### NOTES

1. Roger I. Lee, quoted in Marilyn Field and Kathleen Lohr, editors, *Guidelines for Clinical Practice: From Development to Use*, Institute of Medicine, National Academy Press, Washington, DC, 1992.
2. D. T. Durack, "The Weight of Medical Knowledge," *New England Journal of Medicine*, vol. 298, 1978, pp. 773-775.
3. John E. Wennberg and A. Gittlesohn, "Small-area Variation in Health Care Delivery," *Science*, vol. 182,

Some  
policymakers  
believe clinical  
practice  
guidelines can  
lead to better  
healthcare  
outcomes.

- 1973, pp. 1,102-1,108.
4. John E. Wennberg, Physician Payment Review Commission, 1989.
5. John E. Wennberg et al., "Are Hospital Services Rationed in New Haven or Over-utilized in Boston?" *Lancet*, vol. 1, 1987, pp. 1,185-1,189.
6. Field and Lohr.
7. E. C. Pierce, "The Development of Anesthesia Guidelines and Standards," *QRB*, vol. 16, 1990, pp. 65-70; J. T. Kelly and J. E. Swartout, "Development of Practice Parameters by Physician Organizations," *QRB*, vol. 16, 1990, pp. 54-57; Testimony of the American Society of Internal Medicine to the Ways and Means Committee on Practice Guidelines and the Volume of Services, May 3, 1990.
8. Field and Lohr.
9. Stephen H. Woolf, "Practice Guidelines, A New Reality in Medicine II: Methods of Developing Guidelines," *Archives of Internal Medicine*, vol. 152, 1992, pp. 946-952.
10. Woolf.
11. Pierce.
12. Kelly.
13. Testimony of the American Society of Internal Medicine.
14. Testimony of the American Society of Internal Medicine.

## METHODS FOR TRANSLATING GUIDELINES

To develop methods for translating clinical practice guidelines into medical review criteria, standards of quality, and performance measures, a work group has been organized by the Office of the Forum for Quality and Effectiveness in Health Care, which is part of the three-year-old Agency for Health Care Policy and Research.

The work group, which first met last March, is producing a document that will briefly describe the development of clinical practice guidelines and the methods for deriving medical review criteria, standards of quality, and performance measures.

### ADDRESSING THE ISSUES

The manual will also discuss the issues associated with developing and implementing criteria, standards, and measures. These include who should develop the criteria, standards, and measures; how to choose which criteria to develop; and interpretation and measurement.

Implementation issues include the education and training of those who develop and use the criteria, standards, and measures and how to build the criteria into care and quality improvement systems.

Considerations related to legal issues and legislation will also be discussed, according to David Sundwall, MD, vice president and medical director of AmHS Institute, Washington, DC, who cochairs the work group with Stephen Schoenbaum, MD, deputy medical director, Harvard Community Health Plan, Brookline, MA.

### A MULTIDISCIPLINARY APPROACH

The work group's 18 members, representing the disciplines of medicine, nursing, health information management, health services research, health policy, and law, come from a broad spectrum of organizations—hospitals, managed care organizations, insurance, and long-term care—as well as from academic medicine and nursing.

Federal liaisons from the Department of Defense, Veterans Administration, and the Health Care Financing Administration also consult with the work group.

### A USEFUL TOOL

The group plans to complete its document in 1993. According to Sundwall, the manual is meant to be a source of information and assistance on the issues it raises for consideration. It will be available to a variety of organizations engaged in developing guidelines, evaluating healthcare, or improving the quality of care.

While the guidance in the document is intended primarily as a tool for the panels convened by or contracting with the Agency for Health Care Policy and Research to develop clinical practice guidelines, it is anticipated that many individuals and organizations will find it useful in their quality improvement, utilization review, and education activities.

—Judy Cassidy