

Assessing and Developing Practice Guidelines

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Abstract

Practice guidelines are useful tools for decreasing the wide variations in practice patterns seen across the United States. To ensure the validity and reliability of such guidelines, stringent criteria to ensure quality must be applied during their development. In the past, guidelines were developed on the basis of expert opinion. Today, guidelines are developed through a

systematic review of the scientific literature, during which the strength of available evidence is carefully weighed. Users must be equally critical in their review of the applicability of specific guidelines to their practice, ensuring that the guidelines are appropriate for their patients.

(*Am J Man Care* 1996;2:895-898)

This activity is designed for pharmacists, pharmacy directors, formulary committee members, and quality assurance directors.

GOAL

To understand the criteria necessary for assessing and developing practice guidelines.

OBJECTIVES

1. Discuss the difference between traditional and newer methods of developing practice guidelines.
2. List eight attributes important in assessing the quality of guideline development.
3. Identify four factors important in developing practice guidelines.



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A primary issue in healthcare today is the effect of allocation of resources on patient and cost outcomes. Throughout the United States, methods of caring for patients and achieving good outcomes vary widely.¹ This variation may be partly due to the uncertainty of decision-makers regarding optimal patient management.² Healthcare leaders have promoted practice guidelines as a means of decreasing this variation and helping clinicians select the most cost-effective treatments.

A range of practice guidelines have been developed by persons in both the public and private sectors, including those working for government agencies (eg, Agency for Health Care Policy and Research [AHCPR]), members of professional groups (eg, American Medical Association, American College of Clinical Pharmacy, and College of Gastroenterology), healthcare purchasers, and commercial vendors. The motivation, goals, methodologies, expertise, and presentation styles of each of these groups vary considerably. The purpose of their guidelines also varies; it may be to aid decision-making in clinical practice, to establish performance standards, to set public policy, or to determine if a payer will support a new technology. The guidelines, in turn, may be directed at different groups, including healthcare practitioners, researchers, or patients.

Practice guidelines are not a new concept. For years, guidelines have been loosely referred to as treatment protocols, algorithms, or disease-based medication use evaluations, among other names.

What is fairly new, however, is the growing understanding that effective and efficient guidelines should be objective and based on systematically acquired evidence. Such guidelines are of most value if they are implemented by a local team in an environment in which the structures and processes have been developed to support their effective use.

Traditionally, practice guidelines were based on expert opinion, rather than a systematic review of scientific data. Today, developers formulate guidelines by carefully analyzing available evidence and linking these data to the health and cost outcomes the guidelines are designed to promote.

Assessing the Quality of Practice Guidelines

The process by which guidelines are developed directly influences the authors' conclusions^{3,4}; therefore, users must assess the quality and validity of guidelines much as they do that of clinical trial data. The more objective the methods used to develop the guidelines, the more convincing and appropriate the guidelines will be.⁵ In its publication, *Clinical Practice Guidelines: Directions for a New Program*,⁶ the Institute of Medicine identified eight attributes that can be used to assess the quality of practice guidelines. These attributes relate to the content, development process, and presentation of material and include validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review, and documentation. These attributes provide the foundation for evaluating and applying practice guidelines.

The relevance and importance of a particular set of guidelines is influenced by the goals, scope, and purpose of the guidelines and their target audience. Authors of guidelines should state their goals clearly and concisely. The benefits, potential harm, and costs expected from implementing the guidelines should be described. Developers also should describe why a new guideline is needed, how it can be optimally used, and who will ultimately benefit (eg, the insurer or society as a whole). Guideline developers have various reasons for selecting a particular topic or condition. The AHCPR, for example, focused on otitis media with effusion in young children because "otitis media is the most common diagnosis made by physicians who provide health care for children, because there is a perceived variation in practice patterns by these physicians, and because the annual direct and indirect costs have been estimated in excess of \$3.5 billion."⁷

Users must determine whether particular guidelines are appropriate for their patients. To help users

make this decision, developers should indicate for which patient populations the guidelines are intended. If the prevalence of disease or patient risk factors at a practice site are different from that at the development site, the guidelines may not apply, in part or in full.

The methods by which guidelines are developed must be clearly defined and documented. The persons who participated in the process, body of evidence examined, desired outcomes (eg, decreased mortality or morbidity or increased quality of life), disclosure of how values were assigned to potential outcomes and by whom (eg, healthcare providers, special interest groups, or insurers), and sponsor or funding source should be described. Because the validity of guidelines is influenced by the background and expertise of the participants, key people and their affiliation should be listed at the end of the document. Examples of key people include, but are not limited to, those who coordinated, retrieved, or evaluated evidence; those who wrote the document; and those who internally or externally reviewed the document. The sponsor or funding source should be clearly identified, since it can influence the choice of participants. Each expert panel member should have no conflict of interest; any questionable experience should be described in the document.

To assess the reliability of guidelines, users should consider the amount of variability in the experts' opinions of the strength of the evidence supporting the document. There should be little variability among the different groups participating in the development process, as long as the developers considered the same body of literature. Under these circumstances, any differences in recommendations probably reflect discrepancies in the relative value placed on various health and economic outcomes.

Developing Practice Guidelines

A key aspect of guideline development is participation by representatives of the groups affected by the guidelines. In developing national guidelines for preventing and managing nausea and vomiting, participants might include experts in health economics, practitioners from diverse patient care settings (eg, integrated health systems and managed care), those with clinical expertise (eg, physicians, pharmacists, and hospital administrators), specialists (eg, pediatricians, gastroenterologists, hematologists, and oncologists), and persons from both nonacademic and academic healthcare settings. The purpose of multidisciplinary input into guideline development is to: (1) help build consensus; (2) stimulate participation in

developing and acceptance of the document; (3) provide appropriate expertise in reviewing the document; and (4) make the document clinically applicable to a variety of practice settings.⁶

Before guidelines are developed, authors must specify their criteria for selecting and synthesizing data from different studies. Sources may include expert opinion and published or unpublished clinical or pharmacoeconomic studies. Recommendations should be based on the quality of the available evidence, the type and magnitude of the outcome, and the perceived value of that outcome.⁸ The "strength" or "grade" of evidence should be applied uniformly, using multiple considerations—the overall quality of the studies, the strength of the study design (eg, randomized and placebo controlled), and the type and consistency of the outcomes. Although there is no commonly accepted method of grading evidence, the guidelines of the Canadian Task Force on the Periodic Health Examination, one of the first organizations to popularize the concept of uniform methods, are widely used.⁹ These guidelines primarily consider the strength of evidence based on research design, with a higher rating given to information from well-designed clinical trials and a lower rating assigned to evidence from observational studies. However, the guidelines overlook other determinants of the quality of evidence, such as sample size, patient selection, dose and duration of treatment, measurements used, type of outcome, and statistical methods, all of which can affect the internal and external validity of study results. For example, a single randomized, controlled trial with a small sample size, impractical practice setting, and intermediate outcomes would be weighted the same as a quality randomized, controlled trial with practical endpoints and important outcomes. The Canadian Task Force guidelines were later revised in cooperation with the United States Preventive Services Task Force.¹⁰ In these new guidelines, the study design categories are supplemented with information on quality factors from the published evidence.

When developing practice guidelines, authors must provide practical and unambiguous advice, using clearly defined terms. For example, if the guidelines apply to patients with renal insufficiency, the developers should specifically define this population (eg, patients with a creatinine clearance of less than 50 mL/min but more than 10 mL/min). In this way, users can more clearly understand how the evidence was analyzed and determine the clinical applicability of the guidelines to their practice.

Guidelines need to reflect the best of practice at the time they were written. Users should check the date of development to determine whether the guidelines are still pertinent. In some cases, frequent revisions are necessary to account for changes in practice patterns and newly available scientific data. For example, practice guidelines on managing patients with human immunodeficiency virus may need to be revised more often than those for patients with lower back pain. Although the body of literature is growing in both areas, that for human immunodeficiency virus is accumulating at a faster rate.

Conclusion

Users of practice guidelines must be particularly vigilant in assessing the usefulness and applicability of specific guidelines. At both the national and local levels, clinicians are concerned about the lack of quality control over the process of guideline development. Users should demand more consistent reporting of guideline development methods. They also need a greater understanding of the effective use of guidelines, how guidelines can be coordinated with quality assurance and improvement efforts, and how guidelines can be adapted for use in specific care settings. These processes need to be combined with an appropriate structure and incentives (or disincentives) for following the guidelines in clinical practice. Healthcare organizations should assign teams to review, customize, disseminate, and educate users on the value and implications of following specific practice guidelines.

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CONTINUING PHARMACY EDUCATION

Instructions for Self-Assessment Examination

After reading the article "Assessing and Developing Practice Guidelines," select the best answer to each of the following questions and record the answers on the answer sheet provided. Participants who answer 7 or more of the questions correctly will receive a certificate for 1 contact hour (0.1 CEUs) of continuing education credit. There is a \$5 processing fee for this program. Please note that photocopies of the answer sheet will not be accepted; send originals only.

1. The groups or individuals involved in the guideline development process include:

- a) government agencies
- b) professional organizations
- c) healthcare purchasers
- d) all of the above

2. The process by which guidelines are developed directly influences the conclusions of the authors.

- a) true
- b) false

3. Guidelines are now developed by systematically analyzing available evidence and linking these data to health and cost outcomes.

- a) true
- b) false

4. Which of the following is true?

- a) participants in the guideline development process need not be identified as long as they have no conflicts of interest
- b) the sponsoring agency must be identified
- c) physicians do not necessarily need to be represented in the guideline development process, even if the guidelines are directed toward their practice
- d) the expertise of the participants does not influence the validity of the guidelines

5. The purpose of a multidisciplinary review is to:

- a) build consensus
- b) generate acceptance of the guidelines
- c) develop guidelines applicable to a variety of practice settings
- d) all of the above

6. Which of the following terms is most clearly defined?

- a) patients with seizures
- b) elderly patients
- c) patients with a resting heart rate greater than 70 beats/min
- d) patients with renal failure

7. When should practice guidelines be reexamined and updated?

- a) every 6 months
- b) every 12 months
- c) every 18 months
- d) whenever necessary

8. Which group first popularized the use of uniform methods of rating scientific evidence?

- a) Agency for Healthcare Policy and Research
- b) Canadian Task Force on the Periodic Health Examination
- c) Agency for Advancement of Practice Guidelines
- d) Institute of Medicine

9. A primary purpose of practice guidelines is to:

- a) decrease variations in practice
- b) increase government involvement in clinical practice
- c) eliminate the need for clinical judgment
- d) none of the above

10. To be effective, guidelines must be applied in an environment that:

- a) has processes, structure, and incentives (or disincentives) to support their use
- b) is consistent with the scope of the guidelines
- c) has a patient population dissimilar from that described in the guidelines
- d) both A and B

Assessing and Developing Practice Guidelines

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