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Guidelines International Network: Toward International Standards for Clinical Practice Guidelines

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Guideline development processes vary substantially, and many guidelines do not meet basic quality criteria. Standards for guideline development can help organizations ensure that recommendations are evidence-based and can help users identify high-quality guidelines. Such organizations as the U.S. Institute of Medicine and the United Kingdom's National Institute for Health and Clinical Excellence have developed recommendations to define trustworthy guidelines within their locales. Many groups charged with guideline development find the lengthy list of standards developed by such organizations to be aspirational but infeasible to follow in entirety.

Founded in 2002, the Guidelines International Network (G-I-N) is a network of guideline developers that includes 93 organizations and 89 individual members representing 46 countries. The G-I-N board of trustees recognized the importance of guideline development processes that are both rigorous and feasible even for modestly funded groups to implement and initiated an effort toward consensus about minimum standards for high-quality guidelines. In contrast to other existing standards for guideline development at national or local levels, the key components proposed by G-I-N will represent the consensus of an international, multidisciplinary group of active guideline developers.

This article presents G-I-N's proposed set of key components for guideline development. These key components address panel composition, decision-making process, conflicts of interest, guideline objective, development methods, evidence review, basis of recommendations, ratings of evidence and recommendations, guideline review, updating processes, and funding. It is hoped that this article promotes discussion and eventual agreement on a set of international standards for guideline development.

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* For a list of members of the board of trustees of the Guidelines International Network, see the **Appendix** (available at www.annals.org).

The health care profession relies heavily on the translation of evidence into clinical practice guidelines (1). The U.S. Institute of Medicine (IOM) defines clinical practice guidelines as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (2). Over recent decades, the number of guidelines developed by government and private organizations worldwide has increased exponentially. Clinicians, patients, and other stakeholders struggle with numerous and sometimes contradictory guidelines of variable quality (3).

Development of guidelines within coordinated programs can facilitate meeting quality standards by enabling the efficient sharing of resources and expertise (4). International collaboration offers additional opportunities to enhance guideline development (4). Standards for guideline development can help organizations assure that recommendations are evidence-based and can help users identify high-quality guidelines. Although the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument does not explicitly set standards for guideline development, it is a valuable tool to evaluate the process of practice guideline development (4).

Several groups, such as the IOM (2), World Health Organization (5), National Institute for Health and Clinical Excellence (6), Scottish Intercollegiate Guidelines Network (7), National Health and Medical Research Council (8), many medical societies (9–15), and others (16–24), have proposed standards for guideline developers. Of note, the IOM's recent reports identifying criteria for trustworthy clinical practice guidelines and systematic reviews (2, 25) have received both praise and criticism. Much of the concern about the IOM's criteria centers on the feasibility of implementing the long list of criteria and the applicability to diverse settings (26).

Founded in 2002, the Guidelines International Network (G-I-N) (www.g-i-n.net) is a network of guideline developers composed of 93 organizations and 89 individual members representing 46 countries (as of January 2012) (27). Its online library currently comprises more than 7400 documents, including 3636 guidelines, with a wide range of variation in quality. The Guidelines International Network understands the critical need to minimize the quality differences among guidelines and to promote the development of trustworthy guidelines. In response to calls for international standards to help develop and appraise clinical guidelines (19, 28–30), the G-I-N board of trustees reviewed the current literature and used a consensus process to propose a set of key components for guideline development. The intent is to initiate global discussion and consensus about minimal standards for guideline development.

Methods

The G-I-N board of trustees includes clinicians and guideline developers with specific skills in evidence-based

See also:

Web-Only
Appendix
Conversion of graphics into slides

medicine and guideline development and implementation. The board represents diverse geographic locales, including North America, Europe, Australia, and Asia. The authors of this article are members of the G-I-N board of trustees who were not selected to represent particular organizations.

A search of PubMed, Web sites of organizations that develop guidelines, Google, and Google Scholar identified relevant manuals, protocols, and published articles about guideline development (2, 4–7, 9–25, 27–115). We searched reference lists of identified publications and documents for further sources of information. We applied no language restriction and searched through October 2011.

We identified components of guideline development critical to the development of high-quality guidelines. We also considered practical issues related to incorporating these key components into the guideline development process, as well as issues related to implementation and global adaptation. Only components for guideline development that were deemed essential were used to generate the list of key elements described in this article. We selected the key components by informal consensus, and the article was presented to the full G-I-N board of trustees for approval. Because the purpose of this article is to present components to initiate a debate for the future revision or development of standards for guideline development, we considered using an informal approach to allow inclusion of different perspectives and opinions.

Key Components of a High-Quality and Trustworthy Guideline

Development of clinical guidelines involves several steps that can each be executed with differing degrees of rigor. We believe that the following 11 key components are important minimal criteria for high-quality guidelines. The **Table** presents an overview of the criteria. The Guidelines International Network recommends that guideline developers strive to meet these criteria and recognize that adaptation to local circumstances may be necessary and appropriate. Guideline development organizations should specify how they put each of these key components into effect in documents that detail their methods for guideline development.

1. Composition of Guideline Development Group

A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients or other health care consumers.

The guideline development group is responsible for reviewing the evidence, translating it into practice recommendations, writing the guideline, and assuring that the recommendations are not biased by being based on factors other than the best available scientific evidence. Groups without multidisciplinary membership can have been associated with recommendations that are not evidence-based (53, 72, 75, 80, 102). Thus, guideline development groups should include diverse stakeholders, such as health professionals; content experts; methodologists with skills in evidence appraisal and synthesis; and, ideally, health care consumers and health economists.

A dysfunctional group may also yield unreliable recommendations (90). Therefore, an effective and neutral chair should lead the group to ensure balanced contributions from all members. The primary role of the chair is to facilitate discussion and consensus. The chair should have general knowledge of the topic but does not need be a topic expert. In fact, a chair with topic expertise creates the risk that the chair's preconceived opinions could bias deliberations.

Table. Key Components of High-Quality and Trustworthy Guidelines

Component	Description
Composition of guideline development group	A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.
Decision-making process	A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.
Conflicts of interest	A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.
Scope of a guideline	A guideline should specify its objective(s) and scope.
Methods	A guideline should clearly describe the methods used for the guideline development in detail.
Evidence reviews	Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.
Guideline recommendations	A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.
Rating of evidence and recommendations	A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.
Peer review and stakeholder consultations	Review by external stakeholders should be conducted before guideline publication.
Guideline expiration and updating	A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.
Financial support and sponsoring organization	A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

The size of the guideline development group is also important. Large groups may be difficult to manage, and small groups may lack relevant stakeholders. Although no good evidence supports the appropriate size of the guideline development group (2), our experience suggests that guideline panels of 10 to 20 persons usually work well.

Whether and how to best involve health care consumers in the guideline development process is a topic of debate (77, 84, 98, 116). Consumers' views about the quality of life experienced with different medical conditions and interventions can be valuable (77). However, lack of training in evidence-based medicine and limited scientific literacy can hinder an evidence-based process. If consumers are included as voting members of guideline panels, consumers may need training and support to fulfill their role. To help understand how to effectively include patients in the guideline development process, G-I-N PUBLIC (www.g-i-n.net/activities/gin-public) was formed to develop strategies to aid guideline developers to effectively engage patients, consumers, and their families.

2. Decision-Making Process

A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.

Guideline development, even when evidence-based, is a process that involves group consensus. Consensus is required to select and interpret evidence, translate evidence into recommendations, and determine how to handle situations when evidence is lacking to answer important clinical questions. Although some countries and organizations use formal consensus processes, many organizations use informal processes.

Examples of formal processes include the nominal group technique, Delphi, or formal balloting (50, 52, 109). "Informal process" means using no structured methods to come to a consensus. Formal methods have been shown to result in a less biased and more evidence-based process than informal methods (72, 80, 100). Regardless of the process, the guideline should clearly define a quorum and document the consensus process (50, 52, 109).

3. Conflicts of Interest

A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.

Conflict of interest (COI) disclosure and management policies of various guideline developing organizations vary widely (2). Conflicts of interest are "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by secondary interest" (117). Members of a guideline development group should disclose any personal or household financial and nonfinancial COI relationships related to the guideline topic. If a member or someone in the member's household has a relevant potential financial, nonfinancial, professional, or other personal gain or loss associated with the topic of a guideline, any such conflicts should be disclosed and clearly stated in a guideline document.

Financial COI includes ownership of stocks or shares, paid employment or consultancy, paid board memberships, patent applications, research grants (from any source, whether restricted or unrestricted), honoraria, and gifts. Nonfinancial COI includes leadership or board or committee memberships, involvement with an advocacy group that may gain from a guideline, writing or consulting for an educational company, or having personal convictions (political, religious, ideological, or other) related to the guideline topic that may interfere with an unbiased evidence review or recommendation process. The guideline development group and sponsoring organization must actively and transparently manage COIs by assessing the level of risk and, if necessary, excluding the member with the COI from relevant discussions and decisions.

4. Scope of a Guideline

A guideline should specify its objective(s) and scope.

Guidelines should clearly state their objectives and the key questions that they address. The scope includes diagnostic criteria, benefits and harms of various treatment options, key outcomes that have been evaluated, target patient population, and intended users of the guideline (62, 101).

5. Methods

A guideline should clearly describe the methods used for the guideline development in detail.

A clear description of the development process should accompany all guidelines, either within the guideline document or in a separate, referenced document (118). The description of guideline development methods should reflect the key components as presented in this article and includes the process for choosing group members and a chair, methods of reviewing evidence, the process that the group used to deliberate about the evidence and formulate recommendations, dissemination and implementation of the guideline, and any pertinent review or approval processes.

6. Evidence Reviews

Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.

Most experts agree that trustworthy guidelines are based on high-quality systematic reviews of evidence (2, 51, 103, 119). Systematic reviews use rigorous methods to identify clinical questions, inclusion and exclusion criteria, and methods for rating the quality of available evidence. The Guidelines International Network has developed templates for summarizing studies addressing diagnostic and intervention questions, and templates for prognostic studies and health economics assessments are under development (22). There are papers, including the recent IOM

report, that describe the standards for a good systematic review in detail (25, 120).

7. Guideline Recommendations

A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.

Guideline recommendations should be clear, evidence-based statements that aim to provide guideline users with clear directions for effective delivery of care. The recommendations should be supported by careful consideration of evidence; quantification of the magnitude of benefits and harms, as well as costs when possible; resource and feasibility issues; implementation considerations; patient and caregiver preferences and concerns; and ethical and legal matters. Recommendations related to interventions should use unambiguous, active language that reflects the strength of the evidence. A recommendation should be actionable and use the active voice (121). Guideline developers should aim to use such terms as "should" or "recommend" and to avoid using such vague words and phrases as "may," "can," or "consider," unless real uncertainty exists about the evidence effectiveness, because these terms are not helpful for practical implementation (122).

8. Rating of Evidence and Recommendations

A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.

Guideline developers should synthesize and grade evidence by using a standardized approach. The strength of recommendations should be assigned on the basis of evaluation of the evidence, benefits and harms, consistency, clinical effect, and generalizability and applicability, as well as patient preferences. Clear identification of the quality of evidence helps, and strength of clinical recommendations increases the trustworthiness and improves the implementation of clinical guidelines (32, 43, 76). Several grading systems are currently available, including the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system, which is increasingly being adopted by guideline developers worldwide (34, 66).

9. Peer Review and Stakeholder Consultations

Review by external stakeholders should be conducted before guideline publication.

Guidelines should be reviewed by stakeholders external to the guideline group before publication. Reviewers may include outside experts, representatives of the sponsoring organization, and members of the public (4, 101, 105). The review should include not only content-related review but also methodological review of both the evidence report and the guideline. When selecting peer reviewers, it is important to consider those who are more likely to provide comments based on scientific and clinical knowledge rather than unsubstantiated views (101). A summary of the external review process should accompany a guideline.

10. Guideline Expiration and Updating

A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.

Guidelines become outdated at different rates depending on the availability of new evidence. Therefore, it is important to identify the expiration date of a guideline, as well as an update process, if planned. Developers should prospectively determine whether and when they will update a guideline or when it should be considered inactive if an update is not performed.

11. Financial Support and Sponsoring Organization

A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

Guidelines should identify the sponsoring organization and its role in the development of a clinical guideline. In addition, any honoraria or financial support provided to the authors of a guideline should also be fully disclosed.

Conclusion

The Guidelines International Network's goal in proposing these minimum standards is to promote the development of high-quality guidelines that serve patients well. As a central repository for all clinical guidelines of our member organizations, it is critical for G-I-N to ensure that our members consider our guidelines library as a trustworthy and valuable resource. We currently do not require guidelines to meet our proposed minimum criteria in order to be listed in our library. However, the proposed key components presented in this article should help guideline developers and users assess the strengths and weaknesses of a guideline and thus clearly indicate which guidelines can be considered trustworthy.

We hope that this article will promote discussion and possible agreement among a broad array of guideline developers, although we recognize that small variations at the local level may be inevitable and appropriate. The Guidelines International Network provides a platform for international discussion and will use the organization's infrastructure to promote discussion among our members toward globally endorsed minimum standards for guideline development.

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Appendix: G-I-N Board of Trustees

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