

# Guide to Development of Practice Guidelines

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A commonly accepted definition of a clinical practice guideline is “a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [1]. Guidelines are written to improve the quality of care, to improve the appropriateness of care, to improve cost-effectiveness, and to serve as educational tools [2, 3]. The goal is not to create standards of care; however, other organizations may choose to adopt these guidelines or components thereof for such purposes. Practice guidelines, however, are never a substitute for clinical judgment. Clinical discretion is of the utmost importance in the application of a guideline to individual patients, because no guideline can ever be specific enough to be applied in all situations. To fulfill the objectives of guidelines adequately, standards must be established for the quality of guidelines so that their scientific validity and clarity of communication may be ensured (table 1) [4]. The challenge to guideline writers, therefore, is to adhere to these standards in the guideline development process while also making the document user-friendly.

Because the majority of the guidelines of the Infectious Diseases Society of America (IDSA) will be published in the journal *Clinical Infectious Diseases*, it is essential that the turnaround time from concept to final draft be as short as possible, preferably <12 months. The IDSA Practice Guidelines Committee recommends that guideline developers carefully consider and incorporate the following standards.

## GUIDELINE DEVELOPMENT AND FORMAT

**Choosing guideline topics.** Guideline topics should be chosen for the impact that they will have on the practice of medicine. Topics should come from an area of interest that has a high volume of cases, high cost, issues related to risk management, or significant variation in practice. There should be sufficient evidence available for review to justify the development of a guideline. The scope of the guideline topic should be narrow enough to be thoroughly explored with the time and resources available. In most cases, the IDSA Practice Guidelines Committee will suggest the topic to the committee, but members can certainly suggest topics in areas that they believe warrant such a document.

**Specifying the purpose.** The purpose for which the guideline is being written should be clearly specified. It should be clear to the target audience why this is an important topic and why it has been chosen for review at this time. What is the impact that the guideline is expected to have on the practice of medicine? Clarification of controversy, proper uses of newer technologic or diagnostic tools, and appropriate use of pharmaceuticals are examples of appropriate reasons for guideline development. Unambiguous terminology should be used.

**Choosing the panel participants.** Participants in the guideline development process should represent a range of experts that is sufficiently broad enough to adequately explore the topic. Ideally, 6–10 members should be chosen by the guideline leader. The IDSA Practice Guidelines Committee can be a useful resource in helping to find panel members. When appropriate, it is desirable to include members of related disciplines. Guideline developers are strongly encouraged to include members of relevant professional societies and to work toward consensus in their recommendations. This process can only serve to enhance the validity and

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**Table 1. Recommended timeline for steps in the guideline development process.**

Step	Description	Recommended time to completion
1	Selection of panel	2–4 weeks
2	Introductory meeting of panel members (via conference call or in person, as determined by the panel chair); if the guideline so lends itself, the chair could divide and distribute the assignments among individual panel members; steps 3–5 can be done at the same time	1–2 months
3	Determine the scope of the guideline	Concurrent with step 2
4	Determine the target audience and the target population	Concurrent with step 2
5	Determine how the evidence will be selected (e.g., by means of a MEDLINE search); review the plan with the chair of the Practice Guidelines Committee	Concurrent with step 2
6	Select and review the evidence to be used in writing the guideline (this step should be divided among panel members); set a date for completion	2–3 months
7	Grade the evidence and determine what will be used and what will be discarded	Concurrent with step 6
8	Write the guideline, including an executive summary; if algorithms are used, be sure that they are presented in the proper format; tables and graphs, which are useful for guideline readers, should be provided [5]	3 months
9	Submit the guideline for outside review	Within 9–10 months of the start of the project
10	Modify the guideline on the basis of the outside review	1–2 months
11	Submit the guideline to the IDSA Practice Guidelines Committee for review and publication	Preferably within 12 months of the start of the project
12	Review and update the guideline as appropriate	Every 2 years

**NOTE.** IDSA, Infectious Diseases Society of America.

credibility of the guideline. Inclusion of members of other specialty societies, however, should include a discussion of who will fund their participation.

**Specifying the target population.** The targeted patient population should be clearly specified. Consider age, sex, clinical condition, or other factors that might affect the recommendations and then define these limitations. Give special consideration to (1) the inclusion of special populations, such as pediatric patients, pregnant women, or immunocompromised individuals, and (2) how—or whether—the guideline recommendations are altered by these circumstances. If the recommendations are significantly different for specific populations, it may be best to propose that a separate guideline be developed to encompass these groups.

**Specifying the target audience.** Specify clearly who the target audience is at the beginning of the guideline. Is the guideline primarily intended for primary care physicians, specialty physicians, or another audience?

**Exploring the diagnostic and therapeutic options.** Specify clearly the principal diagnostic or therapeutic options that are available and how they will be explored in the guideline. The reasons why these options were chosen and why other options might not be considered should also be specified.

**Specifying the desired outcome.** Specify the desired outcome of the guideline. If the target audience

adopts the guideline, what health, economic, or other outcomes might be expected?

**Scientific review.** Specify the method by which the guideline has undergone review. Rigorous methods of review establish the scientific validity and credibility of the guideline. Respected peers—those who are not members of the guideline panel but who are experts in the same field—should review guidelines for scientific validity. These outside reviewers should be acknowledged at the end of the guideline document. Guidelines are also reviewed by the IDSA Practice Guidelines Committee for content and format. Each particular guideline group submits its final draft to the Practice Guidelines Committee for approval. After approval is granted, the draft is forwarded to the IDSA Governing Council for final approval and then to *Clinical Infectious Diseases* for publication.

**Updating the guideline.** Specify when and how often the guideline will be reviewed so that it may be updated. On average, guidelines should be reviewed for changes in the field every 2 years. The guideline leader can determine whether the scope of change warrants a full-scale revision of the guideline.

**Suggested format.** The guideline should *not* be a review or meta-analysis of the topic, and it should not be excessively lengthy; a reasonable length might be 20–25 double-spaced pages, plus references. The doc-

**Table 2. Infectious Diseases Society of America–United States Public Health Service Grading System for ranking recommendations in clinical guidelines.**

Category, grade	Definition
Strength of recommendation	
A	Good evidence to support a recommendation for use
B	Moderate evidence to support a recommendation for use
C	Poor evidence to support a recommendation
D	Moderate evidence to support a recommendation against use
E	Good evidence to support a recommendation against use
Quality of evidence	
I	Evidence from $\geq 1$ properly randomized, controlled trial
II	Evidence from $\geq 1$ well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from $>1$ center); from multiple time-series; or from dramatic results from uncontrolled experiments
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

ument should begin with an executive summary that concisely states the major recommendations.

## EVIDENCE REVIEW

Specify the method by which scientific evidence was identified and collected. In many circumstances, scientifically rigorous material may not be available. In such circumstances, it is appropriate to use expert opinion as long as it is clearly indicated and attributed. The basis on which expert opinion was formed should be specified.

Specify the time period during which the evidence was reviewed. How recent is the evidence? Has it been validated in practice?

Identify the evidence by use of citations and references.

Specify the method used for extraction of the data for review (e.g., by means of a MEDLINE search).

Grade evidence according to the standard IDSA evidence-grading system (table 2).

## FORMULATION OF RECOMMENDATIONS

The panel should specify the values used in the development of the recommendations. Were the outcomes considered from the perspective of the patient, the provider, society in general, or the health care administrator? How are competing values balanced?

Do the preferences of the patient affect the choices? Is this discussed in the guideline?

Recommendations should be as specific as possible. Keep in mind the average member of the target au-

dience. How easily can these recommendations be used? Grade the strength of the recommendations and the quality of the evidence by use of the rating scale shown in table 2.

How flexible is the guideline? Can it be adapted for local use?

If the current guideline is making recommendations that differ significantly from those of previous guidelines on the same subject, the differences should be reconciled (e.g., the reason for the difference is new data or differing expert opinion).

## PERFORMANCE AND OUTCOMES MEASURES

Each guideline should suggest at least 1 or 2 performance measures to help guideline users measure the extent of implementation and the effect of implementation of the guideline within their practice or organization. The measures can be process or outcome indicators, or both [6].

## AREAS FOR FUTURE RESEARCH

Guidelines should comment on what is lacking in the existing evidence and should also suggest areas for further study.

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