American Psychiatric Association

Practice Guideline Development Process

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I. BACKGROUND AND DEFINITION

The American Psychiatric Association (APA) began developing practice guidelines in 1991. *Practice guidelines* are defined as systematically developed documents in a standardized format that present patient care strategies to assist psychiatrists in clinical decision making. Although APA guidelines may be used for a variety of reasons, their primary purpose is to assist psychiatrists in their care of patients.

Both the American Medical Association (AMA) and the Institute of Medicine (IOM) have sought to define the key features necessary to ensure that practice guidelines are of high quality. The AMA's attributes apply to the development process, stating that practice parameters or guidelines should 1) be developed by or in conjunction with physician organizations, 2) explicitly describe the methodology and process used in their development, 3) assist practitioner and patient decisions about appropriate health care for specific clinical circumstances, 4) be based on current professional knowledge and reviewed and revised at regular intervals, and 5) be widely disseminated. The IOM's attributes are criteria for evaluating the finished product; these criteria include 1) validity, based on the strength of the evidence, expert judgment, and estimates of health and cost outcomes compared with alternative practices; 2) reliability and reproducibility; 3) clinical applicability and flexibility; 4) clarity; 5) attention to multidisciplinary concerns; 6) timely updates; and 7) documentation. Taken together, the IOM and AMA prescriptives have essentially set national standards for guideline efforts.

II. TOPIC SELECTION

APA's Steering Committee on Practice Guidelines oversees development of APA guidelines. The Steering Committee selects topics for practice guidelines according to the following criteria:

1. Degree of public importance (prevalence and seriousness)
2. Relevance to psychiatric practice
3. Availability of information and relevant data
4. Availability of work already done that would be useful in the development of a practice guideline
5. An area in which increased psychiatric attention and involvement would be helpful for the field

III. CONTRIBUTORS

Each APA practice guideline is developed by a work group of psychiatrists in active clinical practice, including academicians or researchers who spend a significant percentage of their time

in the clinical care of patients. Work group members are selected on the basis of their knowledge and experience in the topic area, their commitment to the integrity of the guideline development process as outlined by the AMA and IOM, and their representativeness of the diversity of American psychiatry.

Many experts in psychiatric treatment, particularly in the area of psychopharmacology, have significant research activities funded by the pharmaceutical industry. Recognizing this, APA has implemented a number of mechanisms to minimize the potential for producing recommendations that are biased because of conflicts of interest from contributors. On appointment, work group members are asked to disclose potential conflicts of interest, and these disclosures are reviewed by the work group chair and the APA Executive Committee on Practice Guidelines. Work group members are asked to decline participation if they feel there are conflicts of interest or biases that could impact their ability to maintain scientific objectivity. At an initial meeting, work group members are also asked to disclose potential conflicts of interest with each other. This transparency helps the group to evaluate and, as necessary, dissent with each other's work during evidence review and draft development. The following statement appears in every practice guideline to clarify this point:

> This practice guideline has been developed by psychiatrists who are in active clinical practice. In addition, some contributors are primarily involved in research or other academic endeavors. It is possible that through such activities some contributors, including work group members and reviewers, have received income related to treatments discussed in this guideline. A number of mechanisms are in place to minimize the potential for producing biased recommendations due to conflicts of interest. Work group members are selected on the basis of their expertise and integrity. Any work group member or reviewer who has a potential conflict of interest that may bias (or appear to bias) his or her work is asked to disclose this to the Steering Committee on Practice Guidelines and the work group. Iterative guideline drafts are reviewed by the Steering Committee, other experts, allied organizations, APA members, and the APA Assembly and Board of Trustees; substantial revisions address or integrate the comments of these multiple reviewers. The development of the APA practice guidelines is not financially supported by any commercial organization.

Potential bias is also minimized by iterative broad review of guideline drafts, as described in Section VI of this document. Finally, no commercial organizations provide support for the development of the APA practice guidelines.

APA is listed as the "author" of practice guidelines, with individual contributions and reviewers acknowledged. Final editorial responsibility for practice guidelines rests with the Steering Committee and the Department of Quality Improvement and Psychiatric Services.

IV. EVIDENCE BASE

The evidence base for practice guidelines is derived from two sources: research studies and clinical consensus. Where gaps exist in the research data, evidence is derived from clinical consensus, obtained through broad review of multiple drafts of each guideline (see Section VI). Both research data and clinical consensus vary in their validity and reliability for different clinical

situations; guidelines state explicitly the nature of the supporting evidence for specific recommendations so that readers can make their own judgments regarding the utility of the recommendations. The following coding system is used for this purpose:

[A] *Randomized, double-blind clinical trial.* A study of an intervention in which subjects are prospectively followed over time; there are treatment and control groups; subjects are randomly assigned to the two groups; and both the subjects and the investigators are "blind" to the assignments.
[A–] *Randomized clinical trial.* Same as above but not double blind.
[B] *Clinical trial.* A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally. Does not meet standards for a randomized clinical trial.
[C] *Cohort or longitudinal study.* A study in which subjects are prospectively followed over time without any specific intervention.
[D] *Control study.* A study in which a group of patients and a group of control subjects are identified in the present and information about them is pursued retrospectively or backward in time.
[E] *Review with secondary data analysis.* A structured analytic review of existing data, e.g., a meta-analysis or a decision analysis.
[F] *Review.* A qualitative review and discussion of previously published literature without a quantitative synthesis of the data.
[G] *Other.* Opinion-like essays, case reports, and other reports not categorized above.

The literature review process is explicitly described in every guideline, including statements concerning

1. Basic search strategy (e.g., keywords, time period covered, research methodologies considered)
2. Sources used for identifying studies (e.g., review articles, texts, abstracting and indexing services, Index Medicus, Science Citation Index, computer search services)
3. Criteria for selecting publications (e.g., how many relevant publications were identified, whether all were reviewed, whether only prospective studies were selected)
4. Review methods (e.g., whether publications were reviewed in their entirety or in abstract)
5. Methods for cataloging reported outcomes (e.g., study design, sample characteristics, relevant findings)

The literature review will include other guidelines addressing the same topic, when available. The work group constructs evidence tables to illustrate the data regarding risks and benefits for each treatment and to evaluate the quality of the data. These tables facilitate group discussion of the evidence and agreement on treatment recommendations before guideline text is written. Evidence tables do not appear in the guideline; however, they are retained by APA to document the development process in case queries are received and to inform revisions of the guideline.

V. FORMAT

Each practice guideline follows a standardized format, with variations as appropriate (e.g., format for a guideline about psychiatric evaluation or a procedure may vary from format for a guideline about a specific illness).

Since the 2000 revision of the guideline on major depressive disorder, the general outline for all guidelines and revisions has been as follows:

Part A. Treatment Recommendations
- I. Executive Summary of Recommendations
- II. Formulation and Implementation of a Treatment Plan
- III. Specific Clinical Features Influencing the Treatment Plan

Part B. Background Information and Review of Available Evidence
- IV. Disease Definition, Epidemiology, and Natural History
- V. Review and Synthesis of Available Evidence

Part C. Future Research Needs

Individuals and Organizations That Submitted Comments

References

Section I provides an overview of the organization and scope of recommendations contained in subsequent sections. Each recommendation is identified as falling into one of three categories of endorsement:

[I] Recommended with substantial clinical confidence.
[II] Recommended with moderate clinical confidence.
[III] May be recommended on the basis of individual circumstances.

Section II presents a synthesis of the information discussed in Section V, directed at providing a framework for clinical decision making for the individual patient.

Section III addresses psychiatric, general medical, and demographic factors influencing treatment, including comorbidities. Relevant ethnic, cross-cultural, social, or extrinsic factors (e.g., cultural mores, family, support system, living situation, health care beliefs) that could potentially preclude or modify the practical application of guidelines and may play a role in health care decisions are emphasized.

Section IV presents the characteristics of the illness using current DSM criteria. Differential diagnosis, appropriate diagnostic procedures, aspects of the epidemiology and natural history with important treatment implications, and issues concerning special patient characteristics are outlined in this section.

Section V presents a review of the available data on all potential treatments, organized according to three broad categories: 1) psychiatric management, 2) psychosocial interventions, and 3) somatic interventions. For each treatment, this information is presented in a standard format:

a. Goals of treatment
b. Efficacy data

c. Side effects and safety
d. Implementation issues (e.g., patient selection, laboratory testing, dosing, frequency, duration)

Part C identifies directions for further research.

Individuals and organizations that submitted substantive comments on guideline drafts are acknowledged.

Last, all cited references are listed.

VI. REVIEW, DISSEMINATION, AND UPDATES

Each practice guideline is extensively reviewed at multiple draft stages. Draft 1 is reviewed by the Steering Committee. Draft 2 is reviewed by approximately 50 reviewers with expertise in the topic, representatives of allied organizations, the APA Assembly, District Branches, the Joint Reference Committee, the Board of Trustees, the Council on Quality Care, other components related to the subject area, and any APA member by request. Draft 3 is reviewed and approved for publication by the Assembly and the Board of Trustees.

The development process may be summarized as follows:

Step 1: The Steering Committee on Practice Guidelines selects about five individuals to serve as the work group chair and members.

Step 2: The work group chair and Department of Quality Improvement and Psychiatric Services staff develop a preliminary outline, to be continuously revised and refined throughout subsequent steps in the development process.

Step 3: A literature search is conducted by APA and/or the work group. Relevant articles from the search are obtained, in abstract or in entirety. The work group reviews these articles, codes them for study design, and constructs evidence tables for each treatment.

Step 4: Draft 1 is written based on evidence tables and outline.

Step 5: Draft 1 is circulated to the work group and Steering Committee for review and comment.

Step 6: Draft 2 is written based on comments received.

Step 7: Draft 2 is circulated for general review.

Step 8: Draft 3 is written based on comments received.

Step 9: Draft 3 is submitted to the formal APA review and approval process (Council on Quality Improvement, Assembly, Board of Trustees).

After final approval by the Assembly and Board of Trustees, each practice guideline is widely disseminated. Practice guidelines are made available to all psychiatrists in a variety of ways, in-

cluding publication in *The American Journal of Psychiatry*. Each practice guideline is revised at regular intervals to reflect new knowledge in the field.

To help maintain currency of guideline recommendations, in 2004 the Steering Committee on Practice Guidelines began publishing "guideline watches," brief articles that highlight significant developments relevant to specific guidelines. As they are completed, watches are made available online in the Psychiatric Practice section of the APA web site at http://www.psych.org. Watches are also included in guideline compendiums available from American Psychiatric Publishing, Inc.