

# New Development Process for Clinical Practice Guidelines of the American Academy of Child & Adolescent Psychiatry

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## Background and Overview

The development and dissemination of clinical practice guidelines is one of the most important activities of a professional medical association.<sup>1</sup> Clinical practice guidelines are defined by the Institute of Medicine (IOM) 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”.<sup>2</sup> Because of their derivation from a critical review of extant literature, clinical guidelines occupy a high position in the hierarchy of “pre-processed” evidence,<sup>3</sup> and as such have the potential for great influence in clinical care.

Over the past several decades, the clinical guideline development process has become increasingly rigorous, in accordance with evolving principles promulgated by influential professional organizations such as the American Medical Association (AMA) and the IOM. Today, “guidelines for guidelines” have reached new heights of specificity and precision, generating the imperative for parallel changes in the guideline development process across all medical specialties. Within the specialty of psychiatry, the American Psychiatric Association (APA) has taken the lead by initiating its new guideline development process based upon IOM principles.<sup>4</sup>

Two critical areas of guideline vulnerability, *rigor* and *transparency*, were highlighted by the most recent IOM report.<sup>2</sup> Rigor refers to the precision with which the extant literature is systematically searched, critically appraised, and rated for quality. Transparency refers to the protection of the guideline development process from conflicts of interest, both actual and perceived. Rigor and transparency are critical components of the guideline development process, as the “trustworthiness” of the guideline derives directly from fidelity to these constructs.

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<sup>1</sup> Rothman DJ et al., Professional medical associations and their relationships with industry – a proposal for controlling conflict of interest. *JAMA* 2009; 301(13): 1367-1372.

<sup>2</sup> Institute of Medicine, *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press, 2011.

<sup>3</sup> *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. Guyatt G, Rennie D (eds.), Chicago, IL: American Medical Association, 2002.

<sup>4</sup> American Psychiatric Association, *New Development Process for Practice Guidelines of the American Psychiatric Association*, 2011. Available at: [www.psychiatry.org/practice/clinical-practice-guidelines/development-process](http://www.psychiatry.org/practice/clinical-practice-guidelines/development-process).

The clinical practice guideline development process described in this document was approved by AACAP Council on June 21, 2013. This new process, superceding the prior AACAP practice parameter development process described in the former *Instructions for Authors of AACAP Practice Parameters*,<sup>5</sup> was created to meet current IOM standards. These standards address establishing transparency, management of conflicts of interest, composition of development committees, methods for systematic reviews of evidence, establishing evidence basis and rating strength of recommendations, articulation of recommendations, external review, and updating.

The new AACAP clinical practice guideline development process builds upon AACAP's previous practice parameter development process, which was designed to conform to early guideline development principles promulgated by the AMA.<sup>6</sup> Under the previous process, which itself evolved over time in accordance with evolving standards of rigor and transparency, AACAP's Work Group (later Committee) on Quality Issues (CQI) developed over 40 practice parameters that have served to encourage best practices in child mental health. Topics covered by these parameters have included the psychiatric evaluation and treatment of most child and adolescent psychiatric disorders, as well as the assessment and management of mental health problems in vulnerable populations of youth, such as youth with physical illness, youth in juvenile detention facilities, and gay/lesbian/bisexual/transgender youth. These parameters have been widely disseminated, read, and cited, as supported by AACAP member survey results and JAACAP impact factor contributions.

The following elements of AACAP's previous practice parameter development process remain in the new process described in this document:

- Appointment of parameter development committee members who are balanced with respect to expertise, academic vs. private practice background, geographic location, and demographic characteristics
- Documentation of the parameter development process
- Involvement of physicians and physician organizations
- Systematic literature review
- Broad, iterative review of parameter drafts
- Specification of the appropriateness of the parameter recommendations to specific clinical conditions and settings
- Specification of the limits of the generalizability of the parameter recommendations
- Approval of parameters by the AACAP Council
- Wide dissemination of parameters in print and electronic media

In addition, the new process adds the following elements intended to enhance the rigor and transparency of the AACAP Practice Parameters (henceforth to be known as Clinical Practice Guidelines [CPGs]):

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<sup>5</sup> American Academy of Child and Adolescent Psychiatry, *Instructions for Authors of AACAP Practice Parameters*, March 2012.

<sup>6</sup> American Medical Association Policy H-410.968.

- CQI co-chairs and members will be required to be free from pharmaceutical industry involvement throughout the course of guideline development, whether salary or research funding, additional income, or in-kind services
- CQI members will be trained in systematic review techniques by acknowledged methodologic experts
- As recommended by the Agency for Healthcare Research and Quality (AHRQ),<sup>7</sup> guideline recommendations will be derived from specific clinical questions in PICO(TS) format; i.e., patient, intervention, comparison, outcome, (and when applicable, timing and setting)
- Separate CQI individuals/groups will review evidence (Information Specialist & Systematic Reviewer [ISSR]) and write guidelines (Guideline Writing Group [GWG])
- The ISSR and GWG will receive input from research experts, clinical experts, AACAP members, and key stakeholders
- Expert clinical opinion (i.e., clinical consensus), when needed in the absence of rigorous research evidence, will be determined by a formal survey of a panel of clinical experts (Clinical Consensus Panel [CCP])
- Guideline recommendations will be separately rated by the GWG according to the quality of the supporting evidence
- Consensus about guideline recommendations will be determined by blind iterative voting by the GWG
- After guideline publication, new evidence will be identified by continuous monitoring of the literature, and guidelines will be updated in a targeted fashion if there are important changes in the supporting evidence

This document is a living document that will be updated as the new guideline development process is implemented and tested. The process used to develop specific guidelines will be described upon their publication. Because of continuous innovation and improvement, the process used may not necessarily match what is described in this document.

## Organizational Structure

The following entities participate in the development, review, and approval of AACAP clinical practice guidelines:

### Development

- CQI Executive Committee (CQI EC)
- CQI Information Specialist & Systematic Reviewer (ISSR)
- CQI Guideline Writing Group (GWG)
- Methodologic consultants
- AACAP staff

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<sup>7</sup> Agency for Healthcare Research and Quality, *AHRQ Effective Health Care Program Stakeholder Guide* (AHRQ Publication No. 11-EHC069-EF), Rockville, MD, 2011. Available at: <http://www.ahrq.gov/clinic/epcpartner/stakeholderguide/stakeholder.pdf>

## **Review**

- Expert Advisors (EAs)
- Clinical Consensus Panel (CCP)
- AACAP Members
- Key Stakeholders

## **Approval**

- AACAP Council

Individuals in each entity are subject to different participation rules, as described below. These rules are intended to minimize potential bias from conflicts of interest and are considered by the CQI to be consistent with the 2011 IOM standards.

## **CQI Executive Committee**

The role of the CQI EC is to define the AACAP guideline development process and ensure adherence to the process. Specific tasks assigned to the CQI EC are the following:

- Select and prioritize guideline topics
- Select and oversee guideline writing groups
- Select and oversee the information specialist & systematic reviewer
- Develop and oversee ongoing training of the CQI in systematic review techniques
- Select expert advisors and oversee expert advisor review
- Select clinical consensus panels and oversee clinical consensus panel review
- Oversee member review
- Select key stakeholders and oversee stakeholder review

On the basis of fidelity to process, the CQI EC approves submission of finalized guidelines to the AACAP Council for association approval.

The CQI EC is comprised of three members plus methodologic consultants. The members include the two volunteer CQI co-chairs and the salaried AACAP staff liaison. The co-chairs are appointed by the AACAP president, and serve for 5-year terms with the possibility of one renewal, with initial terms to begin upon approval of this document by AACAP Council. The staff liaison is assigned by AACAP. Both of the co-chairs must be free of pharmaceutical industry involvement throughout the course of guideline development, whether salary or research support, other income, or in-kind services.

The CQI co-chairs receive authorial credit, alternating the first and second position, followed by the guideline writing group and information specialist & systematic reviewer authors, with “AACAP Committee on Quality Issues” appearing last.

## **CQI Information Specialist & Systematic Reviewer**

The role of the ISSR is to perform critical review of the extant literature pertaining to specific clinical questions. Specific tasks assigned to the ISSR are the following:

- Transforms clinical questions into search terms
- Performs/reviews findings from systematic reviews according to *a priori* specifications
- Determines the quality of the evidence according to *a priori* specifications
- Recommends the strength of the guideline recommendations according to the quality of the evidence
- Manages expert advisor, clinical consensus, AACAP member, and key stakeholder reviews
- After guideline publication, continues to search newly published literature and recommends guideline revision as indicated by new evidence

The ISSR is a contracted specialist selected by AACAP upon recommendation of the CQI co-chairs. The information specialist & systematic reviewer serves per AACAP contract, and must be free of pharmaceutical industry involvement throughout the course of guideline development, whether salary or research support, other income, or in-kind services.

The information specialist & systematic reviewer receives authorial credit (after GWG members), with “AACAP Committee on Quality Issues” appearing last.

### **CQI Guideline Writing Group**

The role of the GWG is to write each clinical practice guideline. Specific tasks assigned to the GWG are the following:

- Formulate clinical (PICO-TS) questions
- Review and integrate comments from reviewers into the clinical questions
- Review conclusions from the systematic review
- Develop the clinical consensus panel survey
- Review findings from the clinical consensus panel survey
- Draft guideline background and rationale
- Draft guideline recommendations and discussion
- Determine the strength of the guideline recommendations according to the quality of the evidence
- Review and integrate comments from reviewers into the guideline drafts
- Revise published guidelines as indicated by new evidence

Each GWG is comprised of three to four volunteer members selected by the CQI EC from the other CQI members who have been appointed by the AACAP president. GWG members serve for 3-year terms with the possibility of one renewal, with initial terms to begin upon approval of this document by AACAP Council. The GWG members must be free of pharmaceutical industry involvement throughout the course of guideline development, whether salary or research support, other income, or in-kind services.

The GWG members receive alphabetical authorial credit after the CQI EC, with “AACAP Committee on Quality Issues” appearing last.

## **Methodologic Consultants**

The role of the methodologic consultants is to train the CQI on systematic review techniques that are in accordance with current IOM standards. The paid methodologic consultants will be selected by the CQI co-chairs and will serve as needed.

## **AACAP Staff**

The role of the AACAP staff is to provide managerial, administrative, publication, and logistical support to the CQI and the guideline process.

## **Expert Advisors**

The role of the EAs is to provide researcher-based review of the clinical questions and guideline background, rationale, recommendations, and discussion. The expert advisors (including the AACAP Research Committee) will be selected by the CQI co-chairs on the basis of their record of published research in the topic area and will serve voluntarily and without compensation in relation to the development of specific guidelines as needed. EAs must make pharmaceutical industry disclosures on appointment and prior to guideline publication per AACAP policy, but there are no specific limitations on participation in the review process. The EAs will not participate in searching literature, rating evidence, grading recommendations, or writing guideline drafts.

The EAs receive acknowledgment credit.

## **Clinical Consensus Panel**

The role of the CCP is to complete the clinical consensus panel survey, when needed, and provide clinician-based review of guideline background, rationale, recommendations, and discussion. The volunteer consensus group panel will be drawn by the CQI co-chairs from extant groups of clinical experts, including the AACAP Assembly of Regional Organizations, relevant AACAP Committees, the Society of Professors of Child and Adolescent Psychiatry, and child and adolescent psychiatry training directors, and will serve voluntarily and without compensation in relation to the development of specific guidelines as needed. The CCP will not participate in searching literature, rating evidence, grading recommendations, or writing guideline drafts.

The CCP groups (not their individual members) receive acknowledgment credit.

## **AACAP Members**

The role of AACAP members is to review guideline recommendations and discussion. Each guideline review will be conducted electronically for a specified period of time. All AACAP members are invited to provide feedback.

The AACAP membership (as a body) receives acknowledgment credit.

## **Key Stakeholders**

The role of the key stakeholders is to review guideline recommendations and discussion. Key stakeholders will be selected by the CQI co-chairs from relevant patient advocacy and professional organizations. Each review will be conducted electronically for a specified period of time.

The key stakeholder groups receive acknowledgment credit.

## **Development Process**

The following steps describe the guideline development process from topic selection to publication. The process requires approximately 1 year from start to publication.

### **Step 1: The CQI EC selects topics for guideline development and appoints the Guideline Writing Group for each guideline.**

Topics for potential guideline development may be nominated by any AACAP member.

The CQI EC selects topics according to the following criteria:

- Degree of public health importance
- Relevance to child and adolescent psychiatric practice
- Likelihood that a guideline would improve patient care
- Time since publication of practice guidelines on the same topic by AACAP or other organizations

To help prioritize topics, the CQI EC may seek input from AACAP Council, AACAP Assembly, AACAP Committees, research and clinical experts, and key stakeholders.

The CQI EC will appoint the GWG based upon CQI member expertise, interest, and availability.

### **Step 2: The Guideline Writing Group formulates clinical questions.**

After the CQI EC selects a topic for guideline development and appoints the GWG for that topic, the GWG formulates 10-20 clinical questions on the topic. Whenever possible, the questions follow a PICO(TS) format; i.e., patient, intervention, comparison, outcome, (and if applicable, timing and setting). If more than 20 questions are needed, the GWG considers narrowing the overall scope of the guideline.

### **Step 3: The Information Specialist & Systematic Reviewer sends the clinical questions to the Expert Advisors for review.**

The ISSR manages the EA review, whose input ensures that the clinical questions are informed by expert researcher opinion on the topic. The Guideline Writing Group revises the clinical questions as indicated based upon the comments received.

### **Step 4: The Information Specialist & Systematic Reviewer performs the systematic review.**

After the GWG finalizes clinical questions on specific topics, the ISSR performs targeted searches of MEDLINE and other pertinent databases according to *a priori* procedures that are consistent with IOM recommendations. If unpublished data are believed to exist, the ISSR also performs gray literature searches (i.e., of unpublished, informally published, or non-peer reviewed papers) to attempt confirmation and if possible obtain unpublished study protocols and data. This may include searching ClinicalTrials.gov, searching FDA online databases, searching abstracts and proceedings of scientific meetings such as the AACAP Annual Meeting, and contacting study authors.

After targeted search results are screened and gray literature searches are completed, the ISSR reviews the results and develops evidence tables for all randomized controlled trials (RCTs) and as needed for observational studies. For each clinical question defined by the GWG, the ISSR suggests a rating of the quality of available evidence, using a modified GRADE method.<sup>8</sup>

Under the GRADE method, the quality of a body of evidence is rated as “high quality”, “moderate quality”, or “low quality”. These categories reflect level of confidence in the estimate of an effect. Evidence from RCTs begins as “high quality” but may be downgraded for reasons including study limitations, inconsistency of results, indirectness of evidence, imprecision, and reporting bias. Evidence from observational studies begins as “low quality”, but if the magnitude of the treatment effect is very large, if there is evidence of a dose-response relationship, and if all plausible biases would decrease the magnitude of an apparent treatment effect, this evidence could be upgraded to “moderate quality”. A rating of “low quality” would generally describe evidence from observational studies that does not merit upgrading, or evidence from RCTs with very serious limitations.

When systematic reviews are available from external sources such as the Cochrane Collaborative or AHRQ, the SR uses these reviews. The ISSR may endorse the conclusions of the external review, or may draw independent conclusions using evidence tables from the external review in combination with internally developed evidence tables.

### **Step 5: The Guideline Writing Group reviews conclusions from the systematic review and creates a Clinical Consensus Panel survey as needed.**

If the evidence base supporting a recommendation is judged by the ISSR to be of low quality, the GWG creates a clinical consensus panel (CCP) survey to assess expert opinion about the recommendation. Expert opinion about recommendations supported by moderate- or high-quality evidence may also be assessed.

### **Step 6: The Information Specialist & Systematic Reviewer sends the Clinical Consensus Panel survey to the CCP for completion.**

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<sup>8</sup> The GRADE method is described at <http://www.gradeworkinggroup.org>.

The ISSR manages the CCP survey, whose input ensures that the guideline recommendations are informed by expert clinical opinion on the topic.

### **Step 7: Based upon the Information Specialist & Systematic Reviewer's systematic review of evidence and data from the Clinical Consensus Panel survey, the Guideline Writing Group drafts the guideline.**

Each guideline includes a brief background and rationale section, followed by specific clinical recommendations that are based upon evidence derived from the systematic review and the clinical survey.

The GWG determines the strength of recommendations using a modified GRADE method. Under this method, recommendations may be rated either “strong” or “weak”, reflecting confidence that the desirable effects of the recommendation outweigh the undesirable effects, i.e., confidence in the net benefit of the recommendation. When benefits clearly outweigh harms, a strong recommendation is appropriate. When benefits are in close balance with harms, a weak statement is appropriate. For clinicians, a strong rating implies that most patients should receive the recommended action, and a weak rating implies that different choices will be appropriate for different patients.<sup>9</sup>

Particularly when recommendations are supported by low-quality research evidence, clinical consensus survey data guide the GWG in determining ratings of strength of the recommendation. As a general principle, actions to be “strongly” recommended must be viewed very favorably by a substantial majority (>80%) of the CCP; whereas actions to be “weakly” recommended must be viewed very favorably by a majority (50-80%) of the CCP.

Statements with strong ratings are phrased “AACAP recommends”, and statements with weak ratings as “AACAP suggests”. If research evidence and clinical consensus are judged to be insufficient to support a “weak” rating, a statement is made that AACAP affirms no endorsement for or against the intervention. Instead, further research may be recommended.

The GWG reaches consensus on the wording and rating of each recommendation or suggestions through iterative blind voting. If the GWG cannot reach consensus about the rating of a recommendation, the rating must be downgraded (and a minority opinion may be described in the discussion section).

Clinical questions, search strategies, and survey data are included in appendices to the guidelines, allowing readers to judge for themselves the credibility of a rating based on their own assessment of the data and the methodology used to obtain it.

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<sup>9</sup> Guyatt GH et al., GRADE Working Group. Rating quality of evidence and strength of recommendations: going from evidence to recommendations. *BMJ* 2008; 336: 1049-1051.

### **Step 8: The Information Specialist & Systematic Reviewer manages reviews of the draft guideline.**

The draft guideline is reviewed by the Expert Advisors, Clinical Consensus Panel, AACAP members, and key stakeholders to insure wide input.

### **Step 9: The Guideline Writing Group finalizes the draft guideline.**

The GWG reviews comments by reviewers and considers revisions. Revisions to the wording or rating of a recommendation require a new consensus of the GWG using iterative blind voting. Such revisions must be consistent with Clinical Consensus Panel survey data obtained. Each recommendation, including its rating, must achieve consensus of the GWG before a guideline can be moved forward for approval. During this step, the CQI EC and GWG may also identify recommendations appropriate for development as performance measures, as well as areas where additional research is needed.

### **Step 10: The CQI EC reviews and edits the guideline and approves for submission to AACAP Council.**

The main purpose of this step is to provide a final check to ensure that policies and procedures for the guideline development process have been followed. Requests from the CQI EC for revision of the wording or rating of a recommendation must return to the Guideline Writing Group for a new consensus determination using iterative blind voting. Edits to a background/rationale or discussion section may be made by the CQI EC without discussion by the GWG.

### **Step 11: AACAP Council votes to approve/disapprove the guideline for dissemination (majority of quorum required).**

The AACAP Council reviews and approves the guideline for dissemination under the imprimatur of AACAP. If Council requests a revision to any recommendation, the proposed revision must return to the Guideline Writing Group for a new consensus determination using iterative blind voting. Such revisions must be consistent with the survey data obtained.

The approved guideline is disseminated in a variety of formats, including online and in print.

### **Review and Revision Process**

After publication, the Information Specialist & Systematic Reviewer continues to search newly published literature and review relevant studies. On an ongoing basis, the ISSR considers if revisions are needed to ratings of quality of evidence in published guidelines.

If the ISSR recommends revising a rating, the Guideline Writing Group recapitulates Steps 7 through 11 of the development process. Revision to a discussion section requires re-doing Steps 9 through 11.

Guidelines remain current for as long as the ISSR and GWG continue to agree that new evidence has not changed the recommendations or ratings. On a regular basis, the online

versions of the guidelines are updated with approved revisions. Each revision is separately dated to indicate when it was last reviewed and approved.

If resources allow, clinical implementation of the recommendations is evaluated, including clinicians' adherence to the recommendations, barriers to implementation, and patient outcomes.

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