

The American Academy of Audiology Clinical Practice Guidelines Development Process

INTRODUCTION

Clinical practice guidelines (CPGs) advance the mission of the American Academy of Audiology (Academy) by providing a framework for clinical recommendations to audiologists for the purpose of providing evidence-based care for individuals with hearing and balance disorders. CPGs have been defined 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” (Institute of Medicine 2011). More specifically, well-developed guidelines have the potential to (1) enhance current, appropriate clinical practice; (2) improve the quality of audiologic diagnostic assessment and treatment; (3) result in better patient outcomes; (4) improve cost-effectiveness of care; and (5) identify areas requiring further research or investigation. CPGs are presented in a manner that affords the practitioner a more complete understanding of the evidence available for each condition, procedure, and/or treatment option presented.

The Academy supports the creation of evidence-based CPGs to ensure applicable and clear recommendations that guide clinical practice. Accordingly, clinical recommendations presented in a CPG reflect a systematic literature search and review of existing scientific evidence published in peer-reviewed journals, in combination with the expertise of subject matter experts. To this end, CPGs define an optimal level of patient care and are used to promote and standardize clinical practice across audiologists.

Effective CPGs have the following characteristics:

- **Validity:** If a guideline is followed it should lead to health gains and predictable costs. This requires that the guideline be developed rigorously and consistent with available scientific evidence.
- **Cost effectiveness:** The improvements in health care should have both identifiable benefits and acceptable costs. It is possible that the best benefits come with a high utilization of resources (cost), thereby offsetting significant improvements in outcomes.
- **Reproducibility:** Given the same evidence, another guideline development panel tasked with the same question, would produce similar recommendations.
- **Reliability:** Given the same clinical circumstances, another health professional would make the decision to apply the recommendations in a similar fashion.
- **Representative membership:** Guideline development should be undertaken by a group that represents key disciplines and stakeholders, including patients, where applicable.

- **Clinical applicability:** The specific population targeted by the recommendations should be defined within the CPGs.
- **Flexibility:** Guidelines should identify possible exceptions to the recommendations, as well as how patient preferences should be included in the clinical decision-making process.
- **Clarity:** The CPG should be reader friendly and include precise directions and definitions.
- **Meticulous documentation:** The development of a CPG should include details of who took part, methods used, assumptions made, and the evidence that supports any recommendations.
- **Periodic review:** Guidelines should also be reviewed periodically, and, where appropriate, be modified to incorporate new knowledge or clinical practice patterns.

DEFINITIONS

Clinical Consensus Document: A statement on a particular procedure, treatment, or process that - generally is agreed upon as representing the current best practice for the topic. Clinical Consensus Documents are produced by a group of experts in that topical area, and has the purpose of providing clinicians with a basis for making sound clinical decisions. Consensus statements generally do not provide specific recommendations, but rather seek to synthesize new information, typically from recent research that may have implications for clinical decision making. The aim of consensus statements is to optimize patient care particularly where evidence is equivocal and the clinician is less certain about the choice of strategy. In such circumstances, the synthesis of carefully weighed opinions of experts may be particularly useful, and can support clinical decision making.

Clinical Practice Guideline (CPG): Formalized statements that include recommendations intended to create best practices and optimize patient care. CPGs are developed through a systematic review of the evidence, an assessment of the potential benefits and harms of the recommendations, and, if appropriate, a cost-benefit analysis of the recommendations. CPGs are not intended to provide a one-size-fits-all approach to patient care, but rather are designed to synthesize the scientific literature to provide guidance for clinical service delivery. Ideally, CPGs provide clinicians with the necessary evidence with which to make clinical decisions regarding their patients.

Position Statement: A position statement is a document that asserts the position of the Academy on a particular issue or topic. Position statements are generally short, focused commentaries that target specific audiences and describe the organizational viewpoint. Position statements may address clinical, economic, political, organizational, or controversial topics, and, as such, may be developed through scientific review, consensus or vote.

Guideline Development Panel: A group of individuals with appropriate yet varied expertise responsible for using systematic literature reviews to generate recommendations to guide clinical

practice in an objective and unbiased manner. All members of the panel may be members of the Academy or external experts invited to participate.

Systematic Review: A scientific investigation that focuses on a specific question; it uses explicit, planned scientific methods to identify, select, assess, and summarize the findings of similar but separate studies; it may or may not include a quantitative synthesis (meta-analysis) of the results from separate studies.

Appropriate Use Criteria (AUC): A document similar to a clinical practice guideline, however, the recommendations are tailored narrowly to specifically address when it is “appropriate” to use a procedure. In this case, “appropriate” refers to a procedure for which the benefits far exceed the risks, or where the different benefits can be derived through the choice of the appropriate procedure. AUC recommendations are tailored generally to the characteristics of the patient, rather than processes of the provider.

Guidance Statements: Statements that are based on reviews of existing guidelines produced by other groups or organizations. A guidance statement may or may not endorse the recommendations in CPGs produced by other organizations, either in whole or part, but should include the necessary rationale for any endorsement based on a review of the literature, recommendations in existing high-quality guidelines, and consideration of the needs and values of the members and their patients.

Evidence-Based: Credible guidelines should be based on a systematic review of research that includes reports of all scientific studies that bear on the topic being addressed. The systematic review should follow a process that includes assessment of the quality of evidence. Transparency is essential so that it is clear to readers what the quality or strength is for the evidence supporting the guideline recommendation.

SCOPE

The Guidelines and Strategic Documents Committee, the Scientific Advisory and Research Council, and the Academy Board of Directors provide oversight for the development and approval of CPGs. Other committees, councils, or organizations may also participate in the process of development of CPGs.

Position statement development will reside with the committee/council and/or board/board members who are best suited to act as subject matter experts of the necessary content. These will be produced in a nimble environment and often quickly to meet the needs of the audiology profession and strategy of the Academy.

PRINCIPLES

The American Academy of Audiology has adopted the eight standards promulgated by the National Academies of Science, Engineering, and Medicine in *Clinical Practice Guidelines We Can Trust* (2011). These standards include the following:

1. **Transparency:** The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible.
2. **Conflict of Interest (COI):** Individuals being considered for membership on guideline development groups should declare all interests and activities potentially resulting in COI with CPG development activity, by written disclosure, including both current and planned COI.
3. **Guideline Development Group Composition:** The CPG development group should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG, including, where appropriate, representatives of patients or consumers.

The writing group will have an assigned Guidelines and Strategic Documents Committee liaison (if that liaison is not the chair of the writing group already) to facilitate the communication and development of the deliverable back to the Committee. Committee liaisons agree to adhere not only to the charge of the committee but to the following items as well:

- a. Help to consistently manage Committee deliverables set forth by the Committee chair through the Council and Academy Board.
 - b. Adhere to deliverable timelines and work with writing groups to meet timeline deliverables.
 - c. Provide regular check-ins and updates on deliverables.
 - d. Help to manage challenges and provide helpful solutions, guidance, and recommendations to writing groups.
4. **Clinical Practice Guideline: Systematic Review Intersection:** When systematic reviews are conducted specifically to inform particular guidelines, the CPG and systematic review team should interact regarding the scope, approach, and output of both processes.
 5. **Establishing Evidence Foundations for and Rating Strength of Recommendations:** For each recommendation the following should be provided:
 - a. An explanation of the underlying reasoning of the recommendation.
 - b. A clear description of potential benefits and harms.

- c. A summary of available relevant evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
 - d. An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
 - e. A rating of the level of confidence in the evidence underpinning the recommendation.
 - f. A rating of the strength of the recommendation, in light of the determinations in sections a-e above.
 - g. A description and explanation of any differences of opinion regarding the recommendation.
6. **Articulation of Recommendations:** Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed. Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.
 7. **External Review:** External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health-care, professional societies), agencies (e.g., federal government), patients, and representatives of the public. Reviewers can be members or nonmembers.
 8. **Updating:** The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.

DEVELOPMENT OF CLINICAL PRACTICE GUIDELINES

Topic Identification. The development of a CPG can result from a request by a member or members of the Academy. Alternatively, the Board of Directors, the Scientific Advisory and Research Council, and/or the Guidelines and Strategic Documents Committee may identify a gap in the availability of existing clinical practice guidelines.

- Proposed topics are submitted to the Guidelines and Strategic Documents Committee for review and to establish relevance. The relationship to existing Academy documents is determined.
- Proposed topics are presented to the Board of Directors for consideration. Included in the submission is the relative merits of the topic, the relationship of the topic to existing Academy documents, the urgency for developing guidelines on this topic, any financial considerations for the development of a guideline (e.g. travel costs, consultant fees, etc.), potential chairs for the panel, and the rationale for including outside organizations or agencies for the development of the CPG.

- The Board of Directors shall determine if the topic is consistent with the strategic direction of the Academy. If approved, the Board of Directors will allocate appropriate resources for the support of the development of the CPG. The Board also will make recommendations for the chair of the panel.

Writing Panel Selection. The chair must be a member of the Academy, but members and nonmembers of the development group may be on the writing panel. Panel members also must be free from COI, and have the necessary time and expertise to contribute to the process of developing the CPG (see Appendix A for more information).

- The chair should be a recognized expert in the topical area encompassed by the CPG. The chair should be approved by the Board before the selection of panel members.
- Members of the writing panel will be selected based upon expertise in the topical area and with consideration of any potential COI. Members of the panel are selected by the approved chair of the panel and are approved by the Guidelines and Strategic Documents Committee.
- Members of the panel must disclose any potential COI to minimize any bias in the development of recommendations. Panel members should disclose any financial or non-financial COI, including any commercial, noncommercial, intellectual, institutional or public relationships that may be pertinent to the content of the guideline. COI may not disqualify an individual from serving on a panel; however, any COI that do exist should be disclosed both before the convening of the panel, and within the CPG document.
- All panel members must agree to keep the process and deliberations of the panel confidential to prevent undue external influence on the outcome.
- All panel members must agree and adhere to a consistent and regular level of commitment to the group and contribute to the development of the document.
- All panel members must attend and participate in group meetings.

Document Development. There are five general steps to the document development process.

1. The specific objectives, role, and scope of the document are established and shared with the panel. General and specific roles and responsibilities, including timelines for completion also are established. Questions for consideration by the CPG panel include:
 - a. What is the purpose of the CPG?
 - b. What is the CPG targeted procedure or intervention?
 - c. What are the important clinical objectives related to the CPG topic?

- d. What is the target patient population?
 - e. Are there potential benefits and/or risks for individual patients associated with the procedure or treatment?
 - f. Who are the CPG's intended users/stakeholders?
 - g. What is the epidemiology of the topic?
 - h. Will the new CPG be related in any manner to existing guidelines established by the Academy?
 - i. What are the expected outcomes at the completion of the project?
2. A detailed and systematic literature review is conducted to identify evidence from research studies about the appropriateness and effectiveness of different clinical strategies that address the topic of the CPG.
 3. The panel constructs the guideline, including the recommendations that guide clinical practice.
 - a. The suggested format for a CPG is shown in Appendix B. The purpose of the suggested format is to improve consistency across all Academy guidelines and to provide a common format for the panel. The format is not necessarily prescriptive, as applying a strict uniform methodology is somewhat problematic when developing CPG because they address such diverse conditions, procedures, and treatment interventions.
 - b. While widespread compliance with evidence-based practice is a goal, guidelines themselves often do not account for severity or complexity of a patient, nor can they account for patient compliance. Moreover, the use of a clinical practice guideline cannot substitute for clinical judgment with respect to individual patients, and therefore should not be used without consideration of the many factors that may be present within a patient encounter. In addition, clinical practice guidelines may not be appropriate as quality outcome measures given the diversity within patient populations. Thus, to the extent possible, CPGs should include:
 - Clear actionable recommendations that can be implemented and measured.
 - Strategies for overcoming barriers to implementation.
 - Systems or solutions that will improve adherence.
 4. An internal and external review process is conducted to vet the document for acceptability, clarity, consistency, and feasibility.
 - a. The draft document written by the panel will receive critical appraisal through a select peer review process whereby nonpanel Academy members will be contacted and asked to read and comment on the draft guideline.

- b. Following select peer review, the revised draft document will be posted on the Academy website for widespread peer review for a period of 30 days. All comments received will be forwarded to the panel chair and disseminated to the members of the panel for consideration and potential revision of the guideline.
- c. Following revision, the final document is submitted to the GSD Committee for submission to the Board of Directors.
5. The document is disseminated to the clinical community.
 - a. The final CPG will be reviewed and approved by the Board.
 - b. The document, or an outline/summary of the document, will be published on the Academy website, in *Audiology Today*, and in the *Journal of the American Academy of Audiology*.

All Academy CPGs will be reviewed by the Guidelines and Strategic Documents Committee every five years after implementation (if the timeline for review is not specifically defined by the task force). At that time, a decision will be made to maintain the guideline as is or to make content and/or editorial changes to the entire guideline, or specific areas within the guideline based on current practice standards. After the initial review, the Guidelines and Strategic Documents Committee will make a determination for a future review timeline (e.g., annually, every two years, or every three years) not to exceed five years for periodic review.

APPENDIX A. Guidelines and Strategic Documents: Writing Group

Formation of the Writing Group

The Guidelines and Strategic Documents Committee identifies writing group nominees, who are audiologist or other experts in the field, for consideration for chair, individual writing group members, and organizations that will be invited to participate in the clinical document development effort. The writing group should be multidisciplinary and balanced.

The writing group should be comprised of a diverse group of men and women from different geographical regions, with experts from both academic and nonacademic settings, ideally avoiding multiple members from the same institution.

In accordance with the Academy policies, writing group members must be members of the Academy. However, if a certain type of expertise is needed for document development, an individual can be appointed to be part of the writing group, only if he or she is NOT eligible for membership.

The writing group will have an identified Committee liaison (if that liaison is not the chair of the writing group already) to facilitate the communication and development of the deliverable back to the Committee.

The roles, responsibilities, and considerations for identifying and appointing document development group members are outlined in the sections that follow.

Size of the Writing Group

The number of writing group members for each document is decided by the Guidelines and Strategic Documents Committee and the document chair. There is no preset limit to the number of authors, but a group size of 5 to 10 members encourages diversity and efficiency yet is small enough to avoid redundancy and delays. For certain documents, it may be necessary to include a larger number of authors (e.g., 11+) to ensure that the document reflects expertise in the field and related disciplines. The number of individuals with a particular expertise needs to be carefully balanced so that one group of experts is not overly influential.

Chair Selection and Responsibilities

The document chair must be a member of the Academy. Document chair must be free from conflicts of interest (COI) and have the necessary time and expertise to contribute to the process of developing the document. In addition, the chair should have the ability to organize and work well with the writing group committed to building consensus.

Roles and Responsibilities of the Chair

- Assist with determining the writing group members, e.g., expertise needed, organizational involvement
- Refine the scope of the document and determine the outline
- Review areas of expertise of the writing group to determine appropriate writing assignments
- Manage the document and provide helpful solutions and guidance to writing groups
- Maintain timeline and encourage the writing group to meet deadlines
- Provide regular check-ins and updates on deliverables
- Write/facilitate writing of sections
- Facilitate consensus throughout development
- Manage the meetings/teleconferences
- Maintain COI policy compliance
- Edit/review full document for consistency of style and voice
- Respond to the Guidelines and Strategic Documents Committee review and peer review
- Participate in development of derivative products as requested

Writing Group Member Selection and Responsibilities

Members of the writing group are selected based upon expertise in the topical area and with consideration of any potential COI. Writing group members are selected by the approved chair of the panel and are approved by the Guidelines and Strategic Documents Committee.

Writing group members must disclose any financial or nonfinancial COI, including any commercial, noncommercial, intellectual, institutional, or public relationships that may be pertinent to the content of the document. COI may not disqualify an individual from serving on a writing group; however, any COI that do exist should be disclosed both before the convening of the panel and during the document development.

Writing Group Member Selection Criteria

- Individual's known contribution to the field on the document's topic or issue
- Individual's expertise in developing clinical practice documents or evidence review methodology
- Individual's ability to meet deadlines and remain committed to a project
- An appropriate balance of writing group members for a broad perspective on the topic
- Representation, when appropriate, from a specific society
- Individual representing a stakeholder important to the specific clinical practice document (e.g., patient, ancillary health care provider, policy expert)

Roles and Responsibilities of the Writing Group Members

- Agree to keep the process and deliberations of the panel confidential to prevent undue external influence on the outcome and to ensure the integrity of the development process
- Disclose all current COI and report any new COI until the term is complete
- Contribute to the development of the document (write and edit assigned sections) meeting deadlines
- Provide appropriate references to support assigned document section(s)
- Attend and participate in group meetings with a commitment to teamwork and clear communication

APPENDIX B. Suggested Format for Clinical Practice Guideline Documents

I. Title Page

1. Full title for condition, procedure, or treatment intervention
2. Full names of authors (members of the panel, including credentials)
3. Date of completion (release date)
4. Print and electronic sources

II. Introduction

1. Purpose/focus of the guideline—the condition, disease, treatment, procedure, technology, etc., addressed in the guideline
2. Goal—what is the guideline expected to achieve; describe need for the guideline
3. Describe intended users and settings in which guideline will be used
4. Describe intended target patient population
5. Selection and background of the writing group, including any conflicts of interest

III. Methodology

1. Describe the systematic methods used to search for evidence; include range of dates and databases searched (e.g., MEDLINE/PubMed; Cochrane Library, etc.); include the criteria for article inclusion
2. Provide criteria used to rate the quality and strength of evidence to support conclusions and recommendations (see Table 2).

Table 1. Level of Evidence Hierarchy for High-Quality Studies

Level	Type of Evidence
1	Systematic reviews and meta-analyses of randomized controlled trials
2	Randomized controlled trials
3	Nonrandomized intervention studies
4	Nonintervention studies: cohort studies, case-control studies, cross-sectional surveys
5	Case reports
6	Expert opinion

Table 2: System for Quality Rating of Individual Studies

Rating	Interpretation of Rating
++	Very low risk of bias. Any weaknesses that are present are very unlikely to alter the conclusions of the study.
+	Low risk of bias. Identified weaknesses or omitted information probably would not alter the conclusions of the study.
-	High risk of bias. Identified weaknesses or omitted information are likely or very likely to alter the conclusions of the study.

Source: Adapted from Cox 2005.

IV. Discussion/Results/Recommendations

1. Provide and discuss the evidence that leads to the conclusions. Make recommendations that are specific and unambiguous.
2. All recommendations will be written in complete sentences.
3. Separate recommendations that apply to specific clinical objectives.
4. Include information regarding areas of uncertainty or controversy in the recommendation as necessary.
5. To the extent possible, quantify benefits, harms, and/or timeframes.
6. Include flexibility in applying recommendations (e.g., special populations), where appropriate.
7. Guidelines should take into account not only whether an effect of an intervention is beyond chance but also other clinically relevant factors, such as:
 - a. The magnitude of effect
 - b. Harms from the intervention
 - c. Convenience and side effects
 - d. The clinical skills necessary to carry out the intervention successfully
 - e. Patient preferences
 - f. Cost
 - g. Cost-effectiveness
 - h. The work force necessary to implement the recommendations
8. Assign classification level to individual recommendations.

V. Conclusion/Summary

1. Provide an overview of presented data.
2. Highlight gaps in existing literature.
3. Describe areas that need further study.
4. Provide recommendations that will encourage research related to guideline topic area.
5. Provide suggested timeline for review of guideline

VI. References (provide a comprehensive list of references and related readings)

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