

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

Evidence-Based Clinical Practice Guidelines

Development and Implementation Manual

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Foreword

Since the publication of the American Academy of Pediatrics' (AAP) first clinical practice guidelines, pediatricians and other child health providers worldwide have enthusiastically received the AAP's recommendations about appropriate care. Methods have blossomed for maintaining transparency, constituting guideline development committees, dealing with conflicts of interest, performing systematic reviews, transforming evidence into recommendations, articulating recommendations, incorporating peer review, updating recommendations when appropriate, and implementing guidance effectively. This manual is an effort to capture and document current best practices in guideline development.

In the 1990s, it became clear that whenever possible, clinical recommendations should be based on the best evidence available rather than simply the well-formed opinions of experts. If high-quality evidence is unavailable, expert opinion could be included but should be identified so that users could separate "facts" from "opinions." The AAP's policies on classifying recommendations and on transparency of the process by which recommendations are developed for evidence-based guidelines represented vanguard thinking when they were published.

Most of the AAP's current recommendations for care are published in the form of clinical reports and policy statements. To date, their development process has slightly differed from that of guidelines with respect to the inclusion of evidence-based clinical recommendations. We hope that this manual will serve as a common set of best practices that can help standardize and elevate the development of all AAP clinical practice guidelines.

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Introduction

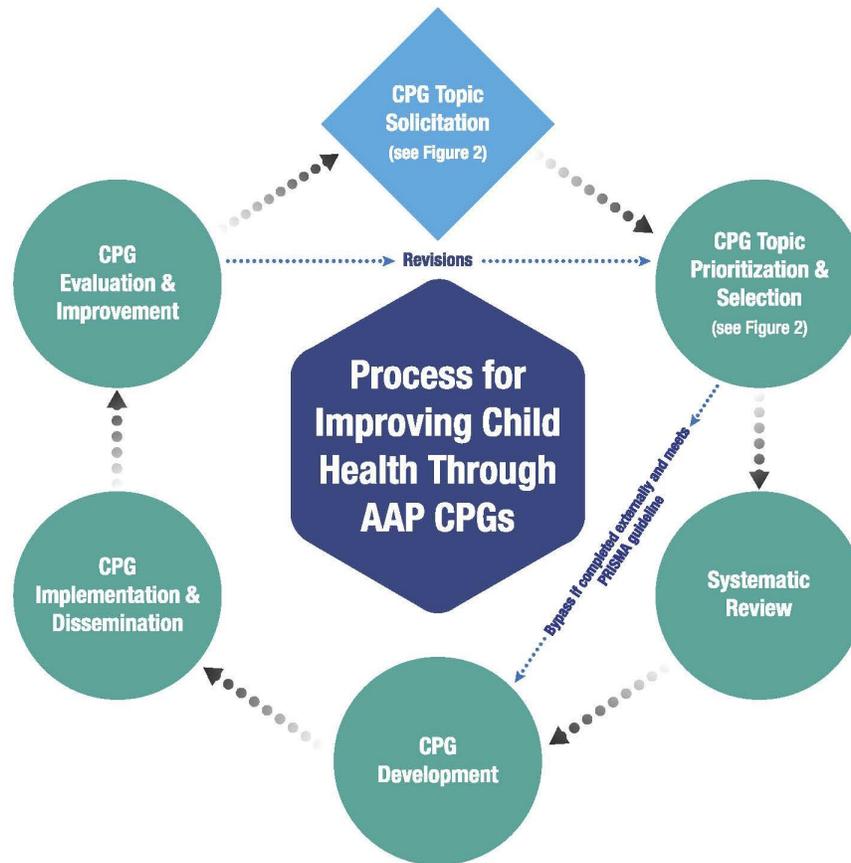
The Institute of Medicine (IOM), now the National Academy of Medicine (NAM), defined a set of aspirational goals for guideline developers. According to *Clinical Practice Guidelines We Can Trust*,¹ in order to be trustworthy:

1. Guidelines must be transparently developed.
2. Conflicts of interest must be disclosed and addressed.
3. Teams must be multidisciplinary and involve all major stakeholders.
4. Systematic review of the literature must be undertaken.
5. Recommendations must be clearly articulated.
6. Recommendations must be linked to their evidentiary foundations.
7. Guidance must be peer reviewed.
8. Systems must be in place to update recommendations when new knowledge arises.

American Academy of Pediatrics Policy Types

The AAP publishes a variety of policy types affirming a position or offering specific guidance or fact-based information, including²: *Clinical Practice Guidelines* (CPGs) – evidence-based clinical guidance that is based on a comprehensive literature review and data analyses with formal rules of evidence in support of each recommendation made; *Policy Statements* – statements that advocate, direct, or detail a public health position of concern to the AAP; *Technical Reports* – reports that are developed based on a review of the literature and data analyses; and *Clinical Reports* – reports that guide pediatricians in the clinical setting by addressing best practices and state-of-the-art medicine. The primary difference between CPGs and other AAP policy types is that guidelines provide evidence-based clinical recommendations and undergo a systematic, rigorous organizational process approved by the Board of Directors. Because of differences in rigor, it is recommended that guidelines, policies, and reports be given titles and contain content that reflect their statement types (e.g., a policy statement should not refer to itself as a guideline). **For the purposes of this manual, the focus is solely on CPGs.**

Figure 1. CPG Process Overview



Executive Summary

General Overview of Chapters

[General Intended Audience: Authors of CPGs, Epidemiologist, COQIPS/Executive Committee/COGD, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists, Payors, Electronic Health Records (EHR) Staff]

I. Chapter 1: Topic Solicitation, Prioritization, and Selection

Objectives

- a. Describe the overall process and methodology of for the solicitation of CPG topics across the AAP, and their prioritization, selection, and final approval
- b. Describe the roles of the Council on Quality Improvement and Patient Safety (COQIPS), COQIPS' Committee on Guideline Development (COGD), the Agency for Healthcare Research and Quality (AHRQ), the Section on Epidemiology, Public Health, and Evidence (SOEPHE), and the AAP Board Policy Committee, Executive Committee, and Board of Directors in CPG topic selection.

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists, Payors]

II. Chapter 2: CPG Subcommittee Selection and Conflicts of Interest Objectives

- a. Describe the selection, structure, and determination of CPG subcommittee members
- b. Describe the selection, duties, qualification, and responsibilities of CPG subcommittee Chair
- c. Describe the identification, selection, qualifications, and responsibilities of CPG subcommittee Vice Chair, methodologist/epidemiologist, Partnership for Policy Implementation (PPI) representative, Implementation Scientist, practicing general pediatricians, content experts (e.g., subspecialists), family representative, Guideline Coach, and AAP staff
- d. Describe Conflict of Interest (COI) policy and External Partnership/Collaborations Memorandum of Understanding (MOU) document structures

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members Conducting Systematic Review, Implementation Scientists, Payors]

III. Chapter 3: Systematic Review and Evidence Aggregation Objectives

- a. Review the process of systematic review, evidence aggregation, and determination of evidence quality
- b. Describe the role of AHRQ and AAP in regard to how the systematic review is conducted
- c. Describe how IOM (now NAM) *Standards for Systemic Reviews* is used as part of systemic review process
- d. Address publication biases and grey literature along with practical considerations when searching for evidence of pediatric topics
- e. Describe the general outline of literature review process

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists, Payors]

IV. Chapter 4: Developing Clinical Recommendations Objectives

- a. Describe the structure and content of CPG recommendations
- b. Discuss how ambiguous, vague, and underspecified language is addressed
- c. Describe how levels of obligation, statements of fact, and verbiage such as “consider” are used
- d. Describe how evidence quality and recommendation strengths are weighed and determined
- e. Describe and define the role of values (i.e., benefit outweighs risks, harms, and costs)
- f. Describe the format and structure determination of *Key Action Statement Profile*
- g. Describe the process for mitigation of conflict and dissenting opinions

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists, Payors]

V. Chapter 5: Guideline Meeting Structure and Support for Guideline Deliverables

- a. Define how the CPG subcommittee will write *Key Action Statements* (KASs)
- b. Describe the structure and support required for the development and publication of KASs
- c. Review the process and timeline of manuscript development within the CPG subcommittee structure along with its communication with AHRQ-EPC and the AAP
- d. Describe authorship criteria using the *International Committee of Medical Journal Editors* recommendations

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists]

VI. Chapter 6: Peer Review in Guideline Development Objectives

- a. Describe the aspects of *Peer, Internal, and External Peer* review in regard to guideline development and the associated process

- b. Define the role of SOEPHE, COQIPS, and the AAP Board with the review of adequacy of transparency of COI and translation from evidence to recommendations

[Intended Audience: Authors of CPGs, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists]

VII. Chapter 7: Ongoing Literature Surveillance and Guideline Updates
Objectives

- a. Define *literature surveillance*
- b. Define which questions and search strategies are used when starting literature surveillance
- c. Describe the need, timeframe, process, and documentation of CPG time stamps and updates

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists, Payors]

VIII. Chapter 8: Implementation
Objectives

- a. Review the overall CPG development process
- b. Describe barriers associated with guideline adoption in various settings and the need to identify CPG end users and relevant stakeholders
- c. Provide a checklist of potential areas for implementation planning
- d. Define trialability and its relation to CPG implementation and dissemination along with the role of the *Implementation Scientist*
- e. Specify deliverables for Implementation Scientist as they relate to implementation tools for various settings

[Intended Audience: Authors of CPGs, Epidemiologist, COQIPS Executive Committee, Board Policy Committee, CPG Authoring Subcommittee, Members of Systematic Review, Implementation Scientists, Payors]

Chapter 1 Topic Solicitation, Prioritization, and Selection

The first step in the AAP process for the development of a CPG is to identify topics consistent with AAP strategic priorities: topics that are important to the health care system, to pediatricians, and to children and their families.

Figure 2. Topic solicitation, prioritization, and selection



1. CPG Topic Solicitation

The Council on Quality Improvement and Patient Safety (COQIPS), through the Committee on Guideline Development (COGD), will solicit intents from all sections, councils, committees, groups, and the AAP Board of Directors (BOD) using a standard guideline topic submission application form. The application form (**see Appendix A**) will include all of the following components:

- Proposed guideline title
- Proposed CPG Chair, stakeholders, and guideline subcommittee members (NOTE: proposed members will be considered; however, they are not guaranteed for selection)
- Topic rationale
- Prevalence of the problem and potential impact of guideline
- Population to be addressed
- Prior systematic reviews or evidence syntheses, and key references
- Proposed key/PICO questions
- Manuscript outline
- Implementation plans
- Proposed timeline

Proposed guideline topics should focus on prevention, diagnosis, treatment, or management of a specific condition. In some circumstances, guideline topics may focus on a technology or individual procedure. The Institute for Healthcare Improvement's Triple Aim framework focuses on improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care.³ With the addition of the quadruple aim, a focus on provider and staff work life; clinical practice guidelines not only set the standard for care and improvement, they also diminish the uncertainty of proper criteria for diagnosing and treating patients through the development of standard clinical recommendations for a variety of comorbidities.

CPG Revisions: CPGs that are 3 years or older and, therefore, up for revision based on the 5-year point of expiration will be considered alongside any new intents for CPGs based on the same

criteria listed above. If current guidelines do not rise to the level of prioritization for revision, the COGD will recommend to the full COQIPS Executive Committee that the guideline be retired. Staff will submit an SBAR memo to the Board Policy Committee with COQIPS' recommendation, and the Board Policy Committee will make the final determination of whether it is appropriate to revise or retire the guideline. Guidelines are considered valid five years post publication, similar to other Academy policy types.

2. CPG Prioritization:

Applications will be placed into a scoring rubric and weighted by the following factors listed in Appendix H. Voting members of the COQIPS EC will review and independently score blinded applications. Once compiled, COGD/COQIPS will submit to the Board Policy committee 1) which applications have been received, 2) scores, and 3) a recommendation for which applications we recommend move forward given capacity.

3. CPG Selection:

When capacity exists to develop CPGs, those approved by the Board Policy Committee will be recommended to the BOD for final approval. If they cannot all be resourced and there are ties, the COQIPS EC will discuss and vote to break the ties and specify the preferred choice(s) for CPGs to develop.

Once applications have been approved by the BOD, the final amount of organizational resources to develop the CPG will be determined by the AAP leadership, considering the CPG prioritization and selection process based on current landscape of activities, strategic direction, and fiscal notes.

Dispute Resolution: If the BOD disagrees with the COQIPS EC recommendations, then the BOD will meet with COQIPS EC to reach a final decision.

AHRQ Topic Nomination and Approval

If a systematic review is needed, the AAP Executive Committee-approved topic nominations can be submitted to AHRQ as a suggestion for a systematic research review by completing a Topic Nomination Form available on the AHRQ Web site at:

<http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/>. Topic nominations submitted to AHRQ include:

- A description of the clinical question(s) about a specific treatment or health care test
- Relevant population(s) and potential coexisting diagnoses
- Health-related benefits and harms
- Importance of topic
- Research implications (e.g., how the research will inform decision-making processes)
- Relevant stakeholders or content experts (optional)
- Information on the nominating group (optional)

AHRQ evaluates and selects systematic review nominations based on 1) health care service priorities; 2) patient population priorities; 3) appropriateness; 4) importance; 5) duplication; 6) feasibility; 7) potential value for a significant health impact, economic impact, potential for change, risk from inaction, ability to address vulnerable populations and inequities, and ability to address a topic with clear implications. Visit the AHRQ Web site to view a sample completed topic nomination form at:

<http://effectivehealthcare.ahrq.gov/tasks/sites/ehc/assets/File/TopicFormRevExample.pdf> and to view previously submitted research topic nominations at:
<http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/read-suggested-topics-for-research/>.

During the AHRQ approval process, it determines whether the topic is appropriate for 1) an effectiveness review or a comparative effectiveness review; 2) a technical brief; or 3) if the topic is not appropriate for a research review. If AHRQ determines that sufficient literature exists and that a systematic review is warranted, they typically approve and fund the systematic review of these topic nominations and produce an evidence report. Upon the determination that AHRQ will approve a topic nomination, the BOD is provided with status updates via the tri-annual management report notifying them that a guideline will be developed.⁴ During this phase, basic timeframes are provided for the development of a draft and final version of the complete evidence report.

It is understood that if AHRQ develops an evidence report on the requested topic that the AAP will develop a guideline. If AHRQ determines that there is insufficient evidence to produce a comprehensive systematic review of the literature, then the intent authors must identify an alternative funding for the systematic review. Alternatively, the AAP may examine whether there are internal or external resources (e.g., grant funding) available.

Following approval of the guideline proposal to develop a clinical practice guideline by COQIPS and BOD, the next phase in the organizational process is the assembly of a CPG subcommittee.

Chapter 2 Team Selection and Conflicts of Interest

Clinical Practice Guideline Subcommittee Selection^{5,6}

The ideal size of a CPG subcommittee is 10-14 members, not counting AAP staff. The final size may be influenced by balancing the need for appropriate team dynamics with funding availability. At a minimum, the team includes a Chair, a Vice Chair, a methodologist/epidemiologist, a Partnership for Policy Implementation (PPI) representative, an Implementation Scientist, content experts, general pediatricians, stakeholders from relevant disciplines, a family representative, a Guideline Coach, and AAP staff. As much as possible, the subcommittee should strive for diversity in membership. Typically, guideline subcommittees participate in a kick-off videoconference, two face-to-face meetings, and teleconferences (as needed). Please note: *Proposal of panel members does not guarantee their participation.*

Chair Selection and Qualifications

Upon receipt of all CPG subcommittee Chair nominations, the Chair is recommended by the COGD to the COQIPS Chair. With approval from the COQIPS Chair and input from guidelines staff, the CPG subcommittee Chair is submitted for review and approval by the AAP EC. Qualifications of the Chair include:

- **The Chair should be a current AAP member (FAAP) and represent the primary audience to whom the guideline’s recommendations are directed.** In most situations, this means the Chair should be a practicing general pediatrician. However, if the guideline primarily targets another discipline (e.g., pediatric emergency medicine, neonatology, etc.), the Chair should come from that discipline. Subspecialist Chairs may be considered if their subspecialty is expected to be targeted by the recommendations. If the guideline subcommittee shares concerns regarding inclusivity and/or transparency, or identifies other issues with the CPG Chair, the COQIPS Chair in collaboration with the COGD Committee will resolve the concerns expeditiously.
- Should have been in active practice in her/his primary specialty within the past 5 years.
- Should have prior experience with evidence-based CPG development (including membership on a previous AAP CPG subcommittee, or equivalent experience).
- Must have demonstrated leadership ability.
- Must be efficient and motivated.
- Must have demonstrated skills in scientific writing.
- Must be familiar with CPG development process as outlined here and the AAP policy *Toward Transparent Clinical Policies*.⁷
- Must adhere to the AAP Policy *Conflict of Interest and Relationships with Industry and Other Organizations*.

Specific responsibilities of the Chair include:

- Maintain climate of trust and mutual respect among subcommittee members.
- Prevent undue bias by individuals on subcommittee.
- Encourage constructive debate without forcing agreement.
- Use negotiation skills to resolve disagreements.
- Collaborate with AAP staff in planning conference calls and meetings.

- Lead discussions in accordance with the meeting agenda.
- Encourage all subcommittee members to contribute to discussions and activities.
- Attend to group processes, communication, and decision making.
- Summarize key decisions including evaluation of the evidence for the CPG.
- Function as first author for the CPG manuscript. Along with AAP staff and Vice Chair, may delegate writing assignments and integrate completed assignments along with group feedback into the draft CPG.
- Work closely with the PPI representative to ensure implementability of final recommendations.

Identification and Selection of the Vice Chair

The Vice Chair of the CPG subcommittee is selected by the Chair with input from AAP staff.

Qualifications of the Vice Chair include:

- Must be a current AAP member (FAAP) and practicing within the past 5 years.
- The Vice Chair should have experience with meeting facilitation.
- The Vice Chair should have some interest in becoming a future CPG subcommittee Chair.
- Must have demonstrated leadership ability.
- Must have demonstrated skills in scientific writing.
- Must be familiar with the CPG development process as outlined here and the AAP policy “Toward Transparent Clinical Policies.” Must adhere to the AAP Policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Specific responsibilities of the Vice Chair include:

- Serve as CPG Chair in the event that the Chair is unable to serve.
- Support the Chair in:
 - Attending to group processes, communication and decision making;
 - Maintaining climate of trust and mutual respect among subcommittee members;
 - Preventing undue bias by individuals on subcommittee;
 - Encouraging constructive debate without forcing agreement;
 - Using negotiation skills to resolve disagreements; and
 - Along with Chair and AAP staff, delegating writing assignments and integrating completed assignments along with group feedback into the draft CPG.

Identification and Selection of Methodologist/Epidemiologist

The Section on Epidemiology, Public Health, and Evidence (SOEPHE) is first contacted for applicants for methodologist/epidemiologist for the specific CPG subcommittee (see Appendix B). The CPG subcommittee Chair and AAP staff will review credentials of volunteers for this position. The CPG Chair will select the methodologist/epidemiologist with input from AAP staff. Qualifications of the methodologist/epidemiologist include:

- Prior CPG development or similar experience;
- Familiarity with guideline methodology;
- Familiarity with the process of systematic reviews;
- Direct experience with prior guidelines;
- Must be familiar with the CPG development process as outlined here and the AAP policy “Toward Transparent Clinical Policies”; and

- Ideally, formal academic training and a degree in epidemiology or equivalent fellowship training.

The candidate must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Specific responsibilities of the methodologist/epidemiologist include:

- Assisting with literature reviews;
- Article retrieval, either by self or in conjunction with clinical librarians;
- Grading articles for methodologic strength;
- Production of technical reports that accompany guidelines;
- Assisting with the production of guidelines;
- Ensuring reference accuracy;
- Participation on regular guideline teleconferences;
- Assistance developing the preliminary and final topic nomination submissions; and
- Consulting with a clinical librarian (e.g., AAP librarian) as needed to ensure well-formed clinical questions and robust search strategy.

At some point between the first and second face-to-face meetings, the methodologist should reproduce the search strategy as described by the AHRQ in their systematic review or replicate the search strategy initiated by the methodologist at the start of the project, using the same inclusion and exclusion criteria to capture any new, potentially relevant data that should be included in the CPG. The methodologist, in collaboration with the Chair and vice-Chair, as well as staff, will determine when the search should be conducted.

Identification and Selection of Partnership for Policy Implementation (PPI) Representative

The PPI was established to increase the ability of pediatricians to implement AAP recommendations at the point of care. A PPI nominee is submitted to guideline staff for consideration to participate on every AAP guideline as a member of the CPG subcommittee. This member will aid in the production of clear guidance on how pediatricians can implement recommendations. When a PPI member is selected to serve on the current PPI group, he or she will shadow on at least one project prior to being the primary member assigned to a guideline or policy statement.

Recommended qualifications for the PPI representative include:

- Clinical informatician, ideally board certified in clinical informatics;
- Ability to use Bridge-Wiz and/or other tools to make recommendations implementable/computable;
- May have ability to create model clinical decision supports such as order sets/rules/forms;
- May map relevant terms to standard clinical computer vocabularies for potential inclusion in guideline implementation materials; and
- Must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Specific responsibilities of the PPI representative include:

- Help author(s) develop clear, action-oriented recommendations;
- Help author(s) identify/define key vocabulary terms;
- Help author(s) identify vague terminology and offers recommendations to strengthen the language or offer greater clarity;
- Help ensure the transparency of the statement's evidence;
- Help lead the algorithm development, if an algorithm is to be included; and
- Help ensure that the statement is written in a way that its recommendations can be incorporated into an electronic health record (EHR) system.

Identification and Selection of Implementation Scientist

Implementation Scientist candidates interested in serving on the CPG subcommittee are solicited by AAP staff through various channels, including COQIPS and its Implementation Committee, the AAP Quality Improvement Innovation Networks (QuIIN), State Chapters of the AAP, Chapter Quality Network (CQN), Education in Quality Improvement for Pediatric Practice (EQIPP), the AAP quality improvement listserv, and the PPI. The CPG Chair and AAP staff will select the most qualified Implementation Scientist based on the nominations received from this candidate pool. Candidates should be familiar with the CPG development process as outlined here and the AAP policy, “Toward Transparent Clinical Policies,” and must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Candidates who have formal quality improvement and patient safety training (eg, Advanced Training Program at Intermountain Healthcare, Lean Six Sigma course, Institute for Healthcare Improvement (IHI) Training, I2S2 at Cincinnati Children’s, etc) are preferred. Candidates should be experienced in creating quality improvement metrics, drafting quality improvement tools and change concepts, and performing quality improvement projects. The Implementation Scientist will be expected to deliver implementation tools and resources following guideline creation, including specific tools that can be implemented by frontline clinicians to accelerate guideline implementation. These resources may include aim statements, key driver diagrams, chart review tools, patient or provider educational resources, and metrics to evaluate whether changes are resulting in improvements. An example of these resources was developed by the Genetics in Primary Care Institute–Quality Improvement Project.⁸ When feasible, the full guideline subcommittee will review, make necessary recommendations for improvement, and approve the implementation tools and resources.

Recommended qualifications for Implementation Scientist include:

- Practiced outpatient or inpatient general pediatrics within the past 5 years;
- Quality improvement project experience;
- Having worked on a quality improvement project through multiple improvement cycles;
- Demonstrated ability to implement projects between different practice settings (beyond his or her own practice);
- Formal quality improvement and patient safety training;
- Experience with measure creation, including measure portfolios to determine impact of interventions; and

- Must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Specific responsibilities of the Implementation Scientist include:

- Help ensure the implementation focus is presented in the content;
- Help ensure that the recommendations are practical and realistic;
- Deliver a set of implementation resources and tools following guideline creation, including aim statements, key driver diagrams, chart review tools, quality metrics to evaluate whether changes are resulting in improvements, and specific tools that can be implemented by clinicians to accelerate guideline implementation;
- Consult with AAP quality improvement networks and the COQIPS’ Implementation Committee for questions or support as needed during this process.
- Attend minimum of one of two face to face meetings;
- Participate in conference calls and emails as needed; and
- May participate in AAP quality improvement project when funding supports testing of guidelines and tools.

Identification and Selection of Practicing General Pediatricians

Each CPG subcommittee must include at least 1 additional general pediatrician other than the Chair or Vice Chair.

Qualifications for practicing general pediatricians include:

- Should be AAP members (FAAPs), and represent the primary audience to whom the guideline’s recommendations are directed and
- Should have been in active practice in his or her primary specialty within the past 5 years.
- Ideally, should have been actively managing patients in the population proposed by the CPG within the past 5 years.

Specific responsibilities of practicing general pediatricians include:

- Help ensure the pediatric generalist perspective is presented in the content;
- Help ensure that the recommendations are practical and realistic;
- Provide input regarding the implementation aspects of the content;
- Attend minimum of one face-to-face meeting (travel reimbursed by AAP);
- Participate in conference calls and e-mails as needed;
- Must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Identification and Selection of Content Experts (eg, Subspecialists)

AAP staff will contact Chairs of relevant AAP sections, councils, and committees for applicants as content experts on the CPG subcommittee. Too many content experts can bias discussions and suppress participation by other subcommittee members. The total number of content experts must not exceed the number of general pediatricians who are not content experts. Content experts should be familiar with the CPG development process as outlined here and the AAP policy “Toward Transparent Clinical Policies” and must adhere to the AAP policy “Conflict of

Interest and Relationships with Industry and Other Organizations.” The CPG Chair and AAP staff will select content experts for the subcommittee.

Identification and Selection of Family Representative

Each CPG subcommittee must include a family representative with experience or knowledge of issues that are important to families affected by the condition being addressed. Having a family representative helps to ensure that the guideline will be relevant to families affected by the recommendations and acknowledges family preferences and choices. Family participation can improve transparency of the guideline development process and ensure that the CPG was not developed to serve special interests. The family representative can help guarantee that guideline recommendations and implementation materials are presented in a manner understandable to most families, and act as a safeguard against conflicts of interest. The family representative should not represent the views of any particular organization, should be familiar with the CPG development process as outlined here and the AAP policy “Toward Transparent Clinical Policies,” and must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Identification of Other Stakeholders

Inclusion of representatives of multidisciplinary stakeholder groups on the subcommittee will help to identify all relevant evidence, encourage support among intended users of the CPG, and help to address practical issues in implementing the CPG. Other stakeholders may be identified from non-pediatric medical specialties and other health disciplines, including nursing, pharmacy, and other allied health fields relevant to the content of the specific CPG. These individuals will be selected by the CPG Chair with input from AAP staff. Stakeholder members of the subcommittee should be familiar with the CPG development process as outlined here and the AAP policy “Toward Transparent Clinical Policies” and must adhere to the AAP policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Guideline Coach

Upon approval of the guideline topic, nominations will be solicited for a Guideline Coach, and the COGD (with input from AAP staff) will from these nominations recommend a Guideline Coach to the COQIPS Chair, Qualifications of the Guideline Coach include:

- Must have participated in the development of an AAP clinical practice guideline
- Should be a Fellow of the American Academy of Pediatrics, and a current AAP member
- Must be available to participate in subcommittee meetings and conference calls as needed

Specific responsibilities of the Guideline Coach include:

- Serve as an expert guideline development resource
- Lead the onboarding and orientation of the guideline Chair/Vice Chair to the AAP guideline development process, which may include participating in one or more conference calls
- Assist the guideline Chair/Vice Chair in orienting the guideline subcommittee to the AAP guideline development process
- Assist the guideline Chair/Vice Chair in facilitating committee meetings, including applying “Mitigation of Conflict and Dissenting Opinions” strategies as needed
- Ensure progression through the CPG development process, including providing updates to the COQIPS EC and COGD, and monitoring of dissenting or conflicting opinions

- Review/provide feedback on draft clinical recommendations
- Advise COGD about ways to improve the guideline development process

Qualifications and Responsibilities of AAP staff

The AAP staff for the CPG subcommittee has prior experience with the development of clinical practice guidelines, familiarity with literature searches, an understanding of study design and medical terminology, and familiarity with the CPG development process as outlined here and the AAP policy “Toward Transparent Clinical Policies.”

Specific responsibilities of AAP staff include:

- Identify guideline group members by working with the CPG Chair, AAP leadership, and relevant external organizations;
- Schedule and handle logistics for all conference calls and face-to-face meetings;
- Work with the Chair to create agendas and distribute materials prior to calls and meetings;
- Identify external peer reviewers;
- Distribute the guideline for reviewer comments and collate comments for distribution to the Chair and subcommittee;
- Proofread the guideline final draft, including checks for grammar and spelling (internal medical editor);
- Submit the full text guideline with accompanying algorithm if applicable, and corresponding significant concerns and responses to significant concerns for review and approval by the AAP board of directors; and
- Assist the Chair in formatting the final document for publication (unless a medical writer is contracted).

Responsibilities of All CPG Subcommittee Members

Regardless of position, all members of the CPG subcommittee have the following responsibilities:

- Fully disclose any potential conflicts of interest;
- Participate in all meetings and conference calls;
- Be committed to teamwork and clear communication;
- Read all relevant materials and give constructive feedback;
- Be prompt in responding to e-mails relevant to the subcommittee;
- Meet deadlines in completing assignments;
- Maintain confidentiality during the development process and until the guideline is published;
- Submit a signed copy (and retain a personal copy) of the AAP Guideline Confidentiality Agreement; and
- If representing another organization, communicate promptly and regularly with it to note any concerns about the CPG, and transmit these concerns back to the subcommittee.

Participation in writing the manuscript of the CPG is not a requirement for subcommittee membership but is decided based on member interest and ability, although all committee members are expected to review the final document. (CPG authors will be identified as distinct

from subcommittee members who did not meet authorship criteria. Criteria for authorship are listed in Chapter 5.)

Conflict of Interest (COI)

It is important to remember that unmanaged intellectual COIs can be as damaging as unmanaged financial COIs to the quality and credibility of the final guideline product. Intellectual COIs can come into play when content experts (e.g., subspecialists) push a view or interpretation of data that they have either developed through clinical trials or other research endeavors and/or upon which they have built their professional reputations. Relevant COIs (e.g., financial, industry relationships, intellectual) of the authoring team will be examined before authors are allowed to participate in the guideline committee.⁹ If existing conflicts are deemed acceptable, relevant conflicts will be documented in the manuscript.

See AAP Policy “Conflict of Interest and Relationships with Industry and Other Organizations.”

Confidentiality

Guideline subcommittee members may in their role be exposed to certain confidential and/or proprietary information, materials or data related to the subcommittee’s work and final document(s). It is important to the integrity of the writing process and final work that this information is kept strictly confidential and not disclosed at any time under any circumstance.

Therefore, as a condition and in consideration of a member’s selection to serve on the guideline subcommittee, and in recognition of the importance of the subcommittee’s work and for mutual consideration, the receipt and adequacy of which are acknowledged by the parties, guideline subcommittee members agree to the following:

- Members will not disclose or cause to be disclosed to anyone or any entity outside of the guideline subcommittee or appropriate AAP staff any confidential and/or proprietary information, materials or data related to the guideline subcommittee’s work, where such information, materials or data have been previously identified in writing or marked by the guideline subcommittee as “Confidential.” This restriction shall apply at any time and in any circumstance, unless otherwise directed by the guideline subcommittee Chair.
- Members will keep all such confidential information in your possession or control in a safe and secure place and will take all reasonable steps to protect against inadvertent disclosure or theft of the information.
- Upon request from the guideline subcommittee Chair, members will promptly destroy all confidential information received or acquired relating to the guideline subcommittee. Notwithstanding the return or destruction of any such confidential information, members will continue to be bound by their obligations under the Nondisclosure Agreement (Appendix I).

Copyright Release and Transfer

In consideration for his or her contributions to the American Academy of Pediatrics (the “Academy”), and for other good and valuable consideration, the receipt of which is hereby acknowledged, guideline subcommittee members grant and assign exclusively to the Academy all right, title, and interest that the member (i.e., author) may now or hereafter own, including copyright and all rights subsumed thereunder, in and to all contributions made by the member

(i.e., author) to all publications (“works”) created in the course of his or her appointment/election as a clinical practice guideline subcommittee member/liason/consultant of their respective guideline. All guideline subcommittee members will be required to sign a copyright release agreement to participate.

External Partnerships/Collaborations

When the AAP determines that it would like to proceed with the development of a joint clinical practice guideline with an external organization, AAP staff will work in concert with the guidelines staff at the corresponding entity to draft and develop a memorandum of understanding (MOU). At a minimum, the MOU should include the following:

- Chair nomination;
- A description of the CPG subcommittee representation;
- Associated costs regarding who will fund the external liaison;
- Anticipated time commitment;
- Anticipated title of the clinical practice guideline;
- COI disclosure requirements;
- Copyright/publication rights (the AAP shall be the only entity to publish the joint guideline in full text);
- Documentation of confidentiality;
- Peer review considerations; and
- Endorsement and approval processes.

Chapter 3

Systematic Review and Evidence Aggregation

Overview of Systematic Review, Evidence Aggregation, and Determination of Evidence Quality

Recommendations in clinical practice guidelines should be built on a foundation of the best available evidence and assembled in a nonbiased manner. A systematic review of the literature for each clinical question to be addressed by a guideline is the most effective way to create this foundation. This work should be completed before the guideline subcommittee meets to draft recommendations. In March 2011, the IOM (now National Academy of Medicine) released a set of national [Standards for Systematic Reviews](#). These standards provide an aspirational roadmap for initiating systematic reviews, finding (selecting) and assessing individual studies relevant to the guideline, and synthesizing (aggregating) the evidence that provides the basis for each recommendation in the guideline.

The IOM systematic review standards represent an ideal approach that requires the availability of substantial resources and skill sets, including research librarians and others with methodological expertise in conducting systematic reviews and quantitative analysis. This IOM roadmap should be followed as closely as possible with the resources available to the subcommittee charged with guideline development. Resource limitations may reduce the degree that a guideline subcommittee is able to comply with these standards, which may also reduce the quality and utility of the guideline. This chapter will review these processes in more detail.

First Steps – Preparing the Foundation Needed for a Systematic Evidence Review

The first step in developing a systematic review of the literature is to determine the capacity and resources needed for the task for the specific guideline. This will depend in part on the scope of the proposed guideline—i.e., the number of recommendations of various types that likely will be made and the range of literature that may need to be reviewed. In general, the greater the number of clinical questions to be addressed, the greater the number of literature searches and volume of literature that will be required.

The systematic review required for development of a new guideline usually is more effort-intensive than for subsequent revisions of the guideline. Exceptions to this may occur when a guideline generates a substantial number of new studies that better address the clinical issues relevant to the guideline and/or a prolonged period of time elapses between the first version (or most recent revision) of a guideline and the current revision.

When AHRQ Conducts a Systematic Review

When an external agency (e.g., AHRQ) is engaged to develop the systematic review for an AAP guideline, the AAP will nominate the appropriate content experts and a key methodologist to serve on the AHRQ technical expert panel as well as to serve as key informants for AHRQ. This is important to ensure that the clinical questions and scope of the project are understood adequately by the external agency group and then adequately addressed in the systematic review. Conference calls are recommended prior to the external group starting its work and then at intervals, with the external agency to review and discuss progress and findings.

When the systematic review is conducted by AHRQ, these roles will not incur a fiscal note on behalf of the AAP. IOM/NAM standard 2.1 outlines 5 areas of expertise to be included:

- Pertinent clinical content
- Systematic review methods
- Searching strategies for relevant evidence
- Quantitative methods (e.g., statistical analysis and interpretation)
- Other, as appropriate (e.g., qualitative methods)

When the AAP Conducts the Systematic Review

If AHRQ does not provide a systematic review, the AAP will decide whether or not to move forward with the guideline topic proposal. If it is determined that the AAP should develop the guideline without the aid of AHRQ, guidelines staff will contract a methodologist from the Section on Epidemiology, Public Health, and Evidence (SOEPHE), and the AAP will determine the funding source to support guideline development.

In instances where the AAP receives external funding to conduct a systematic literature review for another entity, the GET Committee will collaborate with the systematic review panel to ensure that the scope of the work and the clinical questions rise to the level of rigor required for clinical practice guidelines should there be an opportunity to use the research as the foundation for AAP policy.

Developing Questions that Cover Desired Content and Clinical Issues to be Addressed (IOM/NAM Standard 2.5: Formulate the topic for the systematic review)

The leadership of the guideline subcommittee should develop the list of key questions related to diagnosis, treatment, prevention, prognosis and/or other factors that are relevant to the guideline. IOM/NAM standard 2.5.2 suggests that the subcommittee “Develop an analytic framework that clearly lays out the chain of logic that links the health intervention to the outcomes of interest and defines the key clinical questions to be addressed by the systematic review.” A practical approach is to develop a series of flow diagrams that first list the desired outcomes linked back to the health interventions that may be available. The latter could be diagnostic, therapeutic, or preventive measures.

The next step is to generate questions that can be refined to actionable literature searches for evidence that addresses the impact of the interventions on the outcomes. IOM/NAM standard 2.5.3 states “Use a standard format to articulate each clinical question of interest” (eg, think “PICO”: Population, Intervention, Comparison, Outcome).¹⁰ Primary questions may be relatively broad and amenable to having 2 or more secondary questions that are more specific. Each question, whether primary or secondary, may encompass a single or multiple individual recommendations. The goal is to ensure that the systematic review provides a summary of the best available evidence for each recommendation to be made in the guideline.

As the question list is developed, the rationale for each question should be summarized (IOM/NAM standard 2.5.4). The clinical questions should be refined based on input from anticipated end-users and stakeholder groups outside the guideline subcommittee (IOM/NAM standard 2.5.5) when such opportunities are available and feasible.

Developing the Roadmap for the Systematic Review (IOM/NAM Standards 2.6 – 2.8)

After the list of questions has been developed and vetted, a protocol for conducting the systematic review should be developed. IOM/NAM standard 2.6 outlines the content that is desirable for such a protocol (many of these are described in more detail in the next section):

- Description of the overall context and rationale for the review, including both decision-making and research perspectives (IOM/NAM 2.6.1).
- Description of study screening and selection criteria (i.e., what inclusion and exclusion criteria will be used to select studies identified in initial literature searches for further review) (IOM/NAM 2.6.2).
- Precise description of outcome measures, time points, interventions and comparison groups that are needed (IOM/NAM 2.6.3; again, think “PICO”).
- Description of the search strategy(s) to be used to identify relevant evidence (note that this may depend in part on practical limitations and other considerations discussed below) (IOM/NAM 2.6.4).
- Description of criteria for selection of studies from which data will be extracted (IOM/NAM 2.6.5).
- Description of strategy for data abstraction (IOM/NAM 2.6.6).
- Description of process for identifying and resolving disagreement between subcommittee members around any study selection or data extraction decisions (IOM/NAM 2.6.7).
- Description of the desired timetable for conducting the review (IOM/NAM 2.6.11).

In addition to these details, an a priori approach should be specified for critical appraisal of individual studies (IOM/NAM 2.6.8), description of how the body of evidence around each question will be synthesized (IOM/NAM 2.6.9), and justification or decision-making about any pooled analyses (e.g., meta-analysis of patient subgroups, grouping of different means of delivering an intervention, or accounting for differences in how a particular outcome may be measured) (IOM/NAM 2.6.10). These will be reviewed in more detail below.

The degree of detail required for the systematic review protocol will vary depending on the scope and breadth of the guideline, but the individual components listed above generally should be addressed for each systematic review.

To the degree that it is feasible, providing a draft of the systematic review protocol to key stakeholder groups or making it available for some degree of public review and comment is desirable (IOM/NAM standard 2.7). Such scrutiny can uncover areas where greater clarity is needed or identify relevant issues that have been omitted or inadequately considered. The final protocol also can be electronically posted for public review (IOM/NAM standard 2.8). The protocol may be amended as needed once the review has been initiated.

Finding and Synthesizing the Relevant Data (IOM/NAM Standards 3 and 4)

Once the protocol is finalized, the hard work of the systematic review can be started. This involves an appropriately comprehensive search for evidence, identification of relevant studies or other forms of evidence, appraisal of individual studies deemed appropriate for inclusion, and synthesis of the evidence with an assessment of the aggregate quality of evidence found for each question (and ultimately each recommendation that will be made). An epidemiologist is typically contracted from SOEPHE and fiscally supported by the AAP to conduct this process.

Several steps are required to conduct a comprehensive systematic search for available evidence. The best first step is to work with a research librarian or other information specialist (IOM/NAM standard 3.1.1) to review the clinical questions and design search strategies to address each question (IOM/NAM standard 3.1.2). Once search strategies have been drafted, it is wise to have these reviewed by another (independent) librarian or information specialist (IOM/NAM standard 3.1.3).

The primary search for evidence will involve searching bibliographic databases (IOM/NAM standard 3.1.4) such as PubMed (Medline), EMBASE (Excerpta Medica database, produced by Elsevier) which is a bNAMedical and pharmacological database produced by [Elsevier](#), and CINAHL (Cumulative Index to Nursing and Allied Health Literature, produced by EBSCO). It is anticipated that the great majority of moderate- to high-quality studies relevant to pediatric health topics are now captured by PubMed. EMBASE focuses on pharmacologic studies and literature and may provide additional useful scope. CINAHL includes nursing literature (including nursing dissertations and conference proceedings) and information from other allied health disciplines as well as topics in alternative/complementary medicine. Other bibliographic databases and literature citation indexes (IOM/NAM standard 3.1.5) may be included in the search strategy depending on 1) subcommittee discussions with the search librarian/information specialist around likely yields from these sources; and 2) practical considerations of time required and person-power/funding available for “good enough” versus “most comprehensive possible” searches for evidence.

Additional search strategies include review of literature cited as references in studies selected as eligible for inclusion and data abstraction (IOM/NAM standard 3.1.6) and review of subject-specific or regional bibliographic databases, if either is available and other databases are unlikely to provide all relevant evidence (IOM/NAM standards 3.1.8 and 3.1.9).

Once the initial systematic review is completed and the work of the guideline subcommittee on crafting recommendations and determining the evidence grades is finished (see Appendix C, D, E), updates of the literature/evidence review may be needed depending on the time that elapses prior to completion of the final guideline (IOM/NAM standard 3.1.7). See Chapter 7 for more details about literature surveillance.

Publication Biases and Grey Literature

The published literature at times is biased toward studies with positive results. Additionally, sometimes manuscripts for well conducted studies are simply never developed or submitted for publication. Some such studies are described in abstracts presented at research meetings or mentioned in either summaries of clinical conferences or so called “white papers” of various organizations. Collectively, these sources are termed the “grey literature,” as searches of bibliographic databases will not yield evidence of these studies.

IOM/NAM stand 3.2 states that action should be taken to overcome potentially biased reporting of research results. Searching of grey literature databases, clinical trial registries, and other sources of unpublished information about studies are suggested approaches (IOM/NAM 3.2.1). If such studies are sought and found, the researchers who conducted them may be contacted to

provide information on study eligibility and design (IOM/NAM 3.2.2) and to provide the subcommittee with unpublished data, including unreported outcomes (IOM/NAM 3.2.3). Manual searching of selected journals and conference abstracts (IOM/NAM 3.2.4), Web searches (IOM/NAM 3.2.5), and searches for studies in languages other than English (IOM/NAM 3.2.6) may be conducted.

Practical Considerations for Evidence Searches for Pediatric Topics

Depending on the resources available for the guideline subcommittee, decisions regarding the scope of searches may have to be made. Questions to be considered include:

- Should searches be limited to English language articles only (are resources for translation from other languages available)?
- Should articles published in journals not yet listed on Medline or otherwise not available via PubMed be sought, and if so, what additional databases (e.g., EMBASE) should be searched?
- Should efforts be made to review grey literature sources?

Methods and contexts for production of rapid reviews to support clinical recommendations are the subject of ongoing national interest.¹¹ There has not been good literature on how to ensure that “less than fully comprehensive” rapid reviews generate the same unbiased recommendations as a full systematic review. Rapid evidence reviews, thus, are not used for AAP CPGs.

At this time, although there is little formal analysis of the grey literature for pediatric age groups versus adults, the authors of this manual believe that the likelihood of description of high-quality (ie, adequate design including appropriate sample sizes) randomized clinical trials or studies of diagnostic tests being present only in grey literature sources is less than for adults.

Still, the decision to forgo review of grey literature sources or studies not published in English language should be made transparently by the guideline subcommittee along with the review committee (if it comprised people not on the guideline subcommittee) after careful consultation with the research librarian/information specialists who will be assisting with the evidence search. At a minimum, searches of PubMed, EMBASE, CINAHL, and ClinicalTrials.gov should be undertaken. Use of existing systematic reviews relevant to the clinical questions also may be used if available, with updates as needed to fill in gaps from the time of the review to present time.

Screening and Selection of Studies and Search Documentation (IOM/NAM Standards 3.3 and 3.4)

Once literature searches and any other evidence searches have been completed and lists of articles and resources are in hand, these lists must be reviewed to select articles and other data sources that may be of value for the evidence base for individual questions. Each list should be reviewed by 2 or more members of the review team (IOM/NAM 3.3.2) using the inclusion and exclusion criteria previously developed in the review protocol (IOM/NAM 3.2.1).

For most evidence reviews, the volume of titles retrieved in searches will require screening by title and abstract followed by reading of the full text only of articles identified as potentially useful by this screening approach (IOM/NAM 3.3.5). Screeners should be trained using written documentation regarding inclusion and exclusion rules for selection of articles for full review

(IOM/NAM 3.3.4). Selection by 1 reviewer out of 2 or more should be sufficient for full article review, although not necessarily for final inclusion in the database for a particular clinical question.

The role of observational studies is especially important in pediatrics, for which the volume of randomized trials is less than for adults. Observational studies may provide additional evidence of benefits or harms of interventions, taking into account the potential risks of bias in these studies (IOM/NAM 3.3.2, 3.3.6).

As lists of articles and data sources are reviewed, the reviewers should keep a line-by-line description of the process. This includes recording the search strategy used, the date of the search, the database searched, and the Web browser and sites used for the search (IOM/NAM 3.4.1). The disposition of each title or report and reason for exclusion should be listed as well (IOM/NAM 3.4.2):

- Title and/or abstract reviewed and found not to be relevant (e.g., case report, review article, off topic, does not meet inclusion criteria, etc.).
- Full article reviewed and not deemed to meet inclusion criteria, along with a short summary of the reason.
- Full article reviewed and meets inclusion criteria (this will be a small minority of all titles reviewed).

Data Collection and Study Appraisal (IOM/NAM Standards 3.5 and 3.6)

The next step after selection of relevant articles and other data sources is to extract quantitative and other critical data from each study. This is best accomplished by at least 2 reviewers working independently and then comparing results for accuracy (IOM/NAM 3.5.1). Some studies generate 2 or more manuscripts, and this should be taken into account during the data extraction process so as not to double count results from the same study (IOM/NAM 3.5.2). Forms for capture of data extraction should be developed (IOM/NAM 3.5.3) and pilot-tested (IOM/NAM 3.5.4). Different forms may be required for randomized trials of interventions, diagnostic tests, and observational studies of various designs.

The data from each study should be critically appraised. This may be accomplished by evaluation of the study design prior to data extraction or during extraction. Risk of bias in the study design and conduct should be assessed using predefined criteria (IOM/NAM 3.6.1). Assessment tools have been developed for different study designs, and the instrument used should be appropriate for the study design. Examples include:

- Cochrane Handbook for Systematic Reviews of Interventions¹²
- Newcastle – Ottawa Quality Assessment Scale for Cohort Studies¹³
- Newcastle – Ottawa Quality Assessment Scale for Case Control Studies¹³
- Leeflang - Studies of Diagnostic Tests¹⁴

Other assessment scales may be used as appropriate. These are agreed upon prior to conducting the literature search and should be listed in the systematic review protocol.

Each study should be assessed for relevance of the study population, interventions and outcome measures to the guideline (IOM/NAM 3.6.2). Single studies may provide data relevant to 2 or

more questions/guideline recommendations. Study designs are most often of highest quality for the primary study outcomes. When data for secondary study outcomes are used as part of the evidence base for a question or recommendation, care should be taken not to attribute a higher quality of evidence grade if the study design (eg, sample size, duration of follow-up) were not as robust for the secondary outcome as the primary outcome of the study.

Although it is sometimes difficult to ascertain from study publications, the fidelity of implementation of interventions in the study should be assessed (IOM/NAM 3.6.3). In other words, was the study actually conducted in the manner or intent of the study design, or were there deviations that may have impacted the validity of the results?

Synthesizing the Body of Evidence for Clinical Questions (IOM/NAM Standard 4)

Data extracted from the individual studies selected in the review process will be assembled into tables that describe the clinical and methodologic characteristics of the studies. Data should include the sample sizes, demographic characteristics of study subjects (including included or excluded subgroups), and study interval including start and stop dates (IOM/NAM 4.2.1). When necessary, confidence intervals of point estimates and other summary statistics should be determined when these are not provided in the original studies. Numbers needed to treat or to harm also may be useful metrics to calculate the relative benefit versus the relative risk of a specific treatment. The quality of the study design for each study, as assigned by the review team, is to be listed in the data tables.

Comment fields in data tables should include strengths and limitations of the individual studies (IOM/NAM 4.2.2) and how design flaws or issues with study execution may have biased results (IOM/NAM 4.2.3). The rationale for such judgments should be provided in text or footnotes to tables. Relationships, if any, between characteristics of individual studies and their outcomes and any patterns across studies should be described (IOM/NAM 4.2.4). Relevance of individual studies to populations or subgroups and various cointerventions and outcomes should be summarized (IOM/NAM 4.2.5). Sub-tables can be developed to accommodate the volume of summary data that needs to be provided.

After the data from individual studies have been collated and summarized in this qualitative manner, a decision can be made by the review team or guideline subcommittee methodologist (e.g., biostatistician or other person with sufficient quantitative analysis expertise) regarding the utility and statistical legitimacy of developing a pooled estimate (i.e., conducting a meta-analysis) for one or more outcomes (IOM/NAM 4.3). If a meta-analysis is to be performed, methodologists with experience in meta-analysis should design, execute and peer review each meta-analysis (IOM/NAM 4.4.1). An appropriate protocol should be developed for each meta-analysis to address the degree of heterogeneity among studies (IOM/NAM 4.4.2), provide the degree of statistical uncertainty for all pooled estimates (IOM/NAM 4.4.3), and assess the sensitivity of conclusions based on pooled analysis to reasonable changes in any assumptions made or study selection (sensitivity analysis; IOM/NAM 4.4.4).

After all data tables have been constructed and any meta-analyses have been completed for each outcome for each clinical question (or anticipated guideline recommendation), the review committee should systematically assess the body of evidence that will support each

recommendation (IOM/NAM 4.1.1). Characteristics that should be determined in aggregate include:

- Risk of bias;
- Consistency of the evidence;
- Precision of outcome estimates (based on confidence intervals);
- Directness (extent to which the subjects, interventions and outcomes in the aggregate data are similar to the population targeted by the guideline)¹⁵; and
- Potential reporting bias (based on funnel plots or other methods if relevant).

When observational studies are included, and this will be the case for many pediatric clinical practice guidelines, the following factors for each outcome, if relevant, should be assessed (IOM/NAM 4.1.2):

- Dose-response associations (e.g., risk factors, interventions);
- Plausible confounding factors that might change the estimate of the observed effect; and
- Strength of association (e.g., risk difference, odds ratio, relative risk).

Reporting the Results of the Systematic Review (IOM/NAM Standard 5)

When the results of individual studies have been aggregated into evidence bases for each of the clinical questions for which recommendations will be produced in the guideline and the aggregate quality of evidence has been assigned for each, the work of the systematic review team is almost complete.

The remaining task is to produce a formal report that contains the above processes, results, and interpretations. The document is termed a technical report when produced by the AAP guideline subcommittee. When the systematic review is performed by an external agency, that group typically produces a report that may stand as a federal agency publication and/or submitted for peer-reviewed publication in a medical journal. The AAP guideline subcommittee methodologist, along with other subcommittee members, may still produce a technical report that summarizes the external agency report and/or supplements that report with additional analyses and updates from studies published after the external group completed its review.

The AAP technical report for the guideline should include the rationale and objectives for the guideline and systematic review (IOM/NAM 5.1.5), a detailed methods section that includes the systematic review protocol, description of the search strategies, study selection and data abstraction processes, appraisal methods for individual studies and aggregate data for each clinical question, and methods for any analyses undertaken by the guideline subcommittee (eg, meta-analyses) (IOM/NAM 5.1.6). The results section should include the data tables developed and texts that supplement and further explain the findings in the tables (IOM/NAM 5.1.7). The discussion section should include an overall summary of the evidence, strengths, and limitations of the systematic review and any subsequent updates to it, conclusions for each key question, gaps in the evidence, and needs for future research (IOM/NAM 5.1.8).

An abstract (IOM/NAM 5.1.2), executive summary (IOM/NAM 5.1.3), and lay summary (IOM/NAM 5.1.4) also should be produced. A section or appendix that describes any funding sources and COI disclosures should be included (IOM/NAM 5.1.9).

The AAP has a process for internal peer review of technical reports (and guidelines and other policy statements). Comments are solicited and responded to as appropriate. All comments and suggestions for change should be tabulated with responses to each by the review subcommittee. External organizations that are identified as key stakeholders for the guideline also should be allowed to review the technical report and provide comments. Public comment can be sought as well. These processes reasonably comply with IOM/NAM standard 5.2 for peer review of the draft report.

Lastly, when finalized, the technical report produced by the systematic review committee and/or guideline subcommittee is published in Pediatrics (IOM/NAM 5.3). Whenever possible, it is recommended that technical reports are published concurrently with the corresponding clinical practice guideline.

When developing key clinical questions, the PICO acronym refers to the following: “P” is the patient or problem; “I” is the intervention being evaluated; “C” is the comparison of the intervention, and “O” is the outcome. In some instances, “T” is included and refers to time.

TABLE 1. OUTLINE OF LITERATURE REVIEW PROCESS

1. Conduct meeting/call to determine preliminary search strategy

- Clinical practice guideline subcommittee Chair and vice-Chair in collaboration with the epidemiologist to determine initial search criteria and terms.
- Librarian/epidemiologist documents proposed search strategy.
- Search for meta-analyses and evidence-based clinical guidelines first, including Cochrane Reviews, NICE guidelines; only perform a primary literature search starting from the date that last evidence-based clinical guideline ended. If updating an existing AAP guideline, use Elsevier’s SCOPUS abstract and citation database of peer-reviewed literature to search/determine which manuscripts cited prior guideline.

2. Conduct scout search. Initial search to include at a minimum: MEDLINE, CINAHL, EMBASE. Document search strategy and number of documents retrieved.

NOTE: AHRQ has restricted search on occasion to randomized controlled trials (RCTs) and treatment studies. It is recommended that this restriction be followed only if the number of articles returned exceeds some predetermined maximum (e.g., 500 articles).

3. Conduct meeting/call to finalize search strategy

- Review any meta-analyses or evidence-based clinical guidelines that document their search strategy.
- Group reviews search results and refines search strategy and terms.
- Librarian/epidemiologist documents final search strategy.
- Librarian/epidemiologist conducts the search, updates number of documents retrieved, and sends the results to the Chair.
- Guideline subcommittee may add hand-selected articles not found by literature search for consideration.

A) Winnow articles by title/abstract

1. Prepare for article selection

- a. Determine at least 2 reviewers for each article.

2. From review of title/abstract, reviewers to determine relevance to clinical questions.

Optionally can provide numerical rating for strength of evidence. Each reviewer decides if article is in or out. Articles are included if any reviewer opts to include.

3. Summary list of articles included is created and counts of excluded articles and reasons are documented. Full text articles are accessed, or interlibrary loan requests for inaccessible articles are made.

B) Full text selection of articles

1. Make full text review assignments:

- a. Determine which articles will answer each clinical question (ie, the article(s) with the highest evidence level relevant to the clinical question).
- b. Assign 2 reviewers to each clinical question.

2. Reviewers can a) decide article is irrelevant, or b) decide article is relevant and summarize article and add to evidence table.

3. If additional clinical questions arise during review process, may add clinical questions and return to B) 1 to refine search strategy.

4. For each clinical question, one reviewer will summarize relevant articles in evidence profile, and second reviewer will confirm.

5. Final reference list of articles is created, and counts of excluded articles and reasons are documented.

Chapter 4 Developing Clinical Recommendations

Structure and Content of Recommendations

The presence of recommendations is what separates clinical guidelines from other types of medical literature (e.g., original research, reviews, commentaries). Recommendations tell health care professionals what to do and when. Well-articulated recommendations can be translated easily into IF-THEN statements that facilitate implementation and numerators and denominators that define quality measures. It is important to note that recommendations—not guidelines—represent the units of implementation—that is, it is possible to implement one or a few recommendations from one or more guidelines to achieve a quality improvement goal.

To promote clarity, it is useful for clinical recommendations to be explicit about:

WHEN, i.e., under precisely what circumstances,
WHO is the guideline’s intended audience
OUGHT, with what level of obligation,
To do exactly **WHAT** to **WHOM**.

Such a key action statement should be followed by text amplifying:

HOW the recommendation is to be performed, and
WHY the guideline authors made the recommendation—that is, what its evidence base is.

Key Action Statements (KASs) should be formatted to be immediately recognizable as such, for example using boldface fonts. For example:

If an infant under the age of 2 is diagnosed with X, then pediatricians should prescribe drug Y at a dose of 100 mg/kg for 5 days.

Ambiguous, Vague, and Underspecified Language (AVUL)

Ambiguous recommendations are interpretable in more than one discrete way. True ambiguity is uncommon and is most often the result of mixing logical operators (ANDs and ORs) in the same statement or using abbreviations with multiple meanings. More commonly vague and underspecified recommendations are developed that lack crisp thresholds or specificity.

Deliberate Vagueness

Sometimes authors deliberately create vague and underspecified recommendations. This occurs when:

- there is insufficient evidence to be explicit;
- teams are unable to reach consensus;
- there are legal concerns (e.g., fear of setting a standard of care); or
- there are economic reasons for vagueness.

If authors insist on creating vague statements (which will necessarily be more difficult to implement), they should be clear about the reason for the vague recommendation. Such explanations help users to understand how to interpret and apply the underspecified advice.

Verbs

Because recommendations define what practitioners should DO, it is important to use active voice (passive voice masks the responsible actor) and transitive verbs—those that act upon an object. Careful verb selection promotes clear articulation of intent.

Level of Obligation

Recommendations impose obligation. In certain circumstances, for example, when evidence quality is high and benefits far outweigh potential harms, high levels of obligation may be imposed. Alternatively, when evidence quality is low and/or benefits are closely balanced against potential harms, recommendations are more informative and do connote lower levels of obligation. It is important that recommendations convey the appropriate level of obligation intended by the guideline authors.

Empiric studies have shown that clinicians can differentiate at least 3 levels of intended obligation. It is useful to indicate the intended level of obligation imposed by each recommendation strength by using standardized terminology. Depending on whether a recommendation calls for activity or refraining from an activity, we recommend that recommendation developers use the following terms:

Strong recommendations for or against are described with **must (not)** or **should (not)**.
Moderate recommendations for or against are delineated with **should** or **should not**.
Weak recommendations for or against are delineated with **may** or **need not**.

The AAP Committee on Medical Liability and Risk Management has recommended that the AAP not use the terms “must” and “must not” even for high levels of intended obligation because of their potential impact on legal liability. Saying "should" makes it difficult for those pediatricians in rural access to follow the recommendations. "Should, if available," diminishes medico-legal implications for physicians and is acceptable terminology when stronger language is not warranted. Concern arises when statements of fact or opinion replace clearly defined recommendations. Must, should, and ensure are acceptable if feasible, however, such language needs to be supported by evidence.

Statements of Fact

Recommendation writers regularly label statements of fact as recommendations when there is no implied action. For example:

Recommendation 3. Pneumatic otoscopy is the most accurate test for otitis media with effusion.

In this example, no action is called for. Rewriting this information into a directive statement creates an action statement:

Recommendation 3. Clinicians should use pneumatic otoscopy as the primary diagnostic method for otitis media with effusion.

The Dreaded “Consider”

It is tempting to use the term “consider” to water down a recommendation when there is little evidence to support it or benefits are closely balanced against harms. Unfortunately, it is difficult or impossible to measure whether an action has been considered. One can only measure whether it has been performed.

As Peter Drucker (the management guru) has said, “If you can’t measure it, you can’t manage it.” A corollary is “If you don’t measure it, you can’t improve it.” Because the purpose of guidelines is to improve quality of care, being able to measure adherence is critical.

Evidence Quality and Recommendation Strength

Many guideline authors conflate 2 related concepts that should remain distinct: quality of evidence and recommendation strength. Failing to separate these concepts results in confusion for users attempting to implement the recommendation.

Evidence quality refers to “the extent to which all aspects of a study’s design and conduct can be shown to protect against bias and inferential error.”¹⁶ In general, for recommendations regarding treatment, well-designed and well-conducted randomized controlled trials provide high-quality evidence. For studies of tests or screening, other factors, such as test accuracy, may be more applicable in judging high-quality evidence. The lowest-quality evidence is that based solely on expert opinion, case reports and case series, as well as inferencing based on first principles of pathophysiology. That is not to say that such evidence is not useful, but it must be recognized as being subject to a high probability of bias. Additionally, the way a study is conducted and the relevance of the evidence to the recommendation at hand become critical. For example, evidence-based studies in adults may be only indirectly relevant to children.

Evidence quality can be measured at the level of an individual study and also across an aggregate of studies. In judging aggregate evidence support, the consistency of results across studies and the magnitude of effect (large effects are more likely to be valid than smaller effects) are useful.

Evaluation of evidence quality mixes subjective and objective criteria to examine validity, consistency, and applicability of the evidence supporting a recommendation. It produces an indication of the guideline authors’ confidence in their appraisal of benefits and harms.

Many rating schemes have been used to indicate evidence quality. The AAP recognizes 5 levels of evidence quality (A, B, C, D, and X). The exact definition of each level is dependent on the type of studies and the recommendation to be made. For example, if the recommendation is based on studies of treatment, then level A is likely to represent well-designed and well-conducted clinical trials. On the other hand, if the recommendation involves a test procedure, the highest-quality studies may target accuracy in relevant populations. In most cases, level D is the lowest evidence quality and represents expert opinion, case reports, and reasoning from first principles.

Level X evidence is used when high-quality studies have not been performed and are unlikely ever to be performed; yet, the AAP believes it is important to make a strong (or moderate) recommendation. For example, several years ago, in acts of domestic terrorism, anthrax spores were mailed to several locations, exposing the targets, postal workers, and their families. No studies have been performed that demonstrate benefit or harm using ciprofloxacin for prophylaxis; yet, the AAP deemed it was essential to recommend ciprofloxacin to exposed children. Likewise, patients with diabetic ketoacidosis should be given insulin, not oral hypoglycemic agents. It is unlikely that a trial would ever be performed to support that recommendation.

Strength of Recommendation

Guideline implementers are more interested in the guideline authors' assessment of the strength of their recommendations than in evidence quality per se. Recommendation strength indicates the authors' expectation of the level of adherence to a recommendation. Clinicians should follow strong recommendations unless a clear and compelling rationale for acting in a contrary manner is present.

“Strong recommendations” are the optimal source for performance measures. *“Moderate recommendations”* should generally be followed, but users should remain alert to new information and be sensitive to patient preferences. There are 2 varieties of *“Weak Recommendations”*: those based on low-quality evidence and those based on equilibrium between anticipated benefits and harms. In both cases, patient preference should have a substantial role in decision making. It is hard to hold users accountable to adherence to weak recommendations; therefore, they are not a good source for performance measures.

Process of Defining Strength of a Recommendation

After developing clear language regarding precisely when a recommendation is applicable and what exactly it calls for, guideline authors are to next define the benefits and the risks, harms, and costs that are anticipated if the recommendation is undertaken. Recommendations will ideally be presented in the context of the frequency at which benefits and harms occur as well as the magnitude of their impact. Once the attributes have been carefully specified, the authors are called upon to make a value judgment regarding whether benefits or harms predominate or whether there is equilibrium between benefits and harms. This judgment determines the direction of the recommendation. Using the AAP matrix that relates benefit-harms assessment to evidence quality (see Figure 3), the authors determine the strength of recommendation and the appropriate term reflecting level of obligation.

Role of Values

The process of formulating a guideline recommendation requires that the developers judge whether the anticipated benefits of following the recommendation will outweigh risks, harms, and costs of doing so, or whether harms will outweigh benefits. In many cases, there will be an apparent equilibrium in which positive outcomes are expected but at significant risk. Guideline authors apply their personal values to the evidence that is identified regarding each recommendation. Differences in the values applied help to explain conflicting recommendations that come from highly reputable sources—for example, breast cancer screening recommendations from the American College of Radiology and the American Cancer Society

conflict with those from the US Preventive Services Task Force. Each organization reviewed the same evidence but came to different conclusions. It is important for authors to be transparent about the values they apply in creating recommendations. An effective mechanism for enforcing transparency is for authors to enumerate the anticipated benefits and harms and to make a clear statement that they believe that one or the other predominates or benefits and harms are balanced.

Key Action Statement Profiles

There are multiple guideline tools available to assist organizations with developing and formatting key clinical recommendations. There is not one specific software program endorsed by the AAP. Each guideline recommendation should be accompanied by a Key Action Statement Profile.⁵ The KAS profile summarizes the facts and judgments that support and define the recommendation. Each profile should include:

- Aggregate Evidence Quality supporting the recommendation
- Recommendation Strength
- Anticipated Benefits
- Anticipated Risks, Harms, and Costs
- Value Statement, for example, “The CPG Subcommittee believes that the benefits listed above outweigh the risks, harms, and costs described.”
- Deliberate Vagueness (if applicable)
- Specific Exclusions (if applicable)

FIGURE 3.

AGGREGATE EVIDENCE QUALITY	BENEFIT OR HARM PREDOMINATES	BENEFIT AND HARM BALANCED
LEVEL A Intervention: Well designed and conducted trials, meta-analyses on applicable populations Diagnosis: Independent gold standard studies of applicable populations	STRONG RECOMMENDATION	WEAK RECOMMENDATION (based on balance of benefit and harm)
LEVEL B Trials or diagnostic studies with minor limitations; consistent findings from multiple observational studies	MODERATE RECOMMENDATION	WEAK RECOMMENDATION (based on balance of benefit and harm)
LEVEL C Single or few observational studies or multiple studies with inconsistent findings or major limitations.	WEAK RECOMMENDATION (based on low quality evidence)	No recommendation may be made.
LEVEL D Expert opinion, case reports, reasoning from first principles	WEAK RECOMMENDATION (based on low quality evidence)	No recommendation may be made.
LEVEL X Exceptional situations where validating studies cannot be performed and benefit or harm clearly predominates	STRONG RECOMMENDATION	RECOMMENDATION

Mitigation of Conflict and Dissenting Opinions

During the guideline development process, conflicts involving differing opinions between committee members or other stakeholders can arise leading to disagreements regarding the guideline recommendations or key action statements. These conflicts can arise from a variety of reasons including diverse expertise and experience between stakeholders, differing interpretation of the evidence, and a variable level of risk tolerance, amongst others.

Differing opinion and a certain level of conflict is not only expected, but essential during guideline development. However, when these differences become irreconcilable and become a barrier to achieving consensus, the guideline process could be significantly delayed or disrupted.

One of the primary roles of the guideline Chair is to proactively manage conflict. The first and most important step to conflict resolution is prevention. The Chair should establish ground rules

for conduct and decision-making at the first meeting. During meetings, the Chair will reinforce these ground rules and continually re-enforce them over the course of guideline development. In addition to the Chair, a Guideline Coach will be available to assist with the resolution of dissenting or conflicting opinions of guideline subcommittee members.

As the most controversy typically arises during the development of key action statements, it is important to adhere to the AAP process for developing these statements. Committees are to be transparent about all of the factors that are considered (e.g., potential harm, unintended consequences, patient preferences) and views of all of the stakeholders (families, providers, subspecialists, payors).

To better support the Chair during the guideline development process, the guideline Chair and Coach will report on the status of the guideline quarterly to the COGD. Part of this report will include whether the Chair anticipates or is already grappling with challenges with coming to consensus on key action statements. At the call, strategies for resolving these conflicts will be identified.

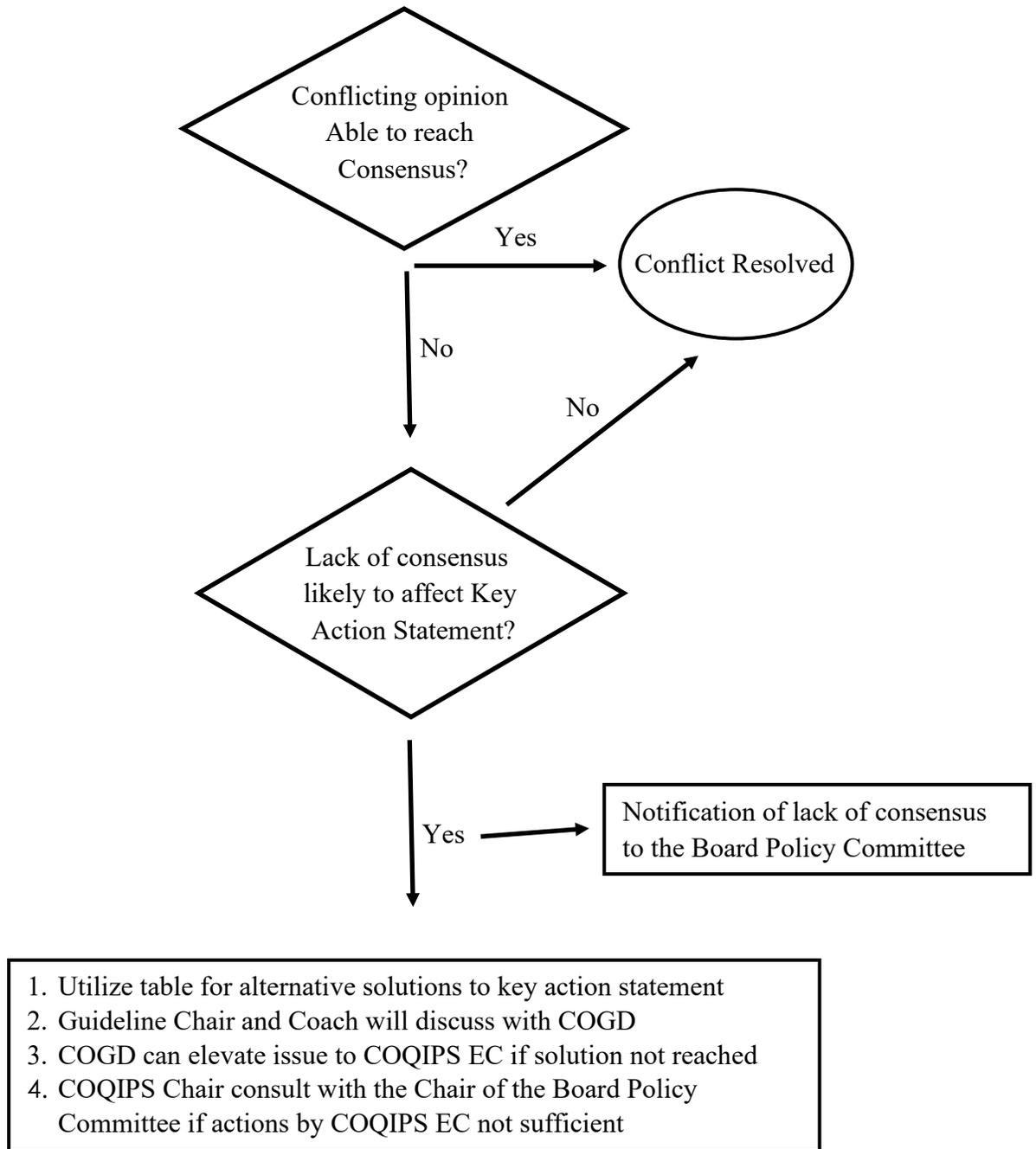
If the conflicts are deemed so severe that the guideline development is at risk, further escalation is needed. COGD will involve the COQIPS Executive Committee and/or COQIPS Chair. Further escalation steps will involve the Board Policy Committee or the AAP Board of Directors.

The table below presents possible solutions for conflicts (Table 2).

Table 2. Alternative solutions when consensus on action statements cannot be reached

Action	Comment
Key Action Statement to propose multiple different options	If the evidence basis supports more than one management option this could be reported by presenting alternatives, and the evidence supporting each option transparently presented
Do not make a recommendation but report the evidence	The committee may feel that due to a lack of consensus an Action Statement cannot be formulated. A review of the current evidence and points of contention should be transparently reported to inform practitioners
Omit Key Action Statement altogether	This should be left as a last resort and only if in the view of the committee completely omitting the action statement will not significantly affect the rest of the guideline

Figure 4. Conflicting Opinion Escalation Algorithm



Chapter 5

Guideline Meeting Structure and Support for Guideline Deliverables

The CPG subcommittee must write Key Action Statements (KASs) based on the evidence that encompass the scope of the guideline and write a manuscript and accompanying documents for *Pediatrics* that will be clear, organized, and understandable to the membership of the AAP. A separate technical report is preferred; however, the content of the technical report may be incorporated into the guideline itself. For a sample project timeline, please refer to Appendix C.

The AAP usually funds 2 in-person meetings, although at times a third has been needed. The following assumes 2 in-person meetings. The meetings usually are held at AAP headquarters in Illinois.

Once the CPG subcommittee has been chosen and the preliminary literature search has begun, a telephone conference or Webinar of the entire subcommittee will be convened to discuss the scope of the project, review financial and intellectual conflicts of interest, and discuss the key questions used in the systematic review (Chapter 3). Additional key questions to complete the scope of the guideline should be discussed and communicated to the AHRQ-EPC and the epidemiologist. There should also be discussions of the preliminary sections of the guideline. Plans for the sequence of activities of the subcommittee should be discussed.

The Chair and Vice Chair should maintain communication with the AHRQ-EPC, if used, and/or the epidemiologist throughout the literature search process.

Kick-off Web-conference Agenda Items for Discussion

- Conflict of interest
- Nondisclosure confidentiality agreements (Appendix I)
- Copyright transfer and release (Appendix J)
- Expense reports and reimbursement policy
- Team norms and expectations for members
- Objectives of first meeting
- COGD Chair and/or Coach joins via phone to present the AAP clinical practice guideline development process;
- SharePoint overview and opportunity to ensure member access to guideline site

First Meeting

The first in-person guideline meeting should be scheduled for when the preliminary draft of the literature search is available. At this time, subcommittee members may provide additional articles not included in the search drafts.

The preliminary agenda of the meeting should include:

- Introductions;
- Overview of specialist roles (PPI representative, epidemiologist/methodologist, Implementation Scientist, etc.);

- Preliminary discussions for guideline focus, potential sections, and Key Action Statements using BridgeWiz;
- Assignment of section leaders and co-leaders; the duties of the section lead are to collate the input of the contributors to that section, seek additional references in conjunction with the epidemiologist, and to prepare a draft of the section); and
- Next steps

The detailed agenda will be determined by the Chair, Vice Chair, and staff. Conference calls can be scheduled at any time if under the purview of the Chair and Vice Chair and staff if it is determined that an additional meeting would be useful.

Between the first and second in-person meetings, the section leads, coleaders, and other subcommittee members, as appropriate, will write first drafts of their assigned section(s). The drafts should be based on the evidence as provided by the AHRQ-EPC and/or the epidemiologist and in consultation with the latter. Additional citations may be included that supplement the best evidence available. Complete reference lists using *Pediatrics* format should be provided. In the draft text, references should be cited in parentheses using first author's last name and date of publication to reduce any confusion concerning references prior to the finalization of the manuscript. Do not number references, references will be numbered following finalization of the manuscript. The section authors will confirm accuracy of references upon finalization. If a single author is cited in the same year for multiple articles, provide additional information to permit distinguishing the article intended. The process should be interactive using e-mail and SharePoint, etc., as determined by the subcommittee. An AAP listserv should be used for communication among the entire group. The Chair and Vice Chair should be included in all communications. They are to review the draft as it develops and provide input as appropriate. Deadlines should be set for submission of initial drafts and distributed to the entire subcommittee for review. A deadline for review and comments should be set. The Chair and Vice Chair will review and further refine the drafts.

During this time, the epidemiologist should begin writing the technical report, including a detailed search strategy that was used to gather the relevant evidence for the guideline.

Second Meeting

The second in-person meeting will be scheduled after the Chair and Vice Chair have reviewed the drafts. The purpose of the second in-person meeting is to review the initial drafts and to write KASs and evidence profiles using Bridge-Wiz, and the AAP matrix that relates benefit-harms assessment to evidence quality (Figure 3).

The preliminary agenda of the meeting should include:

- Reintroductions and changes to the subcommittee;
- Review of the norms and rules;
- Restatement of financial or intellectual conflict(s) of interest;
- Detailed discussion of each section draft without “wordsmithing”;
- Write preliminary evidence profiles; and
- Plan for revised drafts and communication.

The detailed agenda will be determined by the Chair and Vice Chair and staff.

After the second meeting, the section leads and coleaders will revise the drafts according to the discussion and conclusions made at that meeting. Writing must support the KASs using the evidence review in consultation with the epidemiologist. In the text, references should be cited in parentheses using first author's last name and date of publication to reduce any confusion concerning references prior to the finalization of the manuscript. Do not number references, references will be numbered following finalization of the manuscript. The section authors will confirm accuracy of references upon finalization. Questions or problems while writing should be shared using the guideline subcommittee's listserv.

The literature search for new articles should continue throughout the process.

The Chair and Vice Chair will begin to collate the drafts, edit them into a consistent writing style, and submit the drafts to the group for content review and "wordsmithing." Once the draft is completed, it should be submitted for peer review.

Authorship Criteria

The International Committee of Medical Journal Editors recommends that authorship be based on the following 4 criteria¹⁷:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Chapter 6 **Peer Review in Guideline Development**

Peer Review

IOM/NAM standard 2.3 suggests that the systematic review team obtain input from the target audience (end users) of the guideline and from stakeholders (e.g., professional organizations whose membership may be impacted by the guideline) from the outset. The standard goes on to state that the independence of the review team to make final decisions about the design, analysis and reporting of the review should be protected. Thus, peer review is an integral part of guideline development and revision.

People with an obvious conflict of interest (COI) are excluded. It is prudent to include generalists, content experts, and the caregiver perspective (Family Partnership Network) in the peer review process. The AAP typically provides a review period of 30 calendar days. Guidelines typically include implications for populations across several clinical fields, so the AAP is generously inclusive when inviting groups and organizations to participate in the peer review process. Thus, review from specialty groups both within and external to the authors' primary affiliation is mandatory. The AAP will routinely send guidelines to internal groups as appropriate.

Internal Review

The AAP has a 2-step review process. As the guideline subcommittee approaches completion of the draft manuscript, it may reassess the internal stakeholders that should participate in the peer review process by reviewing the AAP's roster of national councils, committees, sections, and other groups. These determinations are typically made when the guideline topic proposal is submitted but usually are revisited and finalized as the completion of the draft guideline approaches. Specific recommendations for peer reviewers should accompany the request for review and are given below.

The process begins with selection of invited reviewers. The Council on Quality Improvement and Patient Safety (COQIPS) always serves as the first reviewing group and must approve the guideline (as written or with recommended edits) before it advances to other groups for review and comment. In addition to COQIPS, several internal groups are mandatory reviewers of all guidelines, including the Committee on Medical Liability and Risk Management (COMLRM), the Committee on Practice and Ambulatory Medicine (COPAM), and the Committee on Child Health Financing (COCHF).

Role of the COQIPS and the Committee on Guideline Development (COGD)

COQIPS reviews and scores all guideline topic submissions. COQIPS serves in an advisory, consultative, and coordinative role.⁴ Their charge is to avoid duplication in the development of AAP clinical practice guidelines and to assist in the adherence to AAP organizational and methodologic processes for guidelines in accordance with available resources. As such, COQIPS reviews all preliminary topic submissions and prioritizes those that will be approved to move forward for consideration by AAP board of directors.

The COGD is a committee within the COQIPS. The COGD ensures that published guidelines meet predetermined standards for evidence-based clinical guidelines, including the following areas:

- Methodology, including the classification and interpretation of evidence;
- Evaluation of recommendations for cost, feasibility, usability, and ethical and clinical soundness;
- Appropriate use of references; and
- Transparency of conflicts of interest.

External Peer Review

External expert groups are also identified when the subcommittee revisits the list of pertinent stakeholders that should participate in the peer review process. Peer review is the first step toward securing endorsement from other appropriate bodies and is useful for ensuring that all relevant stakeholder perspectives are considered. Stakeholders from a variety of practice settings is important, because practicality is an issue. What can be accomplished in an academic center serving a large population may not be feasible for smaller, more rural practices, or practices with a different demographic composition.

The following are criteria that should be delivered to all reviewers, derived in substantial measure from the recommendations of Araujo.¹⁸

1. All potential reviewers should submit a COI form, which should be deemed satisfactory before proceeding further. Reviewers should also submit a statement of affirmation of appropriate qualification for review; that is, each reviewer should have strong familiarity with the topic or about methodology/implementation science.
2. Confidentiality concerning the content and authorship of the manuscript should be maintained by the reviewer where possible (sometimes identification is unavoidable).
3. Reviewers are instructed to review for content only: copyediting will be conducted at a later stage.
4. The sections introduction, methods, results (grading of evidence and strength of recommendations), and discussion should all be explicitly reviewed. Practicality of implementation should be discussed. Papers and studies cited that strongly support results and conclusions should be read by the reviewers with an eye toward verisimilitude: deficiencies in this regard should be noted.
5. Tables, charts, and figures are to be reviewed for comprehensibility and fidelity to the text.
6. Authors should respond to significant comments, and reviewers should review such responses for adequacy and respond to them as well.

In the event that the authors cannot accommodate significant concerns by revision, such comments should be acknowledged in the text of the article and, when appropriate, in the Table outlining recommendations and their strength.

The Section on Epidemiology, Public Health, and Evidence (SOEPHE [as represented by the methodologist]) and COQIPS will be involved in ensuring that the path from evidence to recommendation is transparent. Relevant COIs (e.g., financial, industry-relationships, intellectual) of the authoring team will be documented in the manuscript.⁹ When all comments are received, significant concerns with the manuscript are sent to the AAP Board Policy Committee, which will work with the authoring team to address these concerns. After concerns have been addressed and consensus reached by the peer reviewers providing the significant concerns, the evidence-based clinical guideline is ready for internal copyediting, followed by internal leadership review and publication in *Pediatrics*.

Chapter 7 Ongoing Literature Surveillance and Guideline Updates

Literature Surveillance

Literature surveillance is the periodic scanning of literature to detect when guideline recommendations may require change. There are 2 times in the standard process that literature surveillance is often performed: During guideline development, and between versions of guidelines. In each case, the process for how to manage the literature is similar.

During guideline development, a comprehensive literature search is performed, evaluated, and synthesized into recommendations. It may be many months or even years as the guideline is written and circulated for review, to final stakeholder approval. During this time, many owners are concerned that the evidence upon which their recommendations are based will become out of date and their guideline recommendations obsolete prior to publication. Many CPG subcommittee Chairs have performed periodic surveillance activities in collaboration with the methodologist and subcommittee members, usually every 6 to 12 months, to capture new literature and to ensure that recommendation content and strength do not change. When new literature is identified, it is sometimes erroneously included in a manner that is not consistent with the previously ascertained, evaluated, and synthesized literature. It is important to treat these new articles in the same manner as the previously obtained articles—that is, to evaluate the articles in the evidence table and weigh them together with previously identified articles in the recommendation creation process, to avoid the risk of introducing additional bias into the guideline development process.

AAP staff (guideline staff in collaboration with the Bakwin Library) will collaborate to ensure that the search terms used for the systematic review are captured and run bi-annually post publication for a period of up to three years to capture any relevant literature that may negate or support clinical recommendations affirmed in the guidelines. Guideline staff will forward the results of the search to the epidemiologist, Chair, and vice-Chair on a bi-annual basis for review to determine any potential need to update the guideline for a period of up to three years. Ideally, the search parameters for this search will be the same as for the original search, differing only by the period (dates) of ascertainment. Both MEDLINE and EMBASE allow users to set up a query that will return a list of abstracts that can be examined, on a quarterly (3-month) basis. Review of search strategy should be conducted periodically with the assistance of medical librarians, as MeSH headings will sometimes change or expand. Subcommittees may also decide to restrict the level of evidence in the incremental searches (eg, restrict search to higher-quality evidence). As with the original broad searches, search results are dependent upon quality of classification (eg, if filtering on study type, know that the classification of manuscripts in the database to be searched may not always be 100% accurate). Ideally, this list of abstracts will be seen by 2 reviewers and articles selected for full text review. Articles selected for full text review will be incorporated into evidence tables and recommendations/recommendation strength should be updated as affected by newly identified evidence.

Time Stamps and Updates

Evidence-based clinical guidelines should be reviewed periodically, no later than every 5 years, but ideally every three years in accordance with other Academy policy prior to expiry, if:

- Literature surveillance suggests that significant changes in clinical practice would be supported by strong evidence; or
- Monitoring of implementations suggests that the current guideline results in care that would be unnecessarily harmful to patients.

When an evidence-based clinical guideline is being reviewed, the evidence search should be directed by clinical questions. If the clinical questions dictate that a broader search than the original should occur, then the subcommittee should decide how far back the additional clinical questions should be searched or whether a rapid evidence review process will be undertaken for those selected questions. Otherwise, the search should start from the end of the previous evidence search. The new evidence query should be constructed with the assistance of a methodologist (medical librarian or epidemiologist), as database qualifiers such as MeSH headings may have changed in the interim.

If the previous evidence-based clinical guideline has been assessed and found to be methodologically sound, it can be cited, and original references do not have to be pulled, although evidence tables from previous versions of the guideline can be reviewed so that recommendations can potentially be regraded and/or evidence strength reassigned. AAP evidence-based clinical guidelines should refer transparently to the dates during which evidence is ascertained and search strategy used but need not specify an “expiration” date. If a guideline is sufficiently out of date and rework is not scheduled, the subcommittee may recommend not to renew it.

Authoring Standards for Updates and Revisions

In order to reaffirm Clinical Practice Guidelines, guideline subcommittees must submit reaffirmation requests to the Committee on Guideline Development (COGD) of the Council on Quality Improvement and Patient Safety. If approved, the systematic review will be updated. Then the CPG subcommittee must convene to assess the implications of new, relevant literature on the prior key action statements (KASs) recommendations.

Updated Guidelines

Updated guidelines include updated evidence for existing recommendations.

- Guidelines that have undergone an updated systematic review that **do not** result in changes to the KASs will be re-published as “UPDATED” [Guideline Name].
- Abstract inclusion: X Unchanged KASs
- Document body inclusion: Unchanged KASs

Revised Guidelines

Revised guidelines included updated evidence for revised recommendations.

- Guidelines reaffirmations resulting in changes to KASs will be re-published as “REVISED” [Guideline Name].
- Abstract inclusion: “This guideline contains: X New, X Changed, and X Unchanged KASs”
- Changes will be documented in the beginning of report with below areas:

- New KAS's (if applicable)
- Changed KAS's (if strength of evidence increased or decreased)
- Unchanged KAS's

Chapter 8 Implementation

The chapters thus far in this manual have taken the user through a series of steps to ensure that the guideline is well developed. The reader has been guided on how to find, assess, and summarize the best evidence in the literature and instructed on how to succinctly and transparently propose specific recommendations for the care of children. Following the instructions so far, readers are on their way to developing the best possible guideline, but the guideline is only the means to an end, not the end in itself. The real outcome to which pediatricians all aspire, and for which a guideline is developed, is better health care provision, and ultimately health outcomes, for children. Unfortunately, the best developed guideline will lead to improved health care for children only if it is used by the intended audience. This chapter will improve the guideline developer's awareness of the common barriers to guideline use and of the strategies to overcome them.

Pediatric providers will face many barriers to implementing recommendations and guidelines in their practice setting. An important overarching goal is to change physician behavior, but doing so in a dynamic health care environment can be challenging. Cabana and colleagues provide an excellent framework for the stages leading to behavior change: knowledge, attitudes, and eventually, behavior.¹⁹ Each stage contains a specific set of barriers preventing guideline adoption:

- Knowledge Barriers:
 - Lack of familiarity
 - Lack of awareness
- Attitude Barriers:
 - Lack of agreement with specific guidelines
 - Lack of agreement with guidelines in general
 - Lack of outcome expectancy
 - Lack of self-efficacy
 - Lack of motivation/inertia of previous practice
- Behavior Barriers
 - External Barriers: Patient factors
 - External Barriers: Guideline factors
 - External Barriers: Environmental factors

Early in the AAP guideline development process, the CPG subcommittee should identify the end users and any relevant stakeholders. Depending on the guideline and recommendation, this can range from general pediatric providers to subspecialists, parents, clinics, hospitals, schools, child care professionals, payers, and entire health systems. For example, the bronchiolitis guideline may be intended for clinics, emergency departments, hospitals, and child care professionals, whereas the acute otitis media guideline may be more focused for the ambulatory setting. Next, the subcommittee should identify and prioritize how to address the barriers most likely encountered by the end user and stakeholders across settings (which may include health literacy). For example, the otitis media guideline subcommittee may anticipate family reluctance to change recommended antibiotic use. There are certain steps that can make this easier. The multidisciplinary guideline subcommittee should brainstorm early to identify target users,

stakeholders, and settings. In addition, it may be that in the literature collection phase, some of the articles identified for review by the team would help identify additional barriers relevant to the specific guideline.

For guideline developers who have difficulty identifying the most likely barriers physicians will encounter in the implementation of the guidelines, it is suggested that several representative clinicians or others be included. For instance:

1. 35-year old pediatrician, employed by a large integrated system with electronic health records (EHRs), quality improvement resources, etc.
2. 47-year old pediatrician, partner in a 5-physician suburban practice with EHRs in place
3. 59-year old pediatrician, solo rural practitioner with paper records, heavy Medicaid patient population
4. Family practice physician, 2 physicians with EHRs
5. Emergency medicine or urgent care physician
6. Subspecialist who manages a highly referred population
7. Family or parent of child with condition of interest

Table 3. Implementation Planning Checklist

<u>Where will the guideline be used?</u>	<u>Who will use the guideline?</u>	<u>What are the common barriers for guideline use by front-line clinicians?</u>	<u>What strategies and tools can be developed to overcome these barriers?</u>
Hospital	Physicians	Interruption of patient flow	Family handouts
Emergency department or urgent care setting	Subspecialists	Knowledge	Pathway, algorithm, or flowchart
Inpatient unit	Physician assistants, nurse practitioners	Attitude	Order set
Intensive care unit	Nurses	Behavior	EHR history and physical examination template
Subspecialty clinics or consultative practice	Respiratory therapists	Measurement for improvement	Subspecialty recommendations
Nonacademic/community hospital	Emergency medical technicians	Coordination with partner organizations	MOC collaborative
Ambulatory setting	Family		Translation into other common languages such as Spanish
Private practice	Payors		AAP news outlet communications
Rural or resource limited	Policy makers		ICD-10 codes

Academic setting	Laboratory technicians		Appropriate use guidelines
Home	Hospital administrators		Shared decision tool
School, School-based Health Clinics	Researchers		School policy guide
Daycare	Pharmacists		Daycare policy guide
Government (local, state, or federal)	Physical, Occupational, Speech Therapists		Co-publication with partner organizations (eg, CDC)

CDC, Centers for Disease Control and Prevention; ICD-10, *International Statistical Classification of Diseases, and Related Health Problems, 10th Revision*; MOC indicates maintenance of certification.

It is the specific role of the Implementation Scientist to bring an implementation focus to the guideline development process and to create an implementation toolkit to accelerate guidelines being practically used to improve the care of children. **An example is the toolkit for the Genetics in Primary Care Institute-Quality Improvement Project.**⁸

Specific deliverables for the Implementation Scientist include:

1. Specific tools for front-line clinicians to use to implement these changes, such as mock order sets, flow diagrams of ideal processes, educational materials, shared decision tools, billing codes to electronically identify data, examples of past successful projects, and/or contacts at institutions who have successfully implemented these types of projects and are willing to be contacted by others; and
2. A dissemination plan for how this toolkit will be spread to the maximum number of clinicians.

Additional deliverables may include:

1. Overall aim outcome measure statement for guideline
 - a. Sub-aim statement(s) for process measures;
2. Specific measures, including numerators and denominators, to measure 1) outcomes, 2) processes, and 3) balancing measures related to understanding if these guidelines have been effectively implemented; and
3. Key driver diagram related to the guideline and its implementation.

References

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Appendix A Clinical Practice Guideline Topic Proposal Intent Form

The mission of the American Academy of Pediatrics (AAP) is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. To support this mission, the AAP Board Policy Committee and The Council on Quality Improvement and Patient Safety (COQIPS) is committed to ensuring a rigorous, unbiased guideline development process and towards creating tools for pediatricians at the point-of-care to implement guideline recommendations. Clinical Practice Guidelines (CPGs) are rigorously developed through a systematic review of the evidence, and clinical recommendations are systematically made to reduce bias by considering that evidence, patient preferences, costs, benefits and harms.

This form collects information to understand, provide feedback, and prioritize requests for new CPGs.

CRITERIA FOR ASSESSING GUIDELINE TOPIC PROPOSALS

Complete this guideline topic proposal intent form to recommend the development of a new / or revision of a current or outdated AAP CPG. **This topic proposal intent form must be completed in its entirety and must meet all the following criteria used to assess guideline topics prior to consideration:**

- An established body of published evidence exists on which to base the guideline, or the need to create a structure from which to study a topic
- Wide variability exists within practice or new evidence supports a significant change to current practice
- Substantial anticipated impact of clinical recommendations
 - Number of children or family members impacted by the clinical guidance
 - Number of medical professionals/societies likely to use the clinical recommendations (e.g. Emergency physicians, dentists, oral surgeons, etc.).
 - Affects the practice and science of pediatric medicine
 - Addresses public health concern or crisis
 - Addresses major gaps or important quality, safety, and/or cost outcomes in pediatric care
- Improves ability of pediatric providers to practice medicine

Submit the completed form to kokechukwu@aap.org and allow up to 12 weeks for review.

Submission Date:	
Submitter of the Topic Proposal:	
Name of AAP Section(s)/Council(s)/Committee(s):	
Name of AAP Staff Liaison to Submitter (If applicable):	
Clinical Practice Guideline Tentative Title:	

REVIEW OF CURRENT DOCUMENTS (AAP or EXTERNAL)

1. In the space below, list current AAP guidelines, policies, technical reports, clinical reports, or consensus statements relating to the proposed topic by viewing AAP policies on Gateway at: <http://pediatrics.aappublications.org/collection>. If not applicable, mark N/A.

--

2. In the space below, if there are existing AAP statements related to this topic, please provide a summary and list of references of any new relevant literature/evidence. Please explain what would be gained by creating a CPG, and how it would improve the other statements. If not applicable, mark N/A.

--

3. In the space below, list statements or publications from organizations aligned closely with the AAP that address the topic being proposed. Include references. If such publications exist, explain how the proposed CPG is different, and why it is necessary for the AAP to create its own CPG instead of endorsing the other statement(s). If not applicable, mark N/A.

--

PICOT QUESTIONS AND SYSTEMATIC REVIEW

4. **Potential Key Clinical Questions:** *Provide a list of all the key clinical questions you would like to address within the guideline or consensus statement. If possible provide these questions in PICO format. Use this [link](#) for information on developing your PICO(T) questions.*
(P: Patient/population – How would you describe the patient or population; I: Intervention – What intervention(s) or treatment modality would be considered within the guideline; C: Comparator – What is the main alternative to compare to the intervention; O: What are the important outcomes of interest; T: Time – What is the timeframe to achieve the outcome)

--

5. Has a systematic review covering all relevant clinical questions been conducted? Yes No
 If yes, please explain. If not, explain if you have received or plan to request external funding to conduct a systematic review. Note: If external funding is not anticipated and the topic is approved, the topic will be submitted by AAP staff to the AHRQ for consideration of topic prioritization and funding.

--

6. **Relevant Literature:** Provide a preliminary bibliography of relevant literature/evidence that will support the scope of this guideline. *(Maximum of 10 references.)*

--

CLINICAL PRACTICE GUIDELINE OVERVIEW

7. Who do you foresee benefitting from or using the proposed Clinical Practice Guideline?	
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8. Explain the challenges, opportunity, and impact of the guideline.	
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<p>9. Provide the names of AAP Section, Council or Committees who should be represented on the CPG subcommittee. Have you contacted them regarding this intent?</p>	
<p>10. Provide the names of any potentially relevant <i>external organizational</i> partners/stakeholders.</p>	
<p>11. Is there funding to support representatives from the above listed external stakeholders? <i>If, so please detail the approximate funding available for lodging, travel, and airfare.</i></p>	
<p>12. How might these guidelines be implemented at the point of care to track impact on changes in practice?</p>	
<p>13. What controversies do you feel may arise from publishing this guideline (e.g. Disagreement about recommendations between specialties).</p>	

PROPOSED PANEL SUBCOMMITTEE MEMBERS

The ideal size of a CPG subcommittee is 10-14 members, not including staff. The final size may be influenced by balancing the need for appropriate team dynamics with funding availability. At a minimum, the team includes a Chair, a Vice Chair, a methodologist/ epidemiologist, a Partnership for Policy Implementation (PPI) Representative, an Implementation Scientist, content experts, general pediatricians, stakeholders from relevant disciplines, a Family representative, and AAP staff. The prioritization group will consider suggestions for the Chair and for subcommittee members that will help to create the guideline. As much as possible, the subcommittee should strive for diversity in membership.

Chair Qualifications

- **The Chair should be an FAAP and represent the primary audience to whom the guideline’s recommendations are directed.** In most situations, this means that the Chair should be a practicing general pediatrician. However, if the guideline primarily targets another discipline (e.g., pediatric emergency medicine, neonatology, etc.), the Chair should come from that discipline. Subspecialist Chairs may be considered if their subspecialty is expected to be targeted by the recommendations. Any issues with CPG Chair selection will be resolved by the COQIPS Chair.
- Should have been in active practice in her/his primary specialty within the past 5 years
- Should have prior experience with evidence-based CPG development (including membership on a previous AAP CPG subcommittee, or equivalent experience)
- Must have demonstrated leadership ability
- Must be efficient and motivated
- Must have demonstrated skills in scientific writing
- Must be familiar with the CPG development process as outlined here and the AAP policy *Toward Transparent Clinical Policies*⁵
- Must adhere to the AAP Policy *Conflict of Interest and Relationships with Industry and Other Organizations*.

Vice-Chair Qualifications

The Vice Chair of the CPG subcommittee is selected by the Chair with input from AAP staff. Qualifications of the Vice Chair include:

- Must be a FAAP and practicing within the past 5 years
- The Vice Chair should have experience with meeting facilitation
- The Vice Chair should have some interest in becoming a future CPG subcommittee Chair
- Must have demonstrated leadership ability
- Must have demonstrated skills in scientific writing
- Must be familiar with current versions of the document titled, *Toward Transparent Clinical Policies*
- Must adhere to the AAP Policy *Conflict of Interest and Relationships with Industry and Other Organizations*

14. Provide the names of the proposed panel Chair and vice-Chair. <i>Proposal of panel members does not guarantee their participation. All subcommittee members are confirmed at the discretion of the AAP Executive Committee.</i>	
15. Provide the names of additional proposed panel members and the council, section, or committee he/she represents. <i>Proposal of panel members does not guarantee their participation. All subcommittee members are confirmed at the discretion of the AAP Executive Committee.</i>	

AUTHORSHIP CONSIDERATIONS

16. In the space below, provide a high-level overview of how the lead author(s) were selected and what key attributes will contribute to the success of this document. Highlight any plans to involve an early career physician(s). Please submit a CV (4 pages or less) for each lead author.

COLLABORATING GROUPS DURING INTENT DEVELOPMENT

Internal Groups

17. Identify the internal AAP groups (listed in question 18), who participated in drafting this intent.

SUGGESTED PANEL MEMBER REPRESENTATIVE GROUPS

Internal Groups

18. Check internal AAP groups, listed below, who should participate on the guideline subcommittee panel as a member representative of the below listed group(s).

<p>Committees</p> <p><input type="checkbox"/> Adolescence (COA)</p> <p><input type="checkbox"/> Bioethics (COB)</p> <p><input type="checkbox"/> Child Health Financing (COCHF)</p> <p><input type="checkbox"/> Coding and Nomenclature (COCN)</p>	<p>Councils</p> <p><input type="checkbox"/> Child Abuse and Neglect (COCAN)</p> <p><input type="checkbox"/> Children With Disabilities (COCWD)</p> <p><input type="checkbox"/> Clinical Information Technology (COCIT)</p> <p><input type="checkbox"/> Communications and Media (COCM)</p>
--	---

- Continuing Medical Education (COCME)
- Development (CODE)
- Drugs (COD)
- Federal Government Affairs (COFGA)*
- Fetus and Newborn (COFN)
- Hospital Care (COHC)
- Infectious Diseases (COID)
- Medical Liability and Risk Management (COMLRM)
- Membership (COM)
- Native American Child Health (CONACH)
- Nutrition (CON)
- Pediatric AIDS (COPA)
- Pediatric Education (COPE)
- Pediatric Emergency Medicine (COPEM)
- Pediatric Research (COPR)
- Pediatric Workforce (COPW)
- Practice and Ambulatory Medicine (COPAM)
- Psychosocial Aspects of Child and Family Health (COPACFH)
- State Government Affairs (COSGA)*
- Substance Use and Prevention (COSUP)

Sections

- Administration and Practice Management (SOAPM)
- Adolescent Health (SOAH)
- Advances in Therapeutics & Technology (SOATT)
- Allergy and Immunology (SOAI)
- Anesthesiology & Pain Medicine (SOA)
- Bioethics (SOB)
- Breastfeeding (SOBr)
- Cardiology and Cardiac Surgery (SOCCS)
- Child Death Review & Prevention (PSOCDRP)
- Clinical Pharmacology & Therapeutics (SOCPT)
- Critical Care (SOCC)
- Dermatology (SOD)
- Developmental and Behavioral Pediatrics (SODBP)
- Early Career Physicians (SOECP)
- Emergency Medicine (SOEM)
- Endocrinology (SOEn)
- Epidemiology, Public Health & Evidence (SOEPHE)
- Gastroenterology, Hepatology & Nutrition (SOGHN)
- Hematology/Oncology (SOHO)
- Home Care (SOHCa)
- Hospice and Palliative Medicine (SOHPM)
- Hospital Medicine (SOHM)
- Infectious Diseases (SOID)
- Integrative Medicine (SOIM)
- Internal Medicine/Pediatrics (SOMP)
- International Child Health (SOICH)

- Community Pediatrics (COCP)
- Early Childhood (COEC)
- Environmental Health (COEH)
- Foster Care, Adoption and Kinship Care (COFCAKC)
- Genetics (COG)
- Injury, Violence, and Poison Prevention (COIVPP)
- Quality Improvement and Patient Safety (COQIPS)
- School Health (COSH)
- Sports Medicine and Fitness (COSMF)

Other Committees/Groups

- Disaster Preparedness Advisory Council (DPAC)
- Global Immunization PAC (GI PAC)
- Medical Home Implementation Project Advisory Committee
- Private Payer Advocacy Advisory Committee (PPAAC)
- Family Partnerships Network

Task Forces

- Circumcision
- Diversity and Inclusion
- Pediatric Practice Change
- Sudden Infant Death Syndrome

Sections (cont'd)

- International Medical Graduates (PSOIMG)
- Lesbian, Gay, Bisexual & Transgender Health & Wellness (SOLGBTHW)
- Medicine/Pediatrics (SOMP)
- Minority Health, Equity, and Inclusion (PSOMHEI)
- Neonatal-Perinatal Medicine (SONPM)
- Nephrology (SONp)
- Neurological Surgery (SONs)
- Neurology (SONu)
- Obesity (SOOb)
- Ophthalmology (SOOp)
- Oral Health (SOOH)
- Orthopaedics (SOOr)
- Osteopathic Pediatricians (SOOPe)
- Otolaryngology—Head and Neck Surgery (SOOHNS)
- Pediatric Pulmonology and Sleep Medicine (SOPPSM)
- Plastic Surgery (SOPS)
- Pediatric Trainees (SOPT)
- Radiology (SORa)
- Rheumatology (SORh)
- Senior Members (SOSM)
- Simulation and Innovative Learning Methods (PSOSILM)
- Surgery (SOSu)
- Telehealth Care (SOTC)
- Tobacco Control (SOTCo)
- Transport Medicine (SOTM)
- Uniformed Services (SOUS)
- Urology (SOU)

Other

Please Specify:

SUGGESTED REVIEWING GROUPS

Internal Groups

19. Check internal AAP groups, listed below, who should review the final document during peer review.

Committees

- Adolescence (COA)
- Bioethics (COB)
- Child Health Financing (COCHF)
- Coding and Nomenclature (COCN)
- Continuing Medical Education (COCME)
- Development (CODE)
- Drugs (COD)
- Federal Government Affairs (COFGA)*
- Fetus and Newborn (COFN)
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- Practice and Ambulatory Medicine (COPAM)
- Psychosocial Aspects of Child and Family Health (COPACFH)
- State Government Affairs (COSGA)*
- Substance Use and Prevention (COSUP)

Sections

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- Adolescent Health (SOAH)
- Advances in Therapeutics & Technology (SOATT)
- Allergy and Immunology (SOAI)
- Anesthesiology & Pain Medicine (SOA)
- Bioethics (SOB)
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- Critical Care (SOCC)
- Dermatology (SOD)
- Developmental and Behavioral Pediatrics (SODBP)
- Early Career Physicians (SOECP)
- Emergency Medicine (SOEM)
- Endocrinology (SOEn)
- Epidemiology, Public Health & Evidence (SOEPHE)
- Gastroenterology, Hepatology & Nutrition (SOGHN)

Councils

- Child Abuse and Neglect (COCAN)
- Children With Disabilities (COCWD)
- Clinical Information Technology (COCIT)
- Communications and Media (COCM)
- Community Pediatrics (COCP)
- Early Childhood (COEC)
- Environmental Health (COEH)
- Foster Care, Adoption and Kinship Care (COFCAKC)
- Genetics (COG)
- Injury, Violence, and Poison Prevention (COIVPP)
- Quality Improvement and Patient Safety (COQIPS)
- School Health (COSH)
- Sports Medicine and Fitness (COSMF)

Other Committees/Groups

- Disaster Preparedness Advisory Council (DPAC)
- Global Immunization PAC (GI PAC)
- Medical Home Implementation Project Advisory Committee
- Private Payer Advocacy Advisory Committee (PPAAC)
- Family Partnerships Network

Task Forces

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- Diversity and Inclusion
- Pediatric Practice Change
- Sudden Infant Death Syndrome

Sections (cont'd)

- International Medical Graduates (PSOIMG)
- Lesbian, Gay, Bisexual & Transgender Health & Wellness (SOLGBTHW)
- Medicine/Pediatrics (SOMP)
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- Osteopathic Pediatricians (SOOPe)
- Otolaryngology—Head and Neck Surgery (SOOHNS)
- Pediatric Pulmonology and Sleep Medicine (SOPPSM)
- Plastic Surgery (SOPS)
- Pediatric Trainees (SOPT)
- Radiology (SORa)
- Rheumatology (SORh)

<input type="checkbox"/> Hematology/Oncology (SOHO) <input type="checkbox"/> Home Care (SOHCa) <input type="checkbox"/> Hospice and Palliative Medicine (SOHPM) <input type="checkbox"/> Hospital Medicine (SOHM) <input type="checkbox"/> Infectious Diseases (SOID) <input type="checkbox"/> Integrative Medicine (SOIM) <input type="checkbox"/> Internal Medicine/Pediatrics (SOMP) <input type="checkbox"/> International Child Health (SOICH)	<input type="checkbox"/> Senior Members (SOSM) <input type="checkbox"/> Simulation and Innovative Learning Methods (PSOSILM) <input type="checkbox"/> Surgery (SOSu) <input type="checkbox"/> Telehealth Care (SOTC) <input type="checkbox"/> Tobacco Control (SOTCo) <input type="checkbox"/> Transport Medicine (SOTM) <input type="checkbox"/> Uniformed Services (SOUS) <input type="checkbox"/> Urology (SOU) Other Please Specify:
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External Groups

20. In the space below, provide a list of external groups who should review the final document for endorsement. If none, enter N/A.

FINAL CHECKLIST

<input type="checkbox"/> All 20 sections of the intent have been completed. <input type="checkbox"/> Author/s have reviewed the AAP Clinical Practice Guideline Manual <input type="checkbox"/> Author/s have reviewed the AAP policy statement, “Toward Transparent Clinical Policies”

Please submit the completed form to kokechukwu@aap.org



Appendix B
Section on Epidemiology, Public Health, and Evidence (SOEPHE)
Clinical Practice Guideline Methodologist Pool (CPG-M Pool)
Membership Application

As a producer of clinical practice guidelines for its membership, the AAP seeks to ensure that recommendations are based on current best evidence. Members with expertise in study design, data analysis, literature appraisal, and guideline development are needed to assist the AAP sections, committees, and councils in practice guideline development and revision.

RESPONSIBILITIES

Specific Responsibilities of the Methodologist/Epidemiologist Include:

- Assisting with literature reviews
- Article retrieval, either by self or in conjunction with clinical librarians
- Grading articles for methodological strength
- Production of technical reports that accompany guidelines
- Assisting with the production of guidelines
- Ensuring reference accuracy
- Participation on regular guideline teleconferences
- Assistance developing the preliminary and final topic nomination submissions
- Consulting with a clinical librarian (e.g., AAP Librarian) as needed to ensure well-formed clinical questions and robust search strategy

Those wishing to serve in these capacities should complete the fields below and return this form and a copy of their curriculum vitae to Kymika Okechukwu, Manager, Evidence-based Practice Initiatives, by clicking 'submit' on this form. Acceptance into the CPG-M Pool, although a prerequisite, does not guarantee the opportunity to serve on a guideline subcommittee of the Council on Quality Improvement and Patient Safety (COQIPS). Any efforts short of producing a publication, such as reviewing or grading articles, will be appropriately acknowledged.

Experience in all areas is not required for acceptance as a member.

APPLICANT INFORMATION

Name:

Degrees/Credentials:

Email:

Phone Number:

Mailing Address:

Work Affiliation (optional):

Describe your training background in research design and/or data analysis (include degrees if applicable and title of thesis or dissertation; explain formal and/or informal training, especially if you do not have a formal degree).

Describe your training or experience in literature review, retrieval, and appraisal (include formal or informal courses, workshops attended, and any evidence-based medicine (EBM) teaching experience).

Describe any training or experience you have had in development of clinical practice guidelines.

Describe any training or experience you have had in medical informatics.

Describe any training or experience you have had in policy development.



Appendix C Guideline Reference Evaluation Sheet

Title:

First Author:

PubMed Number:

Population:

Children 0 to 19

Infants

Other; Specify: _____

Study Design:

Cross-sectional (population selected w/o regard to disease status)

Observational study (data collected from an existing situation)

Cohort

Case-control

Experimental study

Randomized controlled trial (RCT)

Prospective

Retrospective

Policy statement. If so, organization: _____

Review article

Case report/case series

Expert opinion

Ill-defined "clinical experience"

Well-defined "clinical experience"

Quality of Reference:

Systematic Bias

Selection bias (false association between exposure and disease)

confounding

confounding by disease severity (more severe disease makes treatment look less effective)

confounding by indication (treatments given to persons with disease and outcomes compared to those without disease and not given treatment)

appropriate matching (against confounders)

Nonsystematic bias (alternative explanation for an association)

Inferential error (problems in data analysis)

Incorrect statistical method selected

Type 1 error: wrongly rejecting the null hypothesis

Score: (Circle 1)		
Poor Quality: 1	Intermediate Quality: 2	Highest Quality: 3
<p>AAP:</p> <ul style="list-style-type: none"> -Case report -Expert opinion based on ill-defined “clinical experience” 	<p>AAP:</p> <ul style="list-style-type: none"> -RCT performed in non-pediatric (nontarget) population -Case control -Cohort study 	<p>AAP:</p> <ul style="list-style-type: none"> -RCT in target population



Appendix D Evidence Table

SECTION / TOPIC								
Citation	Methods	Participants/ Inclusion Criteria	Exclusion Criteria	Interventions	Outcomes	Results	Risk of Bias	Notes/Conclusions
Author, year	Study design	Number of participants Demographics Patient characteristics		Details of study interventions including duration, dosage, etc. Include comparisons	Concise list of a priority outcomes	Study results	Criteria for RCTs or observational studies?	



Appendix E Article Summary Table

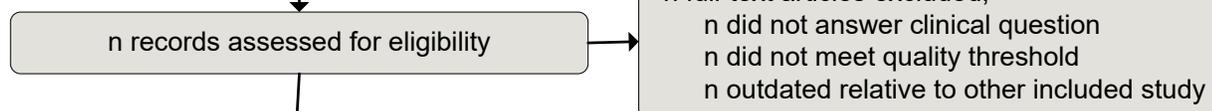
Identification



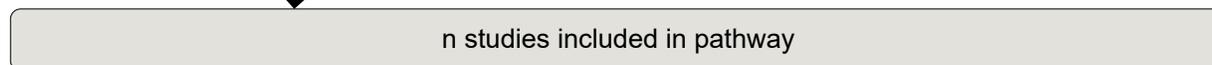
Screening



Eligibility



Included



Flow diagram adapted from Moher D et al. BMJ 2009;339:bmj.b2535



Appendix F Sample Project Timeline

<u>Due Date</u>	<u>Task Name</u>	<u>Duration</u>	<u>Status</u>
	Environmental Scan		
	Topic Identification		
	Development and Submission of CPG Intent	4w	
	Topic Review and Prioritization	12w	
	CPG Board Decision	4w	
	AHRQ		
	<i>Submission</i>	2w	
	<i>Prioritization</i>	24w	
	Subcommittee Assembly	12w	
	Board Approval of the CPG Subcommittee	2w	
	CPG Subcommittee Orientation	12w	
	Clinical Practice Guideline Development		
	<i>Literature Search</i>	12w	
	<i>Data Analysis</i>	12w	
	<i>Manuscript Drafting</i>	28w	
	<i>Algorithm Development</i>	12w	
	<i>Implementation Tool & Resource Development</i>		
	<i>Key Driver Diagram</i>	12w	
	<i>QI Metric(s)</i>	12w	
	<i>Patient/Provider Education</i>	28w	
	Peer Review		
	<i>iThenticate (if new content/topic)</i>	4w	
	<i>COQIPS/COMLRM Review</i>	2w	
	<i>Internal/External Peer Review</i>	4w	
	<i>Revisions</i>	4w	
	Copy Editing & Conflict of Interest		
	<i>Medical Writer Review/Comments</i>	4w	
	<i>Subcommittee Revisions/Approval</i>	1w	
	<i>Conflict of Interest (COI)</i>	2w	
	Leadership Review		
	<i>Chief/Senior Vice President Review</i>	2w	
	<i>Board of Directors Review</i>	2w	
	Executive Committee Approval	1w	
	Dissemination		
	<i>Pediatric Care Online Webinar</i>		
	<i>Press/Media Releases</i>		
	<i>Listserv Outreach</i>		
	<i>AAP News</i>		
	Anticipated Publication		
	<i>Online</i>	2w	
	<i>Print/Hardcopy</i>	2w	



Appendix G Implementation/Dissemination Strategy: Items to Consider

- Submit to GIN Library and National Guidelines Clearinghouse
- Schedule podcast(s), PCO Webinar, and Listserv Live Presentation(s)
 - Phone call with select panel members
- AAP News*, including:
 - Member blast e-mail
 - Press Release
 - Social Messaging
- Pocket cards
 - Guidelinecentral.com
 - Free to create, possible royalties
- Plain language summary
 - Standardized, based on Cochrane for SR PLS
 - FAQ, 8th grade level
- Algorithm
 - Poster flowchart for clinicians
- Patient resources (handouts)
 - Posters for patients
- Fact sheet
- AAP.org
 - Link to guidelines and policies page, home page
 - Text for physicians, patients, media
- Slide set
 - Made available on Web page
 - For states, international interest
 - Standardized, basically Key Action Statements and Recommendation Profiles
- Educational Training
 - EQIPP Module; Other CME and Maintenance of Certification Part IV activities
 - NCE
 - Submit exam questions to ABP
- Work with other societies having related guidelines to compare and contrast
- Performance/quality measures
- Key Driver Diagrams
- Electronic Health Records
 - Codes, logic, info button access, order sets, templates
- Promote funding of identified research gaps
- Investigate whether guideline is making a difference (e.g., is it implementable, can processes be sustained, are there effects on clinical outcomes)



Appendix H

Clinical Practice Guideline Topic Scoring Rubric

Table 4.				
ALL DOMAINS SHOULD BE SCORED BASED ON INFORMATION PROVIDED WITHIN THE <u>CPG INTENT FORM</u>, NOT JUST PERSONAL KNOWLEDGE AND/OR EXPERTISE OF THE SUBMITTED TOPIC				
Domain	Items	Score (1 (worst) to 5 (best))	Multiply by	Weighted score
1. Disease Burden on the Health System <i>Items 7, 8</i>	<p>Do the intent authors demonstrate that this CPG will address a problem with substantial disease burden on the health system?</p> <ul style="list-style-type: none"> - Potential impact of CPG <ul style="list-style-type: none"> o Number of children and families impacted o Which medical professional/societies whom care for children would implement clinical recommendation? o What is the impact on non-pediatric providers? o What is the impact on practice? - Disease/Condition incidence or prevalence - High risk impact of disease/condition for children - High frequency of risk factors associated with the disease/condition - High frequency of avoidable risk factors associated with the disease/condition - Health priorities in agreement with CPG's needs - High impact on national health system - What is impact on science of pediatric medicine? 		1	
2. Economic Impact on the Health System <i>Items 7, 8</i>	<p>Do the intent authors demonstrate that this CPG will address a problem with substantial economic impact on the health system?</p> <ul style="list-style-type: none"> -Economic effects on health system (cost of an individual patient is high during diagnosis or therapeutic process) -Disease/Condition associated with iatrogenic interventions that are significantly high in cost -High impact on national health system - 		1	

<p>3. Effectiveness <i>Items 1 to 8</i></p>	<p>Do the intent authors demonstrate that this CPG will be effective in its implementation based on current methods shown in methodologically adequate studies?</p> <ul style="list-style-type: none"> - Certainty about effectiveness of assessed interventions and technologies 		2	
<p>4. Evidence <i>Items 1 to 8</i></p>	<p>Do the intent authors demonstrate that this CPG will be based on strong evidence?</p> <ul style="list-style-type: none"> - Availability of effective methods shown by methodologically adequate studies 		2	
<p>5. Clinical Practice Variation <i>Items 8, 13</i></p>	<p>Do the intent authors demonstrate substantial and unwarranted variation in practice that could be improved by the CPG?</p> <ul style="list-style-type: none"> - Current evidence is insufficient or variable for disease control in the population - Lack of high-quality CPGs - Availability of high volume of evidence regarding the CPG topic - Evidence of inappropriate use of available technologies used in the treatment of condition (iatrogenic) - Conditions/diseases where effective treatments could reduce mortality or morbidity - Evidence of disagreements between current treatment and literature recommendation - Is there current controversy about topic importance? 		2	
<p>6. Patient Safety <i>Items 7, 8</i></p>	<p>Do the intent authors demonstrate that this CPG will improve Patient Safety?</p> <ul style="list-style-type: none"> - Does the production of guideline on this topic improve patient safety, or effective in reducing harm? - Disease/condition associated with high incidence of adverse events or treatment sequela - High possibility of adverse events 		2	
<p>7. Patient Priorities <i>Item 8</i></p>	<p>Do the intent authors demonstrate that this CPG is of interest to patients and their families?</p> <ul style="list-style-type: none"> - High patient demand or interest - Concerns about patients' quality of life - Feasibility of patient empowerment - High acceptability of the topic between the general public and professionals affected by the use of the CPG 		2	
<p>8. Novel Methodology <i>Item 8</i></p>	<p>Do the intent authors demonstrate that this CPG will address new methods and technology?</p> <ul style="list-style-type: none"> - High importance of new methods and technology assessment - Fast diffusion of non-assessed technologies, availability of resources and sufficient time for technologies implementation 		1	

<p>9. Other social effects/Equity <i>Item 8</i></p>	<p>Do the intent authors demonstrate that this CPG will address social and health inequities?</p> <ul style="list-style-type: none"> - Will reduce inequities when implemented - Closes gap in health care disparities for children and families - Absenteeism from work or school, inability to work, inequities in access to health services - Will the service be available to anyone who requires it? - Will this CPG have a positive or negative impact on minorities' access to health services? - Will the CPG increase health service access to those affected by the condition? 		1	
<p>10. Health Promotion and Disease Prevention <i>Item 8</i></p>	<p>Do the intent authors demonstrate that this CPG will address health promotion and disease prevention?</p> <ul style="list-style-type: none"> - Feasibility of prevention between patients with risk factors - Are there specific activities of health promotion, disease prevention, early diagnosis or treatment? Have all of them shown a reduction in disease burden? 		1	
<p>11. Work Effort</p>	<p>Do the intent authors demonstrate that the CPG is readily feasible to develop and implement without substantial barriers (e.g., complex problems, broad scope, financial, etc.)?</p> <ul style="list-style-type: none"> - Feasibility on recommendations development which will improve health outcomes and cost - Is the proposal politically feasible? - Does it belong to priority health areas according to government policies? - Can the CPG be implemented? For example, will not require an excessive amount of resources and will not present important barriers to implement changes - Will require education to training professionals - Does the proposed topic include a diverse and inclusive stakeholder group? - Complexity of systematic review - Information needs for members and their patients 		1	

TOTAL OF THE WEIGHTED SCORES ABOVE	
Comments to the Board in Relation to the Submitted Intent and/or Domain Scoring Clarification:	

* Clinical Practice Guidelines up for revision will likely be scored higher priority because of decreased complexity and resources and increased alignment with AAP strategic plans.

Adapted from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846928/>

Updated November 2019



Appendix I **Clinical Practice Guideline Subcommittee Nondisclosure Agreement**

As a member of the American Academy of Pediatrics' (AAP) **Clinical Practice Guideline (CPG) Subcommittee on [insert name]**, please review and sign the following agreement acknowledging your participation on the guideline.

Clinical Practice Guideline Ownership

The American Academy of Pediatrics will own all intellectual property rights related to the guideline and its publication in Pediatrics, including but not limited to all written text, full-text tables, slides, graphs, photographs, charts, algorithms, and all deliverables associated with the development of the guideline and any other derivatives of the work (collectively, the "content").

Other derivatives include clinical recommendations, conflict of interest management terms, and any resources or tools developed to support the dissemination and implementation of the guideline.

Responsibilities

As a guideline subcommittee member, you agree to provide any assigned deliverables in a timely manner and in accordance with the timeline for publication. You also agree to carry out the following responsibilities in your role on the guideline subcommittee:

- Participate in all scheduled subcommittees meetings and conference calls
- Review and understand the *AAP Guide to the Development and Implementation of Evidence-Based Clinical Practice Guidelines* and *Toward Transparent Clinical Policies*
- Participate in the dissemination and implementation of the guideline, including, but not limited to the development of the clinical resources and other tools and products related to the guideline, as requested.

Permissions

You agree to inform AAP staff to obtain prior approval before engaging in any marketing, promotional talks, promotional initiatives, and/or consultancies related to the development of guideline during the time of the guideline development. If asked to speak on behalf of the guideline, you agree to contact AAP Staff to facilitate such requests. AAP staff will also assist with the coordination and facilitation of the speaking engagement through the provision of key messages and media training, when necessary. You agree to acknowledge the AAP when presenting on the guideline at all meetings. You agree to contact AAP to receive an AAP-branded PowerPoint template for creating slides.

Confidentiality

In your role on the guideline subcommittee you may have been or may be exposed to certain confidential and/or proprietary information, materials or data related to the subcommittee's work and final document(s). It is important to the integrity of the writing process and final work that this information is kept strictly confidential and not disclosed at any time under any circumstance.

Therefore, as a condition and in consideration of your selection to serve on the guideline subcommittee, and in recognition of the importance of the subcommittee's work and for mutual consideration, the receipt and adequacy of which are acknowledged by the parties, you agree to the following:

- You will not disclose or cause to be disclosed to anyone or any entity outside of the guideline subcommittee or appropriate AAP staff any confidential and/or proprietary information, materials or data related to the guideline subcommittee's work, where such information, materials or data have been previously identified in writing or marked by the guideline subcommittee as "Confidential." This restriction shall apply at any time and in any circumstance, unless otherwise directed by the guideline subcommittee Chair.

- You will keep all such confidential information in your possession or control in a safe and secure place and will take all reasonable steps to protect against inadvertent disclosure or theft of the information.
- Upon request from the guideline subcommittee Chair, you will promptly destroy all confidential information that you have been sent or acquired relating to the guideline subcommittee. Notwithstanding the return or destruction of any such confidential information, you will continue to be bound by their obligations under this Agreement.

Conflict of Interest

You agree to adhere to the AAP Policy *Conflict of Interest and Relationships with Industry and Other Organizations*.

Please sign this letter and return it to Kymika Okechukwu, Manager, Evidence-Based Practice Initiatives at KOkechukwu@aap.org to confirm your understanding and acceptance of these conditions with respect to your participation on the [insert guideline name]. Breach of any of these requirements for participation will result in disciplinary action that may include dismissal from the guideline subcommittee or appropriate sanctions. Thank you very much for your cooperation.

Sincerely,

Judith C. Dolins MPH
Chief Implementation Officer
Sr. Vice President, Community & Chapter Affairs and Quality Improvement

Understood and Accepted By:

Signature _____

Print Name _____

Date _____



Appendix J
COPYRIGHT TRANSFER AND RELEASE

Name (the “author”): _____

Committee/Task Force: _____

Thank you for volunteering to perform service for the American Academy of Pediatrics (AAP) on the committee, task force, or project identified below. In order for the AAP to fully utilize the work product you contribute, please sign the statement below.

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Date

(Print name, name of company/institution, title, and phone number)