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If you use or develop clinical practice guidelines, this manual will likely be of interest. “There are many paths to the top of the mountain,” suggests an old Chinese proverb, “but the view is always the same.”Although many paths lead to guidelines, we offer proven strategies for efficiently crafting a valid and actionable product. The driving force is quality improvement with a continuous effort to balance pragmatism with developmental rigor. The end product is a starting point for performance improvement.

The third edition of this manual builds on earlier publications²,³ by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) to systematize internal guideline development. By following these principles, the AAO-HNSF has published 8 multidisciplinary guidelines, all within 12 to 18 months from conception to completion.⁴–¹¹ Our new manual not only summarizes this experience but allows other organizations to assess and adapt the processes.

Guideline methodology continues to evolve rapidly, with substantive advances since our last manual was published. Standards for trustworthy guidelines have been proposed by the Institute of Medicine¹² and the Guidelines International Network,¹³ computerized decision-support software is available to facilitate actionable and implementable guideline statements,¹⁴ consumer and public involvement in guideline development has become the norm, and conflict of interest

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has taken on increased scope and importance. Moreover, we continue to refine and improve our development processes with each new guideline, striving to meet or exceed current standards.

Our goals in publishing a revised manual are several. First, we sought to provide clinicians with a straightforward explanation of guidelines, considering the increasing prominence of guidelines as a quality metric. Second, we wanted a pragmatic resource, which accurately reflects current practices, to sustain consistent guideline development at the AAO-HNSF. Last, we wanted to share our successful development process with the guideline community at large to encourage an exchange of ideas and to promote best practices.

Guidelines are particularly important when wide regional variations exist in managing a condition. Similarly, the wide variability in guideline methodology, both within and between organizations, is precisely what mandates a systematic approach to guideline development. Despite a plethora of techniques reflected in published guidelines, we could not find a single, comprehensive “how to” manual with a valid and pragmatic approach that could be readily implemented. This work is offered to address this void.

We thank the AAO-HNSF for their trust, support, and flexibility throughout this fruitful collaboration and sincerely hope that you may also benefit from the experience. We humbly acknowledge that ours is one of many paths to implementation, with each new guideline, striving to meet or exceed current standards.

Organizations new to guideline development will benefit from understanding the nuances and complexities of guideline creation and may consider using the process outlined as a starting point for their own endeavors.

Organizations with an established guideline development process may wish to compare their current processes to those described here, potentially identifying areas for improved quality, efficiency, or both.

Members of guideline panels or working groups can derive greater insight and understanding of development methodology, allowing them to contribute most effectively as an author or participant.

Staff supporting guideline development will find practical suggestions on staying focused and efficient and may consider using or adapting the manual as a template for their own processes.

Guideline users are perhaps even more diverse than guideline developers. Whereas most guideline users do not, or want, detailed information on methodology, some understanding is necessary to interpret and use existing products:

- Organizations that use guidelines will gain greater insight into the guideline development process, understanding what makes a guideline valid and actionable, as well as what attributes should be sought when critically assessing a guideline’s potential value.

- Organizations that conduct systematic reviews can interact most effectively with guideline developers.

How to Use This Manual

Throughout the manual, we emphasize principles and practices, recognizing that both are needed to translate concepts into action. Principles underlying practices are always stated, to promote conceptual focus and clarity before getting sidetracked with implementation details. Practices are illustrated with examples from prior AAO-HNSF guidelines to clarify how we chose to implement a principle, with the understanding that other development groups will need to modify the particulars to fit their organizational structure and resources.

The following list describes some of the fundamental principles underlying guideline development that are discussed sequentially in this manual:

1. Medicine and guidelines: why guidelines are an essential for quality care
2. Understanding guidelines: what makes a guideline useful and valid?
3. Principles of guideline development: essential steps and processes
4. Identifying evidence: finding and using best published evidence
5. Identifying topics: how to prioritize quality improvement opportunities
6. Understanding key action statements: the backbone of a clear and usable guideline
7. Understanding action statement profiles: how they promote transparency
8. Understanding recommendation grades: the link between action and evidence
9. Appraising implementability: maximizing the chance to influence clinician behavior

This manual is also intended as a practical resource for use during guideline development. Major sections of the text correspond to the activities involved (Table 1), allowing the user to move from one section to the next as development proceeds. Relevant pages of the manual can be distributed to the guideline development group in advance of conference calls or in-person meetings to facilitate preparation and to ensure appropriate expectations. When significant principles apply to an activity, they are discussed within, or just before, the relevant section.

We have tried to make this manual as reader-friendly as possible, but how to best approach the material will depend on one’s background and perspective. Individuals and organizations involved in guideline development comprise a diverse audience that may benefit from the material in the manual in several ways:

- Organizations new to guideline development will benefit from understanding the nuances and complexities of guideline creation and may consider using the process outlined as a starting point for their own endeavors.

- Organizations with an established guideline development process may wish to compare their current processes to those described here, potentially identifying areas for improved quality, efficiency, or both.

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- Organizations that conduct systematic reviews can interact most effectively with guideline developers.
if they understand the process of moving from evidence to action, how systematic reviews facilitate these efforts, and how recommendations are made when evidence is absent or of low quality.

- **Clinicians with an interest in guidelines** can use them most effectively if they understand how they are developed, what are current best practices, and how guidelines should—and should not—be used to influence clinical care.

- **Consumers or consumer groups** that have identified guidelines of interest will be better able to assess quality, as well as select among multiple guidelines of varying quality, if they appreciate the processes involved in creating valid guidelines.

**Medicine and Guidelines**

The Institute of Medicine has identified 3 crucial tasks for a national system to identify highly effective health care services: priority setting, evidence review, and developing recommendations (guidelines). The last task—creating clinical practice guidelines—is perhaps the most challenging because methodology continues to evolve, the quality and relevance of available evidence are highly variable, and evidence gaps mandate valid processes for incorporating expert consensus.

Guidelines help clinicians translate best evidence into best practice. A well-crafted guideline promotes quality by reducing health care variations, improving diagnostic accuracy, promoting effective therapy, and discouraging ineffective—or potentially harmful—interventions. 

**Table 1. Timetable for Guideline Development**

<table>
<thead>
<tr>
<th>Month</th>
<th>Activity</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>Planning</td>
<td>Define topic; identify leadership, partner organizations, and working group members; tabulate and manage conflicts of interest</td>
</tr>
<tr>
<td>1-2</td>
<td>Stage 1 literature search</td>
<td>Identify existing guidelines and systematic reviews</td>
</tr>
<tr>
<td>3</td>
<td>Conference call 1</td>
<td>Define purpose, timeline, and scope; discuss conflicts of interest; plan stage 2 literature search</td>
</tr>
<tr>
<td>3-4</td>
<td>Stage 2 literature search</td>
<td>Identify randomized controlled trials</td>
</tr>
<tr>
<td>4</td>
<td>Conference call 2</td>
<td>Refine scope and definitions; generate a draft topic list of opportunities for quality improvement</td>
</tr>
<tr>
<td>5</td>
<td>In-person meeting 1</td>
<td>Construct a “straw man” guideline of key action statements and profiles based on topic priorities; outline supporting text for key action statements; discuss writing assignments</td>
</tr>
<tr>
<td>5-6</td>
<td>Stage 3 literature search</td>
<td>Identify best evidence to facilitate writing assignments for specific key action statements</td>
</tr>
<tr>
<td>5-6</td>
<td>Writing assignments</td>
<td>Write the amplifying text for key action statements; chair collates into guideline draft</td>
</tr>
<tr>
<td>7</td>
<td>In-person meeting 2</td>
<td>Refine the key action statements; review amplifying text; revise and complete the action statement profiles; finalize recommendation grades; document any differences of opinion</td>
</tr>
<tr>
<td>7-8</td>
<td>Writing assignments</td>
<td>Revise and polish the draft guideline</td>
</tr>
<tr>
<td>8</td>
<td>Appraising draft guideline implementability</td>
<td>Appraisal of draft guideline clarity, quality, and ability to be successfully implemented</td>
</tr>
<tr>
<td>9</td>
<td>Conference call 3</td>
<td>Review guideline appraisal report; remedy deficiencies</td>
</tr>
<tr>
<td>10-11</td>
<td>Prerelease peer review</td>
<td>External review of draft guideline by representatives of target audience and practice settings</td>
</tr>
<tr>
<td>12</td>
<td>Public comment</td>
<td>Guideline draft released for a period of public comment and review</td>
</tr>
<tr>
<td>13-14</td>
<td>Organizational board review and journal peer review</td>
<td>Review and approval guideline by the board of directors of the sponsoring organization(s), with simultaneous submission to the journal for editorial peer review</td>
</tr>
</tbody>
</table>

This manual offers one approach to efficient guideline development based on experience of the AAO-HNSF, the
The AAO-HNSF guidelines prescribe recommendations in key action statements followed by supporting (amplifying) text. All guideline action statements should ideally be supported by an action statement profile that summarizes clearly the decision-making process in terms of aggregate evidence quality, harm-benefit assessment, development group values, reasons for intentional vagueness, and the role of patient preference. Our newer guidelines feature expanded profiles that explicitly state differences of opinion and level of confidence in the evidence underpinning the recommendation (not just its aggregate quality). Because of their importance, the profiles now appear immediately after key action statements, instead of after the supporting text. Action statement profiles are discussed fully later in this manual.

Understanding Guidelines

As defined by the Institute of Medicine (IOM), clinical practice guidelines are “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”

Despite increasing acceptance of an evidence-based approach to clinical decision making, much clinical practice is still not based on the best available evidence. Guidelines are one way of implementing evidence into practice. They can serve as a guide to best practices, a framework for clinical decision making, and a benchmark for evaluating performance.

Guidelines benefit patients through better outcomes, fewer ineffective interventions, greater consistency of care, and by creating secondary implementation materials (pamphlets, videos, etc). Clinicians can use guidelines to make better decisions, initiate quality improvement efforts, prioritize new research initiatives, and support coverage or reimbursement for appropriate services. Conversely, a flawed guideline could significantly harm both patients and clinicians, thereby mandating sound methodology as a basis for guideline development.

Simply inserting the word guideline in the title of a document does not make it so. Many review articles, consensus statements, practice parameters, and policy recommendations are mistakenly labeled as guidelines, even though they do not possess the methodologic rigor to warrant such a designation. A real
Standards for trustworthy clinical practice guideline have been proposed by the Institute of Medicine and the Guidelines International Network.\textsuperscript{12,13} As summarized in Table 2, there is significant overlap in the proposals, with many common elements and features. Taken together, however, they provide a useful overview of what guidelines should be and how they differ from other literature syntheses. Although based on expert consensus and current best evidence, the validity of these standards is unknown, and they are not uniformly accepted. Nonetheless, they do represent the best standards available for guideline developers, who, in response, have begun to assess the degree to which their organization’s guideline development processes comply.

The Appraisal of Guidelines Research & Evaluation II (AGREE II) instrument is a widely used generic measure of guideline quality that also includes reporting advice and a methodologic framework for guideline development.\textsuperscript{19} Quality guidelines are characterized by, and report clearly, the following attributes:

1. Explicit scope and purpose: Specific descriptions are given of the overall guideline objective(s), the health question(s) covered, and the population (patients, public, etc) to whom the guideline is meant to apply.

2. Stakeholder involvement: The development group includes individuals from all relevant professional groups, patients’ views and preferences of the target population (patients, public, etc) are sought, and target users are clearly defined.

3. Rigor of development: Systematic methods are used to search for evidence; methods for formulating recommendations are clearly described; strengths and limitations of the body of evidence are clearly described; methods for formulating the recommendations are clearly described; recommendations take into account health benefits, side effects, and risks; recommendations are linked explicitly to supporting evidence; the guideline is externally reviewed by experts prior to publication; and a procedure for updating the guideline is provided.

4. Clarity of presentation: Recommendations are specific and unambiguous, different options for management of the condition or health issue are clearly presented, and key recommendations are easily identifiable.

5. Applicability: The guideline provides advice and/or tools on how the recommendations can be put into practice, the guideline describes facilitators and barriers to its application, potential resource implications are considered, and the guideline presents key monitoring and/or auditing criteria.

6. Editorial independence: The views of the funding body have not influenced content; competing interests of guideline development group members have been recorded and addressed.

The Conference on Guideline Standardization (COGS) checklist is another tool that specifies characteristics of a valid and usable clinical practice guideline.\textsuperscript{20} In contrast to the AGREE II instrument, which assesses guidelines after completion, the COGS checklist can be used during development to improve quality. The 18 characteristics in the COGS checklist are shown in Table 3.

Equally important to understanding what guidelines are is a clear appreciation of what guidelines are \textit{not}. Without this perspective, clinicians may become apprehensive about the impact of guidelines on their lives, and organizations may apply guidelines to situations they were never intended.

- Guidelines are \textit{not} reimbursement policies.
- Guidelines are \textit{not} performance measures.
- Guidelines are \textit{not} legal precedents.
- Guidelines are \textit{not} measures of certification or licensing.
- Guidelines are \textit{not} intended for comprehensive management.
- Guidelines are \textit{not} for provider selection or public reporting.
- Guidelines are \textit{not} recipes for cookbook medicine.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance.\textsuperscript{21} Clinicians should always act and decide in a way that they believe will best serve their patients’ interests and needs, regardless of guideline recommendations. Guidelines simply represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.

Guidelines differ from systematic reviews and evidence reports that identify and combine studies using explicit methods to reduce bias but do not typically define appropriate actions or incorporate values. In contrast, a guideline uses information from evidence reviews and other sources to create specific action statements by considering values and linking the strength of recommendation to the quality of evidence. Performance measures operationalize these statements into a format that can be used to assess adherence, taking into account appropriate patient exceptions and exclusions.

Evidence-based clinical practice guidelines are usually not intended for cost control or health care rationing, unless specifically undertaken to assess cost-effectiveness.
Table 2. Standards for Trustworthy Clinical Practice Guidelines (CPGs)

<table>
<thead>
<tr>
<th>Standard</th>
<th>Institute of Medicine (IOM)(^{12})</th>
<th>Guidelines International Network(^{13})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods and scope</td>
<td>The processes by which a CPG is developed and funded should be detailed explicitly and be publicly accessible.</td>
<td>A guideline should specify its scope and objective and clearly describe the methods used for development in detail.</td>
</tr>
<tr>
<td>Conflict of interest (COI)</td>
<td>Prior to selection of the guideline development group (GDG), individuals should declare, in writing, all interests and activities potentially resulting in COI; management of COI includes divestment and exclusions.</td>
<td>A guideline should include disclosure of the financial and nonfinancial COIs for members of the GDG and should also describe how any identified conflicts were recorded and resolved.</td>
</tr>
<tr>
<td>GDG composition</td>
<td>The GDG should be multidisciplinary and balanced, comprising methodological experts, clinicians, and populations expected to be affected by the CPG; patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG.</td>
<td>A GDG should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.</td>
</tr>
<tr>
<td>Evidence reviews</td>
<td>CPG developers should use systematic reviews that meet standards set by the IOM.</td>
<td>Guideline developers should use systematic evidence review methods to identify and evaluate evidence.</td>
</tr>
<tr>
<td>Decision-making process</td>
<td>Not specified</td>
<td>A guideline should describe the process used to reach consensus among the panel members and, if applicable, the sponsoring organization; this process should be established a priori.</td>
</tr>
<tr>
<td>Recommendation wording</td>
<td>Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed; strong recommendations should be worded so that compliance can be evaluated.</td>
<td>A guideline recommendation should be clearly stated and based on scientific evidence of benefits, harms, and, if possible, costs.</td>
</tr>
<tr>
<td>Recommendation strength</td>
<td>Each recommendation should have a clear description of potential benefits and harms, a summary of relevant available evidence (quality, quantity, consistency), an explanation of the part played by other factors (values, opinion, theory, clinical experience), a rating of the level of confidence in (certainty regarding) the evidence, a description and explanation of any differences of opinion, and a rating of recommendation strength.</td>
<td>A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.</td>
</tr>
<tr>
<td>External review</td>
<td>External reviewers should comprise a full spectrum of relevant stakeholders; reviews should be kept confidential; the GDG should consider all reviewer comments and keep a written record of disposition; a draft of the CPG should be made available to the general public for comment.</td>
<td>Review by external stakeholders should be conducted before guideline publication.</td>
</tr>
<tr>
<td>Updating</td>
<td>The CPG publication date, date of evidence review, and proposed date for future CPG review should be documented in the CPG; literature should be monitored regularly and the CPG updated when new evidence suggests a need for modification.</td>
<td>A guideline should include an expiration date and/or describe the process that the GDG will use to update the recommendations.</td>
</tr>
<tr>
<td>Financial support</td>
<td>Not stated</td>
<td>A guideline should disclose financial support for the development of the evidence review and guideline recommendations.</td>
</tr>
</tbody>
</table>
Guidelines seek to produce optimal health outcomes for patients, minimize harm, and reduce inappropriate variations in clinical care. Whereas some of these outcomes may also reduce costs, financial benefits alone are generally not the main focus of an evidence-based clinical practice guideline.

When the focus of a clinical practice guideline is a specific procedure or intervention (eg, tonsillectomy), action statements that describe indications should not be viewed as comprehensive. Guidelines address a limited number of quality improvement opportunities, particularly where there is uncertainty about the effects of treatment or indications for intervention (eg, tonsillectomy for recurrent infection). Conversely, when indications are less controversial (eg, tonsillectomy for obstructive sleep apnea or suspected malignancy), the guideline may not contain any related discussion, but this does not imply a contraindication to the procedure. Organizations seeking to define evidence-based indications for procedures or surgery should use guidelines as a starting point but not as the sole source of information.

**Principles of Guideline Development**

Without substantial advance planning, guideline development is likely to be biased and inefficient. Moreover, an a priori protocol is mandatory to ensure attention to the COGS, AGREE II, Institute of Medicine, and Guidelines International Network quality standards. On the basis of a literature review and direct experience in North America and the United Kingdom, Shekelle and colleagues concluded that 5 steps are involved in the initial development of an evidence-based guideline:

1. Identifying and refining the subject area
2. Convening and running guideline development groups
3. Assessing evidence identified by systematic literature review
4. Translating evidence into recommendations
5. Subjecting the guideline to external review

Turner and coworkers compared approaches to guideline development in 6 handbooks from the Council of Europe, World Health Organization, and national organizations in Australia, Scotland, New Zealand, and the United Kingdom. All handbooks agreed that key aspects of development included a multidisciplinary panel, consumer involvement, identifying clinical questions or problems, systematically reviewing and appraising the literature, a process for drafting recommendations, external consultation and review, and planned updating.

Guyatt and colleagues have focused on grading evidence quality and recommendation strength in guidelines, emphasizing that these are separate and distinct processes essential to establishing and communicating validity. An optimal rating system is characterized by simplicity and transparency for the clinician consumer, sufficient (but not too many) categories, explicitness of methodology for guideline developers, simplicity for guideline developers, consistency with general trends in grading systems, and an explicit approach to different levels of evidence for different outcomes.

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**Table 3. Characteristics of Quality Clinical Practice Guidelines as Described by the Conference on Guideline Standardization**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overview material</td>
<td>Structured abstract including release date, status, and print and electronic sources</td>
</tr>
<tr>
<td>2. Focus</td>
<td>Primary disease/condition and intervention/service/technology</td>
</tr>
<tr>
<td>3. Goal</td>
<td>Goal guideline is expected to achieve, including rationale for topic</td>
</tr>
<tr>
<td>4. Users/setting</td>
<td>Intended users of the guideline and practice settings</td>
</tr>
<tr>
<td>5. Target population</td>
<td>Patient population eligible for guideline plus exclusion criteria</td>
</tr>
<tr>
<td>6. Developer</td>
<td>Organization(s) responsible for development plus author names/credentials</td>
</tr>
<tr>
<td>7. Funding source</td>
<td>Who sponsored development, what was the role, what are conflicts of interest</td>
</tr>
<tr>
<td>8. Evidence collection</td>
<td>Literature search methods, including dates, databases, and filter criteria</td>
</tr>
<tr>
<td>9. Grading criteria</td>
<td>Method for grading recommendation strength and rating evidence quality</td>
</tr>
<tr>
<td>10. Evidence synthesis</td>
<td>How evidence was used to create recommendations</td>
</tr>
<tr>
<td>11. Prerelease review</td>
<td>How guideline developer reviewed and/or tested guidelines prior to release</td>
</tr>
<tr>
<td>12. Update plan</td>
<td>Expiration date for guideline and plans for updating</td>
</tr>
<tr>
<td>13. Definitions</td>
<td>Defines unfamiliar terms and those critical to correct application</td>
</tr>
<tr>
<td>14. Recommendations and rationale</td>
<td>Recommended actions are stated precisely with specific circumstances under which to perform them, as well as explicit linkage to supporting evidence</td>
</tr>
<tr>
<td>15. Benefits and harms</td>
<td>Potential benefits and risks associated with recommendations</td>
</tr>
<tr>
<td>16. Patient preferences</td>
<td>Role in decisions with substantial personal choice or values</td>
</tr>
<tr>
<td>17. Algorithm</td>
<td>Graphical description of the stages and decisions in clinical care</td>
</tr>
<tr>
<td>18. Implementation</td>
<td>Anticipated barriers to implementation, auxiliary materials, and review criteria</td>
</tr>
</tbody>
</table>

*Adapted from the Conference on Guideline Standardization.*
The guideline development process described in this manual addresses the above issues, yet strives for a balance between rigor and pragmatism that maintains efficiency.

Efficiency is critical in guideline development because moving from planning to completion in about 14 months helps avoid a situation in which new evidence continues to appear with a concomitant need to integrate it. With an efficient protocol in place, an organization can stagger guidelines under simultaneous development to result in a finished product every 8 months (depending on resources). The timeline in Table 1 has been developed to ensure rigor in development while promoting efficiency. The remainder of this manual describes the steps listed in Table 1 in terms of general concepts and specific suggestions based on prior experience.

Planning
Define Topic
Guidelines can be developed for a wide range of topics, including conditions (sinusitis, ear infections, sudden hearing loss), procedures (tonsillectomy, tympanostomy tubes), and signs or symptoms (cough, hoarseness). Topics selected for guideline development should be of high priority and feasible.

High-priority topics have the potential for evidence-based practice to improve health outcomes, minimize undesirable variations in care, and reduce the burden of disease and health disparities. The Institute of Medicine has identified the following priority-setting criteria as common to most international guideline development groups:

1. Disease burden. Extent of disability, morbidity, or mortality imposed by a condition, including effects on patients, families, communities, and society overall.
2. Controversy. Controversy or uncertainty around the topic and supporting data.
3. Cost. Economic cost associated with the condition, procedure, treatment, or technology related to the number of people needing care, unit cost of care, or indirect costs.
4. New evidence. New evidence with the potential to change conclusions from prior assessments.
5. Potential impact. Potential to improve health outcomes and quality of life; improve decision making for patient or provider.
6. Public or provider interest. Consumers, patients, clinicians, payers, and others want an assessment to inform decision making.
7. Variations in care. Potential to reduce unexplained variations in prevention, diagnosis, or treatment; the current use is outside the parameters of clinical evidence.

Feasible topics have a sufficient base of high-quality published evidence (ideally randomized, controlled trials) to drive guideline development, have 1 or more existing systematic reviews or meta-analyses already published on relevant issues, and have relatively clear definitions of the condition or procedure under consideration.

A steering committee that includes organizational leadership and broad stakeholder representation can help identify, prioritize, and refine guideline topics. Diversity of expertise and perspective helps minimize bias caused by conflicts of interests.

The AAO-HNSF convened the Guideline Development Task Force in 2006 as a steering committee for developing evidence-based guidelines and related knowledge products. The task force includes representatives of all subspecialty groups within otolaryngology and of all relevant internal Academy groups, including research, patient safety, quality improvement, board of governors, and evidence-based medicine. Topics are solicited with a standardized form, based on principles outlined above, then presented to the task force for ranking and prioritization.

Convene the Guideline Development Group
Perhaps the most important decision in creating a successful guideline relates to composition of the guideline development group (GDG). A group size of 12 to 18 members encourages diversity and efficiency yet is small enough to avoid delays and redundancy.

The group should consist of the (1) chair and 2 assistant chairs; (2) staff lead; (3) methodologist; (4) content experts; (5) stakeholders from all relevant disciplines, including nursing, primary care, and allied health; and (6) 2 consumer representatives. The roles, responsibilities, and considerations for identifying and appointing guideline development group members are outlined in the sections that follow.

Identify Organizational Leadership
A staff lead is assigned as the primary liaison for the group. Qualifications for staff lead include prior guideline development experience, familiarity with literature searches and using a citation database, and a basic understanding of study design, medical terminology, and levels of evidence.

Specific responsibilities of the staff lead include the following:

1. Conducting a preliminary search to assess topic feasibility
2. Identifying guideline group members by working with internal leadership and relevant external organizations
3. Scheduling and handling logistics for all conference calls and group meetings
4. Working with the chair to create agendas and pre-distribute supporting materials
5. Working with the information specialist (medical librarian or search strategist) to coordinate the systematic literature review(s)
6. Organizing literature search results and obtaining full-text articles
7. Appraising the guideline for implementability using predetermined methods
8. Identifying external peer reviewers and collating comments for distribution to the chair
9. Assisting the chair in developing and obtaining permissions for tables and figures
10. Proofreading the guideline final draft, including checks for grammar and spelling
11. Submitting a summary of key action statements and supporting action statement profiles for review and approval by the organizational board of directors
12. Assisting the chair in formatting the final document for publication submission
13. Obtaining copyright transfer and financial disclosure forms from working group members

A methodologist is assigned to ensure that the working group adheres to methodologic standards and protocols endorsed by the organization and to serve as a facilitator who supports the chair during conference calls and meetings. The methodologist should be fluent with guideline methodology, understand the process of systematic review, and have direct experience with prior guidelines developed by the organization.

Developing trustworthy clinical practice guidelines is not intuitive but is an acquired skill that is independent from clinical expertise and accomplishment. Whereas an explicit and comprehensive manual aids the process, it cannot substitute for hands-on experience. Organizational staff that support guideline development should gain expertise through educational programs offered by the Cochrane Colloquium, Guidelines International Network, and other relevant organizations or medical specialty societies.

**Identify Clinical Leadership**

A chair should be identified to lead the group in developing the guideline and to work with the methodologist and staff lead to ensure adherence to methodologic standards. The chair also facilitates the interpersonal aspects of the group processes, so the members work in a spirit of collaboration with balanced contribution from all members.

Specific responsibilities of the chair include the following:

1. Assisting the staff in planning conference calls and meetings
2. Steering discussions according to the agenda
3. Encouraging all members to contribute to discussions and activities of the group
4. Remaining aware and constantly attentive to small group processes, including how the group interacts, communicates, and makes decisions
5. Establishing a climate of trust and mutual respect among members while remaining sensitive to pre-existing interprofessional tensions and hierarchies
6. Maintaining a unified group discussion free of subconversations and dominance
7. Encouraging constructive debate without forcing agreement
8. Winding up repetitive debate and disagreements through careful negotiation
9. Summarizing main points and key decisions of a debate
10. Working with the assistant chairs and support staff to delegate writing assignments and to integrate completed assignments and group feedback into the draft guideline

The chair is appointed by a selection panel that includes organizational leadership, steering committee representation, the guideline staff lead, and the methodologist. An ideal chair should be efficient and motivated, have demonstrated leadership ability, have prior experience with evidence-based guideline development, have demonstrated skills in scientific writing, and be fluent with using the Internet, e-mail, and e-mail attachments. All candidates for chair are asked to declare any conflicts of interest prior to their appointment.

The chair is usually not a content expert for the guideline topic (to avoid excess concentration of power) but should be familiar with the scientific literature and management of the clinical condition. Content experts are usually abundant in an organization and can be readily added to the working group to fill in knowledge gaps. Conversely, the chair should be an impartial leader who stimulates discussion, not an advocate who injects his or her own opinions.

One or 2 assistant chairs should be identified who will be asked to chair the next guideline development effort. To maintain a pipeline of guideline projects, a continuing source of leadership for upcoming projects is needed. The best way to groom new chairs is to have them serve on 1 or 2 prior guideline groups to learn methodology and expectations early on. An ideal assistant chair should have experience with evidence-based medicine but does not necessarily need prior guideline development experience.

The chair is ultimately responsible for moving along the guideline process, keeping the group focused and...
task oriented, and encouraging balanced participation of all working group members. Having more than 1 chair is inadvisable because responsibilities can be easily shifted and diffused. Instead, the structure should include 1 chair and 1 or more assistant chairs, as noted above.

Identify Partner Organizations

Guideline development groups should include individuals from a range of relevant stakeholder groups to minimize bias. Multidisciplinary participation helps identify and evaluate all relevant evidence, builds support among the intended guideline users, and increases the chances of addressing practical problems related to implementation.12,27,28

Many guidelines warrant input from nursing, consumers, and primary care clinicians. Based on the target population and setting, the working group may include internists, pediatricians, geriatricians, family practitioners, and emergency medicine physicians. Additional specialty clinicians are recruited as dictated by the specific topic or condition under study. Allied health professions are similarly recruited and may include audiologists, physical therapists, speech-language pathologists, and others.

An excellent source of consumer participants for guideline development is Consumers United for Evidence-based Healthcare (CUE), a national coalition of health and consumer advocacy organizations, which empowers consumers through critical appraisal of articles, guidelines, and systematic reviews.29 CUE is a project of the US Cochrane Center and works closely with the Cochrane Consumer Network.

If another discipline is to be a full partner in developing the guideline, it is approached early to secure interest and cooperation. Alternatively, working group members can be selected to represent their “discipline,” not their “organization.” In this model, a pediatrician member of the working group would provide essential input for pediatrics as a discipline but would not necessarily represent the American Academy of Pediatrics or imply its specific endorsement of the resulting guideline.

Identify Guideline Development Group Members

In deciding what disciplines to include in guideline development, a useful approach is to ensure that every discipline or organization that would be involved with implementation, including consumers, has a voice at the table. This will nearly always include 1 or more primary care clinicians since invariably they will be involved in counseling the patient and coordinating care with the specialist (Table 4).

A consumer is broadly defined as a recipient of health care (in contrast to a provider) who provides a layperson perspective for the group. Consumers do not require direct experience with the guideline topic but instead serve as an advocate for patients, their proxies, and others potentially affected by the guideline. Consumers serving on a guideline development group can help12

- Improve transparency of process and offer some assurance that the guidelines were not developed to suit special interests
- Present guideline recommendations in ways that are understandable to patients and respectful of their needs
- Act as a safeguard against conflicts of interests

A single specialty group will reach different conclusions than a multidisciplinary group when presented with the same evidence.22 Individuals from a single discipline are often biased toward procedures in which they have a

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Chair</td>
<td>Pediatric otolaryngology, guideline methodology</td>
</tr>
<tr>
<td>2</td>
<td>Assistant chairs</td>
<td>Otolaryngology and pediatric otolaryngology</td>
</tr>
<tr>
<td>1</td>
<td>Methodology consultant</td>
<td>Guideline methodology, neurotology</td>
</tr>
<tr>
<td>1</td>
<td>Staff liaison</td>
<td>Guideline logistics and support</td>
</tr>
<tr>
<td>3</td>
<td>Liaisons</td>
<td>Otolaryngology representing neurotology, AAO-HNS Board of Governors, and AAO-HNS Board of Directors</td>
</tr>
<tr>
<td>3</td>
<td>Primary care clinicians</td>
<td>Pediatrics, developmental pediatrics, family practice</td>
</tr>
<tr>
<td>2</td>
<td>Nonphysician practitioners</td>
<td>Nurse practitioner, physician assistant</td>
</tr>
<tr>
<td>2</td>
<td>Allied health professionals</td>
<td>Audiology, speech and language pathology</td>
</tr>
<tr>
<td>2</td>
<td>Consumer advocates</td>
<td>Consumer advocacy</td>
</tr>
<tr>
<td>1</td>
<td>Resident physician</td>
<td>Otolaryngology</td>
</tr>
</tbody>
</table>

vested interest. Involving multiple disciplines tends to balance bias and produce more valid guidelines.

Potential members of the guideline development group can be identified by organizational leadership, partner organizations, the working group chair, and the staff liaisons. An understanding of evidence-based medicine is desirable. Individuals are invited as representatives of their field or discipline but need not be content experts for the guideline topic. Content experts should be a minority voice on the working group to limit bias.

Specific responsibilities of the guideline development group members include the following:

1. Disclosing fully any potential conflicts of interest
2. Participating in all conference calls
3. Attending all meetings with a commitment to teamwork and clear communication
4. Reading all relevant materials and providing constructive comments and feedback during and between meetings
5. Checking and responding to e-mails on a regular basis
6. Completing personal assignments to meet deadlines
7. Maintaining confidentiality
8. Communicating regularly with their sponsoring group, society, or organization to keep them informed of guideline development and to identify any concerns

Guideline development is not a spectator sport; producing a guideline requires substantial time and effort, which often tends to be underestimated by group members when they sign on. All members have a responsibility to other participants to behave with integrity, commitment, and a fully professional demeanor. One way to ensure commitment is to identify dates and times for all conference calls and in-person meetings in advance and to only accept candidates who agree to full participation.

Despite the upfront commitment of all guideline development group members to participate fully in guideline development, conflicts or unexpected circumstances may arise that threaten validity if an important discipline is not well represented. Therefore, certain disciplines, which include primary care and selected others depending on the topic, should be represented by 2 group members to ensure representation.

To facilitate guideline dissemination and to ensure broad input that represents the needs of members belonging to the organization or society that develops the guidance, we recommend that key leaders of the sponsoring organization be part of the guideline development group. There is no need for these leaders to be content experts on the guideline topic; rather, they serve as a communication bridge by becoming immersed in the process, methodology, and multidisciplinary discussions that underpin the final document. The AAO-HNS requests that the following key leaders be members of the guideline development group, based on availability:

- AAO-HNS president or president-elect
- Board of governors (BOG) chair or chair-elect
- Subspecialty Advisory Council (SSAC) chair or chair-elect

A member of the AAO-HNS Section for Residents and Fellows is also invited to participate, as an educational exercise and to familiarize himself or herself with evidence-based medicine and guideline development methodology (Table 4). Relevant AAO-HNS Education & Scientific committees, including the Centralized Otolaryngology Research Effort, are asked to nominate a member to assist with the guideline’s implementation efforts and to aid the alignment of Academy educational products with the guideline’s key action statements.

The importance of having content experts constitute only a minority of the guideline development group deserves additional emphasis. Content experts are needed to put evidence in context, but having too many can bias discussions and inhibit participation by other group members. All group members are “experts” in representing their specific discipline, including consumers who are experts in advocating for the public, patients, and their proxies. A primary responsibility of the chair is to ensure that all voices are heard and that no single voice or discipline dominates during meetings and conference calls.

Compile Contact Information Grid

The staff lead should compile a grid of contact information for all guideline development group members and organizational representatives. Included in the grid should be (1) name and degrees, (2) expertise or role, (3) organizational affiliation, (4) clinical and academic titles, (5) mailing address, (6) disclosed conflicts of interests, and (7) contact information.

Conflict of Interest Disclosure

Conflict of interest (COI) may be defined as a “set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.” Conflict of interest is an important potential source of bias when developing guidelines because it frequently results in overestimating benefit...
and underestimating harm. There is a high prevalence of nondisclosure of COI among guideline authors (development group members) and a high prevalence of COI among authors who do disclose.30,31

Despite good intentions, it is not appropriate for individuals to self-judge if a particular relationship causes conflict; their role is to declare, not interpret. The group as a whole must ultimately determine if a conflict may result in bias and whether or not the degree of conflict excludes the individual from participating in the entire guideline or selected sections.

Financial relationships are most easily identified and may relate to commercial or noncommercial interests. Examples of direct commercial COIs include employment, consultancies, stock ownership, honoraria, gifts, paid expert testimony, patents or patent applications, and industry-sponsored research or travel for the participant or family members. Noncommercial COIs include research grants and support from governments, foundations, or nonprofit organizations.

Intellectual COI occurs when a person, or professional group, is jeopardized or enhanced by a guideline recommendation. Guyatt and colleagues32 define intellectual COI as “academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual’s judgment about a specific recommendation.” Such conflicts are increasingly recognized and may be powerful motivators for researchers, systematic reviewers, and guideline authors.30 Examples of nonfinancial conflicts of interest include the following12,33:

- Research, publications, or grant support related to the guideline
- Publishing commentaries or correspondence related to the guideline
- Having personal convictions (political, religious, ideological, or other) related to the topic that may interfere with an unbiased writing and publication process
- Being a chair or member of another guideline committee relevant to the topic
- Membership in a related lobbying or advocacy organization
- Leadership or close involvement in an advocacy group that stands to gain from a guideline development group member’s opinion
- Acting as an expert witness or having membership in a governing or advisory board with other organizations or funding bodies
- Family members with the target condition

The AAO-HNSF explicitly describes its COI policy for clinical practice guidelines in its Code for Interaction with Companies.34 Key points are (a) prohibiting direct company support for guideline development, printing, or publication; (b) disclosing all potential COIs of guideline development group members; (c) requiring that a majority of guideline development group members be free of financial COIs; (d) requiring that the chair must be free of financial COIs during guideline development and for 1 year after publication; and (e) disclosing all potential COIs of expert reviewers or advisers who are not officially part of the development group.

Managing COI begins by distributing the completed contact and disclosure list to all guideline development group members for verification. All declared conflicts—financial and intellectual—are discussed with the group and published with the guideline. Serious or irreconcilable conflicts may result in dismissal of an individual from the development group. For each key action statement (recommendation), the group must decide if a member’s COI requires him or her to be excluded from voting, recused from discussion related to that statement, or both. The COI disclosures should be reviewed and updated, as needed, during each conference call, at each in-person meeting, and prior to publication.

**Determine Dates for Conference Calls and Meetings**

Adhering to a predetermined, specific timeline allows publication of the guideline within 14 months. Arranging dates for conference calls and meetings is particularly difficult when dealing with individuals representing multiple organizations and disciplines. Therefore, it is critical to plan early in the process. Ideally, this should occur before guideline development. Group members are invited to participate, with participation contingent on availability for all calls and in-person meetings. Events are planned using the timetable in **Table 1**:

- Conference call 1 takes place in month 3
- Conference call 2 takes place about 4 weeks later, in month 4
- In-person meeting 1 takes place about 4 weeks later, in month 5
- In-person meeting 2 takes place about 6 to 8 weeks later, in month 7

We have found that conference calls are often most feasible if planned to start at 8:00 pm Eastern Standard Time. Calls should be generally scheduled for 2 hours. In-person meetings can begin at noon with a light working lunch to allow attendees to fly in the same morning. Similarly, they can end by 2:00 pm the following day to allow a return flight the same day. A group dinner should be planned the first day. A convenient schedule is to begin on either Friday or Sunday and end the next day.

The importance of having all guideline development group members participate in all conference calls and attend all meetings cannot be overemphasized.
Advance planning is the best guarantee of success, since maximal time is available for group members to adjust their schedules as needed and block out event dates in their calendars. If a group member cannot make this commitment, an alternate should be found as soon as possible.

Identifying Evidence

Purpose

The validity of an evidence-based guideline depends in large part on an unbiased and systematic literature review. The goal is to locate the best evidence from all relevant sources, producing a comprehensive body of evidence that will allow clinical questions to be answered and highlight gaps in the evidence base where formal consensus methods may be needed.

The Role of Evidence in Guideline Development

Although identifying evidence is essential for guideline development, we suggest the proper role is as supporting cast, not protagonist:

- **Evidence as protagonist model.** Some organizations publish “practice parameters” or “evidence-based reviews” as their primary quality products, having the literature search take center stage, with exhaustive evidence tables or textual discussions that rank and summarize citations. If recommendations are made, the strength is linked directly to level of evidence, sometimes with a threshold number of minimum studies of a specific level or combinations thereof, rather than an explicit consideration of benefits, risks, harms, and costs. Recommendations have uncertain validity because there is no systematic process to incorporate costs, harms, adverse events, uncertainty, vagueness, working group values, or patient preference. Moreover, recommendations become difficult to make when evidence gaps exist.

- **Evidence as supporting cast model.** An alternative approach, described in this manual, is to drive guideline development with considerations of quality improvement, using the literature search as one of several factors that help translate evidence into action. In this model, the ratio of benefits to harms and costs is considered equal to, or even greater than, level of evidence in formulating recommendations. Action statement profiles are used to state explicitly how values, patient preferences, differences of opinion, and other factors were incorporated. Recommendations are still possible with evidence gaps, but strength will be limited.

Although it is tempting to exclude topics with limited evidence from guideline development, it is precisely such topics that may benefit users most because of uncertainty and conflicting opinions about appropriate practice. Even if evidence is limited, recommendations are still possible based on observational studies when benefits and harms are identified and lower evidence quality is transparently documented along with our confidence in it.

Using expert opinion or consensus to fill evidence gaps is entirely appropriate, provided this basis is explicit and transparent to the critical reader. Discussing topics with limited evidence allows guideline developers to highlight future research needs and suggest how to best fill existing gaps. The guideline as a whole, however, should focus on topics with high-quality evidence and avoid overreliance on expert opinion or clinical consensus as a primary decision-making strategy.

Literature Search Stages

Searching the literature is an iterative process that is best implemented in 3 stages. The stages correspond to different phases of guideline development and are discussed later in this manual. The 3 stages of searching (Table 1) can be briefly summarized as follows:

1. Identifying systematic reviews and clinical practice guidelines, performed before the first conference call
2. Identifying randomized controlled trials, performed before the second conference call
3. Identifying supplementary literature, performed after the first in-person meeting

All search stages must be documented for transparency and reproducibility. Specific considerations include databases, time periods, keywords, subject headings, language restrictions, use of gray literature (eg, symposium proceedings), and selection criteria, such as filters, algorithms, or inclusion and exclusion criteria. A balance of pragmatism and rigor is required to avoid delays in the development process.

Evidence Quality Assessment

Simply identifying reviews, guidelines, and randomized trials does not ensure quality, and basing decisions on research with weak design or flawed methodology may yield biased or invalid conclusions. Therefore, to filter out potentially biased or poorly conducted studies, quality assessment must be performed as part of the process of...
identifying evidence. Suggestions for assessing reviews, guidelines, and randomized trials are presented later in the manual when the related search stage is discussed.

**Performing Systematic Review and Meta-analysis**

An organization may find it necessary to perform a systematic review as part of guideline development if there are no published reviews or if available reviews are outdated or of poor quality. Systematic review is a rigorous and complex undertaking, which often requires additional expertise, resources, and staff support.

All systematic reviews should be conducted using a priori protocols that adhere to standards for the conduct and reporting of meta-analyses, as suggested in the PRISMA statement for randomized trials and the MOOSE statement for observational studies. The Institute of Medicine has also defined rigorous quality standards for systematic reviews. Systematic reviews can be used to define natural history using placebo group outcomes and the absolute or comparative efficacy of interventions.

Guideline developers may use systematic reviews that have been previously published or performed concurrently. The most important consideration is that regardless of the review origin, it should be of high quality and meet reasonable standards for systematic reviews. Concurrent reviews may be performed by members of the guideline development group (with appropriate expertise) or by an external group or agency. When reviews are conducted specifically to inform particular guidelines, the guideline development group and systematic review team should interact regarding the scope, approach, and output of both processes.

**Key Points to Remember**

1. Identifying evidence involves a 3-stage literature search, with different stages occurring at different times in the development process.
2. The literature search supports guideline development, not vice versa.
3. All aspects of searching must be documented for transparency and reproducibility.
4. Constant vigilance is required to balance rigor vs pragmatism so that guideline development is not stalled or delayed because of overly complex search strategies.

**Stage 1 Literature Search**

**Purpose**

The stage 1 search establishes an evidence foundation for the first guideline development group conference call by identifying existing systematic reviews and practice guidelines related to the current topic. This provides an important perspective on what has already been accomplished, what areas of controversy exist, how robust the evidence base is to support guideline development, and where the greatest opportunities lie for improving upon the existing knowledge base.

The stage 1 search is conducted by an information specialist and coordinated by the staff lead prior to the first conference call. Search parameters are developed by the chair, assistant chair(s), and the methodology consultant with input from the information specialist. The search strategy and parameters are thoroughly documented and published with the guideline. Search results are reviewed by the chair and assistant chairs to eliminate irrelevant items. A summary grid is compiled, and full-text files are obtained for distribution to the development group.

**Identifying Systematic Reviews**

Systematic reviews will greatly facilitate guideline development because they identify and synthesize evidence in a format that is readily usable by the working group. Systematic reviews and meta-analyses are found by:

- Identifying Cochrane Reviews and Protocols via the Cochrane Collaboration website (www.cochrane.org) and by searching the Cochrane Database of Abstracts of Reviews of Effects (DARE)
- Locating evidence reports sponsored by the Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov), which are often developed to support guideline development and may contain useful evidence tables, systematic reviews, and meta-analyses
- Searching standard databases—MEDLINE, EMBASE, and Cumulative Index to Nursing and Allied Health Literature (CINAHL)—using systematic review or meta-analysis as a publication type or text word in the title or abstract
- Using search filters of known validity for identifying systematic reviews
- Searching clinical evidence available from the BMJ publishing group (www.clinicalevidence.bmj.com)

Guideline statements should ideally be based on systematic reviews of randomized trials, but for many subspecialty or surgical topics, randomized trials are sparse (or nonexistent), and reviews may be “empty” or absent. In the absence of systematic reviews, the search for supporting evidence should itself be systematic—conducted and documented by an information specialist—with any statements adjusted to account for level of confidence (or certainty) that the group assigns.

**Identifying Clinical Practice Guidelines**

Clinical practice guidelines may already exist for the topic under consideration but do not preclude further guideline development. Existing guidelines may be outdated or may not have been developed with the methodologic rigor or...
relevancy that is currently sought. These documents, however, are a useful starting point for group discussions. Clinical practice guidelines can be identified by

- Searching the National Guidelines Clearinghouse (www.guideline.gov), an initiative of AHRQ that serves as a public resource for evidence-based guidelines
- Searching the database maintained by the Guidelines International Network (www.g-i-n.net), which includes guidelines, evidence reports, and systematic reviews
- Searching standard electronic databases for guideline or practice parameter as a text word in the title or abstract

Assessing Quality

Systematic reviews published by the Cochrane Collaboration or government agencies (AHRQ) are typically of high methodologic quality and may not require further assessment. Conversely, reviews authored by individuals or other organizations are highly variable in rigor and quality. Minimum quality criteria for systematic reviews might include (a) clear objective and methods defined explicitly by the reviewers, (b) an explicit search strategy described with full details (dates, databases, search terms, language restrictions, and criteria for including articles), and (c) valid data extraction, usually performed by at least 2 independent investigators, to abstract data and descriptive information from the source articles to minimize bias.

Clinical practice guidelines are highly variable in quality regardless of origin. Minimum quality criteria might include (a) explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) explicit system for ranking evidence, and (e) explicit system for linking evidence to recommendations.

Conference Call 1: Defining Scope

Purpose

The first conference call (Table 1) sets the stage for guideline development by introducing working group members, defining the guideline timeline and scope, discussing and managing conflicts of interest, and planning for the stage 2 literature search. The call is planned to last 2 hours and may be recorded for future reference.

The staff lead records minutes of the call, for dissemination and review by the group after the call concludes. The main purpose is to document process, workflow, and decisions made, thereby avoiding the discussion of settled controversies. The group chair takes additional notes during the call to record ideas, concepts, definitions, and key phrases that may later prove difficult to reproduce or remember.

Predistribute Electronic Materials

Documents should be distributed by e-mail prior to the conference call for review by participants. In addition, it is recommended that all materials distributed to the guideline development group be stored in the cloud (Internet) for future reference. Many online services are now freely available for online collaboration and storage. Materials specific to the guideline that should be distributed include

- Agenda for the conference call
- Working group contact information grid with conflict of interest disclosures
- Summary grid of relevant systematic reviews and guidelines identified in the stage 1 literature search
- Relevant sections of the guideline development manual

General materials that should be distributed include

- A copy of 1 or more recently published guidelines from the sponsoring organization4-11 to serve as a model of how the finished product will look (all previously published AAO-HNSF guidelines are available at www.entnet.org/guidelines)
- Reporting checklist from the COGS20
- Articles by Norris and colleagues30 and by Choudhry and coworkers42 about conflict of interest disclosure and its relevance to guideline developers

Review Contact Information, Titles, and Organizations

Group members should review contact information and titles for accuracy. Group members should briefly introduce themselves, including their areas of expertise and experience in developing prior guidelines and their role in the workgroup. Any conflicts of interest are declared, elaborated upon, and vetted by the group. The need for any additional group members should be discussed, taking care to be sure that all relevant disciplines are adequately represented.

Introduce Purpose, Methodology, and Timeline

The purpose of sponsoring organization(s) in developing the guideline should be specified and can be revised and updated as development proceeds. The purpose can often be divided into 2 distinct but related components:

1. Objective (ie, general) goals that implementation of the guideline are intended to bring about
2. Rationale, that is, reasons for developing recommendations, including why the guideline is needed (eg, evidence of practice variation or inappropriate practice)

Here is an example of how the purpose was stated in the AAO-HNSF guideline on tonsillectomy in children: “The primary purpose of this guideline is to provide clinicians with evidence-based guidance in identifying children who are the best candidates for tonsillectomy. Secondary objectives are to optimize the perioperative management of children undergoing tonsillectomy, emphasize the need for
evaluation and intervention in special populations, improve counseling and education of families of children who are considering tonsillectomy for their child, highlight the management options for patients with modifying factors, and reduce inappropriate or unnecessary variations in care."9

As another example, consider this statement of purpose from the AAO-HNSF guideline on sudden hearing loss: “The purpose of this guideline is to provide clinicians with evidence-based recommendations in evaluating patients with sudden hearing loss (SHL), with a particular emphasis on managing sudden sensorineural hearing loss (SSNHL). The panel recognized that patients enter the healthcare system with SHL as a nonspecific, primary complaint. Therefore, the initial recommendations of the guideline deal with efficiently distinguishing SSNHL from other causes of SHL at the time of presentation. By focusing on opportunities for quality improvement, the guideline should improve diagnostic accuracy, facilitate prompt intervention, decrease variations in management, reduce unnecessary tests and imaging procedures, and improve hearing and rehabilitative outcomes for affected patients.”11

After the guideline purpose has been discussed, the consultant provides a very brief overview of development methodology. Points worthy of emphasis include the following:

- The guideline will be developed using an explicit, evidence-based process that is consistent with current standards for trustworthy guidelines and follows a published, a priori protocol.
- The published guideline will meet or exceed reporting standards defined by the COGS statement and AGREE instrument.19,20
- The process will involve 3 conference calls and 2 in-person meetings.
- The goal is to produce a document with key action statements for clinicians, highlighting the key areas of behavior change and quality improvement defined by the guideline development group that address the stated purpose.
- The guideline will incorporate about 10 to 18 key action statements, each of which is followed by a summary action statement profile and supporting text on why the statement is made and how the recommendation may be carried out. Each key action statement will have an associated strength of recommendation based on the quality and consistency of supporting evidence plus a consideration of the benefit-harm relationship for any interventions.
- The document will conclude with implementation considerations and recommendations for future research. In addition, a reference will be made as to when the guideline will be updated in the future.

Discuss Conflicts of Interest

According to the guideline, group members are directed to the contact list, which was prepared by the staff lead in advance of the call and includes potential financial and intellectual COIs that have been declared by the development group. The group will then decide if any particular relationships are significant enough to preclude participation of any individual(s) from further service in the guideline development group. Relationships should be thoroughly documented and included in the guideline manuscript.

Since more than 80% of guideline authors, in general, have potential COIs, the existence of a relationship alone is not sufficient to preclude participation.42 At the AAO-HNSF, they are excluded only if the nature of the relationship is considered by the group to interfere with objective participation. On the basis of the nature of the disclosed relationship, a member may be asked to not participate in a specific section of the guideline where a conflict may produce bias.

Determine Guideline Scope

A well-crafted guideline has a clearly defined scope. Defining scope will occupy most of the first conference call and may require a second for completion. Inexperienced guideline developers attempt to cover all aspects of a condition, resulting in a broad scope that will stall development efforts. The key to progress is a razor-sharp focus from the start, recognizing that some issues important to some stakeholders will inevitably be left out.

Clinicians may have trouble embracing the concept of a focused guideline with restricted scope and a limited number of recommendations. Instead, the desire will be to include a broad range of topics, similar to what appears in a traditional review article or book chapter. Topics deemed important by the group, but not accommodated in the guideline action statements, may still be discussed in the supporting text or in an appendix, provided it is clearly identified as based on consensus or expert opinion.

An example of a clearly defined scope appears in the AAO-HNSF guideline on polysomnography for sleep-disordered breathing prior to tonsillectomy in children: “The guideline is intended to focus on a limited number of quality improvement opportunities, deemed most important by the working group, and is not intended to be a comprehensive, general guide for prescribing polysomnography for
Tonsillectomy candidates and patients with sleep-disordered breathing. In this context, the purpose is to define actions that could be taken by otolaryngologists to deliver quality care. Conversely, statements in this guideline are not intended to limit or restrict care provided by clinicians based on assessment of individual patients.”  

**Define target condition or procedure.** The group should identify the conditions, procedures, or signs or symptoms for which the guideline is intended. This may be a single condition or a list of potential target conditions, which could later be condensed into those that can be realistically examined by the group within its allotted time. A guideline can be procedure based instead of disease oriented. For example, the emphasis can be on “tonsillectomy” as a procedure instead of tonsillitis as an acute or chronic condition, or sore throat as a symptom.

Any diseases or procedures should be explicitly defined by the group. Definitions derived from publications on the topic can be used, if available, but a multidisciplinary group can often improve upon definitions advanced by an individual or single discipline. This is a particularly valuable contribution when existing definitions are controversial or unclear.

The definition of the target or procedure should be clear and concise (Table 5). The definition, however, should be distinguished from diagnostic criteria, which are typically specified later in the guideline and have more precise and detailed information to guide clinicians.

**Define target patient or clinical presentations.** The guideline development group should specify the type of patient for whom the guideline is intended as precisely as possible. The target patient can be specified in terms of demographics, presenting signs and symptoms, past health history, results of previous diagnostic tests, or similar criteria.

Equally important as defining the target patient is defining clearly the types of patients or clinical presentations that are beyond the scope of the group’s analysis. One or more exclusion criteria should generally accompany the definition. For example, consider this definition from the AAO-HNSF guideline on tonsillectomy in children:

**Table 5. Sample Definitions from Clinical Practice Guidelines**

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>Tonsillectomy guideline⁹</td>
<td>Tonsillectomy is defined as a surgical procedure performed with or without adenoidectomy that completely removes the tonsil, including its capsule, by dissecting the peritonsillar space between the tonsil capsule and the muscular wall. Depending on the context in which it is used, it may indicate tonsillectomy with adenoidectomy, especially in relation to sleep-disordered breathing.</td>
</tr>
<tr>
<td>Sudden hearing loss guideline¹¹</td>
<td>Sudden hearing loss is defined as a rapid onset, occurring over a 72-hour period, of a subjective sensation of hearing impairment in 1 or both ears.</td>
</tr>
<tr>
<td>Benign paroxysmal positional vertigo guideline⁷</td>
<td>Positional vertigo is defined as a spinning sensation produced by changes in head position relative to gravity. Benign paroxysmal positional vertigo is defined as a disorder of the inner ear characterized by repeated episodes of positional vertigo.</td>
</tr>
<tr>
<td>Cerumen impaction guideline⁶</td>
<td>Cerumen impaction is defined as an accumulation of cerumen that causes symptoms, prevents a needed assessment of the ear canal/tympanic membrane or audiovestibular system, or both. Although “impaction” usually implies that cerumen is lodged, wedged, or firmly packed in the ear canal, our definition of cerumen impaction does not require a complete obstruction.</td>
</tr>
<tr>
<td>Adult sinusitis guideline⁵</td>
<td>Rhinosinusitis is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. The term <em>rhinosinusitis</em> is preferred because sinusitis is almost always accompanied by inflammation of the contiguous nasal mucosa. Rhinosinusitis may be further classified by duration as acute (less than 4 weeks), subacute (4-12 weeks), or chronic (more than 12 weeks with or without acute exacerbations).</td>
</tr>
</tbody>
</table>

Time spent explicitly defining the target condition or procedure may be viewed as unnecessary by some group members, with statements like “everyone knows already what is meant by ‘tonsillectomy’ (or some other topic).” A few minutes of discussion, however, will invariably show a range of opinions and definitions and, it is hoped, will justify why time must be spent on this important exercise.
surgery, or other partial removal techniques of the tonsil because of the relatively sparse high-quality published evidence on these techniques and limited long-term follow-up. Similarly, the guideline does not apply to populations of children excluded from most tonsillectomy research studies, including those with diabetes mellitus, cardiopulmonary disease, craniofacial disorders, congenital anomalies of the head and neck region, sickle cell disease, and other coagulopathies or immunodeficiency disorders.

Here is another example of target patient definition from the AAO-HNSF guideline on cerumen impaction:

The target patient for this guideline is over 6 months of age with a clinical diagnosis of cerumen impaction. The guideline does not apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratitis obtraniis; prior radiation therapy affecting the ear; previous tympanoplastomy/myringoplasty or canal wall down mastoidectomy. However, the guideline will discuss the relevance of these conditions in cerumen management. The following modifying factors are not the primary focus of the guideline, but will be discussed relative to their impact on management: non-intact tympanic membrane (perforation or tympanostomy tube); ear canal stenosis; exostoses; diabetes mellitus; immunocompromised state; or anticoagulant therapy.

Define the intended audience and practice settings. The decision about the intended users of the guideline needs to be made early in the process since it influences decisions about the interventions that will be considered and the audiences to which the language in the final product and specific implementation suggestions will be directed. Ideally, a representative of each target audience group or organization should be included in the guideline development group. Stakeholder representatives should also be involved in reviewing and pretesting the document.

Practice settings should also be defined since a guideline may be applicable only in selected settings (eg, rural, primary care, hospital emergency room, operating room, managed care, specific geographic regions). The working group should identify those settings in which using the guideline would be appropriate as well as settings where it should not be applied.

Here is an example of how practice setting was defined in the AAO-HNSF otitis media with effusion guideline: "The guideline is intended for use by providers of health care to children, including primary care and specialist physicians, nurses and nurse practitioners, physician assistants, audiologists, speech-language pathologists, and child development specialists. The guideline is applicable to any setting in which children with otitis media with effusion would be identified, monitored, or managed."

As another example, consider the definition used in the guideline on polysomnography: "The target audience is otorhinolaryngologists in any practice setting where a child would be evaluated. Although the guidance was developed with input from other specialties, the intent is to provide guidance specifically for otorhinolaryngologists—head and neck surgeons."

Identify interventions to consider and exclude. The group should generate a list of the clinical interventions (treatments, diagnostic tests, preventive measures) that will be considered in developing the guideline. All interventions potentially relevant to the topic should be included, with the intent of being overly comprehensive. A sample list developed for use in a sinusitis guideline is shown in Table 6.

A similar list of exclusions should be generated. For example, some groups may be reluctant to evaluate drugs, procedures, or other interventions that have only recently been introduced into practice and have limited experience regarding long-term benefits and harms. Other groups may find these relevant. Any exclusions should be specifically noted in the list of interventions considered (Table 6).

Identify outcomes to consider. Outcomes should be selected prospectively that limit scope and provide measures against which to evaluate the effectiveness of the recommendation’s limit.

- Health status outcomes are direct measures of physical morbidity, emotional well-being, mortality, or some other health-related construct. Examples include audiometric hearing levels or survival rates for head and neck cancer (eg, 2-year, 5-year, and 10-year rates).
- Functional health status measures reflect how a person functions physically, emotionally, and socially, with or without aid from the health care system. There are many general- and disease-specific surveys available to assess this construct.
- Quality-of-life measures reflect how a person perceives his or her functional health status. Like patient satisfaction, this is an inherently subjective construct that can be measured with surveys.

Other measures to consider include cost, quality, and utilization. Often the outcome of interest is related only tenuously to the proposed interventions. In such cases, proxy indicators of outcome or process may be selected.
Here is an example of outcome definition from the AAO-HNSF acute otitis externa guideline: “The primary outcome considered in this guideline is clinical resolution of acute otitis externa. Additional outcomes considered include minimizing the use of ineffective treatments; eradicating pathogens; minimizing recurrence, cost, complications and adverse events; maximizing the health-related quality of life of individuals afflicted with acute otitis externa; increasing patient satisfaction; and permitting the continued use of necessary hearing aids.”

As another example, consider the definition from the cerumen impaction guideline: “The primary outcome considered in this guideline is resolution or change in the signs and symptoms associated with cerumen impaction. Secondary outcomes include complications or adverse events. Cost, adherence to therapy, quality of life, return to work or activity, return physician visits, and effect on co-morbid conditions (e.g., sensorineural hearing loss, conductive hearing loss) were also considered.”

Define Parameters for the Stage 2 Literature Search

The stage 2 literature search, described in the next section, identifies randomized controlled trials. During the first conference call, the parameters of the literature search conducted by the information specialist are discussed and defined.

- The group should define any constraints on the initial literature search: published vs unpublished data, language restrictions (e.g., English language only), time periods (e.g., 1980 or later), or age groups (e.g., adults, children, or both).
- The group should discuss keywords for the search. If systematic reviews are already published (or in process at Cochrane), the search strategies used are reviewed for relevance to the current project. Suggestions for MeSH (medical subject heading) terms or other search keywords are solicited.
- The group should discuss strategies for randomized controlled trials that will be combined with the keywords to identify evidence.
- The group should discuss bibliographic sources that will be used for the search, including the role of gray literature (e.g., symposium proceedings).

Table 6. Sample List of Interventions Considered in Guideline Development for Sinusitis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
<th>Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targeted history</td>
<td>Watchful waiting/observation</td>
<td>Topical steroids</td>
</tr>
<tr>
<td>Physical examination</td>
<td>Education/information</td>
<td>Immuno therapy</td>
</tr>
<tr>
<td>Anterior rhinoscopy</td>
<td>Systemic antibiotics</td>
<td>Nasal lavage</td>
</tr>
<tr>
<td>Transillumination</td>
<td>Topical antibiotics</td>
<td>Smoking cessation</td>
</tr>
<tr>
<td>Nasal endoscopy</td>
<td>Oral/topical steroids</td>
<td>Hygiene</td>
</tr>
<tr>
<td>Nasal swabs</td>
<td>Systemic/topical decongestants</td>
<td>Education</td>
</tr>
<tr>
<td>Antral puncture</td>
<td>Antihistamines</td>
<td>Pneumococcal vaccination</td>
</tr>
<tr>
<td>Culture of nasal cavity, middle meatus, or other site</td>
<td>Mucolytics</td>
<td>Influenza vaccination</td>
</tr>
<tr>
<td>Imaging procedures</td>
<td>Leukotriene modifiers</td>
<td>Environmental controls</td>
</tr>
<tr>
<td>Blood tests: complete blood count, others</td>
<td>Nasal saline</td>
<td></td>
</tr>
<tr>
<td>Allergy evaluation and testing</td>
<td>Analgesics</td>
<td></td>
</tr>
<tr>
<td>Immune function testing</td>
<td>Complementary and alternative medicine</td>
<td></td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>Postural drainage/heat</td>
<td></td>
</tr>
<tr>
<td>Pulmonary function tests</td>
<td>Biopsy (excluded from guideline)</td>
<td></td>
</tr>
<tr>
<td>Mucociliary dysfunction tests</td>
<td>Sinus surgery (excluded from guideline)</td>
<td></td>
</tr>
</tbody>
</table>

*Adapted from Rosenfeld et al.*

Working Group Assignments and Deadlines

At the end of the call, the group reviews specific assignments or requests for additional information made during the call. Deadlines are assigned for completing the assignment, emphasizing the importance of responding within the time frame specified.

After the call, the staff leads forwards notes and minutes to the chair for review and clarification. The revised minutes are distributed to the group for review and feedback. The definitions, scope, and purpose are further refined by email exchange before the next conference call.

Key Points to Remember

1. The stage 1 literature search for systematic reviews and clinical practice guidelines must be performed, assessed by the chair and assistant chairs for relevance and quality, and compiled into a summary grid before the call.
2. Most of the call will be spent defining the target condition or procedure using clear, concise language that can be readily understood by all readers.
3. A sharply defined purpose and scope for the guideline will facilitate future efforts.
4. A comprehensive list of interventions and outcomes to include and exclude, with input from all guideline development group members, will facilitate topic proposal during conference call 2.
5. Emphasis is placed on broad concepts and group consensus; details and specifics are filled in after the call via e-mail exchange.

Stage 2 Literature Search

Purpose

The second step in identifying evidence is to assess the quantity and scope of randomized controlled trials (RCTs) available to support guideline development. Recommendations for therapy are strongest when supported by RCTs or systematic reviews of RCTs, and a paucity—or surplus—of quality studies may affect group decisions.

The stage 2 search should be coordinated by the information specialist, with support from the staff lead, before the second working group conference call using parameters defined by the working group during the first conference call. Search results are reviewed by the chair and assistant chairs to eliminate irrelevant items. Remaining RCTs are organized by broad subject headings to facilitate group discussion and reference. A summary grid is compiled and distributed to the working group. The grid is most useful if some brief, descriptive information is included for each trial, such as sample size, blinding (open, single, or double), and industry funding (no or yes).

High-quality studies to support recommendations about prevalence, prognosis, or diagnostic testing are usually not RCTs and will not be identified in the stage 1 or 2 searches (unless a systematic review has been published). Evidence to support these types of recommendations is identified in the stage 3 searches that are conducted after the first conference call.

Assessing Quality

Randomized controlled trials are highly variable in methodology and validity. A simple and efficient scale (Jadad scale) can be used to rank quality from 1 (poor) to 5 (excellent) based on (a) method and adequacy of randomization, (b) method and adequacy of masking, and (c) reporting of withdrawals and dropouts. A similar quality scale is available for randomized trials included in systematic reviews.

An alternative to quality assessment is to determine the risk of bias. There is low correlation between risk of bias overall and quality scores (eg, Jadad), but risk of bias assessment better differentiates effect size estimates, with more conservative estimates for studies at low risk. The most popular risk of bias tool, developed by the Cochrane Collaboration, assesses (a) random sequence generation, (b) allocation concealment, (c) blinding of participants and personnel, (d) blinding of outcome assessment, (e) incomplete data, (f) selective reporting, and (g) other bias.

Table 1

| Randomized controlled trial as a publication type, or |
| randomized, placebo, or randomly in the abstract, or |
| clinical trials as topic as a MeSH term, or |
| trial in the title, and |
| restricts the final set (1 or 2 or 3 or 4) by excluding animals as a MeSH term |

Conference Call 2: Identifying Topics

Purpose

The primary purpose of the second conference call (Table 1) is to refine and polish the concepts developed in the first call, particularly the scope and definition(s). The interval between the first and second conference calls should be kept short, ideally about 4 weeks, to facilitate recall and sustain momentum.

The stage 2 literature search is now available and will help identify errors, omissions, and exclusions in the earlier discussion. The call ends with a discussion of quality improvement opportunities that are used to form a preliminary topic list, which will be further refined and prioritized.
by electronic mail exchange after the call. The call is planned to last 2 hours and may be recorded.

**Predistribute Electronic Materials**

Documents should be distributed by e-mail and stored electronically prior to the conference call for review by participants before the call. Materials for predistribution include the following:

- Agenda for the conference call
- Updated working group contact information grid with conflict of interest disclosures
- Results of the stage 2 literature search for randomized controlled trials
- Minutes of the first call, updated to include postcall assignments and e-mail exchanges
- Relevant sections of the guideline development manual
- Any other information on content or methodology identified by working group members that would be helpful in educating the group or stimulating discussion

**Review First Conference Call and Timeline**

Minutes from the first conference call are reviewed, with emphasis on the guideline purpose, scope, and definitions. Feedback is also solicited on the stage 2 literature search, especially from the group content experts, regarding content, organization, and possible omissions.

- Decisions made at the first meeting are reviewed and updated. Revisions to the definition(s), scope, or purpose are discussed in detail until consensus is achieved. Some changes will likely occur, now that the group is more familiar with the topic and available evidence.
- It is essential to arrive at an unambiguous definition of scope. If issues arise that require additional discussion, they can be dealt with by e-mail after the call or, if needed, an additional conference call with all group members or a subgroup.
- The stage 2 literature search is briefly reviewed and discussed, beginning with a discussion of methodology by the staff lead and chair. Feedback from the content experts is important to ensure the search is comprehensive, well organized, and free of obvious omissions.
- The timeline is discussed, emphasizing dates for the in-person meetings, which should have been decided well in advance of this call.

**Begin Discussion of Topics for Key Action Statements**

The heart of a guideline is a series of **key action statements** that reflect issues deemed most important by the group. Although there is no rigid guide as to the number of key statements, AAO-HNSF guidelines usually include 10 to 18 based on the guideline scope. Since each statement will require supporting text and an action statement profile, the number is limited for feasibility and timeliness. The goal is to achieve maximal quality improvement with a manageable set of actions.

Quality health care is ideally patient centered yet also accounts for the needs of the population. A useful definition of quality for guideline development is how well physicians and health care institutions fulfill their care obligations to individual patients and how well patients, physicians, and health care institutions enable these obligations to be fulfilled justly across the population. The goal is to improve desired health outcomes that are consistent with current professional knowledge.\(^{49}\)

The process for developing key action statements begins by asking the working group to suggest **topics** that represent opportunities for quality improvement within the guideline scope. A given topic may become the basis for a key action statement or, if deemed of lesser importance, may be incorporated into the supporting text of a related statement. Opportunities for quality improvement may be broadly summarized as follows\(^{15}\):

1. Promoting appropriate care
2. Reducing inappropriate or harmful care
3. Reducing regional variations in delivery of care
4. Improving access to care
5. Educating and empowering clinicians and patients
6. Facilitating coordination and continuity of care
7. Facilitating ethical care

After reviewing the above list with the group, the chair solicits feedback for quality improvement topics. The following points should help in moving the discussion along:

- Begin by asking the group, “If we could only discuss a few aspects of this condition or procedure, what topics would we focus on to most improve quality of care and patient outcomes?” A related question is, “What should we focus on to minimize harm?”
- Additional topics may be gleaned from the literature searches. Examining the scope of guidelines and systematic reviews from the stage 1 search is often very useful. Similarly, the availability of randomized controlled trials, identified in the stage 2 search, is a superb source of feasible topics to consider.
- Last, the group should review the intervention list from the previous conference call (Table 6) to
ensure that no important aspects of management were omitted from the discussion.

Recall that the quality-driven approach allows all important topics to be included, at least initially, even if the supporting evidence is weak or limited. Although recommendations are facilitated by strong evidence, important topics with weak evidence may still become key action statements if there is a clear preponderance of benefit or harm. The group should focus on potential quality impact in selecting topics, not primarily on level of evidence.

Topic suggestions should be short and simple, emphasizing content, not structure. No attempt should be made at this time to create polished action statements. The topic list is often much longer than the eventual list of key action statements. All group members must contribute to ensure multidisciplinary involvement. At least 20 to 35 topics are desired, roughly twice the number of anticipated key action statements.

Compose Preliminary Topic List

As topics are suggested by working group members, the chair composes a simple list, assisted by the staff lead. The goal is to have a starting point for electronic exchange after the call that will refine and complete the entries. A sample topic list developed from conference call 2 for a sinusitis guideline included the following:

1. Initial management of acute sinusitis: observation vs antimicrobials
2. Optimizing diagnostic accuracy for acute sinusitis
3. What is an appropriate medical evaluation?
4. Antimicrobial selection for acute sinusitis: when to change, duration
5. Indications for imaging studies (plain radiographs, computed tomography) in sinusitis
6. Symptomatic relief for acute sinusitis, especially if antimicrobials are withheld
7. Effectiveness and benefit of adjunctive measures for sinusitis
8. Indications for allergy/immunology assessment
9. Indications for nasal endoscopy in sinusitis
10. Categorizing acute vs chronic vs recurrent acute: terminology issues
11. Environmental control measures: smoking, environmental tobacco smoke, allergens
12. Prevalence of antimicrobial resistance/resistant organisms for acute sinusitis
13. Control of allergies as adjunctive therapy for sinusitis
14. Preventing recurrent sinusitis
15. Interpretation of imaging findings
16. Patient education, information therapy
17. Importance of identifying modifying factors or underlying conditions (eg, cystic fibrosis, prior surgery, immune deficiency, immotile cilia)
18. Can sinusitis be managed over the phone (without office assessment)?

Many of the topic suggestions for sinusitis were the basis for key action statements, but the final wording had little relationship to how the topic first appeared. Topics are best viewed as the raw material for deriving key action statements, which is the subject of the first in-person meeting. The purpose of conference call 2, as well as the subsequent electronic exchange, is to create a robust platform of raw material to assist the group at the meeting.

The Importance of Multiple Chronic Conditions

Despite the high prevalence of comorbidities and multiple chronic conditions, most guidelines are developed for individuals with a single disease, rather than for people with several diseases. Therefore, the guideline development group should explicitly address the importance of multiple chronic conditions as factors that might modify treatment, outcome assessment, follow-up care, or any other aspect of management. About 25% of Americans have multiple chronic conditions (rising to 75% around age 65 years), such as arthritis, asthma, respiratory disorders, diabetes, heart disease, hypertension, or mental and cognitive disorders.

Guideline developers should determine the most relevant chronic conditions coexisting with the guideline topic and assess how they might interfere with recommended actions. One way to accomplish this is to include “modifying factors” or “multiple chronic conditions” as a topic or a specific chronic condition as a topic if warranted. Given the increasing prevalence of patients with multiple chronic conditions, guidelines should be explicit and transparent about the degree to which they were considered in formulating topics and how their presence might alter prescribed management.

Despite the increasing prevalence of multiple chronic conditions, many RCTs frequently exclude patients with them from their study sample. This limits the generalizability of conclusions based on these studies to patients with multiple chronic conditions and decreases the level of confidence in the evidence as a basis for recommendations.

Moving from Broad Topics to Answerable Questions

Whereas a topic list, such as that shown above, is a useful starting point for prioritizing guideline content, the topics may be too broad and unfocused to generate meaningful questions that can subsequently be transformed into key action statements. As keenly observed by John Ruskin, “To
be able to ask a question is clearly two-thirds of the way to
getting it answered."

One of the best ways to craft an answerable clinical
question is using the PICO format, which has 4 basic com-
ponents: population, intervention, comparator, and outcome.
These may be extended to PICOTS, by adding time frame
and setting (Table 7). Questions may be framed under the
broad categories of treatment, harm, diagnosis, and prog-
nosis, and they may or may not include the optional compo-
nents of comparator, time frame, and setting. The value of
PICO-type questions has been established in evidence-based
medicine, literature searching, and general librarianship.

During the conference call, the methodologist should famil-
iarize the guideline development group with the PICOTS
format and the benefits of posing answerable questions. Time
permitting, 1 or more of the proposed topics can be translated
into PICOTS questions to illustrate the process. The remainder
can be done through e-mail exchange after the call.

**Working Group Assignments and Deadlines**

At the end of the call, the group reviews specific assignments
or requests for additional information made during the call.
The following types of assignments will follow the call:

1. **Finalizing the topic list.** The preliminary topic list
   is sent to all working group members for revision
   and comment soon after the call. Members are
   requested to add any new topics, thought of after

the call, to the existing list. A final topic list is
compiled by the staff lead, which will be used to
rank and prioritize topics as described in the next
section.

2. **Adding PICOTS questions to the topics.** All topics
should be refined into 1 or more related PICOTS
questions, to help guideline development group
members make more informed decisions when
later ranking and prioritizing the list.

3. **Drafting the introduction and guideline purpose.**
The chair or his or her designee(s) should create a
rough draft of the first 2 sections of the guideline,
the Introduction and the Guideline Purpose, using
prior guidelines as examples. The Introduction
states why the topic was chosen, why it is impor-
tant, precisely how the topic is defined (using lan-
guage developed by the group), and to whom the
guideline does—and does not—apply (scope). The
section on Guideline Purpose states what the group
seeks to achieve, what is the anticipated impact of
the guideline on clinical care, and to what specific
audience and situations the guideline is intended.

4. **Drafting the health care burden section.** The assist-
ant chairs are asked to compose a brief summary
of health care burden for the guideline topic, about
4 to 8 paragraphs in length, which addresses issues
of incidence, prevalence, direct cost, and indirect
cost. This section will eventually be incorporated

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**Table 7. The PICOTS Format for Asking Answerable Clinical Questions**

<table>
<thead>
<tr>
<th>Component</th>
<th>Comment</th>
<th>Diagnosis Question Example</th>
<th>Treatment/Harm Question Example</th>
<th>Prognosis Question Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>Patient, population, or problem to which the question applies</td>
<td>Adults with acute upper</td>
<td>Adults with acute bacterial</td>
<td>Adults with acute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>respiratory infection</td>
<td>sinusitis</td>
<td>bacterial sinusitis</td>
</tr>
<tr>
<td>Intervention</td>
<td>Service, planned action, prognostic factor, or cause of interest</td>
<td>History, physical</td>
<td>Antibiotic therapy for</td>
<td>Prognostic factors, including</td>
</tr>
<tr>
<td></td>
<td></td>
<td>examination, or diagnostic test</td>
<td>7 to 10 days</td>
<td>age, illness severity,</td>
</tr>
<tr>
<td>Comparator (optional)</td>
<td>When applicable, an alternative intervention or comparison</td>
<td>None</td>
<td></td>
<td>comorbid conditions (eg, allergic rhinitis)</td>
</tr>
<tr>
<td>Outcome(s)</td>
<td>Measurements to determine the impact of the intervention and comparator</td>
<td>Distinguish bacterial vs</td>
<td>Clinical improvement of</td>
<td>Identify patients who are</td>
</tr>
<tr>
<td></td>
<td></td>
<td>viral sinusitis</td>
<td>presenting signs and symptoms;</td>
<td>likely to benefit most from</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>harms and adverse events</td>
<td>antibiotic therapy</td>
</tr>
<tr>
<td>Time frame (optional)</td>
<td>Timing or time frame of interest</td>
<td>Within the first 3 weeks</td>
<td>During and after treatment</td>
<td>During and after treatment</td>
</tr>
<tr>
<td>Setting (optional)</td>
<td>Clinical care or other setting of interest</td>
<td>Any setting</td>
<td>Any setting</td>
<td>Any setting</td>
</tr>
</tbody>
</table>

"The PICOTS question would be the following: “For adults with acute upper respiratory infection, how can history, physical examination, and/or diagnostic tests be used to distinguish bacterial from viral infection within the first 3 weeks of illness?”

"The PICOTS question would be the following: “For adults with acute bacterial sinusitis, what is the impact of antibiotic therapy for 7 to 10 days vs placebo or no therapy to clinical improvement (of presenting signs and symptoms) and on adverse events during and after treatment?”

"The PICOTS question would be the following: “For adults with acute bacterial sinusitis, what prognostic factors (eg, age, illness severity, comorbid conditions) can be used to identify patients most likely to benefit from antibiotic therapy during and after treatment?”
into the introductory text and is a basis for stimulating interest by the media, public, and other stakeholders after publication.

5. **Specific information requests.** Any requests for additional information to clarify issues discussed during the call are reviewed and assigned to specific group members for action. The need for any supplemental literature searches is also discussed.

Deadlines are assigned for completing any assignments, emphasizing the importance of responding within the time frame specified. Group members are reminded of the dates for the upcoming in-person meetings.

**Key Points to Remember**

1. The stage 2 literature search for randomized controlled trials must be performed, assessed by the chair and assistant chairs, and compiled into a summary grid before the call.
2. Much of the call will be spent on refining and polishing the guideline scope and definitions.
3. A topic list is generated based on literature searches and on group input regarding opportunities for quality improvement.
4. The group is introduced to the PICOTS format for composing answerable questions.
5. Emphasis is placed on creating a preliminary topic list, which will be refined after the call and serve as a starting point for creating key action statements at the next meeting.

**Planning for In-Person Meeting 1**

**Logistics**

The room should be large enough to comfortably accommodate the working group and facilitate discussion. One suggestion is to use a rectangular or U-shaped seating arrangement, with the chair and assistant chairs at the head and participants along the sides.

A digital projector and screen are used for presentations (see below) and for real-time projection of meeting notes, reviewing the guideline drafted sections, and developing key action statements. The screen should be large enough to be readily seen in all parts of the room. Internet access should be available for literature searches and to address questions that arise during the meeting.

**Presentations**

The first in-person meeting will ideally have several focused presentations to set the stage for the ensuing discussions. The following topics are suggested, allowing 30 minutes for each:

1. Overview of guideline methodology, presented by the consultant or methodologist, to familiarize members with the development process and show examples from other guidelines of what the group is seeking to accomplish.
2. Current controversies in managing the guideline topic, presented by a content expert, to illustrate issues the group will be discussing and to orient group members who may have limited knowledge of the guideline topic.
3. Systematic reviews and guidelines, presented by the staff lead, to summarize the stage 1 and stage 2 literature search findings.
4. How to create a dummy, key action statement, presented by the staff lead and chair, to familiarize the working group with the meeting’s objective.
5. A brief overview of the electronic storage site: by this stage in the development process, working group members should be familiar with the site, but the overview may assist those less familiar with the technology.

**Creating a Guideline Template**

Progress at the first meeting is facilitated if the chair or staff lead creates a guideline template that will be updated in real time during the meeting. The template is based on the format used in previously published guidelines by the organization. An outline of the major sections in AAO-HNSF guidelines is shown in Table 8.

**Ranking Topics and Assigning Evidence**

The final topic list, based on electronic exchange after the second conference call, is made into a 3-column table. The first column, left blank, has the heading “Rank”; the second column, containing the topics, has the heading “Topic”; and the final column, “PICOTS Questions,” contains any PICOTS questions that have been developed to substantiate the importance of the topic and feasibility of creating answerable related questions. The order of the topics is not important and can simply correspond to the sequence in which they were suggested by the group.

The staff lead distributes the topic list to working group members with the following instructions, replacing the number “31” in this example with the total number of topics:

Please rank the 31 topics below in order of importance for inclusion in this guideline by placing a number from 1 to 31 under the “Rank” column. Please use each number only once. Assign the number “1” to the most important topic, “2” to the next most important, “3” to the third most important topic, and so forth. Number “31” will be the least important topic. The table should not be sorted but should be left in the original order. In addition, please send any comments to [staff lead e-mail address]. Thank you for your time.
The scoping process often benefits from input beyond the guideline development group to ensure that important topics have not been overlooked. While the group is ranking the initial topics, the list may also be sent for review and comment to the organization’s board of directors, board of governors, the general public, and any relevant consumer or advocacy groups.

The rank lists are collated by the staff lead to determine the mean rank score for each topic, with lower scores indicating higher priority. A table is created with the items sorted by rank score with additional columns for the topic, number of systematic reviews relevant to the topic (based on the stage 1 search), and number of randomized trials relevant to the topic (based on the stage 2 search). An example of a completed topic rank list is shown in Table 9. The literature search in compiling this table does not need to be exhaustive at this stage; it is simply intended as a guide to the evidence landscape for the upcoming meeting.

Understanding Key Action Statements

The recommendations in a guideline can only be implemented if they are clear and identifiable. This goal is best achieved by structuring the guideline around a series of key action statements, which are supported by amplifying text, action statement profiles, and recommendation grade. Unfortunately, recommendation statements are often not readily identifiable in published guidelines, and many statements are not executable as written. This section introduces the concept of key action statements, laying the foundation for developing the statements from the topic list at the first in-person meeting.

Clarity and precision in guidelines not only facilitate implementation by clinicians and patients but also facilitate incorporating guideline recommendations (eg, action statements) into decision support tools. This is particularly important when using guidelines as a foundation for performance measures, which mandate clarity regarding precisely what is recommended, the type of patient to whom it applies, and other details for specifying numerators, denominators, and programming rules.

Crafting Valid Recommendation Statements

The group must understand the purpose and structure of key action statements before they can begin creating them...
from the prioritized topic list. Key statements are action-oriented prescriptions of specific behavior from a clinician. As such, they should suggest measurable activities that can form the basis of performance measures or other quality initiatives.

An ideal key action statement describes

- *When* (ie, under what specific conditions)
- *Who* (specifically)
- *Must, should, or may* (ie, the level of obligation)
- *Do what* (precisely what actions)
- *To whom*

Key action statements should be brief yet precise. The supporting text, which immediately follows the action statement profile, amplifies *why* the recommendation is important and *how* it is to be carried out.
Examples of Key Action Statements

Examples of key action statements from prior guidelines are listed below with the specific action requested in italics. These examples are polished statements developed after extensive discussion and not necessarily what was initially proposed based on the topic list.

- Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy.
- Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.
- Clinicians should diagnose presumptive idiopathic sudden sensorineural hearing loss if audiometry confirms a 30-decibel hearing loss at 3 consecutive frequencies AND an underlying condition cannot be identified by history and physical examination.
- Clinicians should educate patients with idiopathic sudden sensorineural hearing loss about the natural history of the condition, the benefits and risks of medical interventions, and the limitations of existing evidence regarding efficacy.
- Clinicians should communicate polysomnography results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy in a child with sleep-disordered breathing.

All of the statements above apply to “clinicians” as the “who,” followed by the word should and then an action statement. The word should qualifies the strength of the statement and is replaced by may if the level of evidence is not strong or the harm-benefit relationship is unclear. Recommendations supported by consistent, high-quality evidence and a strong preponderance of benefit over risk, harm, and cost may occasionally be associated with the term must. Developers should understand the possible legal and reimbursement ramifications when using that term.

One of the best ways to understand the “action” component of key action statements is to distinguish statements of fact, which are found in many evidence reports and practice parameters, from statements of action (Table 10), which are the heart and soul of a true clinical practice guideline. Only the latter can serve as a platform to implement guideline recommendations and develop measures to assess performance.

Understanding Action Statement Profiles

**Action Statement Profiles and Transparency**

An essential part of guideline development is transparency in how policy statements are developed and classified as recommendations. An elegant way of accomplishing this is to add an “action statement profile,” listing all decisions made by the group, between each key action statement and the associated supporting text. Action statement profiles assist guideline writers and users by

1. Encouraging an explicit and transparent approach to guideline writing
2. Forcing guideline developers to discuss and document the decision-making process
3. Creating “organizational memory” to avoid re-discussing already agreed-upon issues
4. Allowing guideline users to rapidly understand how and why statements were developed

<table>
<thead>
<tr>
<th>Table 10. Comparison of Statements of Fact vs Statements of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statement of Fact</strong></td>
</tr>
<tr>
<td>Voice therapy has been shown to improve voice-related quality of life for patients with dysphonia.</td>
</tr>
<tr>
<td>Patient education is important regarding idiopathic, sudden sensorineural hearing loss.</td>
</tr>
<tr>
<td>Acute otitis externa (swimmer’s ear) is associated with moderate to severe pain.</td>
</tr>
<tr>
<td>Antibiotic therapy does not improve recovery after tonsillectomy in children.</td>
</tr>
<tr>
<td>Polysomnography performed with a portable monitoring device is less accurate in children than laboratory-based polysomnography.</td>
</tr>
</tbody>
</table>
5. Helping identify aspects of a guideline best suited to performance assessment

Action statement profiles appear immediately after the boldfaced key action statement as a bulleted list with the following headings, defined in Table 11:

- Aggregate evidence quality
- Level of confidence in evidence
- Benefit
- Risks, harms, costs
- Benefit-harm assessment
- Value judgments
- Intentional vagueness
- Role of patient preferences
- Exceptions
- Policy level
- Differences of opinion

Table 11. Action Statement Profile Constructs for Key Action Statements

<table>
<thead>
<tr>
<th>Construct</th>
<th>What to Include in the Profile</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggregate evidence quality</td>
<td>Specify as A, B, C, D, or X</td>
<td>There are no strict rules and the level of evidence does not automatically drop to the lowest study type included. Rather, the group should reach a consensus rating and document the rationale.</td>
</tr>
<tr>
<td>Level of confidence in evidence</td>
<td>Estimates the group's confidence, or certainty, in the aggregate evidence underpinning the recommendation.</td>
<td>Rated as “high,” “medium,” or “low” based on the quantity, consistency, precision, and generalizability of the aggregate evidence.</td>
</tr>
<tr>
<td>Benefit</td>
<td>List the favorable changes in outcomes, as defined by the group, which would likely occur if the action statement were followed.</td>
<td>Include qualitative and quantitative information, the latter often abstracted from randomized trials and reviews. Be explicit and comprehensive.</td>
</tr>
<tr>
<td>Risks, harms, costs</td>
<td>List the adverse events or other unfavorable outcomes that may occur if the action statement were followed.</td>
<td>Include qualitative and quantitative information, and report with the same rigor and detail used in defining benefits; include direct and indirect costs, if applicable.</td>
</tr>
<tr>
<td>Benefit-harm assessment</td>
<td>Classify as a “preponderance of benefit over harm” (or vice versa) or a “balance of benefit and harm.”</td>
<td>Stronger recommendations are possible when clear benefit is not offset by important harms or costs (or vice versa); conversely, when the benefit is small or offset by important adverse events, the balance between benefit and harm prevents a strong recommendation.</td>
</tr>
<tr>
<td>Value judgments</td>
<td>Summarize value judgments used by the group in creating the action statement; if none were involved, state “none.”</td>
<td>Translating evidence into action often involves value judgments, which include guiding principles, ethical considerations, or other beliefs and priorities; stating them clearly helps users understand their influence on interpreting objective evidence.</td>
</tr>
<tr>
<td>Intentional vagueness</td>
<td>State reasons for any intentional vagueness in the action statement; if none was intended, state “none.”</td>
<td>Action statements should be clear and specific, but there may be reasons the group chooses to be vague (e.g., concern over setting a legal precedent); acknowledging these clearly promotes transparency.</td>
</tr>
<tr>
<td>Role of patient preferences</td>
<td>Specify as large, moderate, small, or none, based on the opportunity for shared decision making with the patient or proxy.</td>
<td>Weaker evidence with favorable natural history suggests a large role, whereas strong evidence with clear benefit limits the role.</td>
</tr>
<tr>
<td>Exceptions</td>
<td>List situations or circumstances where the action statement should not be applied.</td>
<td>Clear exceptions are of particular importance when guidelines are adapted to measuring performance.</td>
</tr>
<tr>
<td>Policy level</td>
<td>Strength of the action statement</td>
<td>The strength of the key action statement conveys the level of obligation and expected adherence.</td>
</tr>
<tr>
<td>Differences of opinion</td>
<td>A description and explanation of any differences of opinion regarding the recommendation</td>
<td>Rate as “none,” “minor,” or “major” and explain if anything other than “none.”</td>
</tr>
</tbody>
</table>
The action statement profile makes explicit and transparent the process by which evidence and opinion are transformed into recommendations about appropriate care. The group sequentially describes each aspect of the profile.

To illustrate the structure of action statement profiles, examples from the AAO-HNSF guideline on tonsillectomy in children are provided below. Each profile lists the associated key action statement followed by the supporting rationale. Note that these do not describe “level of confidence” or “differences of opinion” because these were added to the profiles after completion of this particular guideline. Details on determining the aggregate evidence quality are provided in the next section.

The first sample action statement profile accompanies a key action statement deemed a “strong recommendation” in the final guideline based on evidence quality and harm-benefit assessment. Note the detailed information provided under aggregate evidence quality and exclusions.

**Sample key action statement 1:** Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy. Action statement profile:

- Aggregate evidence quality: Grade A, randomized controlled trials and multiple systematic reviews, for preventing postoperative nausea and vomiting; grade A, randomized controlled trials and 1 systematic review, for decreased pain and shorter times to oral intake
- Benefit: Decreased incidence of postoperative nausea and vomiting up to 24 hours posttonsillectomy, decreased times to first oral intake, and decreased pain as measured by lower pain scores and longer latency times to analgesic administration
- Harm: No adverse events in all randomized control trials except one, which reported increased hemorrhage as a secondary outcome unadjusted for other risk factors
- Cost: Direct cost of medication and indirect costs of drug administration
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Decreased postoperative pain, nausea, and vomiting are likely to result in increased patient satisfaction and decreased incidence of overnight hospital admission, associated with lower total health care costs compared with direct and indirect costs of drug administration.
- Role of patient preferences: None
- Intentional vagueness: None

**Sample key action statement 2:** Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year or at least 5 episodes per year for 2 years or at least 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and 1 or more of the following: temperature >38.3°C, cervical adenopathy, tonsillar exudates, or positive test for group A β-hemolytic streptococcus. Action statement profile:

- Exclusions: Patients with endocrine disorders who are already receiving exogenous steroids or in whom steroid administration may interfere with normal glucose-insulin regulation (eg, diabetics)
- Policy level: Strong recommendation

The second sample action statement profile accompanies a key action statement deemed an “option” in the final guideline. Note the relative balance of harm vs benefits, the explicit statements about value judgments, and the opportunity for shared decision making with patients.

- Aggregate evidence quality: Grade B, well-designed randomized controlled trials with minor limitations; some grade C observational studies
- Benefit: Modest reduction in the frequency and severity of recurrent throat infection for up to 2 years after surgery; modest reduction in frequency of group A streptococcal infection for up to 2 years after surgery; improved disease-specific quality of life
- Harm: Risk and morbidity of tonsillectomy in patients appropriately selected for the procedure, including, but not limited to, persistence of throat infection, pain, and missed activity after surgery, hemorrhage, dehydration, injury, and anesthetic complications
- Cost: Direct cost of tonsillectomy; direct nonsurgical costs (antibiotics, clinician visit) and indirect costs (caregiver time, time missed from school) associated with recurrent infection
- Benefit-harm assessment: Balance of benefit and harm
- Value judgments: Importance of balancing the modest, short-term benefits of tonsillectomy in carefully selected children with recurrent throat infection against the favorable natural history seen in control groups and the potential for harm of adverse events, which, although infrequent, may be severe or life-threatening
- Role of patient preferences: Large role for shared decision making in severely affected patients, given favorable natural history of recurrent throat
infections and modest improvement associated with surgery; limited role in patients who do not meet strict indications for surgery
- Intentional vagueness: None
- Exceptions: None
- Policy level: Option

The third sample action statement profile accompanies a key action statement deemed a “strong recommendation against” in the final guideline. Note the preponderance of benefit over harm, intentional vagueness surrounding the word routine, and the exceptions.

**Sample key action statement 3**: Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy. Action statement profile:

- Aggregate evidence quality: Grade A, randomized controlled trials and systematic reviews, showing no benefit in using perioperative antibiotics to reduce posttonsillectomy morbidity
- Benefit: Avoidance of adverse events related to antimicrobial therapy, including rash, allergy, gastrointestinal upset, and induced bacterial resistance
- Harm: None
- Cost: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although the panel recognizes that antimicrobial therapy is often used in perioperative management, this practice is suboptimal given lack of demonstrable benefits in randomized control trials plus the well-documented potential adverse events and cost of therapy.
- Role of patient preferences: None
- Intentional vagueness: The panel advises against routine antimicrobial therapy, recognizing that there may be individual circumstances in which use of antimicrobials for a given patient is deemed appropriate by the clinician.
- Exceptions: Patients with cardiac conditions requiring perioperative antibiotics for prophylaxis against bacterial endocarditis or implants; patients undergoing tonsillectomy with concurrent peritonsillar abscess
- Policy level: Strong recommendation against

As recommended by the Institute of Medicine, we added “level of confidence” and “differences of opinion” to our action statement profiles. The level of confidence relates to quantity, consistency, precision, and generalizability of the aggregate evidence, which is distinct from evidence level. It is possible to have “low” confidence in evidence from randomized trials if the trials are inconsistent, have design flaws, and relate poorly to the guideline’s target population. Conversely, it is possible to have “high” confidence in observational studies if consistent, well designed, and applicable to patients covered by the guideline.

Differences of opinion among guideline development group members can occur with any components of the action statement profile. Mechanisms for resolving disagreements should be specified early in the development process, such as a member vote with a specified threshold for approval (eg, 50%, 70%). Any differences of opinion are rated as “minor” or “major” with an explanation of what occurred and how it was resolved.

**Assigning an Aggregate Level of Evidence**

Guideline groups often have difficulty reaching consensus on the aggregate level of evidence supporting a key action statement. The aggregate is not based simply on the highest or lowest quality single study identified but rather is a composite rating of the quality, consistency, and relevance of the overall group of studies. Assigning a rating always incorporates some component of judgment, which is permissible provided that the group is consistent and clearly states the reasoning involved under the “aggregate evidence quality” section of the action statement profile (Table 11).

The goal of the evidence review is to determine our confidence in the factors of benefit (eg, magnitude of each beneficial effect) offset by our confidence in our understanding of the risks, harms, and costs. Evidence for harms should be assessed with the same diligence applied to evidence for benefit. The purpose of the evidence review is to help us understand the benefit-risk equation.

Many rating scales have been developed, both for individual studies and for aggregate assessments. The AAO-HNSF originally used the scale proposed the American Academy of Pediatrics21 for its clarity and simplicity. The aggregate levels of evidence in this scale are best suited for statements about treatment but are more difficult to apply to statements that deal with diagnosis, prognosis, or harm. Moreover, the revised and updated levels of evidence from the Oxford Centre for Evidence-Based Medicine (OCEBM) assign greater value to systematic reviews (compared with individual studies) and to observational studies with dramatic effects.55 For consistency with the OCEBM levels and to accommodate multiple statement types (treatment, harm, diagnosis, and prognosis), the AAO-HNSF developed the aggregate evidence scale in Table 12.

In nearly all situations, the aggregate evidence level can be designated as A, B, C, or D using the criteria in
Table 12. Aggregate Grades of Evidence by Question Type

<table>
<thead>
<tr>
<th>Grade</th>
<th>OCEBM</th>
<th>Treatment</th>
<th>Harm</th>
<th>Diagnosis</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>Systematic review&lt;sup&gt;b&lt;/sup&gt; of randomized trials</td>
<td>Systematic review&lt;sup&gt;b&lt;/sup&gt; of randomized trials, nested case-control studies, or observational studies with dramatic effect&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Systematic review&lt;sup&gt;b&lt;/sup&gt; of cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Systematic review&lt;sup&gt;b&lt;/sup&gt; of inception cohort studies&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>B</td>
<td>2</td>
<td>Randomized trials or observational studies with dramatic effects or highly consistent evidence</td>
<td>Randomized trials, or observational studies with dramatic effects or highly consistent evidence</td>
<td>Cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Inception cohort studies&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>C</td>
<td>3-4</td>
<td>Nonrandomized or historically controlled studies, including case-control and observational studies</td>
<td>Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case-series, case-control, or historically controlled studies</td>
<td>Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards</td>
<td>Cohort study, control arm of a randomized trial, case series, or case-control studies; poor quality prognostic cohort study</td>
</tr>
<tr>
<td>D</td>
<td>5</td>
<td>Case reports, mechanism-based reasoning, or reasoning from first principles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>NA</td>
<td>Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: NA, not applicable; OCEBM, Oxford Centre for Evidence-Based Medicine.
<sup>a</sup>Adapted from Howick and coworkers<sup>55</sup>.
<sup>b</sup>A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.
<sup>c</sup>A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Recall, however, that these designations apply <i>only</i> to the aggregate evidence level and not to the individual, contributing studies. At times, the group may decide to extrapolate evidence from similar but not directly comparable patients (eg, using findings from a study of adults in making a recommendation for the pediatric population), especially if high-quality evidence is found. The basis for extrapolating data and the assumptions made should be stated concisely and explicitly as part of the aggregate evidence level description. Any effect of extrapolation on the level of confidence in the evidence should also be stated.

A final category of evidence is “grade X,” used for exceptional situations where validating studies cannot be performed and there appears to be a clear preponderance of benefit or harm. This special category is appropriate in rare circumstances where the group has defined a need for a key action statement to improve quality, but the nature of the situation is unlikely to ever result in high-quality evidence. For example, in randomized trials, it would be unethical to study antimicrobial prophylaxis for anthrax, or ototoxic vs non-ototoxic ear drops for acute otitis externa with a nonintact tympanic membrane perforation, or prolonged observation of otitis media with effusion in children with developmental delays or disorders.

Expert opinion is the lens through which evidence gains context and meaning, but it is not a level of evidence unto itself. Developing recommendations always requires the opinion of experts to identify, interpret, and apply the evidence. Ratings about the level or quality of evidence apply directly to the supporting literature, not the opinions that follow its interpretation.

**Understanding Recommendation Grades**

Although many different methods have been proposed for grading recommendation strength, most developers agree that determining the strength of action is distinct from rating the aggregate quality of evidence. High-quality evidence (eg, grade A) does not always justify strong...
recommendations, and recommendations—or even strong recommendations—may be possible despite lower quality evidence (e.g., grade B, C, or X). The primary modifying factor in this regard is the benefit-harm assessment, as defined in the preceding section on action statement profiles.

The method for determining strength of recommendation developed by the American Academy of Pediatrics (AAP) is simple, transparent, and clinically relevant. Similar to the GRADE approach, the aggregate evidence level and benefit-harm assessment are the primary rating determinants. GRADE is more complex, however, and offers only 2 levels of action strength ("strong recommendation" and "weak recommendation") in contrast to the 3 levels from the AAP ("strong recommendation," "recommendation," and "option"). The authors' empiric experience in developing guidelines suggests that 3 levels support more flexible decision making and are better accepted by clinicians.

Using 3 levels of recommendation is supported by research into the obligation level conveyed by terms commonly found in clinical practice guidelines. Despite a large number of descriptive terms, the obligation levels cluster into 3 distinct levels: must conveys the highest obligation level, may the lowest, and should an intermediate level. These terms can be used to strengthen a connection between recommendation language and expected adherence to recommendations. For example, a "strong recommendation" carries an obligation of must or should, a "recommendation" an obligation of should, and an "option" an obligation of may. Should is the most commonly used term in published guidelines.

The strength of recommendation is best viewed as a relative constraint on clinician behavior (Table 14). In general, less frequent variation in practice is expected for a strong recommendation than might be expected for a recommendation. The desire of many authors to make uniformly strong recommendations must be tempered by the reality of the evidence quality and benefit-risk assessment.

Assigning a strength of recommendation to a key action statement should be very straightforward after assigning an aggregate level of evidence and performing the benefit-harm assessment. As shown in Table 13, however, when there is a preponderance of benefit over harm, the group may choose between "recommendation" and "strong recommendation" with level B or X evidence quality. Once a choice is made, the reasons should be stated in the action statement profile, usually under the "values" section.

To understand better how the strength of recommendation is determined by the aggregate quality and benefit-harm assessment, consider the statements below from various AAO-HNSF guidelines. In each case, Table 13 can be used to cross-check the link between evidence, harm-benefit, and action strength.

The following key action statements are "strong recommendations," meaning clinicians should follow this guidance unless a clear and compelling rationale for acting in a contrary manner is present.

- Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy. Strong recommendation based on grade A aggregate evidence (randomized controlled trials and systematic reviews of randomized controlled trials) with a preponderance of benefit over harm.
Clinicians should counsel patients with incomplete hearing about possible benefits of amplification and hearing-assistive technology (HAT) and other supportive measures. Strong recommendation based on grade A aggregate evidence (systematic reviews and observational studies) with a preponderance of benefit over harm.

Before performing tonsillectomy, the clinician should refer children with sleep-disordered breathing for polysomnography if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses. Recommendation based on grade C aggregate evidence (observational studies and 1 systematic review of observational studies on obesity) with a preponderance of benefit over harm.

Clinicians should not obtain radiographic imaging, vestibular testing, or both in a patient diagnosed with benign paroxysmal positional vertigo (benign, paroxysmal positional vertigo), unless the diagnosis is uncertain or there are additional symptoms unrelated to benign, paroxysmal positional vertigo that warrant testing. Recommendation against based on grade C aggregate evidence for vestibular testing (diagnostic studies with limitations in referred patient populations and observational studies) and radiographic imaging (observational studies) with a preponderance of benefit over harm.

The following key action statements are “recommendations,” meaning clinicians should generally follow this guidance but also should be alert to new information and sensitive to patient preferences.

### Table 14. Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

<table>
<thead>
<tr>
<th>Strength</th>
<th>Definition</th>
<th>Implied Obligation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong recommendation</td>
<td>A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.</td>
<td>Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.</td>
</tr>
<tr>
<td>Recommendation</td>
<td>A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.</td>
<td>Clinicians should also generally follow a recommendation but should remain alert to new information and be sensitive to patient preferences.</td>
</tr>
<tr>
<td>Option</td>
<td>An option means that either the quality of evidence is suspect (grade D) or that well-done studies (grade A, B, or C) show little clear advantage to one approach vs another.</td>
<td>Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.</td>
</tr>
</tbody>
</table>

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*Adapted from the American Academy of Pediatrics.*

*See Table 12 for definitions of evidence grades.*
The following key action statements are “options,” which offer clinicians flexibility in their decision making but may set boundaries on alternatives. Patient preference should have a substantial role in influencing clinical decision making.

- Clinicians may offer corticosteroids as initial therapy to patients with idiopathic sudden sensorineural hearing loss. **Option** based on grade B aggregate evidence (systematic reviews of randomized trials with methodological limitations) with a balance between benefit and harm.11
- The clinician may obtain nasal endoscopy in diagnosing or evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis. **Option** based on grade D aggregate evidence (expert opinion) with a preponderance of benefit over harm.5

Key action statements that lead to recommendations or strong recommendations are most desirable in guidelines, but options and no recommendations may also serve an important educational role. Options are helpful in addressing controversial aspects of management when anticipated benefits are offset by harms, especially when wide practice variation exists but evidence is sparse. A clear, systematic review and interpretation of the evidence, using expert consensus to fill gaps, may be very helpful to clinicians, consumers, and policy makers in facilitating decisions.

**In-Person Meeting 1: Drafting Key Action Statements**

**Purpose and Organization**

The goal of this meeting to develop a “straw man” draft of the guideline’s key action statements based on the prioritized topic list and the corresponding PICOTS questions. A consensus is reached regarding key statements, the messages to be delivered, and the order in which they are to be presented. Action statement profiles are drafted with the knowledge they will be revised at in-person meeting 2, when the group is more fully informed about the underlying evidence and other components of the profile. The template resulting from this meeting facilitates working group assignments to sketch in the supporting text and other details prior to the next meeting.

As one of only 2 in-person meetings during guideline development, the venue must be organized efficiently. One suggestion is to begin at noon and end at 2:00 PM the next day, with 2 working lunches and a group dinner. The noon start allows some members to arrive the same morning, and the early afternoon finish allows all members to return the same day. In between, there are about 10 hours of working time, excluding the dinner. This time allotment, combined with effective leadership from the chair and consultant, should be adequate for completing the meeting agenda.

**Predistribute Electronic Materials**

Documents should be distributed by e-mail and stored electronically prior to the conference call for review by participants before the meeting. Materials for predistribution include the following:

- Agenda for the conference call
- Updated working group contact information grid with conflict of interest disclosures
- Minutes of the second conference call
- Prioritized topic list with PICOTS questions and the number of relevant randomized trials or systematic reviews
- Draft introductory sections of the guideline: introduction, purpose, and health care burden
- Selected full-text documents, including guidelines and systematic reviews, if available
- Relevant sections of the guideline development manual—including the sections on key action statements, action statement profiles, and grading recommendations—which should be read in advance of the meeting
- Any other information on content or methodology identified by working group members that would be helpful in educating the group or stimulating discussion

**Presentations by Methodology and Content Experts**

The prearranged presentations on methodology and content are given at the start of the meeting. Presentations should be informative, not didactic, focusing on ideas and concepts to stimulate the group rather than attempting to make definitive statements. Current methodology and common pitfalls in guideline development should be described.

**Reviewing the Draft Introduction, Purpose, and Health Care Burden**

The introductory sections of the guideline, composed by the chair and assistant chairs after the second conference call, are reviewed and discussed by the group for broad concepts, clarity, and consistency. The first 2 sections are based largely on discussions at the first 2 conference calls, and the content should accurately reflect group decisions made regarding scope, purpose, and definitions. Members should focus on identifying sections of the text in need of revision, clarification, or documentation but should not be concerned about the nuances of wording. There will be ample opportunity in future e-mail exchanges to wordsmith the final document.

An efficient method of group review of guideline text is to project the relevant section on a screen using a...
Group Facilitation

The productivity of the guideline development group will largely depend on the ability to interact in a calm, respectful manner that encourages full participation and open discussion. Although this may occur spontaneously, effective group facilitation is usually needed to ensure the right outcome. The guideline chair is the primary group facilitator with the methodologist and staff leads providing additional support.

Facilitation deals with how the group approaches big concepts, identifies their learning needs, and remains on task to accomplish goals. Group facilitation is more about process than content, aiming to make the process easier and more convenient rather than provide definitive answers. A good facilitator strives to enable discussion, encourage understanding, ask open-ended questions, promote group dynamics (giving everyone a chance to speak), and provide feedback that bolsters the group. The facilitator’s role is not to dominate the discussion.

Some points to keep in mind regarding facilitation include the following:

- Establish ground rules, which may be as simple as beginning on time, respecting each other’s opinions, listening to others, and debating, not arguing.
- Remind group members that they are representing a specific point of view or discipline (eg, primary care, specialty [or subspecialty] care, consumer advocacy, nonphysician providers, allied health professionals), not serving as the official voice of their sponsoring organization.
- Encourage consumers and other nonphysicians to contribute since they may feel intimidated in a room dominated by physicians.
- Beware of content experts and senior leaders in the field who may hold strong opinions and have significant intellectual bias that creates unbridled passion for contributing to discussions, sometimes to the extent that it drowns out other voices.
- Defer discussions to a later time if an impasse is reached since progress is more likely to be made when passions have cooled and calm thinking prevails.
- Remember that as the chair, you may be wrong when pointing out errors or inconsistencies; a healthy dose of humility is always advised.
- Delegate 1 or more assistants to keep track of time to prolonged discussions that create a sense of urgency in completing the task at hand.

Creating a Draft Guideline from the Topic List

The group now begins the important task of creating a draft list of key action statements for the guideline based on the prioritized topic list. This is not an exercise in linguistic perfection but instead emphasizes a logical sequence of proposed actions that capture opportunities for quality improvement.

Keeping in mind the quality-driven nature of the process, the chair leads the group in deciding which topics on the prioritized list will be used to create action statements. Invariably, there will be some obvious choices that stand out since they are likely the reason the guideline was undertaken.

Don’t be surprised if the task of creating key statements seems awkward or chaotic at first; developing simple, but insightful, action-oriented statements is difficult, even for seasoned guideline writers.

Some considerations in selecting topics include the following:

1. Try to identify a few critical, “must-have” topics or statements from the list. For example, if the group could change clinician behavior or public policy only in a few critical areas, what would they be? If there is a perception that the condition is currently managed poorly, what should be done differently? Opinions may differ considerably, but some consistent items will invariably emerge.
2. Next, consider topics with high priority scores and supporting evidence that includes systematic reviews, randomized trials, or both. Strong evidence supports strong recommendations when the benefit to harm balance is favorable.
3. Include topics that can most influence quality of care, even if systematic reviews and randomized trials are not available. Recommendations may still be possible if benefits exceed harms, based on lower quality evidence or working group consensus. Guideline users are often most perplexed by clinical decisions that are not informed by high-quality evidence. Expert consensus about these questions can be quite useful, so long as it is clear that consensus-based recommendations differ from evidence-based recommendations.
4. Develop a logical sequence of statements that moves from broad concepts (eg, diagnosis, modifying factors, initial management), to more specific
concerns (eg, therapeutic alternatives, use of diagnostic tests, outcome assessment), to concluding aspects of providing care (eg, treatment failures, recurrence, prevention).

5. Link topics that are deemed not suitable for a key action statement to the supporting text of related statements, thereby allowing the group to include some discussion of the topic without having to justify a distinct action statement and action statement profile.

6. Consider topics with lower priority scores that are nonetheless supported by systematic reviews or randomized trials as potential key action statements, especially when the volume of high-quality evidence is substantial.

As each topic is discussed, the group, assisted by the consultant, should draft a rough version of a related key action statement. To facilitate this process, the AAO-HNSF uses the BRIDGE-Wiz software application, developed by the Yale Center of Medical Informatics, to support the working group’s discussions. The BRIDGE-Wiz application (Building Recommendations In a Developer’s Guideline Editor) uses a sequential, step-like process to guide the group in developing action statements. BRIDGE-Wiz requires the group to outline (1) when (ie, precisely under what circumstances), (2) who, (3) ought (with what level of implied obligation), (4) to do what, and (5) to whom. The “how and why” of the statement are covered in the associated supporting text.

The most important word in a key action statement is the verb describing the action to be taken. Most guideline-prescribed activities can be described with a limited vocabulary of actions, shown in Table 15.61

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Obtain or collect additional data through inquiry, observation, laboratory testing, or other investigative procedures whose intent is not curative</td>
</tr>
<tr>
<td>Prescribe</td>
<td>Order a treatment requiring medication or durable medical equipment</td>
</tr>
<tr>
<td>Perform</td>
<td>Perform therapeutic procedure: order activities that are therapeutic in nature</td>
</tr>
<tr>
<td>Educate/counsel</td>
<td>Inform the patient about means to improve/maintain health, or instruct on how to perform specific activities</td>
</tr>
<tr>
<td>Dispose</td>
<td>Initiate an activity to direct the flow of patients, such as admit, discharge, follow-up, transfer, and so on</td>
</tr>
<tr>
<td>Monitor</td>
<td>Make serial observations according to specific criteria and schedule</td>
</tr>
<tr>
<td>Refer/consult</td>
<td>Direct a patient to another clinician for evaluation, treatment, or both</td>
</tr>
<tr>
<td>Prepare</td>
<td>Make ready for particular guideline-directed activity by training, equipping, or gaining new knowledge (eg, having procedures in place)</td>
</tr>
<tr>
<td>Document</td>
<td>Record 1 or more facts in the patient record</td>
</tr>
<tr>
<td>Advocate</td>
<td>Argue in support of a policy</td>
</tr>
<tr>
<td>Diagnose/conclude</td>
<td>Determine a diagnosis or clinical status</td>
</tr>
</tbody>
</table>

*Listed in order of declining prevalence based on Essaihi et al.61

As each topic is discussed, the group, assisted by the consultant, should draft a rough version of a related key action statement. To facilitate this process, the AAO-HNSF uses the BRIDGE-Wiz software application, developed by the Yale Center of Medical Informatics, to support the working group’s discussions. The BRIDGE-Wiz application (Building Recommendations In a Developer’s Guideline Editor) uses a sequential, step-like process to guide the group in developing action statements. BRIDGE-Wiz requires the group to outline (1) when (ie, precisely under what circumstances), (2) who, (3) ought (with what level of implied obligation), (4) to do what, and (5) to whom. The “how and why” of the statement are covered in the associated supporting text.

The most important word in a key action statement is the verb describing the action to be taken. Most guideline-prescribed activities can be described with a limited vocabulary of actions, shown in Table 15.61

This list is not intended to be restrictive but rather to help the group in getting started with creating the statements. Other verbs can be used provided they offer clear guidance.

BRIDGE-Wiz is a standalone desktop application that runs on both Windows and Macintosh platforms. As a software wizard, it leads the user in real time, while working with the guideline development group, through the following steps for each key action statement:

1. Choose an action type from a dropdown list (eg, examine, test, perform, educate)
2. Choose a verb based on the action type from a dropdown list
3. Define the object for the verb (to complete the action clause)
4. Add action(s), using AND or OR conjunctions for linkage
5. Check executability (eg, is each action stated specifically and unambiguously?)
6. Define precisely the conditions under which the action is to be performed
7. Check decidability (eg, would users consistently determine if a condition was met?)
8. Describe benefits followed by risks, harms, and costs if the statement were executed
9. Judge the benefit-harms balance (preponderance or equilibrium)
10. Select aggregate evidence quality that supports the recommendation
11. Review the proposed strength of recommendation and the term for the level of obligation (may, should, or must)
12. Define the actor (usually “clinicians”)
13. Choose a recommendation style from the several options offered
14. Edit the key action statement that is generated in a word processor

Guideline authors should remember the intended audience and ensure that their guidance is applicable. For example, a recommendation that “patients should not be exposed to passive cigarette smoke” is only actionable if the intended audience includes smokers. A preferable statement directed to an intended audience of (nonsmoking) clinicians would be to counsel patients about the importance of avoiding cigarette smoke.

Ambiguity and Vagueness in Action Statements

Key action statements should be clear and precise to avoid inconsistent interpretation and prevent inappropriate practice variation. Having drafted a list of key statements, the group should review the list for ambiguous or vague actions.

Ambiguity is present when a term can reasonably be interpreted in more than one discrete way.2 True ambiguity is almost always unintentional and readily correctible when identified. Examples might include interpretation of an acronym in more than one way (eg, LAD = left anterior descending, left axis deviation, and lymphadenopathy; MS might be interpreted as morphine sulfate, magnesium sulfate, or multiple sclerosis).

- We differentiate truly ambiguous statements from vague and underspecified statements. Vagueness is present when a word’s meaning is not well defined, lacking a crisp threshold in a single dimension. Examples include using terms such as short, febrile, or old, which are open to broad interpretation. Underspecified statements lack specificity in multiple dimensions, such as “sufficiently ill” or “severe asthma.”
- Modifying phrases introduce another form of vagueness. Examples include “it is prudent to recommend.” The passive voice is always vague because the essential “who” of the statement is missing. Similarly, asking clinicians to “consider” an action results in an unmeasurable outcome.
- Sometimes guideline developers introduce statements of fact as recommendations (eg, “adjuvant hormone therapy for locally advanced breast cancer results in improved survival in the long term”). Such statements (Table 10) are not executable because the specific action required is never defined.

Although key guideline statements should generally be precise and unambiguous, there may occasionally be a need for deliberate vagueness or underspecification. Reasons for intentionally creating vague recommendations include the following16:

- Insufficient evidence: the available literature has not addressed critical topics or the conclusions of published studies are suspect because of methodological flaws
- Inability to achieve consensus among the authors regarding evidence quality, anticipated benefits and harms, or interpretation of the science base (which should be documented in the action statement profile under “differences of opinion”)
- Legal considerations: unwillingness to create a potential legal “standard of care”
- Economic reasons: one approach is clearly best but may not be affordable
- Ethical/religious issues: for example, attitudes about the “the burden” or “futility” of care, premarital sex, use of blood products

An explicit statement of the reasons for writing deliberately vague recommendations can help users interpret and apply them, which is why “intentional vagueness” is included as an explicit construct in the action statement profile (Table 11).

Refining the Draft Guideline Key Statements

The group should now review and discuss the proposed outline of key action statements for the draft guideline. Is the sequence logical? Have all major quality concerns been addressed? Are there any obvious omissions or inconsistencies? Do the statements reflect the concerns of all disciplines in the working group?

A logical sequence of key action statements is important for clarity and will also facilitate writing if later statements build upon concepts developed in earlier text. The order of statements can always be adjusted later, but effort at this time to ensure smooth, conceptual flow is time well spent.

As mentioned before, the goal is not to have a perfect list of statements but rather to have an acceptable list that serves as a platform for moving forward with guideline development. The list can be revised as the process proceeds, but ideally the agreed-upon structure should be maintained. A draft list of guideline key action statements is shown in Table 16, based on the topic list for the hoarseness guideline shown in the preceding section. Note that the wording is rough and the strength of action (should vs may vs must) will be determined subsequently based on the associated action statement profile.

Define Supporting Text and Literature Search Needs

Following each key action statement, authors should write several paragraphs of supporting (amplifying) text that develop the rationale for the statement, present the underlying evidence (answering “why?”), and provide sufficient detail or references that members of the intended audience will be able to carry out (answering “how?”). It is important at this stage to remain focused on the recommendation.
statement and not to strive for encyclopedic coverage of the topic. Concisely stated guidance is more likely to be read and followed.

Although the text will not be written at this time, the group should discuss each key statement sequentially and outline concepts for the supporting text (Table 17). Ideas are recorded under each statement with the results displayed for immediate group feedback. The BRIDGE-Wiz software also includes a “comments” box on every data entry screen, which can be used to record ideas, concepts, and issues for discussion in the supporting text. The goal at this stage is define broad concepts; no attempt is made to create definitive language or statements. The supporting text, however, must thoroughly answer “why” the action statement was included (usually in the first paragraph of the text) and “how” it will be carried out (the remainder of the section). This is similar to the “methods” section of a scientific article in that enough detail should be provided for the reader (in this case, the guideline user) to reproduce or carry out the intervention in a clear and consistent manner.

Any topics or issues that were considered important by the group but were not chosen to be key recommendations can nonetheless be discussed in the text under a related key statement heading. By denoting a topic to the amplifying text, information can still be incorporated without the rigor needed to support a key recommendation.

Guideline authors need to be careful not to make substantive recommendations in the amplifying text. In contrast, they should be explicit about the evidence base, or lack thereof, for the actions proposed.

Before moving on to the next key action statement, the group must discuss the need for any stage 3 literature searches to support the statement. For example, a search may be needed to fill an evidence “gap” for a key action statement. A statement in the otitis media with effusion guideline reads, “Clinicians should document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with otitis media with effusion.”43 Since no reviews or randomized trials were identified to support this, additional searches were done on the value of documentation, in general, in ambulatory care settings. Two references were identified to support the importance and value of appropriate documentation.

Considerations in planning the stage 3 literature searches include the following:

- If the key action statement is already supported by systematic reviews or randomized trials, there may be no need for an additional literature search.
- If the key action statement is not supported by high-level evidence, or if additional information is required to answer questions posed in the supporting text, a stage 3 search should be planned. The group specifies the search parameters using a PICO format, which allows the staff to conduct an efficient search based on a predefined patient population, intervention, comparison, and outcomes.
- Although the stage 3 searches do not require the methodological rigor used in the stage 1 and 2 searches, the staff lead must reasonably document the search terms and processes to ensure transparency in reporting. Additional internal or external staff may be needed to complete the searches in a

Table 16. Draft Key Action Statements from the American Academy of Otolaryngology—Head and Neck Surgery Foundation Guideline on Hoarseness

| 1. Diagnosis: Clinicians should diagnose hoarseness in a patient with altered vocal quality, pitch, or effort that impairs voice or alters voice-related quality of life. |
| 2. Laryngoscopy: The clinician should visualize the larynx of a patient with hoarseness if there is concern of a serious underlying etiology [if possible, list specific criteria here instead of the vague term concern of a serious underlying etiology]. |
| 3. Modifying factors: Clinicians should assess the patient with hoarseness by history and/or physical examination for factors that modify management such as 1 or more of the following: immunocompromised state, prior laryngeal surgery, [list here, succinctly, all of the major factors; the list does NOT have to be completely inclusive]. |
| 4. Ancillary testing: Clinicians should not obtain computed tomography (CT), magnetic resonance imaging (MRI), or electromyography (EMG) of the patient with a primary complaint of hoarseness prior to visualization of the larynx. |
| 5. Laryngopharyngeal reflux: Clinicians may/should not routinely prescribe antireflux medications in patients with hoarseness. |
| 6. Corticosteroid therapy: Clinicians should not (routinely) prescribe [oral] corticosteroids to treat patients with hoarseness. |
| 7. Voice therapy: (A) Clinicians should advocate voice therapy for patients diagnosed with hoarseness that persists longer than 3 weeks or is recurrent and reduces voice-related quality of life. (B) Clinicians should/must visualize the larynx before prescribing voice therapy and document/communicate the results to the speech-language pathologist. |
| 8. Clinicians should not prescribe antibiotics for the treatment of hoarseness or laryngitis in the absence of concurrent bacterial infection. |
| 9. Clinicians should educate patients with hoarseness that surgery is a possible intervention. |
| 10. Clinicians may/should educate/counsel patients with hoarseness about control measures. |
| 11. The clinician may/should prescribe botulinum toxin injections for the treatment of hoarseness spasmodic dysphonia. |
timely fashion or work with the information specialist, based on the number required.

- One or more stage 3 searches may be required for the supporting text of a single key action statement. Parsimony and precision are encouraged to limit the search burden and keep the process as focused as possible.

When a key statement is supported by multiple randomized controlled trials, the group should identify and assess existing systematic reviews or meta-analyses. If none exist, an internal systematic review may be planned provided that time, resources, and expertise are available. If an existing, but outdated, systematic review is found, it may be possible to modify or update the data without conducting an entirely new review.

**Writing Assignments and Deadlines**

At the conclusion of the first in-person meeting, the chair distributes writing assignments to group members. Group members set and agree to deadlines for preparation of their assignments that will allow the project to remain on track. A democratic process helps to ensure adherence.

Each key statement and supporting text is assigned a primary author, who composes a draft that is reviewed by a secondary author with complementary expertise. For example, a statement about surgery might have a surgeon and primary care clinician as primary and secondary authors, respectively. If the group includes representatives of consumer groups and advance practice nursing, they may serve as reviewers, authors, or both. A sample writing assignment grid is shown in Table 18.

The goal of each writing assignment is to ensure that rationale for the related key action statement is explained fully, the logic behind the statement is apparent, all medical terms and actions are clear and unambiguous, and that best evidence supporting the statement is explained and referenced. Since most working group members will likely never have encountered this type of assignment, the chair must

### Table 17. Sample Key Action Statement with Suggestions for Writing the Supporting Text

<table>
<thead>
<tr>
<th>Key action statement:</th>
<th>Clinicians should use topical antimicrobials for initial therapy of diffuse, uncomplicated acute otitis externa. Systemic antimicrobial therapy should not be used unless there is extension outside the ear canal or the presence of specific host factors that would indicate a need for systemic therapy.</th>
</tr>
</thead>
</table>
| Concepts to include in the supporting text: | - Define *uncomplicated*  
  - Explain why oral antibiotics, particularly those approved for children, have limited coverage of acute otitis externa pathogens; conversely, how topical drops overcome this  
  - Discuss harms: side effects of systemic antimicrobials (allergy, rash, resistance, gastrointestinal upset); how topical drops avoid these problems  
  - Mention that there are no studies of oral vs topical; however, describe cohort studies of outcomes, clinical efficacy, and microbiologic efficacy of topical drops  
  - Identify candidates for systemic therapy, in addition to topical therapy: acute otitis media, immunocompromise, diabetes, irritated bone |

### Table 18. Sample Writing Assignment Grid from the American Academy of Otolaryngology—Head and Neck Surgery Foundation Hoarseness Guideline

<table>
<thead>
<tr>
<th>Key Action Statement</th>
<th>Primary Author</th>
<th>Secondary Author</th>
<th>Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diagnosis</td>
<td>Member A</td>
<td>Member B</td>
<td></td>
</tr>
<tr>
<td>2. Laryngoscopy</td>
<td>Member C</td>
<td>Member D</td>
<td></td>
</tr>
<tr>
<td>3. Modifying factors</td>
<td>Member E</td>
<td>Member F</td>
<td></td>
</tr>
<tr>
<td>4. Ancillary testing</td>
<td>Member G</td>
<td>Member H</td>
<td></td>
</tr>
<tr>
<td>5. Laryngopharyngeal reflux</td>
<td>Member B</td>
<td>Member D</td>
<td>Member I</td>
</tr>
<tr>
<td>6. Corticosteroid therapy</td>
<td>Member F</td>
<td>Member J</td>
<td>Member I</td>
</tr>
<tr>
<td>7. Voice therapy</td>
<td>Members J and K</td>
<td>Member L</td>
<td></td>
</tr>
<tr>
<td>8. Antimicrobial therapy</td>
<td>Member M</td>
<td>Member A</td>
<td>Member N</td>
</tr>
<tr>
<td>9. Surgery</td>
<td>Member O</td>
<td>Member E</td>
<td>Member G</td>
</tr>
<tr>
<td>10. Prevention</td>
<td>Member L</td>
<td>Member O</td>
<td>Member N</td>
</tr>
<tr>
<td>11. Botox therapy</td>
<td>Member P</td>
<td>Member C</td>
<td></td>
</tr>
</tbody>
</table>
provide clear and specific written instructions to guide the process (Table 19). The chair should review these instructions with the group to clarify any uncertainty and to emphasize the importance of following them explicitly.

Key Points to Remember

1. The prioritized topic list, based on e-mail exchange after conference call 2, must be completed before the meeting.
2. The primary goal is to draft the guideline’s key action statements and to outline broad concepts that will form the supporting text.
3. Emphasis is placed on creating a clear and logical draft that addresses quality opportunities from the topic list and takes advantage of available high-quality evidence.
4. Writing assignments developed during this meeting will require more time from working group members than any other part of the guideline process.

Stage 3 Literature Search

Purpose
The final step in identifying evidence is driven by the specific key action statements developed by the working group, which form the core of the guideline. These statements reflect opportunities for education and quality improvement, which may not necessarily be supported by existing systematic reviews or randomized controlled trials. Therefore, the stage 3 searches focus on identifying best published evidence to facilitate writing assignments for specific action statements and to subsequently assist the group in determining the corresponding action statement profiles and strengths of recommendation.

As discussed in the preceding section, the group should identify the need for stage 3 searches when discussing the guideline topic list and composing the list of concepts to be covered in the corresponding supporting text.

The stage 3 searches should be coordinated by the staff lead, working with the information specialist, after the first in-person meeting. Search results should be grouped by major subheadings (eg, etiology, diagnosis, therapy, prognosis) available in standard electronic databases. Search results are sent to the group member assigned as the primary writer for the specific action statement. The writer eliminates irrelevant items, leaving a core of evidence that is distributed to the group for reference along with the statement that prompted the literature search.

Identifying Supplementary Evidence
Supplementary evidence can be identified by using PICOTS-type questions, which pose a well-focused question that can serve as the basis for the literature search.63 The
rationale and format of PICOTS questions have been discussed earlier in this document, with examples in Table 7. Any PICOTS questions that were formulated earlier to support specific topics can be used at this time for the literature search.

If a specific action statement is already supported by high-quality evidence such as systematic reviews or randomized controlled trials, additional stage 3 searches may be unnecessary. When high-quality evidence is sparse, however, a PICOTS-type question may be formulated for each action statement to facilitate the search.

Writing Assignments

Group Writing Assignments

Timely completion of group writing assignments is mandatory to keep guideline development on schedule. The staff lead and, if necessary, the chair should send reminders in advance of deadlines and monitor when assignments are completed. Delinquent group members should be contacted to ascertain the reason for delay and identify remedial action. In some cases, assignments may need to be modified.

Additional Literature Search and Systematic Review

The need for a search may only become apparent once the author assigned to write the text begins the task and becomes more familiar with the material. In this circumstance, the author may conduct his or her own search, with or without assistance from the staff lead.

Table 7.

If any systematic reviews or meta-analyses are required, they are planned with the group consultant or methodologist. This will entail substantial added effort because of the methodological rigor needed to produce a valid, unbiased, publication-quality systematic review. Whenever possible, guideline topics should be selected based on a foundation of existing systematic reviews, rather than attempting to create reviews from scratch. Sometimes, however, the need to create a review is unavoidable, and the project should be approached with realistic expectations regarding the time and effort involved.

Systematic reviews or meta-analyses conducted to support the guideline are conducted with an a priori protocol to justify publication as an independent manuscript. Attempting to incorporate the review into the guideline text is ill advised, because the reporting detail needed to demonstrate validity of the review will overwhelm the guideline with unnecessary technical details. Only a brief, readable summary is included, with external reference to the systematic review manuscript, which is submitted separately for publication.

Collation of Writing Assignments into First Draft

As the staff lead receives the completed writing assignments (by electronic mail), they are collated into a first draft of the guideline, using the previously described template (Table 8). The goal is to create the draft before the next in-person meeting while still allowing sufficient time for preliminary feedback by the group.

Prior to the second in-person meeting, the collated first draft should be reviewed by the chair to align ideas and concepts provided by the writing assignments, although editing may be necessary to standardize the writing style. Writing assignments are best viewed as raw material for composing the draft to ensure a balanced, multidisciplinary product. Authors of the original writing assignment will have ample opportunity to comment on any changes made by the chair in style or format for consistency with the remainder of the guideline.

The effort required by the chair in collating the writing assignments should not be underestimated. The assignments are likely to vary greatly in quality, completeness, and punctuality. Consequently, the chair may need to revise substantial portions of submissions and fill in conceptual gaps not covered. Some groups use professional medical writers to collate and improve the consistency of submissions.

When complete, the first draft of the guideline is distributed by e-mail to guideline development group members for review and comment. Using the “line numbers” feature of the word processor facilitates commenting by line number. The document is distributed as a read-only file (eg, pdf format) to prevent direct modification and force the use of comments based on stable line numbers.

Comments from the group are collected and collated by the staff lead, who then distributes the final list to the chair for incorporation into the draft. Strict accounting of responses to substantive comments is critical to avoid a situation in which the same topic is revisited on multiple occasions. A recommended approach is for the staff lead to create a 4-column table (Table 20) in which all comments received from group members are listed by line number. The “disposition” states how the chair handled the comment and will assure members that their concerns have been addressed.

The chair revises the guideline draft based on the collated comments and dispositions. Any changes made to the draft are performed using the “track changes” feature of the word processor, so they are easily identifiable. The revised guideline and the summary table of comments are distributed to working group members before the next meeting.
In-Person Meeting 2: Refining the Guideline

Purpose
The purpose of this meeting is to polish the key action statements, review supporting text, and refine action statement profiles for each action statement. The main product of the meeting is a second draft of the guideline that accurately reflects the logic and goals of the working group. In addition, the group incorporates suggestions for implementation and future research into the guideline.

Predistribute Electronic Materials
Documents should be distributed by e-mail and stored electronically prior to the conference call for review by participants before the meeting. Materials for predistribution include the following:

- Agenda for the conference call
- Updated working group contact information grid with conflict of interest disclosures
- Document containing all of the unedited writing assignments

Draft guideline based on edited writing assignments and initial group feedback
- Relevant pages of the guideline development manual
- Any other information on content or methodology identified by working group members that would be helpful in educating the group or stimulating discussion

Reviewing Front Matter
The main goal of reviewing the draft guideline is to achieve a logical, consistent document that accurately reflects the group intentions, minimizing vagueness and underspecification. The goal is not to quibble over semantics, grammar, or sentence structure, all of which waste valuable time and can be done through electronic mail exchange.

The chair, assisted by the consultant, must effectively manage time and the group dynamics during the meeting to facilitate steady progress and to ensure that a minority of voices do not dominate the session.

<table>
<thead>
<tr>
<th>Line</th>
<th>Source</th>
<th>Comment</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>515</td>
<td>Fred</td>
<td>Change “may be” to “is”</td>
<td>Done</td>
</tr>
<tr>
<td>524-26</td>
<td>Sara</td>
<td>[very important] The statement regarding susceptibility to deficits in older children is not validated. I would delete.</td>
<td>I agree; the paragraph reads better without it.</td>
</tr>
<tr>
<td>526</td>
<td>John</td>
<td>. . . reading ability due to prolonged MEE? Or to the hearing loss associated with it?</td>
<td>Sentence was deleted.</td>
</tr>
<tr>
<td>529</td>
<td>Sara</td>
<td>“Given enough time” we’re all dead! Get rid of that phrase!</td>
<td>Done</td>
</tr>
<tr>
<td>533-6</td>
<td>Mike</td>
<td>Would be useful to add the relative risk for these—would indicate the degree of risk they convey</td>
<td>The odds ratios for all are about 2.0-3.0; we decided previously as a group not to put these in.</td>
</tr>
<tr>
<td>547</td>
<td>Fred</td>
<td>Would start new paragraph at “Conditions”</td>
<td>Done</td>
</tr>
<tr>
<td>554</td>
<td>Karen</td>
<td>Define sound field.</td>
<td>Reworked and defined</td>
</tr>
<tr>
<td>566</td>
<td>John</td>
<td>Not acceptable, “or surgery” should not be there.</td>
<td>Sorry, but the rest of the group disagrees. We are listing surgery here as an option based on individual circumstances, not as a recommendation as in the prior guideline. The existing evidence is not strong enough to eliminate surgery as an option.</td>
</tr>
</tbody>
</table>
Begin by reviewing the guideline front matter, which includes information about purpose and disease burden. Since this was already reviewed once at the prior meeting, the process should not require substantial time. The document is revised in real time by the chair or his or her designate, and requests for additional information or fact checking are assigned for completion after the meeting.

Reviewing the draft guideline presents an ideal opportunity for identifying research and implementation needs, beyond any already specified in the writing assignment. Throughout the meeting, thoughts related to opportunities for effective implementation and future research are recorded:

- **Implementation needs.** One group member, ideally an assistant chair, is assigned by the chair to record implementation needs. Consider what exactly will be needed for the target clinician to effectively and efficiently perform what is requested in the key action statement. Examples include fact sheets, brochures, algorithms, visual aids, and videos.
- **Research needs.** Another member, ideally an assistant chair, is assigned to record ideas for future research. As the group discusses supporting text, evidence voids become apparent, creating the perfect opportunity to decide what is needed to fill the void.

### Reviewing Action Statements and Supporting Text

Next, each key action statement is reviewed by the group along with the supporting text. The chair and consultant lead the discussion, striving for balanced input from the group and efficient use of time. The chair or his or her designate records changes to the guideline in real time, projecting the guideline for all to see and using “track changes” on the word processor to clearly identify what has been altered.

The following sequence is advised when reviewing each action statement and supporting text:

1. Read the key action statement to the group and identify any potential words or actions that are vague, underspecified, or unclear.
2. Skip any discussion of the action statement profile for now, since a more informed discussion can occur after the amplifying text is fully reviewed.
3. Assess the introductory paragraphs of supporting text to determine if they effectively engage the reader by giving an overview of the rationale for the key action statement and how following it will improve quality of care (the “why”).
4. Review all remaining paragraphs for content, sequence, and conceptual clarity. Is the purpose of each paragraph clear? Do the paragraphs follow a logical sequence? Did the writers cover all concepts in the original writing assignment?
5. Determine if the action specified in the statement is described with enough detail and clarity to enable a typical guideline user to perform what is requested (the “how”).
6. Consider the need for 1 or more subheadings in the supporting text if the section is long or if there are several discrete concepts that would benefit from segregation.

### Reviewing Action Statement Profiles and Recommendation Strength

One of the most important goals of sequentially reviewing the key action statements and accompanying text is to reach consensus on the action statement profiles (Table 11). Although the profile statements should be concise, at this stage it is better to be more verbose and err on the side of overexplanation than risk not being clear on why decisions were made. The profiles can subsequently be edited for brevity and consistency.

Action statement profiles are a primary means of promoting transparency in guideline development and must be developed with care and consistency. Additional time spent ensuring full consensus on the profiles will facilitate grading recommendation strength.

Once the profile has been agreed upon for a specific key action statement, the group reviews the strength of recommendation for consistency with Table 13. This should be very straightforward if the action statement profile was fully discussed. At times, however, the strength of recommendation does not “make sense” to 1 or more group members. When this occurs, the action statement profile is reviewed, especially the aggregate evidence quality, to ensure accuracy of the information and that no important evidence was overlooked.

An accurate, explicit action statement profile offers the most compelling argument for the group to accept a recommendation grade that challenges existing biases and preconceptions. Special attention should be given to the aggregate evidence level and the descriptions of benefit and harms/risks/costs since these are the primary determinants of recommendation strength.

Assigning a level of confidence to the evidence. Now that the guideline development group is thoroughly familiar with the evidence underpinning each action statement, the level of confidence should be estimated as high, medium, or low in the second bullet-point of the action statement profile (Table 11). There is a direct relationship between the level
of confidence in the aggregate evidence supporting a prescribed action and the level of obligation that can reasonably be assigned (Table 14).

The GRADE approach offers a comprehensive method of assessing risk of bias (level of confidence) for guideline developers based on study limitations, imprecision, inconsistency, and indirectness. A simple adaptation is presented in Table 21 that can be used by the development group to guide the discussion and reach consensus on the level of confidence for the aggregate evidence in each action statement profile. As the potential quality concerns increase, the confidence in the evidence decreases and should be rated as “low” when multiple, significant concerns are present.

When the guideline development group concludes there is “low” confidence in the evidence for a specific recommendation, a decision is required as to whether the aggregate level should be downgraded. For example, a systematic review of randomized trials might be downgraded from level A to level B because of limitations in the source articles, wide 95% confidence intervals in effect sizes, or unexplained heterogeneity (inconsistency) among the studies. Recommendations based on observational studies could similarly be downgraded if plagued by unclear subject selection criteria, loss to follow-up, and failure to consider confounding factors.

Conversely, a body of evidence with very high confidence may at times be upgraded if the group agrees it is warranted. The most common reason for upgrading the aggregate level of evidence is when a large or dramatic effect (outcome) occurs in high-quality observational studies, which is already incorporated into Table 12 in the columns for “treatment” and “harm” (grade B, OCEBM level 2). Other reasons for upgrading include when there is a dose-response gradient or when all plausible confounding factors or other biases increase confidence in the outcomes. In general, the group should only upgrade evidence when there is clear consensus that the action is warranted.

Any decisions by the group regarding level of confidence and its impact on aggregate evidence level must be clearly documented in the relevant sections of the action statement profile, including the “values” section, if appropriate. Since there are no precise formulas or any strict rules for rating level of confidence, the group is obligated to make clear the reasoning applied. Additional justification can be given in the supporting text as needed, especially if the decisions alter the final recommendation strength.

### Table 21. Assessing the Level of Confidence in the Aggregate Evidence

<table>
<thead>
<tr>
<th>Quality Domain</th>
<th>Specific Concerns that Reduce the Level of Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study limitations (risk of bias) for</td>
<td>1. Lack of allocation concealment: investigators can tell to which group the next patient will be assigned</td>
</tr>
<tr>
<td>randomized controlled trials</td>
<td>2. Lack of blinding: patients, investigators, assessors</td>
</tr>
<tr>
<td></td>
<td>3. Loss to follow-up: imbalanced loss among groups; lack of intention-to-treat analysis</td>
</tr>
<tr>
<td></td>
<td>4. Selective outcome reporting: incomplete reporting of some outcomes and not others</td>
</tr>
<tr>
<td>Study limitations (risk of bias) for</td>
<td>1. Problems with selection (inclusion/exclusion) criteria: inadequate description, nonconsecutive samples; unclear comparison or control group</td>
</tr>
<tr>
<td>observational studies</td>
<td>2. Flawed measurement of exposure or outcome</td>
</tr>
<tr>
<td></td>
<td>3. Failure to control confounding: failure to account for prognostic factors; lack of statistical adjustment</td>
</tr>
<tr>
<td></td>
<td>4. Loss to follow-up: 20% of more of sample</td>
</tr>
<tr>
<td>Imprecision</td>
<td>1. Few studies and/or small sample sizes</td>
</tr>
<tr>
<td></td>
<td>2. Main outcomes are not described using 95% confidence intervals (CI) or the CIs are very wide</td>
</tr>
<tr>
<td></td>
<td>3. Values at the upper or lower range of the 95% CI might change the recommendation</td>
</tr>
<tr>
<td>Inconsistency</td>
<td>1. Results vary widely across studies</td>
</tr>
<tr>
<td></td>
<td>2. Significant heterogeneity found in systematic review</td>
</tr>
<tr>
<td>Limited generalizability (indirectness)</td>
<td>1. Differences between the study population(s) and the guideline target population</td>
</tr>
<tr>
<td></td>
<td>2. Differences in interventions used by the investigator(s) compared with the guideline intervention</td>
</tr>
<tr>
<td></td>
<td>3. Differences in outcome measure(s)</td>
</tr>
</tbody>
</table>

Determination of patient preferences. In contrast to the paternalistic approach to medical decision making that dominated most of the 20th century, the medical community and public are increasingly embracing shared decision making. The process of shared decision making is more properly defined in terms of a continuum, ranging from physician-driven decisions to patient- or agent-driven decisions, made almost entirely by the patient or surrogates (parents, guardians, family members, etc). The goal of shared decision making is to ensure consistency with the patient’s wishes and values.
For some guideline action statements, where the evidence base demonstrates clear and convincing benefit (e.g., a strong recommendation), the role of patient preference is diminished. Nonetheless, clinicians should provide patients with clear and comprehensible information on the benefits to facilitate patient understanding, adherence to therapy, and improved outcomes. In cases where evidence is weak or benefits unclear (e.g., an option), the role of patient preference is typically large, necessitating a collaborative effort between the clinician and an informed patient. Factors that might influence patient preference include (but are not limited to) absolute benefits (numbers needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

The anticipated role of patient preferences is rated as small, moderate, or large in each action statement profile. Input from the consumer representatives on the guideline development group is often extremely helpful in reaching consensus regarding the appropriate rating. A useful perspective on shared decision making is found in the Salzburg Statement, which calls on clinicians to

- Recognize that they have an ethical imperative to share important decision with patients
- Simulate a 2-way flow of information and encourage patients to ask questions, explain their circumstances, and express their personal preferences
- Provide accurate information about options and the uncertainties, benefits, and harms of treatment in line with best practice for risk communication
- Tailor information to individual patient needs and allow them sufficient time to consider their options
- Acknowledge that most decisions do not have to be taken immediately, and give patients and their families the resources and help to reach decisions

Moving the process along. Repeat the steps above until all key action statements and supporting text are discussed and consensus has been reached on composition and structure. Some sections will invariably require more discussion than others, but time must be allowed for adequate discussion of all statements and supporting text. If a section requires significant rewriting, reorganization, or additional citations, the specific needs are recorded as an action item that will be addressed immediately after the meeting by the chair or his or her designee.

Outline of Key Action Statement Topics
After the key action statements have been discussed and the sequence agreed upon by the group, a table is added to the guideline summarizing the statement topics and strengths. An example is the table included in the AAO-HNSF sudden hearing loss guideline (Table 22). The purpose is to orient...

<table>
<thead>
<tr>
<th>Table 22. Outline of Key Action Statement Topics in the American Academy of Otolaryngology—Head and Neck Surgery Foundation Sudden Hearing Loss Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of Patients with Sudden Hearing Loss (Evidence-Based Statement)</td>
</tr>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Exclusion of conductive hearing loss (statement 1)</td>
</tr>
<tr>
<td>Modifying factors (statement 2)</td>
</tr>
<tr>
<td>Computed tomography (statement 3)</td>
</tr>
<tr>
<td>Audiometric confirmation of ISSNHL (statement 4)</td>
</tr>
<tr>
<td>Laboratory testing (statement 5)</td>
</tr>
<tr>
<td>Retrocochlear pathology (statement 6)</td>
</tr>
<tr>
<td>Shared decision making</td>
</tr>
<tr>
<td>Patient education (statement 7)</td>
</tr>
<tr>
<td>Treatment</td>
</tr>
<tr>
<td>Initial corticosteroids (statement 8)</td>
</tr>
<tr>
<td>Hyperbaric oxygen therapy (statement 9)</td>
</tr>
<tr>
<td>Other pharmacologic therapy (statement 10)</td>
</tr>
<tr>
<td>Salvage therapy (statement 11)</td>
</tr>
<tr>
<td>Follow-up</td>
</tr>
<tr>
<td>Outcomes assessment (statement 12)</td>
</tr>
<tr>
<td>Rehabilitation (statement 13)</td>
</tr>
</tbody>
</table>

Abbreviation: ISSNHL, idiopathic sudden sensorineural hearing loss.
readers to the structure and content of the guideline and to highlight stronger statements for easy identification.

Consider the Need for an Algorithm

Many guidelines benefit from having 1 or more clinical algorithms that graphically display decision logic and sequences of activities (Figure 1). Including an algorithm in a guideline can (1) rapidly convey the scope and organization of the guideline; (2) result in faster learning, higher retention, and better compliance by the practice community; and (3) specify appropriate indications for particular management strategies.

Algorithms are most useful when the decision logic of a guideline is complex and the temporal sequence of activities is unclear.

Figure 1. Example of an algorithm from the American Academy of Otolaryngology–Head and Neck Surgery Foundation clinical practice guideline on acute otitis externa (AOE). Reproduced with permission from the American Academy of Otolaryngology–Head and Neck Surgery.

- Use rounded rectangles to describe a clinical state at entry or completion of a decision sequence, diamond-shaped or hexagonal decision nodes to indicate branch points leading to alternate pathways, and rectangles to indicate diagnostic and therapeutic actions. Diamonds and rectangles correspond to the key recommendations in the guideline.
- Reduce clutter by maintaining a logical flow within the algorithm, usually down the page with side issues, smaller subpopulations, and problems not covered moving off to the side.
- Insert decision nodes wherever a significant patient preference-dependent decision must be made. Such nodes will generally be placed before treatment rectangles where patient input plays a key role in decision making.
- Be sure that each question node has at least 2 exit arrows, one for yes and one for no. Decision nodes should have at least 2 exit arrows, corresponding to each major decision outcome (eg, yes, no; platelet count <50,000, 50,000 to 150,000, or >150,000).
- Avoid crossing arrows if at all possible. When crossing is unavoidable, use a curved “overpass” to make it clear that one arrow is crossing over another.

Define Implementation and Identify Obstacles

A well-crafted guideline includes a plan for how the recommendations will be implemented and anticipates obstacles to implementation. As suggested earlier, a running list of implementation issues and needs should be maintained by one of the assistant chairs and updated as discussion proceeds during the second in-person meeting. Issues to consider in this section include (a) plans for distribution and dissemination of the guideline, (b) anticipated obstacles to implementation and proposed solutions, and (c) evaluation plans to assess the impact of the guideline on clinical care processes and patient outcomes. The life span of the guideline should also be specified, with a statement about when review or revision is planned. Additional details about updating guidelines are provided later in the manual.

Working Group Assignments and Next Steps

The chair reviews specific assignments made during the meeting and assigns deadlines for completion. The chair will also compile a revised guideline based on decisions made at the meeting plus information received from assignments. The final revision should include a section about future research needs.

Key Points to Remember

1. The draft guideline, based on e-mail exchange after conference call 2, must be completed before the meeting.
The primary goal is to achieve consensus on the organization and content of the guideline. Emphasis is placed on creating clear and logical supporting text that facilitates completing an action statement profile for each key action statement, which will determine the strength of action for the corresponding key statement.

Lists are compiled for implementation considerations and future research needs.

### Appraising Draft Guideline Implementability

Guideline appraisal is valuable at this stage to ensure that the guideline is clear and adheres to current methodological standards and (importantly) that recommendations can be implemented in a manner that is likely to influence clinician behavior. This can be accomplished by staff at the sponsoring organization, some of whom have not participated in the guideline development process.

The Yale Center for Medical Informatics has developed an online Guideline Implementability Appraisal (eGLIA) tool to aid developers in identifying and remediying potential problems with validity or implementation before publication. The staff lead, in conjunction with 2 internal staff members, reviews the guideline draft across a set of 6 global dimensions followed by an examination of each of the guideline’s key action statements. Each action statement is appraised across 8 dimensions of guideline implementability (Table 23).

The guideline is reviewed by staff members who are unfamiliar with the guideline’s content and who have not been involved in its development. This approach often highlights areas that may be missed otherwise. The staff lead then reconciles any differences between the 2 reviews, and the eGLIA tool generates a report highlighting all potential barriers for implementation.

The following examples illustrate how feedback from the GLIA assessment identifies areas for improvement in guideline statements. In each case, the specific key action statement under analysis is stated followed by the general and specific areas of concern:

**GLIA analysis of the draft statement on advocating for polysomnography from the polysomnography guideline.**

The clinician should advocate for polysomnography prior to tonsillectomy for sleep-disordered breathing in children for whom the need for surgery is uncertain or when there is discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing.

1. The recommended action should clarify that the statement refers only to children without any of the following conditions: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.
2. The recommendation may require a change in clinician behavior for those who do not currently advocate for polysomnography prior to tonsillectomy.

**GLIA analysis of the draft statement on watchful waiting from the acute sinusitis guideline.**

Observation without use of antibiotics is an option for selected adults with uncomplicated acute bacterial rhinosinusitis based on illness severity and assurance of follow-up.

1. The recommendation (and its discussion) is not concise: the raw meta-analysis data in the discussion could be referenced rather than included.
2. The recommendation is not compatible with existing attitudes and beliefs of the guideline’s intended users: may require convincing clinicians not to use antibiotics.

### Table 23. Dimensions of Implementability for Guideline Recommendations

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Decidability</td>
<td>Precisely under what circumstances to do something</td>
</tr>
<tr>
<td>2. Executability</td>
<td>Exactly what to do under the circumstances defined</td>
</tr>
<tr>
<td>3. Effect on process of care</td>
<td>The degree to which the recommendation affects the usual workflow in a typical care setting</td>
</tr>
<tr>
<td>4. Presentation and formatting</td>
<td>The degree to which the recommendation is easily recognizable and succinct</td>
</tr>
<tr>
<td>5. Measurable outcomes</td>
<td>The degree to which the guideline identifies markers or end points to track the effects of implementation of this recommendation</td>
</tr>
<tr>
<td>6. Apparent validity</td>
<td>The degree to which the recommendation reflects the intent of the developer and the strength of the evidence</td>
</tr>
<tr>
<td>7. Novelty and innovation</td>
<td>The degree to which the recommendation proposes behaviors considered unconventional by clinicians or patients</td>
</tr>
<tr>
<td>8. Flexibility</td>
<td>The degree to which a recommendation permits interpretation and allows for alternatives in its execution</td>
</tr>
</tbody>
</table>

*Adapted from Shiffman et al.73*
3. The recommendation does not consider coincident drug therapy and common comorbid conditions: is this recommendation valid in all populations (eg, elderly, diabetics, hospitalized patients)?

Conference Call 3: Ensuring Implementability

The purpose of this call is to review the guideline appraisal report, address any deficiencies identified, and plan for external peer review. In advance of the call, the guideline appraisal report should be distributed to group members.

- The section of the report focusing on the global dimensions is reviewed and discussed. If any deficiencies were noted, they are discussed and corrected if necessary.
- Each key action statement is then reviewed and discussed sequentially. If any implementation barriers were identified, the group discusses potential solutions, which typically involve rewording or clarifying segments of the text.

Now is not the time for major changes in the structure or order of key action statements unless the GLIA report identifies a serious deficiency that requires corrective action. The group should focus on remediying barriers to implementation identified in the report, without revisiting peripheral issues. If the conversation does digress, often the action statement profiles can be used as “organizational memory” as to why earlier decisions were made.

Suggestions are next solicited for external peer reviewers to review the draft guideline. Peer reviewers should represent the intended target audience and practice settings, and they are selected with input from the chair, working group members, Academy committee chairs, specialty leaders, and others.

Soliciting peer reviewers may take up to 6 weeks. The staff lead is responsible for contacting the organizations previously identified and gathering the names and contact details of all reviewers. In addition, the staff lead must ensure that each reviewer completes a conflict of interest disclosure form prior to distribution of the guideline. The guideline’s chair, assistant chair, and consultant should be made aware of any potential conflicts of reviewers.

Distributing the draft guideline as a pdf file has the advantage of making it impossible for a reviewer to simply type changes into the guideline text (which will greatly complicate the staff lead’s ability to identify them). The pdf file also ensures that all reviewers use the same line numbers, since numbers may not match when different word processing programs or operating systems are used.

External reviewers should be informed in advance that all comments provided will be vetted by the chair and assistant chairs, but there is no guarantee that every requested change will be made. Furthermore, unlike traditional editorial peer review, this is usually one-time event; the reviewers may not be provided with a revised document for further comment because doing so at this time is impractical and will create unacceptable delays. The reviewers are asked to focus on 3 main guideline attributes: validity, reliability, and feasibility:

1. **Valid** guidelines include all relevant literature, have explicit links between decisions and scientific evidence, and clearly distinguish and justify situations where expert judgment or group consensus is used to support recommendations.

2. **Reliable and reproducible** guidelines allow a knowledgeable peer reviewer to arrive at conclusions similar to those of the development group when considering the evidence.
3. Feasible guidelines are clearly written, are user-friendly, allow for flexibility in individual clinician decisions, and are suitable for routine use in intended settings.

Comments from the external reviewers are collected and collated by the staff lead. A recommended approach is for the staff lead to create a 4-column table (Table 24) in which all comments received are listed by line number. The comment table is distributed by the staff lead to the guideline’s chair and assistant chairs who complete the “dispositions” column, stating how each comment was handled and assuring external reviewers that their concerns have been addressed.

All reviewer comments deserve a response, but not every comment must be incorporated into the guideline. Whether to reject, accept, or partially accept a comment is determined by the chair and assistant chairs. When responding to the reviewers, it may be helpful to consider the 4 broad categories of concerns listed in Table 25.

The chair revises the guideline draft based on the collated comments and dispositions. Any changes made to the draft are performed using the “track changes” feature of the word processor, so they are easily identifiable. The revised guideline and the summary table of de-identified comments are distributed electronically to external peer reviewers.

In addition to the period of external review, guidelines are subsequently made available for a 2-week period of public comment. The final guideline draft is posted on the Academy’s website, and the comment period is highlighted via member communication, press releases, and direct solicitation to pertinent organizations such as consumer advocacy groups. All comments are addressed as outlined previously, with the chair and assistant chair stating their “dispositions.” The guideline document is refined as necessary using “track changes.”

The final guideline draft and the summary table of external reviewer comments and public review comments are distributed electronically to the working group for review and approval.

Two issues that deserve emphasis during external review are confidentiality and conflict of interest. All reviewers must sign a confidentiality statement and disclose any potential financial or other conflicts of interest.
Organizational Board Approval of Guideline

Prior to publication, the guideline should be distributed for approval to the board of directors of the sponsoring organization(s). The procedure will vary based on organizational policy, but the process used at the AAO-HNS is as follows:

1. The staff lead prepares and executive summary of the guideline that contains the (a) Introduction section, (b) Purpose section, (c) all key action statements with their corresponding action statement profiles, and (d) Implementation section.
2. The executive summary and full-text guideline are distributed to the board members for review, comment, and approval. The summary grid of external peer review comments and their disposition may also be included.

Because the document is based on evidence, any substantive changes requested by an oversight body (eg, the organizational board of directors) must be supported and accompanied by additional evidence. The oversight body should be informed, however, that the purpose of review is not to rewrite the guideline but rather to ensure that the guideline has been developed using approved methodology and that the recommended actions are clear, appropriate, and consistent with the organization’s mission.

Any comments or concerns expressed by the board are responded to by the chair, with input from the working group solicited as needed.

Publication and Disclaimers

The final guideline is converted by the staff liaison and chair into a manuscript that meets publication requirements from the sponsoring organization’s official journal. Ideally, the manuscript is submitted to the journal simultaneous with the organizational board review, which allows time for the journal peer-review process.

Although the guideline has undergone extensive internal and external review prior to manuscript
Responding to the comments of journal peer reviewers must be handled delicately since many concerns are likely valid and intended to improve the quality of the work. The suggestions in Table 25 should help in formulating a response and in revising the manuscript. In contrast to external reviewers, journal peer reviewers have the opportunity to provide additional feedback in response to a revised manuscript with point-by-point responses to the reviewer’s concerns. A sincere attempt should be made to incorporate most of the reviewer’s suggestions.

A copy of the chair’s summary table of external reviewer comments and their disposition should be submitted to the managing editor to document the external review and remain on file in lieu of traditional editorial peer review. Depending on the length of the document, the guideline may be published as a supplement or within the main journal. If the guideline is lengthy and published as a supplement, an executive summary may be prepared for publication in the main journal to promote awareness. The summary should contain condensed versions of the introductory segments, a tabular listing of all key action statements, full action statement profiles for the action statements, and condensed versions of supporting text.

Guidelines should be published with an accompanying disclaimer, created by the organization’s legal counsel, to set clear bounds on the intended use of the document. The AAO-HNSF adds a brief disclaimer to the abstract and a longer disclaimer to the end of the manuscript. Having a disclaimer in the abstract is advised because individuals without access to the full text may cite only the abstract text.

Here is the AAO-HNSF disclaimer text added to the end of the abstract:

This clinical practice guideline is not intended as a sole source of guidance in managing [topic specified here]. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition, and may not provide the only appropriate approach to diagnosing and managing this problem.

Here is the AAO-HNSF disclaimer text added to the end of the manuscript:

This clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing [GUIDELINE TOPIC]. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition, and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates and do not and should not purport to be a legal standard of care. The responsible physician, in lights of all the circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), Inc. emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

Dissemination and Implementation

Dissemination (raising awareness) is the precursor to implementation (affecting change) and begins with publishing the guideline. The guideline chair, working with the staff lead, should prepare a summary of newsworthy points from the guideline, which the organization’s public relations department can use in a press release. Embargo and publication dates are coordinated among all involved organizations.

Issues that should be addressed in the press release, or in other documents prepared for dissemination, include the following:

- Why is the topic of the guideline important?
- How and by whom was the guideline developed?
- Who is the target audience (eg, what types of patients, providers, settings)?
- What is the main public health message, stated succinctly and in lay terms?
- What are the key messages, and what do they mean for clinicians and patients?
- What changes in practice or health outcomes might the guideline produce?
- Are any barriers to implementation anticipated?
- What gaps in care were identified?
- What are the key messages, and what do they mean for clinicians and patients?
- What changes in practice or health outcomes might the guideline produce?
- Are any barriers to implementation anticipated?
- What gaps in care were identified?

Dissemination may also include blast e-mails, postings, and links on the organization’s website; articles in the
The conceptual framework for guideline implementation continues to evolve and is being affected by new distribution venues (eg, tablet computers, smartphones, electronic health records). Strategies that have been used by guideline developers include short versions, patient (plain language) versions, recommendation summaries, algorithms, patient and caregiver resources, and attempts to individualize recommendations to specific patient needs.75 Manuscripts can also include links to illustrative videos and other supporting materials accessible online.

Awareness of the guideline is increased by ensuring that the National Guideline Clearinghouse (NGC) receives a copy of the final publication with appropriate copyright release to produce a summary document. Furthermore, each guideline should be submitted and referenced in the Guidelines International Network (G-I-N) to support further dissemination. Efforts to create performance measures based on the guideline should be planned when appropriate and are facilitated by clear action-oriented recommendations supported by high-quality evidence.

In general, performance measures are likely to be most valid when built around strong recommendations and recommendations, where the benefit-risk deliberation shows a preponderance of one or the other, and good quality evidence supports the policy.

Performance measures are unlikely to be valuable if built around (1) statements that are vague or underspecified; (2) recommendations where anticipated benefit is balanced by anticipated risk, harm, and cost; or (3) recommendations are based on evidence that may change.

### Update

Guidelines should describe how and when the need for an update will be assessed. Situations that might require clinical guidelines to be updated include the following:76:

- Changes in evidence that bear on the existing benefits and harms of interventions
- Changes in outcomes considered important
- Changes in available interventions
- Changes in evidence that current practice is optimal
- Changes in values placed on outcomes
- Changes in resources available for health care

The AAO-HNSF guidelines are updated at a minimum of 5 years after publication. An earlier update may take place if any of the situations previously noted becomes apparent.

The first stage of the update process is to convene a guideline update group. This should consist of a chair,

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**Table 26. Guideline Update Summary Table for Key Action Statements**

<table>
<thead>
<tr>
<th>Key Action Statement</th>
<th>Action Statement Profile</th>
<th>Assessment of Relevancy (Select One from the List Below)</th>
<th>Comments/New Evidence (Please Provide References)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. Differential diagnosis: Clinicians should distinguish diffuse AOE from other causes of otalgia, otorrhoea, and inflammation of the external ear canal. Recommendation based on observational studies with a preponderance of benefit over risk</td>
<td>Aggregate evidence quality: C, observational studies and D, expert opinion Benefit: improved diagnostic accuracy Harm: none Cost: none Benefits-harm assessment: preponderance of benefits over harm Value judgments: importance of accurate diagnosis Role of patient preferences: none Policy level: recommendation</td>
<td>Keep as is/still valid</td>
<td>Keep but modify/needs revisions</td>
</tr>
</tbody>
</table>

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assistant chair, a methodology consult, and between 2 and 5 content experts. The members can be identified from the original guideline panel, those with previous guideline experience, and AAO-HNS members such as those from content committees.

Prior to the guideline update group reviewing the original guideline, an executive summary is distributed to a small group of external reviewers for their feedback. Between 5 and 10 reviewers are sought, and they should include representatives from AAO-HNS content committees, the AAO-HNS Board of Governors, subspecialty society members, other pertinent disciplines, and consumer advocacy groups. The executive summary should include the original guideline’s introduction and purpose sections along with each of the guideline’s key action statements and respective action statement profiles.

Reviewers are asked to complete a summary grid, review each key action statement, and provide a suggested disposition (keep as is, keep but modify, or discard). They also identify any new or pertinent evidence and submit additional quality improvement opportunities, not addressed in the original guideline, for which new action statements could be developed. An example of the summary table used for the update of one key action statement from the acute otitis externa guideline is provided in Table 26.

In addition to the external review, a literature search should be performed to identify new randomized control trials, systematic reviews, and clinical practice guidelines published since the guideline’s release. Ideally, as with previous literature searches, an information specialist should be identified to coordinate the search.

The guideline update group should convene via conference call to review the original guideline’s key action statements, the feedback provided by reviewers, and the results of the literature search. The conference call should proceed by carefully reviewing each of the guideline’s key action statements to determine if a revision is required. In some cases, an original key action statement may no longer be relevant or may have become redundant and be removed from the guideline. In addition, the guideline update group should discuss any quality improvement opportunities that were submitted during the review process and decide if any new action statements should be added during the guideline update.

At this point, the group should determine the extent of the update required. In addition, the composition of the group should be reassessed based on the planned extent of the update. There are 3 different levels of update:

1. Reaffirmation, if no significant changes are required. Working by conference call, the guideline development group prepares a brief statement for publication in the organization’s journal stating how the group reached this decision and the length of the reaffirmation (guidelines may only be reaffirmed once).
2. Minor update, if revisions to the key action statements are required that do not substantially change the conclusions or recommendations. The guideline development group convenes for 1 or more conference calls followed by a 1-day, in-person meeting.
3. Major update, if revisions that substantively change recommendations or include new key action statements are required. The guideline development group convenes for 1 or more conference calls followed by a 1- or 2-day, in-person meeting.

Any new key action statements will be developed with the methodology previously described; this includes the use of BRIDGE-Wiz. After completing the update, the finalized draft will undergo a guideline implementability appraisal with eGLIA. Any additional revisions to the draft will be incorporated after the completion of the GLIA assessment, and the document will be distributed for a further period of external review. Publication, dissemination, and implementation proceed as outlined in preceding sections.

Author Contributions
Richard M. Rosenfeld, writer, reviewer; Richard N. Shiffman, writer, reviewer; Peter Robertson, writer, reviewer.

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