Guidelines and Professional Medical Associations

Best Practices & Overcoming Obstacles

Richard Rosenfeld, SUNY Downstate
Peter Robertson and Stephanie Jones, AAO-HNS
Who are we?

The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) is the world's largest organization representing specialists who treat the ear, nose, throat, and related structures of the head and neck.

The Academy represents more than 12,000 otolaryngologist—head and neck surgeons who diagnose and treat disorders of those areas.

Headquarters in Alexandria, VA
Our staff

AAO-HNSF Guideline Staff
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Seth Schwartz, MD, MPH, Chair Guideline Development Task Force
### AAO-HNS Guidelines Usage Summary

The following table contains the cumulative number of page views for each AAO-HNSF guideline listed on the National Guidelines Clearinghouse (NGC) website from the time the guideline was posted to the NGC through June 2012.

<table>
<thead>
<tr>
<th>Title</th>
<th>Date released</th>
<th>Page views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Practice Guideline: Acute Otitis Externa</td>
<td>7/14/2006</td>
<td>59,543</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Adult Sinusitis</td>
<td>8/22/2008</td>
<td>53,840</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Cerumen Impaction</td>
<td>4/17/2009</td>
<td>22,742</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Hoarseness (Dysphonia)</td>
<td>4/23/2010</td>
<td>15,120</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Tonsillectomy in Children</td>
<td>5/13/2011</td>
<td>12,389</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children</td>
<td>12/16/2011</td>
<td>3,956</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Sudden Hearing Loss</td>
<td>4/26/2012</td>
<td>2,203</td>
</tr>
</tbody>
</table>
Standards for Developing Trustworthy Clinical Practice Guidelines

Updated IOM Definition of Clinical Practice Guidelines

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.

Leaders
Officers, Directors, Journal, Education, Communications

Members
Clinicians
Academics
Specialty Societies
Board of Governors
Physicians in training

Staff
Strategic Planning
Engagement
Authorship
Travel opportunities
Presentations

Organizational Culture
G-I-N Congress Follow up!

The G-I-N 2012 Conference was a full success which has broken all records: Almost 600 delegates across 45 countries attended the event. The conference programme included 5 stimulating plenary sessions and 19 interactive workshops and panel sessions, 80 short oral presentations and almost 200 posters.

- Access the conference presentations
- Access the conference proceedings
- View the programme
- View pictures of the conference - selection
- View pictures of the conference via Flickr
- Access the conference press kit
- Access the German language satellite symposium
- Visit the conference website

Follow G-I-N 2012 on Twitter
### Key Components of High-Quality and Trustworthy Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition of guideline development group</td>
<td>A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.</td>
</tr>
<tr>
<td>Decision-making process</td>
<td>A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.</td>
</tr>
<tr>
<td>Conflicts of interest</td>
<td>A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.</td>
</tr>
<tr>
<td>Scope of a guideline</td>
<td>A guideline should specify its objective(s) and scope.</td>
</tr>
<tr>
<td>Methods</td>
<td>A guideline should clearly describe the methods used for the guideline development in detail.</td>
</tr>
<tr>
<td>Evidence reviews</td>
<td>Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.</td>
</tr>
<tr>
<td>Guideline recommendations</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>Rating of evidence and recommendations</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>Peer review and stakeholder consultations</td>
<td>Review by external stakeholders should be conducted before guideline publication.</td>
</tr>
<tr>
<td>Guideline expiration and updating</td>
<td>A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.</td>
</tr>
<tr>
<td>Financial support and sponsoring organization</td>
<td>A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.</td>
</tr>
</tbody>
</table>
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 1. Establishing Transparency

1.1 The processes by which a clinical practice guideline is developed and funded should be detailed explicitly and publicly accessible.

A Manual for Developing Evidence-Based Clinical Practice Guidelines

Rosenfeld & Shiffman, Otolaryngol HNS 2006

- **Planning** of leadership, panel members
- **Conference calls** to define scope, establish definitions, prioritize topics
- **Systematic search** for guidelines, meta-analyses, key articles, and RCTs
- **Meetings** to review methodology, assign writing, wordsmith guideline
- **External appraisal** for validity and implementability
- **Peer review** and organizational approval

Otolaryngol Head Neck Surg 2006; 135(Suppl):S1-S29
<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 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 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>
IOM Standard 1
Establishing Transparency

1.1 The processes by which a CPG is developed and funded should be explicitly and publicly accessible.

Manual Publicly available at

Version 3 will be available in the January 2013 issue of Otolaryngol Head Neck Surg
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 2. Conflict of Interest (COI)

2.1 Prior to the selection of the guideline development group (GDG), candidates should declare all potential COIs with development group activity, by written disclosure to those convening the GDG.

2.2 All COI of each GDG member should be reported and discussed by the group. Members with COIs should represent not more than a minority of the GDG.

Disclosure

“The Act of Revealing Something”

The potential for conflict of interest can exist whether or not an individual believes it affects his or her scientific judgment.

“Perhaps the most significant likely pitfall of disclosure is... the likelihood of a kind of moral licensing on the part of the profession as a whole – the rationalization that, with disclosure, the profession has dispensed with its obligation to deal with conflicts of interest.”

Lowenstein et al. JAMA 2012; 307:669-70
How the AAO-HNSF CPG Development Process Measures Up

IOM Standard 2
Management of Conflict of Interest (COI)

2.1 Prior to the selection of the guideline development group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.

2.2 Disclosure of COIs within GDG: All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of work.

2.3 Divestment: Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations.

2.4 Exclusions: Whenever possible GDG members should not have COI.

In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.

Members with COIs should represent not more than a minority of the GDG.
G-I-N North America
Webinar Series

WEBINAR: "NEW IOM STANDARDS FOR TRUSTWORTHY GUIDELINES: IMPLICATIONS FOR THE NORTH AMERICAN GUIDELINE COMMUNITY"
The audio file of this webinar featuring Rick Shiffman is available.
Read More...

WEBINAR: "NEW IOM STANDARDS FOR TRUSTWORTHY SYSTEMATIC REVIEWS: IMPLICATIONS FOR THE NORTH AMERICAN GUIDELINE COMMUNITY"
The audio file and the slides from this webinar featuring Dr. Chris Schmid are available.
Read More...

"AHRQ AND NGC APPROACH TO ADDRESSING THE IOM STANDARDS: IMPLICATIONS FOR THE NORTH AMERICAN GUIDELINE DEVELOPMENT COMMUNITY"
The audio file for this webinar, including the slides, are now available.
Read More...

WEBINAR: BEST PRACTICES FOR MANAGING CONFLICT OF INTEREST IN GUIDELINE DEVELOPMENT
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Read More...

WEBINAR: NEW TECHNOLOGIES TO FACILITATE CLINICAL PRACTICE GUIDELINE DEVELOPMENT
The recording (audio and slides) for this webinar is now available.
Read More...

WEBINAR: A METHODOLOGY FOR CONDUCTING RAPID EVIDENCE REVIEWS
The recording (audio and slides) for this webinar is now available.
Read More...

WEBINAR: G-I-N STANDARDS FOR TRUSTWORTHY GUIDELINES: DIFFERENCES AND SIMILARITIES WITH IOM STANDARDS

www.g-i-n.net/activities/g-i-n-na/g-i-n-na-events-activities/g-i-n-na-webinar-series
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 3. Guideline Development Group (GDG) Composition

3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the guideline.

Multidisciplinary Guideline Panels

Why Bother to Diversify?

- Increases the probability that all relevant scientific evidence will be located and critically evaluated
- Increases the chances that the panel will address practical problems relating to application of the guidelines
- Helps build support among the groups for whom the guideline is intended
- May produce more reliable results by balancing biases of the various individuals on the panel

# Guideline Development Group for Tympanostomy Tubes

## Table 4. Example of a Multidisciplinary Guideline Development Group from a Clinical Practice Guideline on Tympanostomy Tubes

<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>


50:50 Ratio of Otolaryngologists to Other Clinicians
Barriers to Capacious, Non-Foreclosed Thought

Rita Charon, MD, PhD
Director, Narrative Medicine Program, Columbia, University

Lack of Time
Habits and Routines
Narrow Range of Thought
Fear of Novelty & Uncertainty

Foreclosed = rule out or prevent (a course of action)
Begin with the End in Mind

Habit #2, Stephen Covey

Members of the guideline development group *do not* have to all be content experts!
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 3. Guideline Development Group (GDG) Composition

3.2 Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient, and a patient advocate or patient/consumer organization representative in the GDG.

Project of the US Cochrane Center that works closely with the Cochrane Consumer Network

National coalition of health and consumer advocacy organizations, which empowers consumers through critical appraisal of articles, guidelines, and systematic reviews

CUE is an excellent source of consumer participants for guideline development panels

http://apps1.jhsph.edu/cochrane/usccc.htm
IOM Standard 3
Guideline Development Group (GDG) Composition

3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the clinical practice guideline.

3.2 Patient and public involvement should be facilitated (at least at the time of clinical question formulation and draft CPG review) a current or former patient, and a patient advocate or patient/consumer organization representative in the GDG.

3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.
Consumer Involvement in Guidelines
What are the Possibilities?

Communication
(e.g. patient/public versions of CPG, decision aids and information material)

Consultation
(e.g. consultation on scope or draft CPG, literature review, focus groups)

Participation
(e.g. Patient/public representative on GDG)

What do Consumers contribute to GDGs?

Passion
Perspective
Skepticism

Respect for harms
Patient education
Shared decisions
G-I-N Working group
to support patient & public involvement (PPI)
• Guideline developers, researchers and patient/public representatives
• “Toolkit”; workshops; publications

Corinna Schaefer, Loes Knaapen, Madeleine Wang, Jane Cowl, Trudy van der Weijden, Javier Gracia

www.g-i-n.net/activities/gin-public
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 4. Systematic Reviews

4.1 CPG developers should use systematic reviews that meet IOM standards.

4.2 When reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.

Partners in Evidence-Based Medicine

AAO-HNS and the Cochrane Collaboration

Publications in the Academy Journal

AAO-HNS Cochrane Scholars travel grants

Cochrane content at the AAO-HNS meeting

Support for guideline development

Recognition at the BOD
IOM Standard 4
**Clinical Practice Guideline – Systematic Review Intersection**

4.1 Clinical practice guideline developers should use systematic reviews that meet standards set by the Institute of Medicine’s Committee on Standards for Systematic Reviews of Comparative Effectiveness Research

4.2 When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 5. Evidence Foundations

5.1 For each recommendation provide:

- Clear description of benefits & harms
- Quality, quantity, and consistency of the available aggregate evidence
- Role of values, opinion, theory, and clinical experience in deriving the recommendation
- Rating of confidence in the evidence
- Rating of the strength of recommendation
- Explanation of any differences of opinion

Action Statement Profiles and Guideline Development

1. Encourage an explicit and transparent approach to guideline writing
2. Force guideline developers to discuss and document the decision making process
3. Create “organizational memory” to avoid re-discussing already agreed upon issues
4. Allow guideline users to rapidly understand how and why statements were developed
5. Facilitate identifying aspects of guideline best suited to performance assessment
<table>
<thead>
<tr>
<th>Grade</th>
<th>OCEBM Level</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(^b) of randomized trials, nested case-control studies, or observational studies with dramatic effect(^b)</td>
<td>Systematic review(^b) of randomized trials, nested case-control studies, or observational studies with dramatic effect(^b)</td>
<td>Systematic review(^b) of cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Systematic review(^b) of inception cohort studies(^c)</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(^c)</td>
</tr>
<tr>
<td>C</td>
<td>3-4</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>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.

\(^a\) Adapted from Howick and coworkers.\(^55\)

\(^b\) A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

\(^c\) 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.
Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least:

- 7 episodes in the past year, or
- 5 episodes per year in the preceding 2 years, or
- 3 episodes per year in the preceding 3 years,

With documentation in the medical record for each episode of sore throat and one or more of the following:

- temperature $>38.3\, \text{C (101F)}$, or
- cervical adenopathy (tender or $>2\, \text{cm}$), or
- tonsillar exudate, or
- positive test for group A beta-hemolytic streptococcus.

Option based on systematic reviews and randomized controlled trials with minor limitations, with relative balance of benefit and harm.
Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes the past year or 5 episodes per year for 2 years or 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and one or more of the following: T>38.3C, cervical adenopathy, tonsillar exudate, or positive test for group A beta-hemolytic streptococcus.

**Option based on systematic reviews and randomized controlled trials with minor limitations, with a relative balance of benefit and harm.**

**Evidence profile:**
- **Aggregate evidence quality:** Grade B, randomized controlled trials with minor limitations
- **Benefits:** 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
- **Risk, harm, cost:** Risk and morbidity of tonsillectomy including, but not limited to, pain and missed activity after surgery, hemorrhage, dehydration, injury, and anesthetic complications; direct non-surgical costs (antibiotics, clinician visit) and indirect costs (caregiver time, time missed from school).
- **Benefits-harm assessment:** Balance of benefit to harm
- **Value judgments:** Importance of balancing the modest, short-term benefits of tonsillectomy in carefully selected children against the favorable natural history seen in control groups and the potential for harm or adverse events, which although infrequent, may be severe or life-threatening
- **Intentional vagueness:** None
- **Patient preference:** Large role for shared decision-making in severely affected patients, given the 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
- **Exclusions:** None

Otolaryngol Head Neck Surg 2011
Classifying Recommendations for Practice Guidelines

AAP Steering Committee on Quality Improvement and Management

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Well-designed, randomized controlled trials or diagnostic studies on relevant populations</td>
<td>Strong Recommendation</td>
<td>Option</td>
</tr>
<tr>
<td>B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies</td>
<td>Recommendation</td>
<td></td>
</tr>
<tr>
<td>C. Observational studies (case control and cohort design)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D. Expert opinion, case reports, reasoning from first principles</td>
<td></td>
<td>No Recommendation</td>
</tr>
</tbody>
</table>

Pediatrics 2004; 114:874-877
IOM Standard 5
Establishing Evidence Foundations for and Rating Strength of Recommendations

5.1 For each recommendation, the following should be provided:
An explanation of the reasoning underlying the recommendation, including:

- A clear description of potential benefits and harms
- A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence
- An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation
- A rating of the strength of the recommendation in light of the preceding bullets
- A description and explanation of any differences of opinion regarding the recommendation
<table>
<thead>
<tr>
<th>Quality Domain</th>
<th>Specific Concerns that Reduce the Level of Confidence</th>
</tr>
</thead>
</table>
| Study limitations (risk of bias) for randomized controlled trials | 1. Lack of allocation concealment: investigators can tell to which group the next patient will be assigned  
2. Lack of blinding: patients, investigators, assessors  
3. Loss to follow-up: imbalanced loss among groups; lack of intention-to-treat analysis  
4. Selective outcome reporting: incomplete reporting of some outcomes and not others |
| Study limitations (risk of bias) for observational studies | 1. Problems with selection (inclusion/exclusion) criteria: inadequate description, nonconsecutive samples; unclear comparison or control group  
2. Flawed measurement of exposure or outcome  
3. Failure to control confounding: failure to account for prognostic factors; lack of statistical adjustment  
4. Loss to follow-up: 20% of more of sample  
1. Few studies and/or small sample sizes  
2. Main outcomes are not described using 95% confidence intervals (CI) or the CIs are very wide  
3. Values at the upper or lower range of the 95% CI might change the recommendation |
| Imprecision                                         | 1. Results vary widely across studies  
2. Significant heterogeneity found in systematic review |
| Inconsistency                                       | 1. Differences between the study population(s) and the guideline target population  
2. Differences in interventions used by the investigator(s) compared with the guideline intervention  
3. Differences in outcome measure(s) |
| Limited generalizability (indirectness)             | 1. Differences between the study population(s) and the guideline target population  
2. Differences in interventions used by the investigator(s) compared with the guideline intervention  
3. Differences in outcome measure(s) |
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 6. Articulation of Recommendations

4.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed.

4.2 Strong recommendations should be worded so that compliance with the recommendations can be evaluated.

Clinicians should assess patients with BPPV for factors that modify management, including impaired mobility or balance, CNS disorders, a lack of home support, and increased risk for falling.

The clinician may offer vestibular rehabilitation, either self-administered or with a clinician, for the initial treatment of BPPV.

Clinicians should not obtain radiographic imaging or vestibular testing in a patient diagnosed with BPPV, unless the diagnosis is uncertain or there are additional symptoms or signs unrelated to BPPV that warrant testing.

Clinicians should not routinely treat BPPV with vestibular suppressant medications, such as antihistamines or benzodiazepines.
Guidelines ARE NOT Review Articles!

Guidelines contain key statements that are *action-oriented* prescriptions of specific behavior from a clinician.

- **Gather**
  - **Test**
  - **Monitor**

- **Interpret**
  - **Conclude**

- **Perform**
  - **Prescribe**
  - **Educate**
  - **Document**
  - **Prepare**

- **Dispose**
  - **Procedure**
  - **Consult**
  - **Advocate**
Building Better Guidelines with BRIDGE-Wiz

Shiffman and Rosenfeld et al, JAMIA 2012

Description of a software assistant for structured action statement creation to promote clarity, transparency and implementability

1. Choose an action type
2. Choose a verb
3. Define the object for the verb
4. Add actions
5. Check executability
6. Define conditions for the action
7. Check decidability
8. Describe benefits, risks, harms & costs
9. Judge the benefit-harms balance
10. Select aggregate evidence quality
11. Review proposed strength of recommendation and level of obligation
12. Define the actor
13. Choose recommendation style
14. Edit the final statement

Perioperative Antibiotics: Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.

**Strong recommendation based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm.**

**Evidence profile:**
- **Aggregate evidence quality:** Grade A, randomized controlled trials and systematic reviews showing no benefit in using perioperative antibiotics to reduce post-tonsillectomy morbidity
- **Benefits:** Avoidance of adverse events related to antimicrobial therapy, including rash, allergy, gastrointestinal upset, and induced bacterial resistance
- **Harms:** None
- **Cost:** None
- **Benefits-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 the lack of demonstrable benefits in randomized controlled trials plus the well-documented potential adverse events and costs of therapy
- **Intentional vagueness:** The word “routine” is used recognizing that there may be individual circumstances in which antimicrobials for a given patient are deemed appropriate by the clinician
- **Patient preference:** None
- **Exclusions:** Patients with conditions requiring antibiotic prophylaxis; peritonsillar abscess

*Otolaryngol Head Neck Surg 2011; 14(Suppl):S1-S30*
Classifying Recommendations for Practice Guidelines

AAP Steering Committee on Quality Improvement and Management

Evidence Quality

A. Well-designed, randomized controlled trials or diagnostic studies on relevant populations
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C. Observational studies (case control and cohort design)
D. Expert opinion, case reports, reasoning from first principles

BENEFITS-HARMs ASSESSMENT

Preponderance of Benefit or Harm

Balance of Benefit and Harm

Strong Recommendation
Option
Recommendation
Option
No Recommendation

Pediatrics 2004; 114:874-877
IOM Standard 6
Articulation of Recommendations

6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed.

6.2 Strong recommendations should be worded so that compliance with the recommendations can be evaluated.
## External Guideline Appraisal

**Guideline Implementability Appraisal (GLIA)**

**Yale Center for Medical Informatics**

<table>
<thead>
<tr>
<th>Decidability</th>
<th>Precisely under what circumstances to do something</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Executability</strong></td>
<td>Exactly what to do under the circumstances defined</td>
</tr>
<tr>
<td><strong>Effect on process of care</strong></td>
<td>Degree to which the recommendation impacts workflow in a typical case setting</td>
</tr>
<tr>
<td><strong>Presentation and formatting</strong></td>
<td>Degree to which the recommendation is recognizable and succinct</td>
</tr>
<tr>
<td><strong>Measurable outcomes</strong></td>
<td>Degree to which the guideline identifies markers or endpoints to track the effects of implementation</td>
</tr>
<tr>
<td><strong>Apparent validity</strong></td>
<td>Degree to which the recommendation reflects the intent of the developer and the strength of evidence</td>
</tr>
<tr>
<td><strong>Novelty / innovation</strong></td>
<td>Degree to which the recommendation proposes behaviors considered unconventional</td>
</tr>
<tr>
<td><strong>Flexibility</strong></td>
<td>Degree to which a recommendation permits interpretation and allows for alternatives in execution</td>
</tr>
</tbody>
</table>

BMC Med Informatics Decis Making 2005; 5:23-31
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 7. External Review

7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations, agencies, patients, and representatives of the public.

7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to comments.

### Who Should Review the Guideline?

**Table 4. Example of a Multidisciplinary Guideline Development Group from a Clinical Practice Guideline on Tympanostomy Tubes**

<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,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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>

<table>
<thead>
<tr>
<th>Lines</th>
<th>Comment</th>
<th>Action</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>The general language level and content for the introduction, especially the first two paragraphs, would seem to be below the level of the target audience (namely clinicians managing otitis media). If this is intentional, no reason to address specifically.</td>
<td>No change</td>
<td>The Introduction section, which is intended to provoke interest in the document, is purposefully worded in simpler language since it will be read by patients, the public, and media reporters, in addition to clinicians.</td>
</tr>
<tr>
<td>3</td>
<td>&quot;middle-ear space&quot; And all similar wording needs hyphens</td>
<td>No change</td>
<td>ASHA’s style guide, among others, suggest keeping as is with no hyphen</td>
</tr>
<tr>
<td>4</td>
<td>would restate that OM is 2nd most common illnesss (to URL's)</td>
<td>Change made</td>
<td>Restated as suggested.</td>
</tr>
<tr>
<td>5</td>
<td>Line is difficult to read suggest change &quot;other than&quot; to second only to upper respiratory infection&quot; which makes the passage easier to understand</td>
<td>Change made</td>
<td>Changed as suggested.</td>
</tr>
<tr>
<td>6</td>
<td>define &quot;young&quot; children (is that 6 to 12 mos?)</td>
<td>Change</td>
<td>Change &quot;Young children...&quot; to &quot;Children under 7 years of age...&quot;</td>
</tr>
<tr>
<td>7</td>
<td>effusion--needs to be specified for less knowledgeable reader</td>
<td>No change</td>
<td>Please refer to Table 1 where OME w/ effusion is defined.</td>
</tr>
<tr>
<td>8</td>
<td>summary of benefits of tubes</td>
<td>No change</td>
<td>Thank you for your comment.</td>
</tr>
<tr>
<td>9</td>
<td>SNHL definition as written implies it includes central (cortical) hearing loss instead of being limited to sensory (hair cell) and eighth nerve loss.</td>
<td>Change made</td>
<td>Thank you for your comment, we have incorporated your suggested edits into the definition.</td>
</tr>
<tr>
<td>10</td>
<td>conductive hearing loss: &quot;abnormal processing and transmission of sound...&quot;; including &quot;processing&quot; in this definition is confusing. SNHL: should eliminate &quot;auditory cortex where sound is ultimately processed&quot; to definition as it is unnecessary to the definition of SNHL.</td>
<td>Change made</td>
<td>Thank you for your comment, we have incorporated your suggested edits into the definition.</td>
</tr>
<tr>
<td>11</td>
<td>Tymp tubes generally last several months to several years, depending on tube insertion design and placement location in the tympanic membrane.</td>
<td>Change made</td>
<td>Thank you for your comment, we have incorporated your suggested edits into the definition.</td>
</tr>
<tr>
<td>12</td>
<td>Screening has the potential of missing hearing loss. Diagnostic test should be the goal and should be performed by or under the supervision of an audiologist.</td>
<td>No change</td>
<td>The term &quot;hearing assessment&quot; in Table 1 is used to encompass a broad standardized methods to gather information about hearing status, of which screening is a part. This differs from hearing testing, which would not include screening.</td>
</tr>
<tr>
<td>13</td>
<td>Retraction pocket definition describes only retraction into middle ear. Attic retraction pockets, which are of greater concern, are not necessarily included in this definition (e.g. pars flaccida retraction pockets may not involvse middle ear space)</td>
<td>Change made</td>
<td>Changed &quot;...into the middle ear with...&quot; to &quot;into the middle ear or attic with...&quot;.</td>
</tr>
</tbody>
</table>
How the AAO-HNSF CPG Development Process Measures Up

IOM Standard 7
External Review

7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g. healthcare, specialty societies), agencies (e.g. federal government), patients, and representatives of the public.

7.2 The authorship of external reviews submitted by individuals and/or organizations should be kept confidential unless that protection has been waived by the reviewer(s)

7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers’ comments

7.4 A draft of the CPG at the external review stage or immediately following it (i.e. prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.
<table>
<thead>
<tr>
<th>Type of Concern</th>
<th>Suggestions for Responding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns substantiated with research evidence</td>
<td>All concerns supported by literature citations must be taken seriously, with a revision in the guideline when appropriate.</td>
</tr>
<tr>
<td>Concerns based on experience, personal bias, or expert opinion</td>
<td>These can be difficult to deal with, largely because they do not always have a rational or evidence-based foundation. They must still be addressed and, if appropriate, could be mentioned in the supporting text.</td>
</tr>
<tr>
<td>Concerns based on misinterpretation</td>
<td>If a reviewer misinterprets part of the guideline, it is likely that readers will also have trouble. These concerns put the burden on the guideline authors to clarify what was meant by rewriting the relevant text.</td>
</tr>
<tr>
<td>Concerns based on misunderstanding of guideline methodology</td>
<td>Clinicians may be very critical of or even vehemently opposed to guidelines for many reasons, often because they consider themselves better qualified than the development group. Others consider guidelines “cookbook medicine” that impairs individual, experience-based care. Guidelines produced with an a priori protocol, such as that described in this manual, can be defended from this type of criticism because they adhere to trustworthy standards (Table 2). Concerns in this category are a “teachable moment” but must be handled with the knowledge that the reviewer is most likely not interested in being taught.</td>
</tr>
<tr>
<td>Concerns about abuse, misuse, and legal precedents</td>
<td>There is often a fear that guidelines will be misused or abused by insurers, organizations, or attorneys to deny payment, restrict care, or establish legal standards. This is not the purpose of guidelines, and disclaimers are included to this effect. These problems could occur with any document or publication, and invoking them as a reason to not publish guidelines cannot be substantiated.</td>
</tr>
<tr>
<td>Concerns about spelling, grammar, terminology, and choice of words</td>
<td>These are the easiest comments to deal with and often are extremely helpful in picking up oversights by the authors. Changes are made as appropriate.</td>
</tr>
</tbody>
</table>
Standards for Developing Trustworthy Clinical Practice Guidelines

Standard 8. Updating

7.1 The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.

7.2 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations.

IOM Standard 8

Updating

8.1 The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.

8.2 Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.

8.3 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence show that a recommended intervention cause previously unknown substantial harm; that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective; or that a recommendation can be applied to new populations.
Organizational Culture

Leaders
Officers, Directors, Journal, Education, Communications

Members
Clinicians
Academicians
Specialty Societies
Board of Governors
Physicians in training

Staff
Strategic Planning
Engagement
Authorship
Travel opportunities
Presentations

Organizational Culture
# Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards

Two More Decades of Little, If Any, Progress

Justin Kung, MD; Ram R. Miller, MD; Philip A. Mackowiak, MD

## Table 2. Frequency of Adherence to Institute of Medicine Standards for Development and Format

<table>
<thead>
<tr>
<th>Organization Type, Guidelines, No. (%)</th>
<th>All (114)</th>
<th>US (68)</th>
<th>Non-US (46)</th>
<th>US Government Agency (15)</th>
<th>Subspecialty Societies (41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee selection process stated</td>
<td>34 (29.8)</td>
<td>24 (35.3)</td>
<td>10 (21.7)</td>
<td>11 (73.3)</td>
<td>10 (24.4)</td>
</tr>
<tr>
<td>COIs stated</td>
<td>42 (46.8)</td>
<td>28 (41.2)</td>
<td>14 (30.4)</td>
<td>8 (53.3)</td>
<td>12 (29.3)</td>
</tr>
<tr>
<td>Chair has COI</td>
<td>30 (71.4)</td>
<td>18 (64.3)</td>
<td>12 (85.7)</td>
<td>6 (75.0)</td>
<td>7 (58.3)</td>
</tr>
<tr>
<td>Co-chairperson has COI</td>
<td>38 (90.5)</td>
<td>25 (89.3)</td>
<td>13 (92.9)</td>
<td>7 (97.5)</td>
<td>9 (75.0)</td>
</tr>
<tr>
<td>Information scientist</td>
<td>27 (92.3)</td>
<td>12 (41.0)</td>
<td>14 (92.9)</td>
<td>3 (67.9)</td>
<td>7 (17.1)</td>
</tr>
<tr>
<td>Patient or patient representative</td>
<td>19 (16.7)</td>
<td>5 (7.4)</td>
<td>14 (30.4)</td>
<td>1 (6.7)</td>
<td>4 (9.8)</td>
</tr>
</tbody>
</table>

Abbreviations: COI, conflict of interest; US, United States.

*Number (percentage) meeting standard.
G-I-N North America (NA)

Challenges faced by North American groups are not unique, but there are enough shared issues to justify a regional community. G-I-N North America (G-I-N NA) was officially launched in May 2011 during an invited presentation at The Institute of Medicine’s workshop on implementing standards for trustworthy clinical practice guidelines.

ABOUT G-I-N NA

Why a G-I-N North American Community, aims and objectives.

Read More.

G-I-N NA EVENTS & ACTIVITIES

Access information on past and future webinars and other events organised by G-I-N North America.

Read More...

G-I-N NA MEMBERSHIP

Purpose of G-I-N North America and benefits of joining.