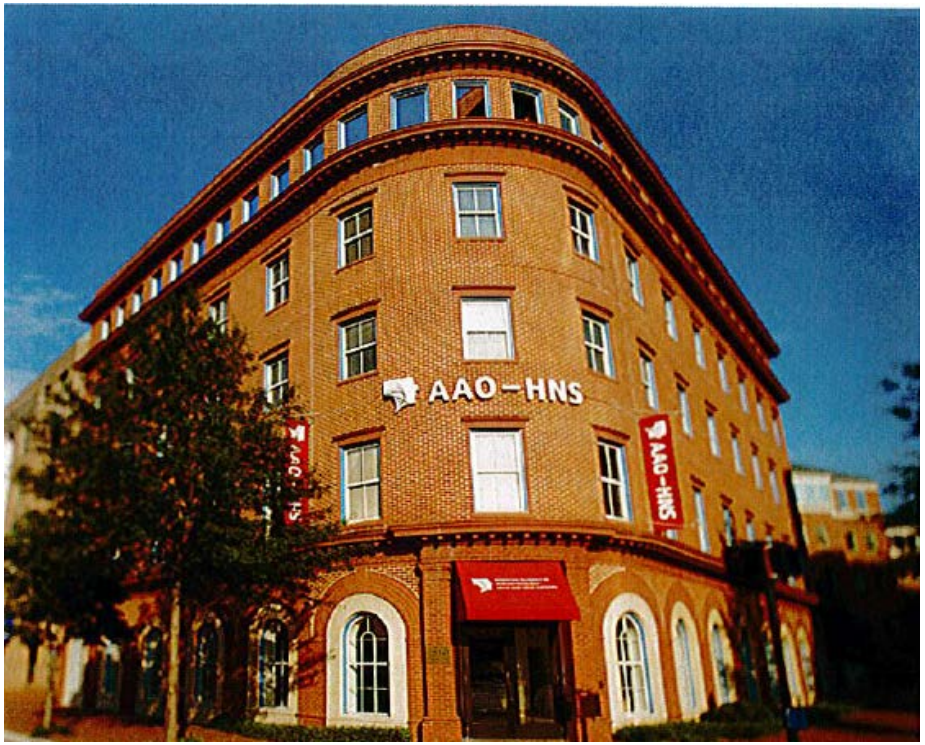
Guidelines and Professional Medical Associations

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

Jean Brereton, MBA, Senior Director, Research, Quality and Health Policy (0.25 FTE)

Stephanie Jones, Director, Research & Quality, AAO-HNSF (0.25 FTE)
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Caitlin E. Murray, Research and Quality Analyst (0.75 FTE)

Guideline Consultants

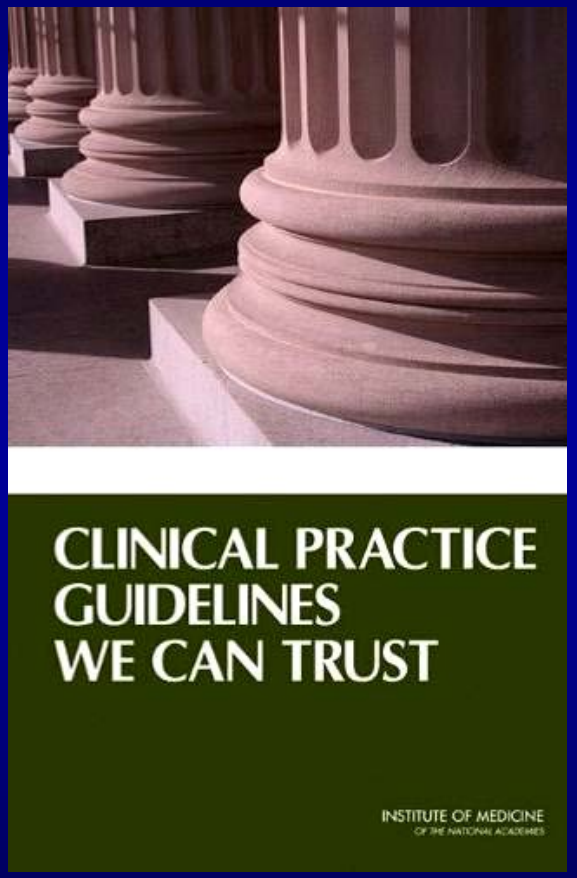
Richard M. Rosenfeld, MD, MPH, Sr. Consultant for Quality and Guidelines
Seth Schwartz, MD, MPH, Chair Guideline Development Task Force

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.

Title	Date released	Page views
Clinical Practice Guideline: Acute Otitis Externa	7/14/2006	59,543
Clinical Practice Guideline: Adult Sinusitis	8/22/2008	53,840
Clinical Practice Guideline: Cerumen Impaction	4/17/2009	22,742
Clinical Practice Guideline: Benign Paroxysmal Positional Vertigo	4/17/2009	31,972
Clinical Practice Guideline: Hoarseness (Dysphonia)	4/23/2010	15,120
Clinical Practice Guideline: Tonsillectomy in Children	5/13/2011	12,389
Clinical Practice Guideline: Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children	12/16/2011	3,956
Clinical Practice Guideline: Sudden Hearing Loss	4/26/2012	2,203

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

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

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Welcome

Dear fellow G-I-N members:

We are all back to work after celebrating the 10th anniversary of Guidelines International Network (G-I-N) and attending a very successful 9th annual meeting in Berlin. I was truly impressed by the high quality of the scientific content as well as lively and active participation from the floor. I would like to congratulate and thank the attendees and presenters for making it such a great educational experience for all of us. I believe that the

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

What's New

enGINe September 2012

In this issue you will read feedback from the membership survey, learn more about the activities of the G-I-N groups and of the Board, performed by G-I-N these past months and as always be provided with an update on relevant literatures and guidelines from the G-I-N library.
Sep 25, 2012

- German Language Satellite Symp...
- Presentations G-I-N 2012 Confe...
- Assessment G-I-N 2012
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More ...

www.g-i-n.net

Annals of Internal Medicine | CLINICAL GUIDELINE

Guidelines International Network: Toward International Standards for Clinical Practice Guidelines

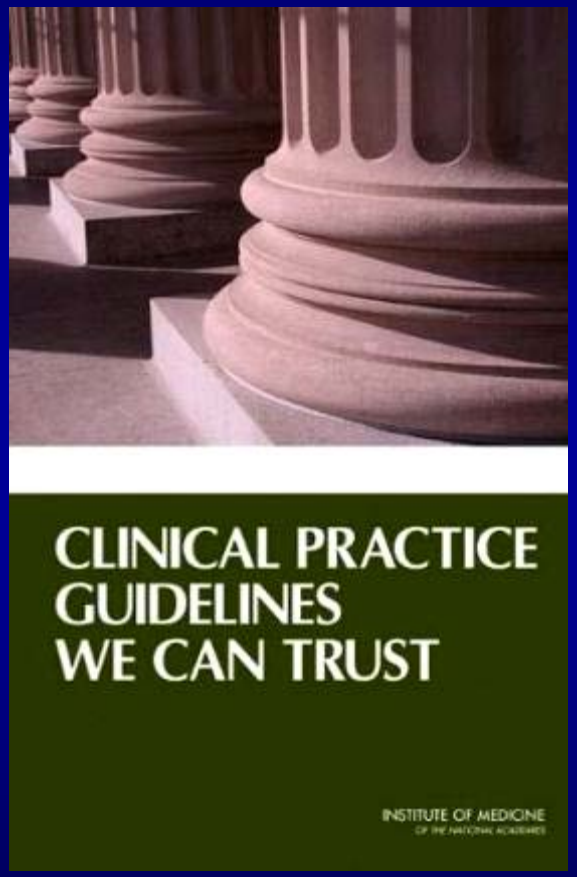
Amir Qaseem, MD, PhD, MHA; Frode Forland, MD, DPH; Fergus Macbeth, MD; Günter Ollenschläger, MD, PharmD, PhD; Sue Phillips, PhD; and Philip van der Wees, PhD, PT, for the Board of Trustees of the Guidelines International Network*

Table. Key Components of High-Quality and Trustworthy Guidelines

Component	Description
Composition of guideline development group	A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.
Decision-making process	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.
Conflicts of interest	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.
Scope of a guideline	A guideline should specify its objective(s) and scope.
Methods	A guideline should clearly describe the methods used for the guideline development in detail.
Evidence reviews	Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.
Guideline recommendations	A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.
Rating of evidence and recommendations	A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.
Peer review and stakeholder consultations	Review by external stakeholders should be conducted before guideline publication.
Guideline expiration and updating	A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.
Financial support and sponsoring organization	A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

Ann Intern Med 2012; 156:525-531

Standards for Developing Trustworthy Clinical Practice Guidelines



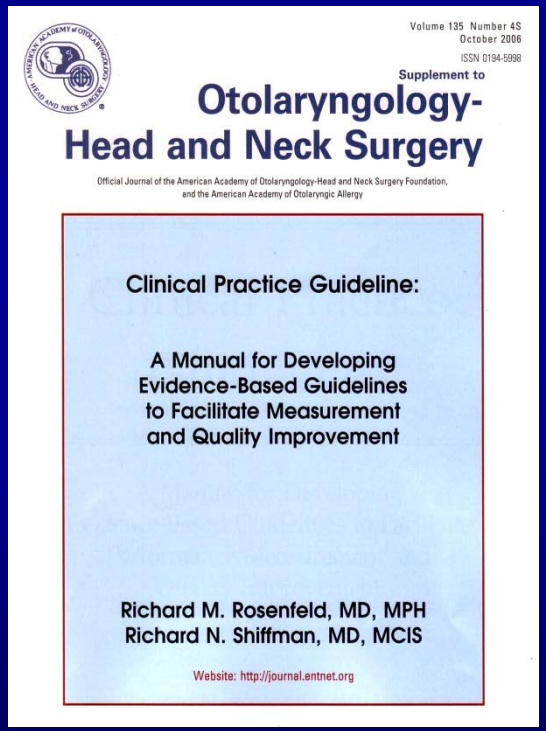
Standard 1. Establishing Transparency

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

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

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 1. Timetable for Guideline Development

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

How the AAO-HNSF CPG Development Process Measures Up

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

http://www.entnet.org/Practice/upload/Rosenfeld-and-Shiffman-2009-6.pdf

Version 3 will be available in the January 2013 issue of Otolaryngol Head Neck Surg

Otolaryngology–Head and Neck Surgery (2009) 140, S1-S43

GUIDELINES

Clinical practice guideline development manual: A quality-driven approach for translating evidence into action

Richard M. Rosenfeld, MD, MPH, and **Richard N. Shiffman, MD, MCIS,**
New York, NY; and New Haven, CT

No sponsorships or competing interests have been disclosed for this article.

ABSTRACT

BACKGROUND: Guidelines 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. Despite a plethora of published guidelines, methodology is often poorly defined and varies greatly within and among organizations.

PURPOSE: This manual describes the principles and practices used successfully by the American Academy of Otolaryngology—Head and Neck Surgery to produce quality-driven, evidence-based guidelines using efficient and transparent methodology for action-ready recommendations with multidisciplinary applicability. The development process, which allows moving from conception to completion in 12 months, emphasizes a logical sequence of key action statements supported by amplifying text, evidence profiles, and recommendation grades that link action to evidence.

CONCLUSIONS: As clinical practice guidelines become more prominent as a key metric of quality health care, organizations must develop efficient production strategies that balance rigor and pragmatism. Equally important, clinicians must become savvy in understanding what guidelines are—and are not—and how they are best utilized to improve care. The information in this manual should help clinicians and organizations achieve these goals.

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."[1] Although many paths lead to guidelines, we offer proven strategies for crafting a valid and action-ready product within 12 months. 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.

This manual builds on an earlier publication[2] by American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) to systematize internal guideline development. By following these principles, the AAO-HNS published five multidisciplinary guidelines in five years, *all within 12 months from conception to completion*.[3-7] Each guideline presented a fresh opportunity to test and refine prior efforts, necessitating a revised and greatly expanded manual only three years after initial publication. Our new manual not only summarizes this experience, but allows other organizations to assess and adapt the processes.

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. Secondly, we wanted a pragmatic resource, which accurately reflects current practices, to sustain consistent guideline development at the AAO-HNS. Lastly, 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-HNS 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 the mountain top, and look forward to further refinement based on reader feedback and ongoing experience.

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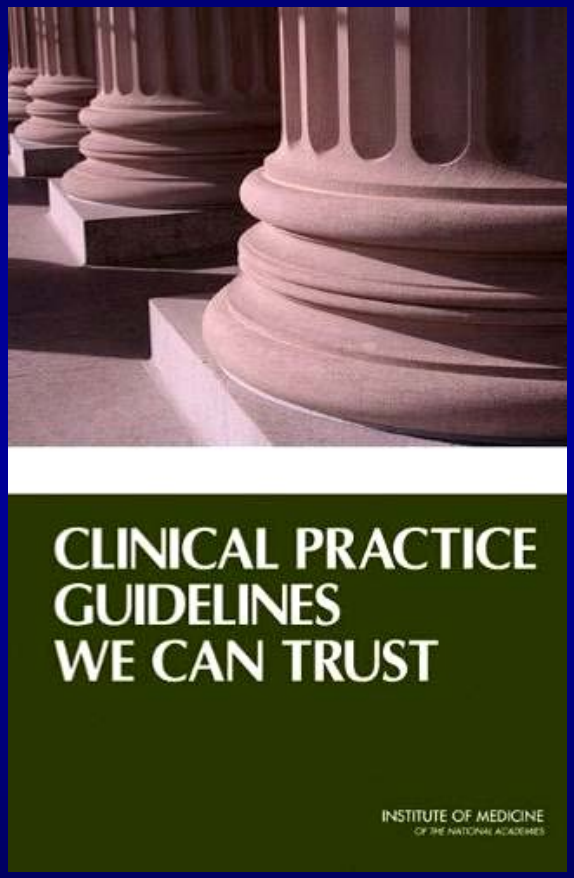
0194-5998/$36.00 © 2009 American Academy of Otolaryngology–Head and Neck Surgery Foundation. All rights reserved.
doi:10.1016/j.otohns.2009.04.015

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.

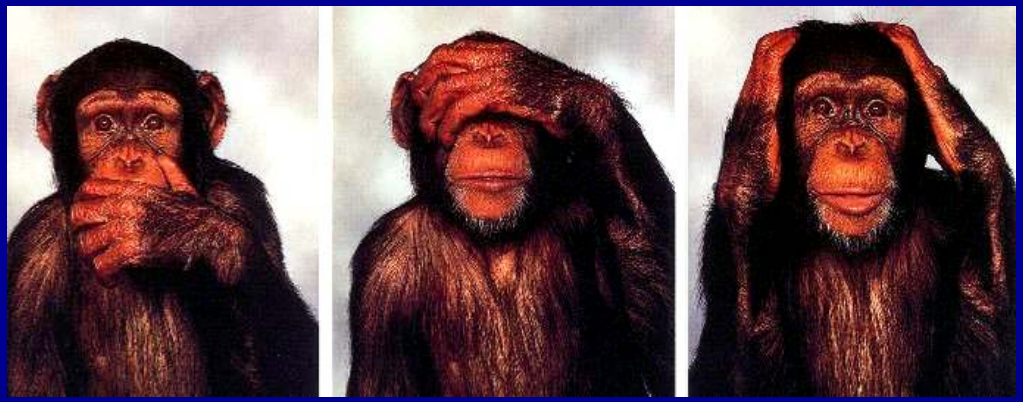
2.2 All COI of each GDG member should be reported and **discussed by the group**. Members with COIs should represent not more than a **minority of the GDG**.

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

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.

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G-I-N North America
Webinar Series

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The audio file of this webinar featuring Rick Shiffman is available.

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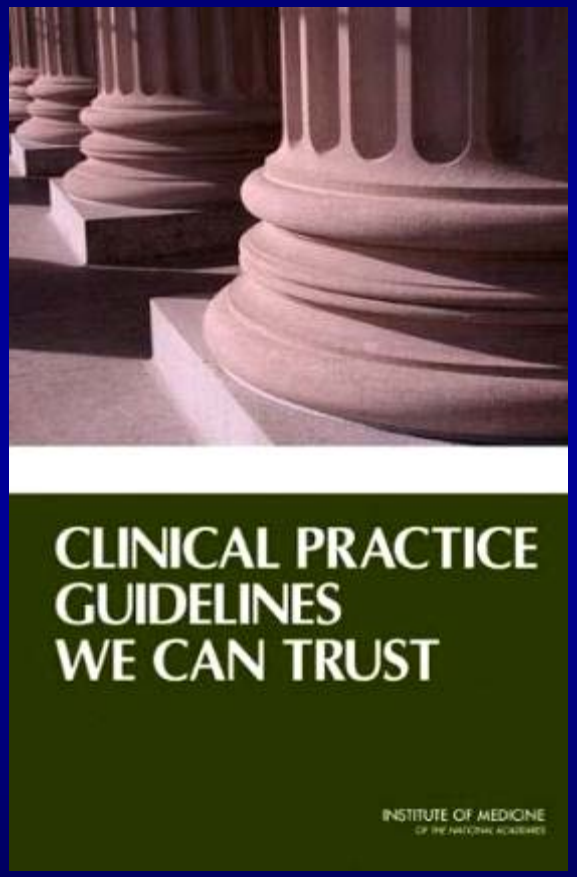
Standards for Developing Trustworthy Clinical Practice Guidelines



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.

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

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

Shekelle et al. Clinical guidelines: developing guidelines. BMJ 1999; 318:593-6
Institute of Medicine. Clinical practice guidelines. Washington DC: Nat'l Academy Press, 1990

Guideline Development Group for Tympanostomy Tubes

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

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

Abbreviation: AAO-HNS, American Academy of Otolaryngology—Head and Neck Surgery.

50:50 Ratio of Otolaryngologists to Other Clinicians

Barriers to Capacious, Non-Foreclosed Thought

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

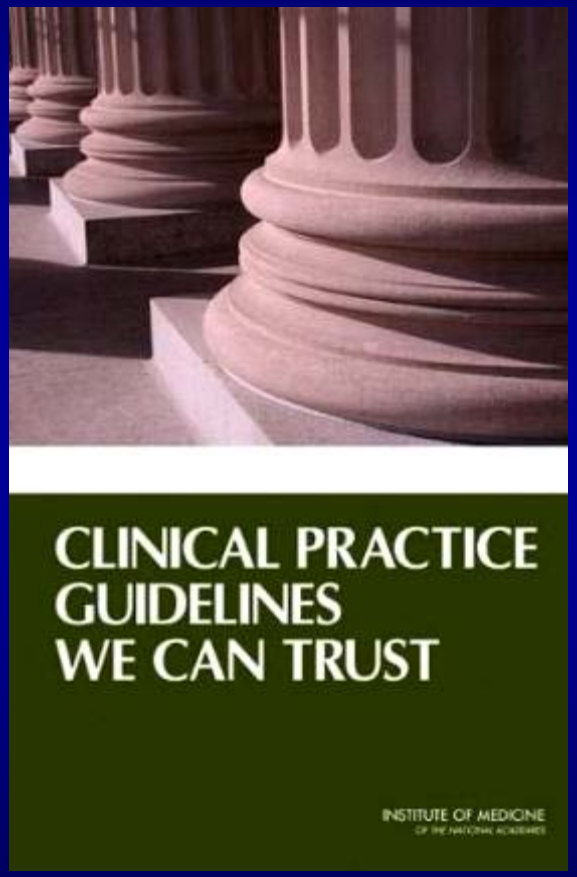
Foreclosed = rule out or prevent (a course of action)

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

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

CUE and Guidelines

- 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

How the AAO-HNSF CPG Development Process Measures Up

IOM Standard 3

Guideline Development Group (GDG) Composition

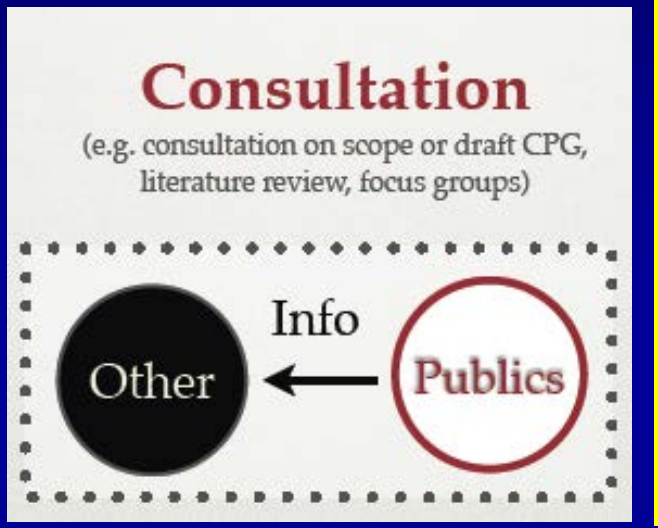
3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the clinical practice guideline.

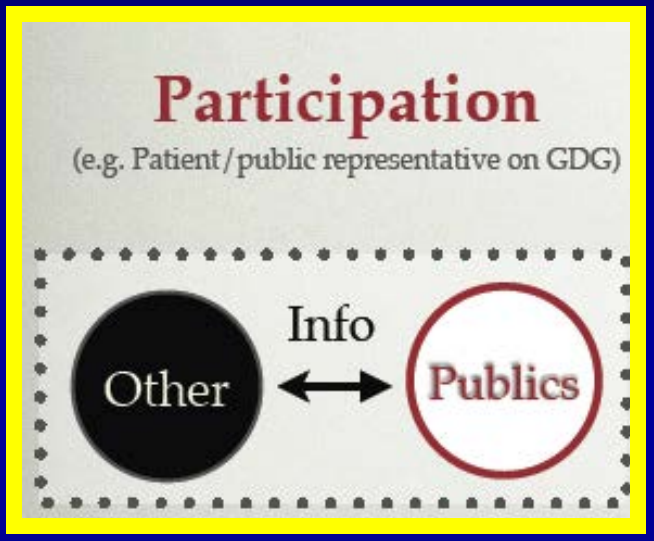
3.2 Patient and public involvement should be facilitated (at least at the time of clinical question formulation and draft CPG review) a current or former patient, and a patient advocate or patient/consumer organization representative in the GDG.

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?





What do Consumers contribute to GDGs?

Passion	Respect for harms
Perspective	Patient education
Skepticism	Shared decisions

G-I-N PUBLIC

G-I-N Working group

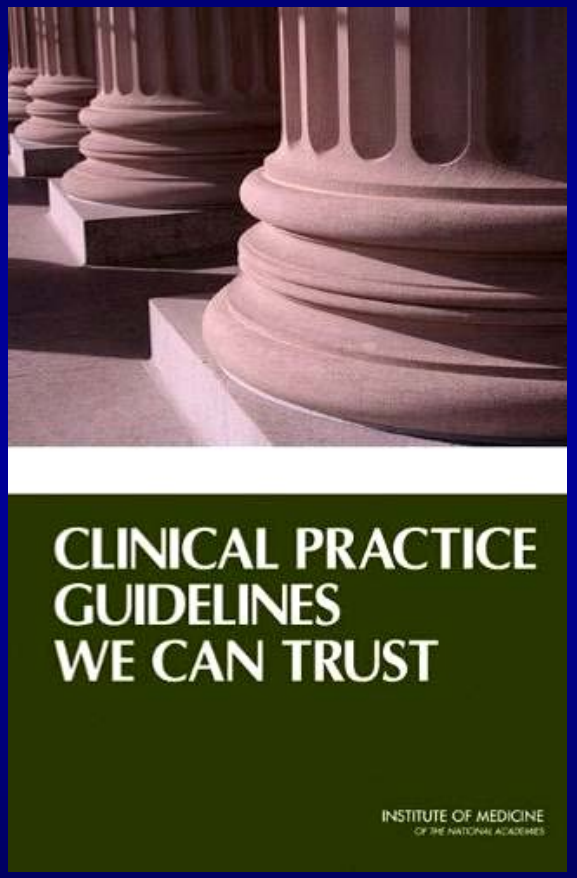
to support patient & public involvement (PPI)

- 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

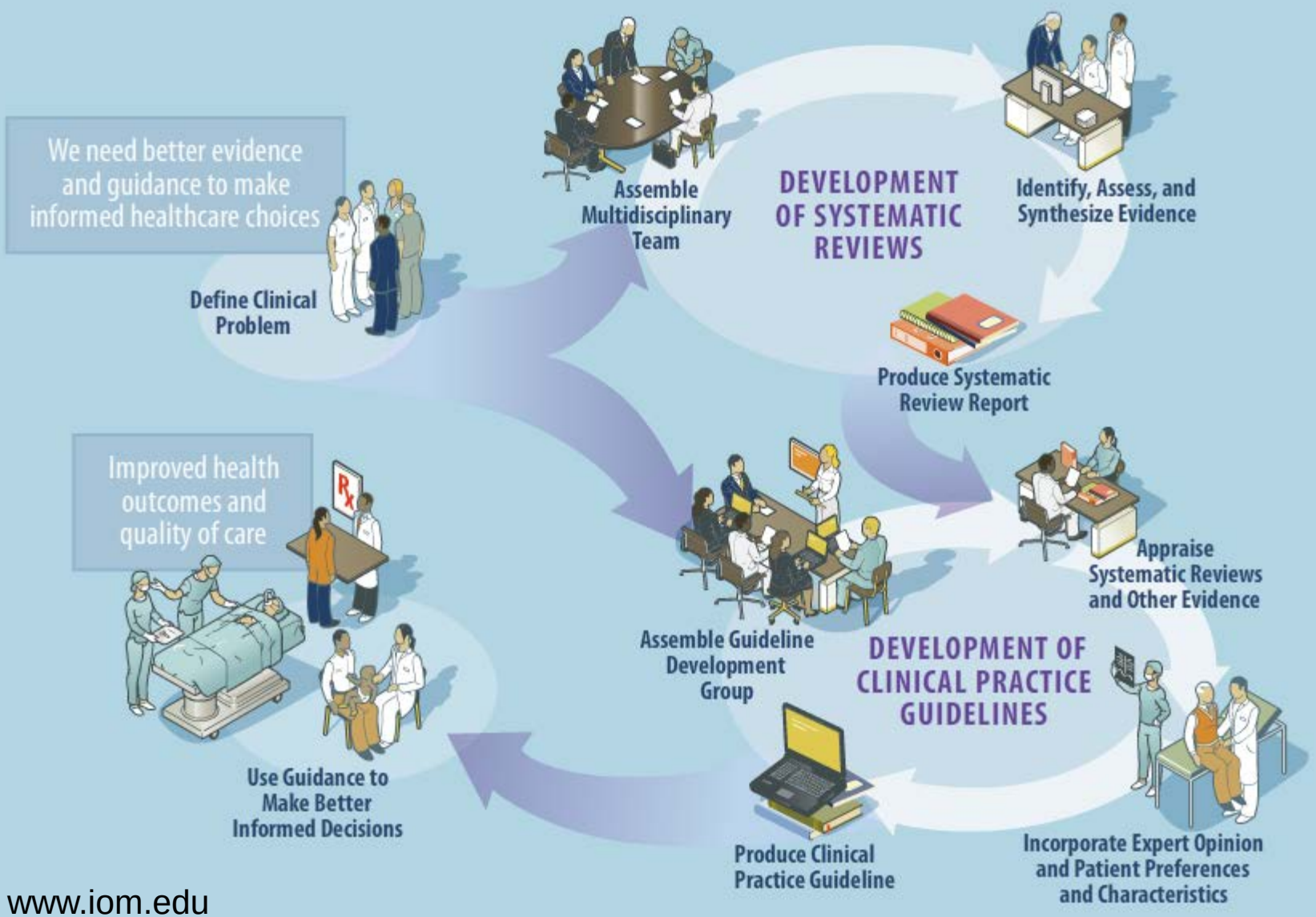
4.1 CPG developers should use **systematic reviews** that meet IOM standards.

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.

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

Systematic Reviews and Clinical Practice Guidelines Improve Healthcare Decision Making

Click on any text for more information



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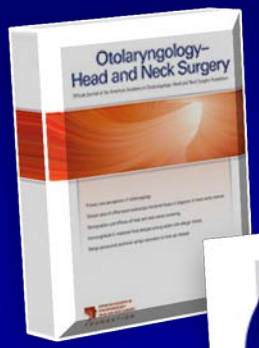
AAO-HNS and the Cochrane Collaboration



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

How the AAO-HNSF CPG Development Process Measures Up

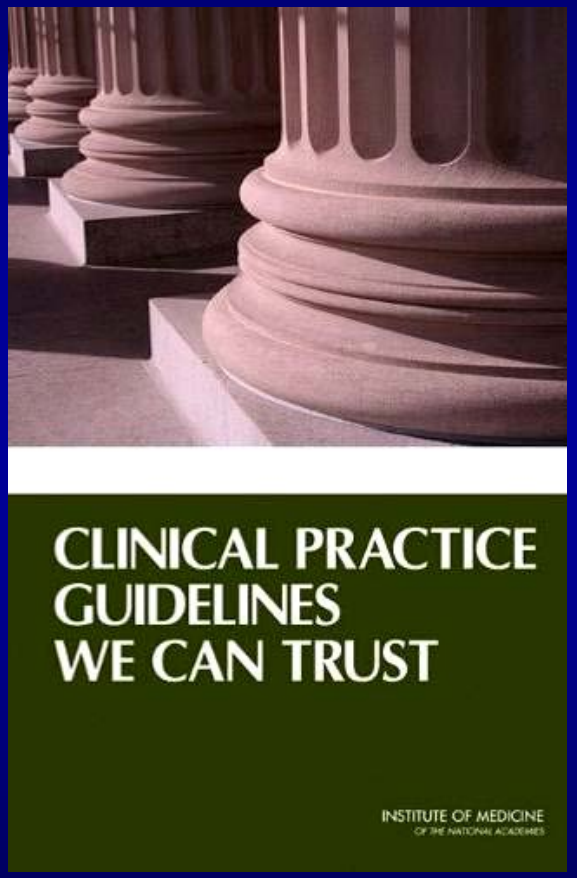
IOM Standard 4

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 <u>each recommendation</u> 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**

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

Key action statement with recommendation strength and justification

Supporting text for key action statement

Action statement profile:

- Aggregate evidence quality:
- Confidence in evidence:
- Benefit:
- Risk, harm, cost:
- Benefit-harm assessment:
- Value judgments:
- Intentional vagueness:
- Role of patient preferences:
- Differences of opinion:
- Exclusions:

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 12. Aggregate Grades of Evidence by Question Type[a]

Grade	OCEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect[b]	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials, or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	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	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	NA	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

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.

Rosenfeld, Shiffman, Robertson. Guideline Manual, 3rd ed. Otolaryngol Head Neck Surg 2013

AAO-HNS Tonsillectomy Clinical Practice Guideline

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 >38.3C (101F), or
- cervical adenopathy (tender or >2cm), 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.

Otolaryngol Head Neck Surg 2011

AAO-HNS Tonsillectomy Clinical Practice Guideline

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.

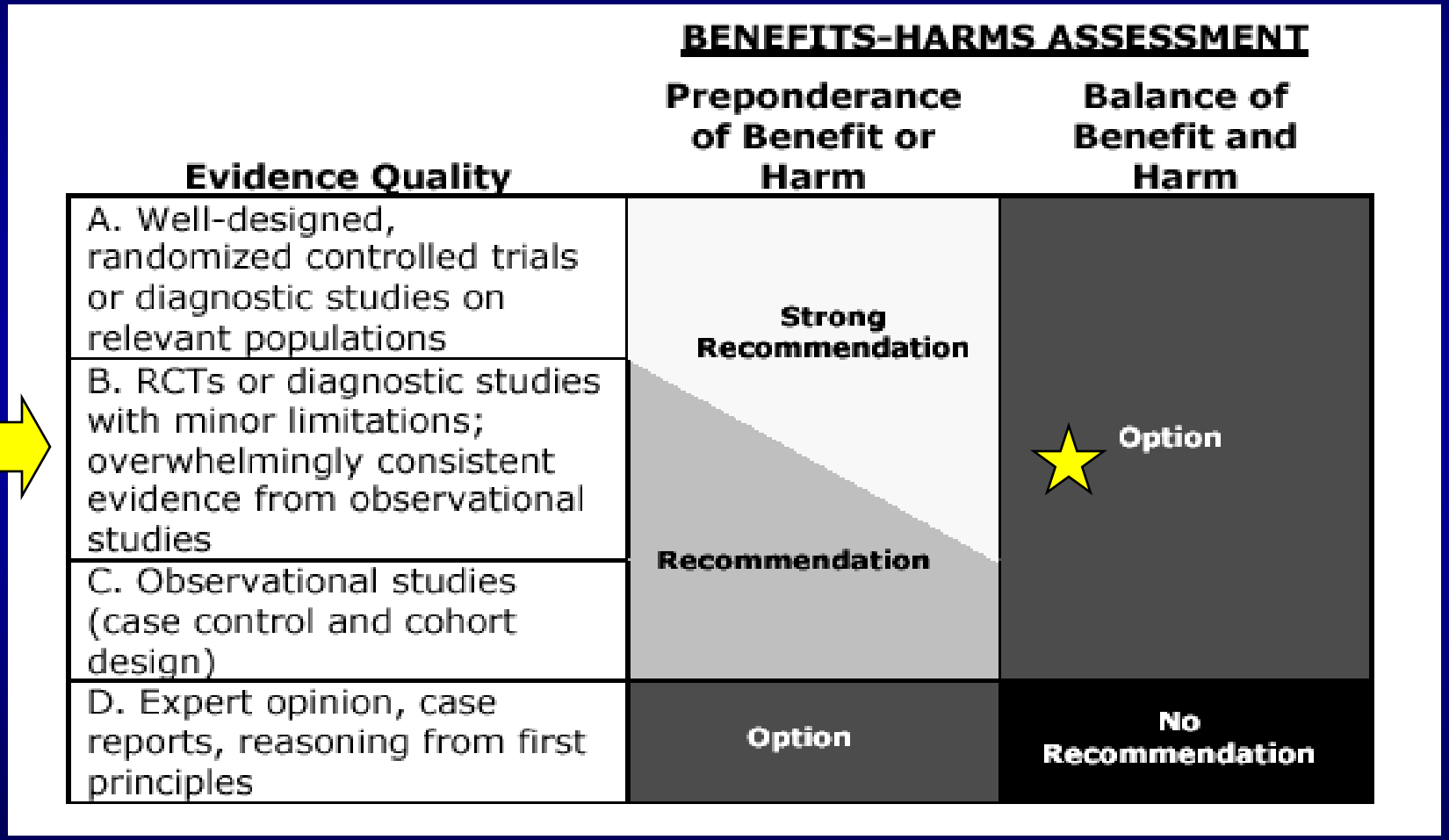
Evidence profile:

- 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



Pediatrics 2004; 114:874-877

How the AAO-HNSF CPG Development Process Measures Up

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:

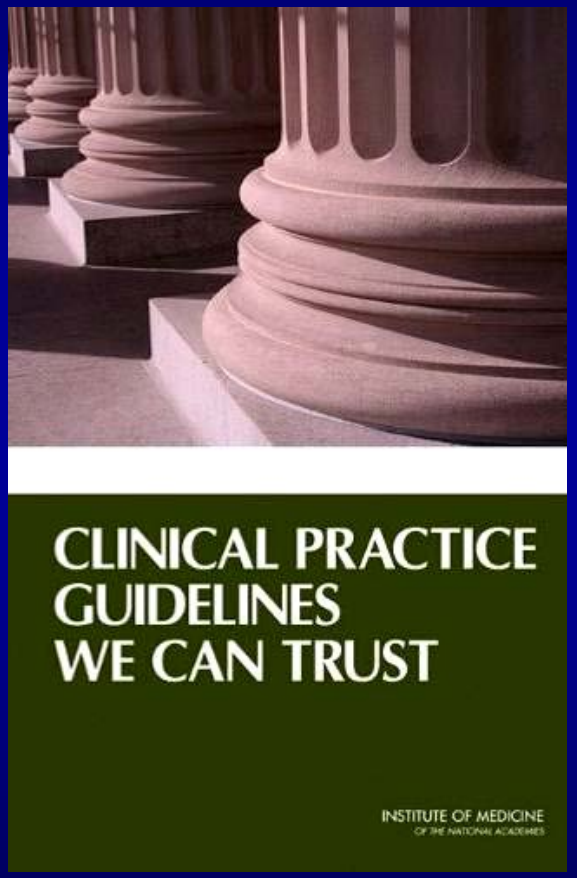
- A clear description of potential benefits and harms
- A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence
- An explanation of the part played by 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 21. Assessing the Level of Confidence in the Aggregate Evidence

Quality Domain	Specific Concerns that Reduce the Level of Confidence
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
Imprecision	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
Inconsistency	1. Results vary widely across studies 2. Significant heterogeneity found in systematic review
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)

Adapted from GRADE

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.

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

Key Action Statements on Benign Paroxysmal Positional Vertigo (BPPV)

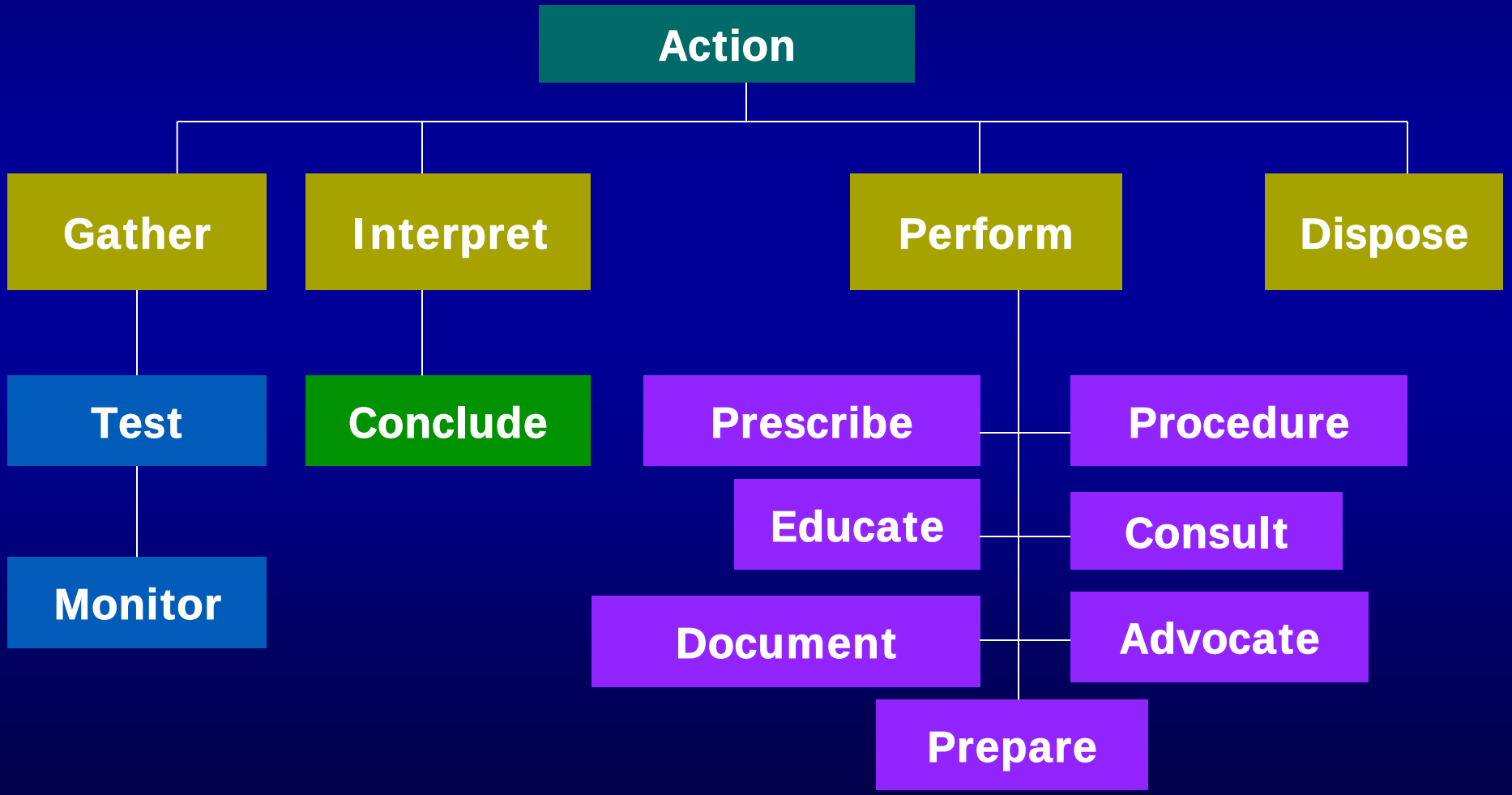
BPPV is a disorder of the inner ear characterized by repeated episodes of a spinning sensation (vertigo) from changes in head position relative to gravity

- 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.

Bhattacharyya et al, Otolaryngol Head Neck Surg 2008; 139(Suppl):S47-81

Guidelines ARE NOT Review Articles!

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



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

J Am Med Inform Assoc 2002; 19:94-101.

AAO-HNS Tonsillectomy Clinical Practice Guideline

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.

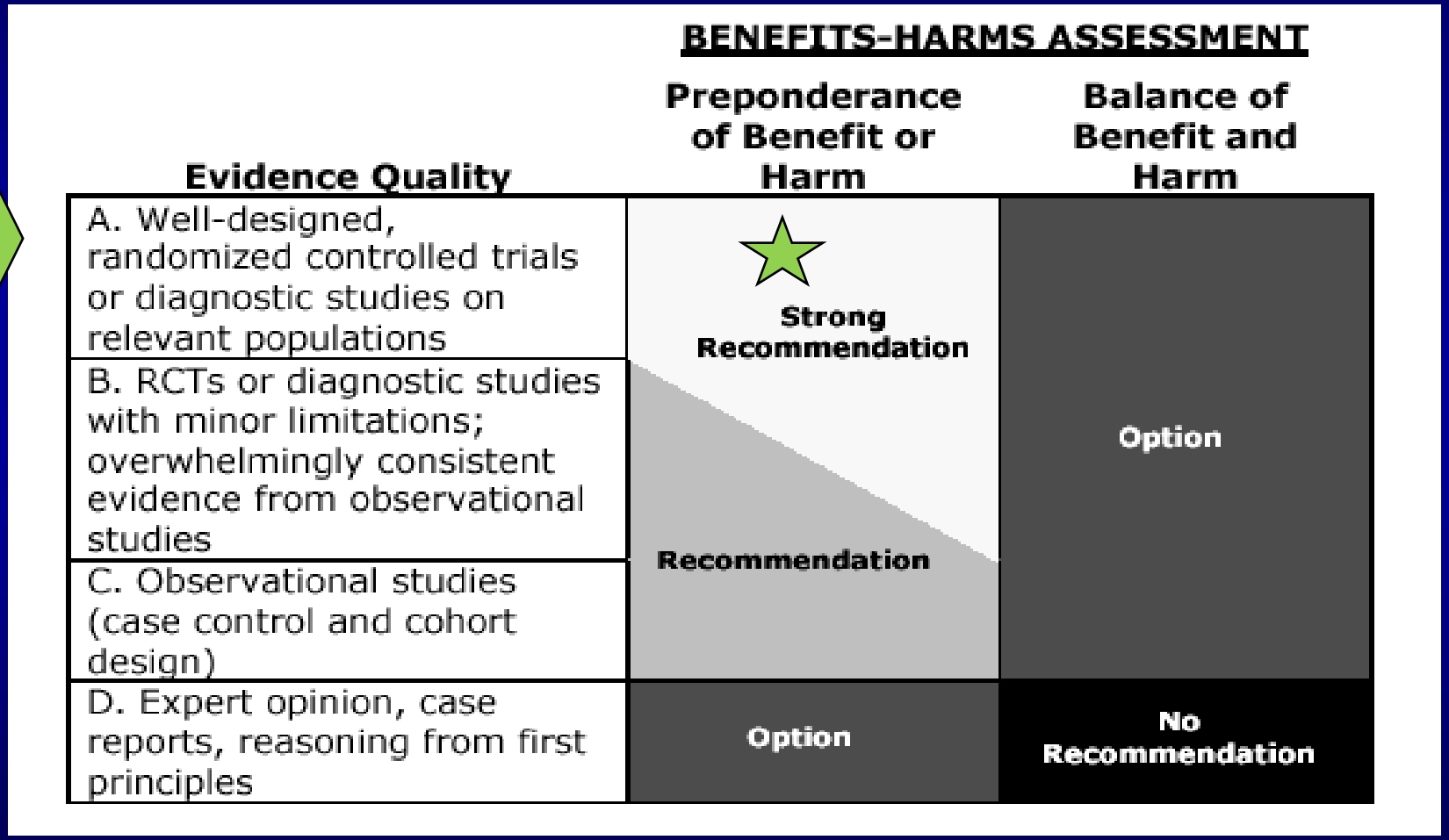
Evidence profile:

- Aggregate evidence quality: Grade A, randomized controlled trials and systematic reviewsshowing 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



Pediatrics 2004; 114:874-877

How the AAO-HNSF CPG Development Process Measures Up

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.

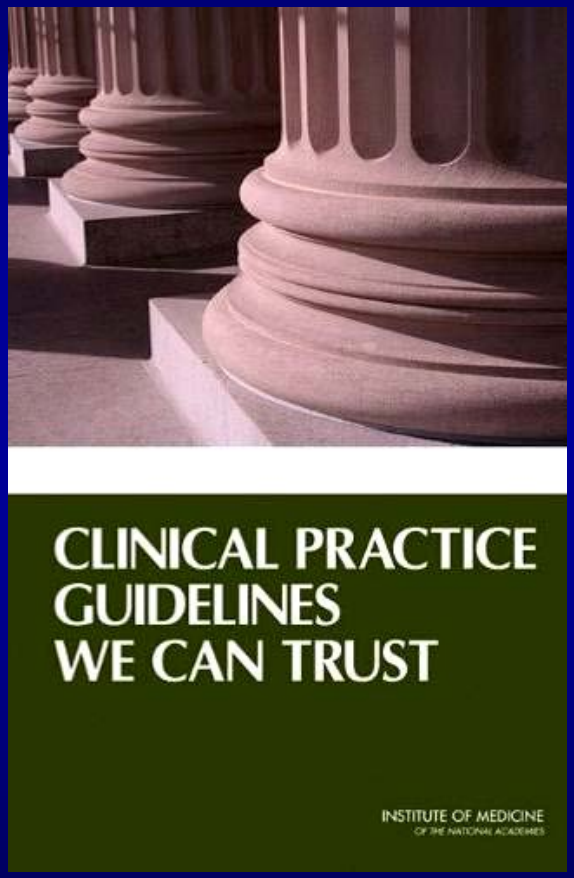
External Guideline Appraisal

Guideline Implementability Appraisal (GLIA)
Yale Center for Medical Informatics

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

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.

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

Who Should Review the Guideline?

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

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

Abbreviation: AAO-HNS, American Academy of Otolaryngology—Head and Neck Surgery.

Written Record of Reviewer Comment Disposition

1	Lines	Comment	Action	Disposition
2	62-89	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.	No change	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.
3	64	“middle_ear space” And all similar wording needs hyphens	No change	ASHA's style guide, among others, suggest keeping as is with no hypen
4	85	would restate that OM is 2nd most common illnesss (to URI's)	Change made	Restated as suggested.
5	85	Line is difficult to read suggest change "other than" to ,second only to upper respiratory infection" which makes the passage easier to understand	Change made	Changed as suggested.
6	86	define "young" children (is that 6 to 12 mos?)	Change	Change "Young children..." to "Children under 7 years of age..."
7	95	effusion--needs to be specified for less knowledgeable reader	No change	Please refer to Table 1 where OME w/ effusion is defined
8	95-99	summary of benefits of tubes	No change	Thank you for your comment.
9	101	SNHL definition as written implies it includes central (cortical) hearing loss instead of being limited to sensory (hair cell) and eighth nerve loss.	Change made	Thank you for your comment, we have incorporated your suggested edits into the definition
10	Table #1	conductive hearing loss: "abnormal processing and transmission of sound.."; including "processing" in this defintion is confusing. SNHL: should eliminate "..auditory cortex where sound is ultimately processed" to definition as it is unnecessary to the definition of SNHL.	Change made	Thank you for your comment, we have incorporated your suggested edits into the definition
11	Tube insertion	Tymp tubes generally last several months to several years, depending on tube design *and placement location in the tympanic membrane.*	Change made	Thank you for your comment, we have incorporated your suggested edits into the definition
12	101	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.	No change	The term "hearing assessment" 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.
13	101	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 invovle middle ear space)	Change made	Changed "...into the middle ear with..." to "into the middle ear or attic with..."

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)

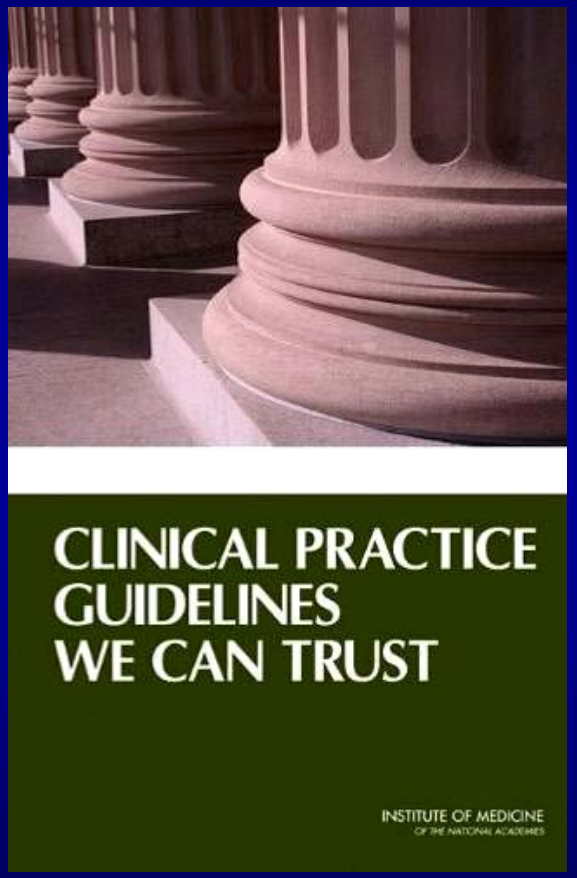
7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments

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 25. Responding to Concerns Expressed by Guideline Reviewers

Type of Concern	Suggestions for Responding
Concerns substantiated with research evidence	All concerns supported by literature citations must be taken seriously, with a revision in the guideline when appropriate.
Concerns based on experience, personal bias, or expert opinion	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.
Concerns based on misinterpretation	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.
Concerns based on misunderstanding of guideline methodology	Clinicians may be very critical of or even vehemently opposed to guidelines for many reasons, often because they consider themselves better qualified to have written the document 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.
Concerns about abuse, misuse, and legal precedents	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.
Concerns about spelling, grammar, terminology, and choice of words	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.

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.

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

How the AAO-HNSF CPG Development Process Measures Up

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.

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

ONLINE FIRST | HEALTH CARE REFORM

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

Standard	Organization Type, Guidelines, No. (%)[a]				
	All (114)	US (68)	Non-US (46)	US Government Agency (15)	Subspecialty Societies (41)
Committee selection process stated	34 (29.8)	24 (35.3)	10 (21.7)	11 (73.3)	10 (24.4)
COIs stated	42 (46.8)	28 (41.2)	14 (30.4)	8 (53.3)	12 (29.3)
Chair has COI	30 (71.4)	18 (64.3)	12 (85.7)	6 (75.0)	7 (58.3)
Co-chairperson has COI	38 (90.5)	25 (89.3)	13 (92.9)	7 (97.5)	9 (75.0)
Information scientist	27 (23.7)	13 (19.1)	14 (30.4)	2 (20.0)	7 (17.1)
Patient or patient representative	19 (16.7)	5 (7.4)	14 (30.4)	1 (6.7)	4 (9.8)

Abbreviations: COI, conflict of interest; US, United States.
[a]Number (percentage) meeting standard.

Arch Intern Med 2012; doi:10.1001/2013.jamaintermed.56

www.g-i-n.net/activities/g-i-n-na