

American Academy of Otolaryngology—Head and Neck Surgery Foundation Clinical Consensus
Statement Manual

Background

A Clinical Consensus Statement (CCS) reflects information synthesized from an organized group of expert opinion in a written document. CCSs should reflect the expert views of a panel of individuals who are well-versed on the topic of interest while carefully examining and discussing the scientific data available. They are not to be confused with a formal evidence review and are not developed in accordance with clinical practice guidelines.¹ In addition, a CCS is not intended as a legal document or primary source of detailed technical information.

The purpose of the expert panel is to synthesize information, along with possible conflicting interpretations of the data, into clear and accurate answers to the question of interest. Moreover, the CCS may reflect uncertainties, opinions, or minority viewpoints. Medical safety and effectiveness should also be emphasized during controversy over preventive, therapeutic, or diagnostic options, or when the issue is of public or professional interest. The CCS development process should be explicit and transparent, using the best published evidence available to guide decisions. The emphasis on expert opinion creates potential for biases, making it essential for developers to state group values and fully disclose conflicts of interest.

Unlike specialty-specific guidelines which could encompass other disciplines, CCSs are limited to otolaryngology related topics. Because clinical evidence is lacking, the terms "evidence-based," and "guideline" should not be used in the context of CCSs. Nonetheless, the development panel must conduct a systematic review to ensure that the best available evidence is identified to support decisions, even if this evidence is limited to case series or previously published consensus documents. Findings of a consensus panel should be stated as "opinions" or "suggestions," NOT as "recommendations."

Method

A Consensus Method (CM) is a formal process that allows information to be synthesized into CCSs for topics where evidence is lacking or non-existent. Furthermore, CMs allow the insights of appropriate experts to be solicited and may fill the gap for areas void of quality research evidence. Three commonly known methods include: 1) The Delphi Method, 2) The Nominal Group Technique, and 3) The Consensus Development Conference.

AAO-HNS plans to use the Delphi method for the development of clinical consensus statements. The Delphi Method is a multiple iteration technique usually meant to be anonymous with the purpose of refining the expert opinion and ultimately arriving at a combined or consensual position². The process includes gathering of experts who answer questionnaires (rating of recommendations for our purposes) developed by chair(s) who have the appropriate clinical expertise. Responses to questionnaires will be reviewed by chair and redistributed if consensus is not reached for two or more rounds or until consensus is reached (*see figure 1*). After each round, a facilitator (chair) provides an anonymous summary of the experts' forecasts from the previous round as well as the reasons they provided for their judgments. Thus, participants are encouraged to revise their earlier answers in light of the replies of other members of the group. It is believed that during this process the range of the answers will decrease and the group will converge towards the "correct" answer.

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNS) Guideline Development Task Force (GDTF) will assemble an expert panel that is an independent, broad-based, and non-advocacy group with appropriate expertise. The purpose is to evaluate available scientific information on issues decided upon by the AAO-HNS GDTF. The appropriate expert panel will be tasked with the development of statements that advances understanding of the issue under consideration and will be useful to health professionals and the public.

The topic is considered for a CCS by the Guideline Development Task Force (GDTF). Interested individuals or groups must agree to complete and submit a “Topic Submission Form” to the GDTF. Topics for CCS will be selected based on but not limited to the following criteria:

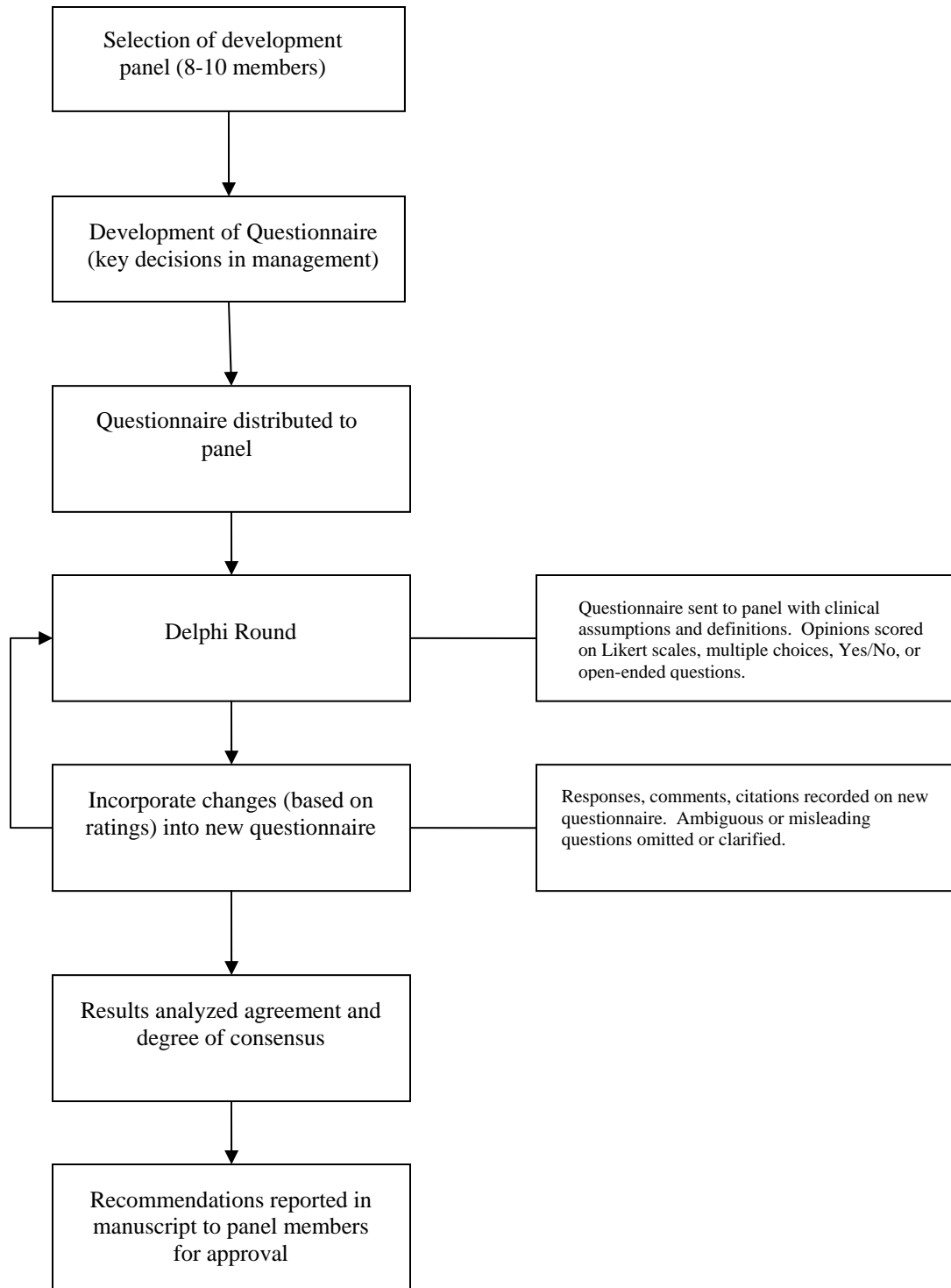
- Burden of illness
- Potential for quality improvement
- Availability of existing evidence
- Guideline Endorsement
- Degree of Actionability
- Socioeconomic burden to society
- Socioeconomic burden to physicians

Once a topic has gone through the above process and evaluated by the GDTF as amenable for a CCS, a full preliminary literature review will be conducted either by an AAO-HNSF staff, or by the topic submitter themselves.

To produce an AAO-HNS CCS, the Modified Delphi Method will be used through these general steps:

- a) Expert panel recruitment and appointment
- b) Consensus questionnaire development by the chair(s)
- c) Administer questionnaires (two to three rounds) by chair(s) to panel members.
- d) Consensus is reached through teleconference
- e) Results are finalized
- f) Final review by GDTF

The logistics of these steps are explained further in the Development Timeline Section on Page 3.



<i>Phase</i>	<i>Activity</i>
Prewrite	1. Topic is submitted to the Guidelines Development Task Force, presented and approved as amenable for a CCS.
Prewrite	2. A full preliminary literature review will be conducted by designated AAO-HNS staff or by the initiating topic submitter.
Month 1	3. The consensus panel chair should be appointed as a result of expertise in the area of interest.
Month 1	4. Other panel members should be appointed in coordination with the panel chair.
Month 1	5. All panel members will be required to provide a written declaration of conflict of interest in addition to periodic disclosure.
	6. Development and finalizing of questionnaire by chair(s). Questionnaires should be based on initial literature review and reflect the current controversies, gap in care and/or knowledge, variation in care, etc. discussed in the literature.
Month 2-4	7. Meeting #1 (may be in person) will mark the beginning of manuscript development and allow the opportunity for the panel to meet and discuss the overview of consensus development
Month 5	8. Conference calls should be used as needed until CCS completion.
As Needed	9. The completed structure of the CCS is as follows: - Executive Summary - Abstract - Introduction - Methods - Evaluation - Management - References
	10. Bulletin and/or Journal staff at AAO-HNS should be notified of the topic choice and submission timeline.
	11. AAO-HNS staff will generate a list of external peer reviewers [10-15] to provide feedback on final draft of the CCS, ideally using appropriate AAO-HNS committees. These reviewers will also be asked for feedback on the appropriate venue for publication submission – i.e. Journal, Bulletin, etc. [If the Journal is selected, the comments of the external reviewers will be attached electronically and substitute for peer review for submission to the Journal.]
	12. In addition, appropriate Bulletin and/or Journal staff should be given updates on draft completion, and external peer review comments received (if applicable). Also concurrent printing in appropriate subspecialty or sister society publications should be considered.
	13. Manuscripts should be no larger than 3,000 words and should undergo external peer review prior to final publication.
	14. The CCS process should be approved by the AAO-HNS Board of Directors. Any manuscripts submitted following the process should be sent to the Board of Directors at the AAO-HNS for final sign-off.
	15. AAO-HNS staff will be responsible for Journal, Bulletin and/or website submission.

Executive Summary

Abstract

Introduction

1. Statement of need for the CCS: it should be stated early on why the question was felt suitable for a CCS, and not a more formal venue such as the Specialty-Specific or Multi-Specialty Guideline.
2. Description/definition of the procedure or condition
 - A. Anatomy/physiology
 - B. Etiology/pathology
3. Current controversies
 - A. Health policy implications
 - a. Gap/variations in care
 - b. Cost to treat/burden
 - c. Diagnosis-related coding, hospital reimbursement, mortality/morbidity statistics, etc.

Methods

Consensus panels should be encouraged to include a methods section on how consensus was achieved, either formally or informally. Literature search processes should be documented. The methods section should provide explicit information to the reader that the information contained in the document is based on consensus and expert opinion.

Evaluation

4. Diagnosis
 - A. Clinical indications
 - B. Diagnostic testing required
 - C. Diagnostic testing that is not required or should not be done
5. Patient characteristics and modifying factors
 - A. Natural history and risk stratification
 - B. Information for members about the patient population that undergo the procedure – whatever we know from the literature about age, gender, co-morbid conditions, etc.
 - C. Changes in the population over time – e.g., cochlear implants now done on younger children and older adults.

Management

6. Treatments
 - A. Clinical Indications for Treatment Modality discussed
 - B. Risks, benefits and harms
7. Expected outcomes
 - A. Patient characteristics that are correlated with better or worse outcomes
 - B. Expected recidivism rates (i.e., number of patients who are likely to have to undergo a repeat procedure or revert to pre-surgery health status over time)
8. Complications
 - A. Information from the literature about common complications
 - B. Information from the literature about expected complication rates (e.g., bleed rates after tonsillectomy)
9. Communicating with patients

- A. While normally one would expect the physician to discuss all of the above information with patients prior to surgery, there may be key elements we want to emphasize in this section that are related to informed consent, pre-operative or post-operative care/safety

References

References

1. Rosenfeld RM, Shiffman RN. Clinical practice guidelines: a manual for developing evidence-based guidelines to facilitate performance measurement and quality improvement. *Otolaryngology Head Neck Surg* 2006 Oct;135(4 Suppl):S1-28.
2. Helmer, O, Rescher NH. *On the Epistemology of Inexact Sciences*. Los Angeles, CA. Rand Corporation. 1960.
3. Park RE, Fink A, Brook RH, et al. Physician ratings of appropriate indications for six medical and surgical procedures. *AM J Public Health* 1986;76:766
4. Brook RH, Chassin MR, Fink A, et al. A Method for The Detailed Assessment of the Appropriateness of Medical Technologies. *Int J Technol Assess Health Care* 1986;2:53.