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#### **Abstract**

Objective. Sudden hearing loss is a frightening symptom that often prompts an urgent or emergent visit to a health care provider. It is frequently, but not universally, accompanied by tinnitus and/or vertigo. Sudden sensorineural hearing loss affects 5 to 27 per 100,000 people annually, with about 66,000 new cases per year in the United States. This guideline update provides evidence-based recommendations for the diagnosis, management, and follow-up of patients who present with sudden hearing loss. It focuses on sudden sensorineural hearing loss in adult patients aged 18 and over and primarily on those with idiopathic sudden sensorineural hearing loss. Prompt recognition and management of sudden sensorineural hearing loss may improve hearing recovery and patient quality of life. The guideline update is intended for all clinicians who diagnose or manage adult patients who present with sudden hearing loss.

Purpose. The purpose of this guideline update is to provide clinicians with evidence-based recommendations in evaluating patients with sudden hearing loss and sudden sensorineural hearing loss, with particular emphasis on managing idiopathic sudden sensorineural hearing loss. The guideline update group recognized that patients enter the health care system with sudden hearing loss as a nonspecific primary complaint. Therefore, the initial recommendations of this guideline update address distinguishing sensorineural hearing loss from conductive hearing loss at the time of presentation with hearing loss. They also clarify the need to identify rare, nonidiopathic sudden sensorineural hearing loss to help separate those patients from those with idiopathic sudden sensorineural hearing loss, who are the target

population for the therapeutic interventions that make up the bulk of the guideline update. By focusing on opportunities for quality improvement, this guideline should improve diagnostic accuracy, facilitate prompt intervention, decrease variations in management, reduce unnecessary tests and imaging procedures, and improve hearing and rehabilitative outcomes for affected patients.

Methods. Consistent with the American Academy of Otolaryngology—Head and Neck Surgery Foundation's Clinical Practice Guideline Development Manual, Third Edition, the guideline update group was convened with representation from the disciplines of otolaryngology—head and neck surgery, otology, neurotology, family medicine, audiology, emergency medicine, neurology, radiology, advanced practice nursing, and consumer advocacy. A systematic review of the literature was performed, and the prior clinical practice guideline on sudden hearing loss was reviewed in detail. Key action statements (KASs) were updated with new literature, and evidence profiles were brought up to the current standard. Research needs identified in the original clinical practice guideline and data addressing them were reviewed. Current research needs were identified and delineated.

Results. The guideline update group made strong recommendations for the following: clinicians should distinguish sensorineural hearing loss from conductive hearing loss when a patient first presents with sudden hearing loss (KAS I); clinicians should educate patients with sudden sensorineural hearing loss about the natural history of the condition, the benefits and risks of medical interventions, and the limitations of existing evidence regarding efficacy (KAS 7); and clinicians should counsel patients with sudden sensorineural hearing loss who have residual hearing loss and/or tinnitus about the possible benefits of audiological rehabilitation and other supportive measures (KAS 13). These strong

recommendations were modified from the initial clinical practice guideline for clarity and timing of intervention.

The guideline update group made strong recommendation against the following: clinicians should *not* order routine computed tomography of the head in the initial evaluation of a patient with presumptive sudden sensorineural hearing loss (KAS 3); clinicians should *not* obtain routine laboratory tests in patients with sudden sensorineural hearing loss (KAS 5); and clinicians should *not* routinely prescribe antivirals, thrombolytics, vasodilators, or vasoactive substances to patients with sudden sensorineural hearing loss (KAS 11).

The guideline update group made recommendations for the following: clinicians should assess patients with presumptive sudden sensorineural hearing loss through history and physical examination for bilateral sudden hearing loss, recurrent episodes of sudden hearing loss, and/or focal neurologic findings (KAS 2); in patients with sudden hearing loss, clinicians should obtain, or refer to a clinician who can obtain, audiometry as soon as possible (within 14 days of symptom onset) to confirm the diagnosis of sudden sensorineural hearing loss (KAS 4); clinicians should evaluate patients with sudden sensorineural hearing loss for retrocochlear pathology by obtaining a magnetic resonance imaging or auditory brainstem response (KAS 6); clinicians should offer, or refer to a clinician who can offer, intratympanic steroid therapy when patients have incomplete recovery from sudden sensorineural hearing loss 2 to 6 weeks after onset of symptoms (KAS 10); and clinicians should obtain follow-up audiometric evaluation for patients with sudden sensorineural hearing loss at the conclusion of treatment and within 6 months of completion of treatment (KAS 12). These recommendations were clarified in terms of timing of intervention and audiometry, as well as method of retrocochlear workup.

The guideline update group offered the following KASs as options: clinicians may offer corticosteroids as initial therapy to patients with sudden sensorineural hearing loss within 2 weeks of symptom onset (KAS 8); clinicians may offer, or refer to a clinician who can offer, hyperbaric oxygen therapy combined with steroid therapy within 2 weeks of onset of sudden sensorineural hearing loss (KAS 9a); and clinicians may offer, or refer to a clinician who can offer, hyperbaric oxygen therapy combined with steroid therapy as salvage

therapy within I month of onset of sudden sensorineural hearing loss (KAS 9b).

#### Differences from Prior Guideline

- Incorporation of new evidence profiles to include quality improvement opportunities, confidence in the evidence, and differences of opinion
- Included 10 clinical practice guidelines, 29 new systematic reviews, and 36 new randomized controlled trials
- Highlights the urgency of evaluation and initiation of treatment, if treatment is offered, by emphasizing the time from symptom occurrence
- Clarification of terminology by changing potentially unclear statements; use of the term *sudden* sensorineural hearing loss to mean idiopathic sudden sensorineural hearing loss to emphasize that over 90% of sudden sensorineural hearing loss is idiopathic sudden sensorineural hearing loss and to avoid confusion in nomenclature for the reader
- Changes to the key action statements (KASs) from the original guideline:
  - KAS 1: When a patient first presents with sudden hearing loss, conductive hearing loss should be distinguished from sensorineural.
  - KAS 2: The utility of history and physical examination when assessing for modifying factors is emphasized.
- o KAS 3: The word *routine* is added to clarify that this statement addresses a nontargeted head computed tomography scan that is often ordered in the emergency room setting for patients presenting with sudden hearing loss. It does not refer to targeted scans such as a temporal bone computed tomography scan to assess for temporal bone pathology.
- KAS 4: The importance of audiometric confirmation of hearing status as soon as possible and within 14 days of symptom onset is emphasized.
- KAS 5: New studies were added to confirm the lack of benefit of nontargeted laboratory testing in sudden sensorineural hearing loss.
- KAS 6: Audiometric follow-up is excluded as a reasonable workup for retrocochlear pathology.

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Magnetic resonance imaging, computed tomography scan if magnetic resonance imaging cannot be done, or, secondarily, auditory brainstem response evaluation are the modalities recommended. A time frame for such testing is not specified, nor is it specified which clinician should be ordering this workup; however, it is implied that it would be the general or subspecialty otolaryngologist.

- KAS 7: The importance of shared decision making is highlighted, and salient points are emphasized.
- KAS 8: The option for corticosteroid intervention within 2 weeks of symptom onset is emphasized.
- KAS 9: Changed to KAS 9a and 9b; hyperbaric oxygen therapy remains an option but only when combined with steroid therapy for either initial treatment (9a) or for salvage therapy (9b). The timing is within 2 weeks of onset for initial therapy and within 1 month of onset of sudden sensorineural hearing loss for salvage therapy.
- KAS 10: Intratympanic steroid therapy for salvage is recommended within 2 to 6 weeks following onset of sudden sensorineural hearing loss. The time to treatment is defined and emphasized.
- KAS 11: Antioxidants were removed from the list of interventions that the clinical practice guideline recommends against using.
- KAS 12: Follow-up audiometry at conclusion of treatment and also within 6 months posttreatment is added.
- KAS 13: This statement on audiologic rehabilitation includes patients who have residual hearing loss and/or tinnitus who may benefit from treatment.
- Addition of an algorithm outlining KASs
- Enhanced emphasis on patient education and shared decision making with tools provided to assist in the same

### **Keywords**

practice guidelines, sudden hearing loss, sudden sensorineural hearing loss, intratympanic steroids, hyperbaric oxygen, evidence-based medicine

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#### Introduction

Sudden hearing loss (SHL) is a frightening symptom that often prompts an urgent or emergent visit to a clinician. This guideline update focuses on sudden sensorineural

hearing loss (SSNHL), the majority of which is idiopathic and, if not recognized and managed promptly, may result in persistent hearing loss and tinnitus and reduced patient quality of life (QOL). SSNHL affects 5 to 27 per 100,000 people annually, with about 66,000 new cases per year in the United States. Throughout this guideline, the following definitions are used (see **Table 1**):

- SHL is defined as a rapid-onset subjective sensation of hearing impairment in 1 or both ears. The hearing loss in SHL may be a conductive hearing loss (CHL), sensorineural hearing loss (SNHL), or mixed hearing loss (MHL), defined as both CHL and SNHL occurring in the same ear. CHL and the conductive component of MHL may be due to an abnormality in the ear canal, tympanic membrane ("eardrum"), or middle ear.
  - Physical examination will help determine if there is obstructing cerumen or a foreign body in the ear canal, if there is a perforation of the tympanic membrane, or if there is fluid in the middle ear.
  - Tuning fork testing will enable the initial treating clinician to distinguish CHL from SNHL, so that the SSNHL evaluation and management pathway can be triggered appropriately.
- SSNHL is a subset of SHL that (a) is sensorineural in nature, (b) occurs within a 72-hour window, and (c) meets certain audiometric criteria.
  - SNHL is sometimes referred to colloquially as "nerve hearing loss" and indicates abnormal functioning of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing.
  - The most frequently used audiometric criterion for SSNHL is a decrease in hearing of greater than or equal to 30 decibels affecting at least 3 consecutive frequencies. Because premorbid audiometry is generally unavailable, hearing loss is often defined in relation to the opposite ear's thresholds.
  - The guideline update group (GUG) acknowledges that in both clinical practice and research studies, less stringent criteria for SSNHL are employed.
  - SSNHL is often but not always accompanied by tinnitus and/or vertigo. The tinnitus may persist and may be disturbing to the patient.
- Idiopathic sudden sensorineural hearing loss (ISSNHL) is defined as SSNHL with no identifiable cause despite adequate investigation. This is the situation in 90% of patients with SSNHL and is the primary focus of this clinical practice guideline (CPG) update. The use of SSNHL in this document is equivalent to ISSNHL, as determined after the appropriate workup denoted in key action statement (KAS) 1 and KAS 2.

Table 1. Definitions of Common Terminology.

Term	Definition	
Sudden hearing loss (SHL)	A rapid-onset subjective sensation of hearing impairment in 1 or both ears	
Sensorineural hearing loss (SNHL)	Hearing loss resulting from abnormal function of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing	
Conductive hearing loss (CHL)	Hearing loss resulting from a problem conducting sound waves anywhere along the route through the outer ear, tympanic membrane, or middle ear	
Mixed hearing loss (MHL)	Hearing loss resulting from both SNHL and CHL occurring in the same ear	
Sudden sensorineural hearing loss (SSNHL)	A subset of SHL that (a) is sensorineural in nature, (b) occurs within a 72-hour window, and (c) consists of a decrease in hearing of greater than or equal to 30 decibels affecting at least 3 consecutive frequencies	
Idiopathic sudden sensorineural hearing loss (ISSNHL)	SSNHL with no identifiable cause despite adequate investigation	
Salvage therapy	Any therapy offered after 2 weeks from symptom onset (even if initial therapy was observation)	

The SSNHL definition used throughout this guideline is ≥30 dB SNHL at 3 consecutive frequencies based on its consistent use in the literature and National Institute on Deafness and Other Communication Disorders (NIDCD) criteria<sup>5</sup>; however, the GUG recognizes that in clinical practice, expanding the definition to cases with less than 30 decibels of hearing loss may be considered. The GUG recognizes that the NIDCD definition is not universally used and, accordingly, published evidence not using this definition was considered.

The distinction between SSNHL and sudden conductive or mixed hearing loss is one that should be made by the initial treating health care provider in order for early diagnosis and management to be instituted. Moreover, nonidiopathic causes of SSNHL must be identified and addressed during the course of management; the most pressing of these are vestibular schwannoma (acoustic neuroma), stroke, malignancy, noise, and ototoxic medications.<sup>6-9</sup>

Much of the literature indicates that 32% to 65% of cases of SSNHL may recover spontaneously. 4,10 Clinical experience, however, shows that these numbers may be an overestimation. It is important to remember that tinnitus is a frequent comorbidity that may persist and, with time, may become the patient's primary concern. Details on tinnitus management can be found in the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) Clinical Practice Guideline: Tinnitus. 11 The prognosis for recovery is dependent on a number of factors, including patient age, presence of vertigo at onset, degree of hearing loss, audiometric configuration, and time between onset of hearing loss and treatment. 10,12,13 In addition, the psychological and communicative detriment experienced during an acute episode of SHL, and then in potentially unrecovered hearing loss and persistent tinnitus, creates a strong desire for treatment. 14,15

Treatment options that have been proffered for SSNHL are myriad and include systemic and topical steroids, antiviral agents, hyperbaric oxygen therapy (HBOT), rheologic agents, diuretics, other medications, herbal and other complementary and alternative treatments, middle ear surgery for fistula repair, and observation alone.

Long-term follow-up is recommended as some patients (up to one-third) will have an underlying cause that is eventually identified but was not evident at initial presentation. In addition, the patient with partial or no hearing recovery and/or persistent tinnitus will require ongoing management from otolaryngological, audiological, and psychological perspectives. In

This multidisciplinary guideline update is intended for all clinicians who diagnose or manage adult patients (aged 18 years and older) who present with SHL. After addressing causes, diagnosis, and treatments of sudden conductive/mixed hearing loss briefly, this guideline update will go on to address SSNHL in detail.

The incidence of this symptom, the debilitating consequences of missed early diagnosis and management, the presentation of the patient to a variety of health care providers, the abundance of small series and case reports regarding treatment, and the paucity of randomized controlled trials (RCTs) assessing interventions created a pressing need for the original evidence-based guideline to aid clinicians in managing SSNHL in 2012<sup>10</sup> and for this update now. Moreover, wide variations in evaluation, treatment, counseling, and follow-up of patients with SSNHL continue to exist within the United States and worldwide. Such variations are usually ascribed to heterogeneity in clinical practice and training rather than to differences in clinical need.

Data show that, since publication of the initial sudden hearing loss CPG, adherence to KAS recommendations is not universal. Among otolaryngologists, there is high adherence to the recommendations to rule out CHL, avoid a routine head computed tomography (CT) scan, and to perform a retrocochlear workup. There is moderate adherence to the recommendations to avoid routine laboratory assessment and avoid other treatments (nonsteroid/non-HBOT). In this specialty group, however, there is low adherence to the recommendations for patient education regarding the natural history of SSNHL and for counseling regarding hearing rehabilitation. As for the original CPG's statements regarding systemic steroid therapy as an option for primary treatment and

intratympanic (IT) steroid therapy as a recommendation for salvage treatment, otolaryngologists in this study opted to prescribe both interventions—initial oral steroid therapy and salvage IT steroid therapy.

Nonotolaryngologists more commonly ordered routine head CT and performed routine, nontargeted (often called "shotgun") laboratory assessments despite recommendations against these actions. They did not pursue retrocochlear workup or provide patient education as recommended.

Ten research needs were identified in the original SHL CPG. These included the following:

- Determine a standardized and evidence-based definition of SSNHL.
- 2. Investigate the effectiveness of corticosteroid treatment vs a placebo.
- 3. Further investigate the benefit of HBOT and standardized HBOT treatment protocols for ISSNHL.
- 4. Develop standardized outcome criteria to aid the comparison of clinical studies.
- 5. Further study IT steroids as salvage therapy with particular attention to the optimal medications, dosage, concentrations, timing, and administration schedules for IT therapy.
- Develop criteria to determine at what level of hearing recovery IT steroids would be offered as salvage.
- 7. Determine the percentage of patients who gain serviceable hearing as a result of treatment.
- 8. Investigate the use of "combined therapy," such as oral and IT steroids, in patients with ISSNHL.
- 9. Develop long-term follow-up protocols for patients with ISSNHL.
- 10. Evaluate therapies using standardized definitions and treatment protocols across studies.

The current CPG update addresses the research questions that have been answered and the research needs that remain. In addition, novel agents in trials are mentioned so that the reader may be alerted to new developments in the field.

The incomplete adoption of CPG recommendations and the ongoing lack of consensus on all aspects of the care of the patient with SSNHL further support the need for a user-friendly evidence-based CPG update to highlight and encourage use of best practices.

## **Guideline Scope and Purpose**

The purpose of this multidisciplinary guideline update is to provide clinicians with evidence-based recommendations in evaluating patients with SHL, with emphasis on managing SSNHL. The guideline update is intended for all clinicians who are likely to diagnose and manage adults aged 18 years and older with SHL and applies to any setting in which an adult with SHL would be identified, managed, or monitored. The recommendations outlined in this guideline update are not intended to represent the standard of care for patient management, nor are the recommendations intended to limit

treatment or care provided to individual patients. The guideline update is not intended to replace individualized patient care or clinical judgment. Information for patients is also provided, in appropriate language, to facilitate understanding and shared decision making.

Although the guideline update focuses primarily on managing SSNHL, the GUG recognized that patients enter the health care system with SHL as a nonspecific primary complaint. Therefore, the initial recommendations of the guideline update address an efficient manner by which to distinguish SNHL from CHL at the time of presentation. This distinction will often fall to the primary care or emergency room physician or other health care provider. Therefore, there is detailed discussion in this CPG of what otolaryngologists might consider obvious in the physical examination, including the use of tuning forks to distinguish CHL from SNHL. The purpose of the guideline update is not to present an exhaustive approach to managing CHL.

This is a multidisciplinary and interprofessional (herewith referred to by the term *multidisciplinary*) update of the first CPG on ISSNHL developed in the United States. This guideline update will provide evidence-based recommendations for clinicians based on multidisciplinary consensus and careful consideration of the benefits vs harms of suggested actions. By focusing on opportunities for quality improvement, the update should further improve diagnostic accuracy, facilitate prompt intervention, decrease inappropriate variations in management, reduce unnecessary tests and imaging procedures, and improve hearing and rehabilitative outcomes for affected patients.

#### **Health Care Burden**

The incidence of SSNHL is reported as 5 to 27 per 100,000 people annually (United States), with some estimates ranging as high as 160 per 100,000 (Germany). The US data may be underestimated as individuals who experience mild SHL and/or a quick, spontaneous resolution may not seek medical care.

For most patients with SHL, their medical journey often starts at an emergency room, walk-in or urgent care clinic, or primary care physician's office. Even using the lower incidences quoted above, this represents between 15,000 and 60,000 patients seen in US urgent/emergency care or primary care clinics for this problem annually.

Coexistent morbidities such as dizziness and tinnitus pose considerable disease burdens for the patient with SSNHL. Dizziness is present in 30% to 60% of cases of SSNHL. 12,21,22 The presence of dizziness or vertigo at time of onset of SSNHL is seen often in more severe cases and is frequently associated with poorer prognosis for hearing recovery. Tinnitus is nearly universal in SSNHL and, if persistent and bothersome, may pose a significant economic and psychological burden. 11,23 Recovery of hearing after SSNHL is often accompanied by improvement of the attendant tinnitus. Residual tinnitus may exacerbate or supersede the psychological and functional burden of nonrecovered hearing loss in SSNHL. 24

The audiological needs of patients with SSNHL are considerable and can be costly. Patients with sudden unilateral hearing loss have immediate difficulty with conversation on the involved side and overall hearing in noisy environments. If they have preexisting hearing loss from common causes such as presbycusis and noise exposure, SSNHL will compound the problem. In patients with SSNHL, the hearing asymmetry often results in the inability to determine where a sound originates, which can be frustrating and even disorienting to the listener. The inability to localize sound may make it difficult for patients who rely on hearing to avoid dangerous situations such as crossing a busy street, thereby posing safety concerns. Repeated audiometric assessment with continued follow-up is needed. Rehabilitation of patients with persistent hearing loss following SSNHL can involve hearing aids, surgically implantable hearing devices, or both, with significant resultant expense to the patient and to the health care system.

The significant impact of unilateral SNHL on patients' QOL has been shown in adults and children. <sup>25,26</sup> Sudden SNHL, particularly when accompanied by tinnitus and dizziness, can result in even greater decrements in QOL. <sup>10,14,23</sup> Patients may experience fear and frustration at the inability to identify a cause for their hearing loss.

The cumulative weight of this disease burden underlies the importance of an updated CPG to optimize care of patients with this debilitating condition.

#### **Methods**

### General Methods and Literature Search

In developing this update of the evidence-based CPG, the methods outlined in the AAO-HNSF's *Clinical Practice Guideline Development Manual, Third Edition* were followed explicitly.<sup>27</sup>

An executive summary of the original Clinical Practice Guideline: Sudden Hearing Loss<sup>10</sup> was sent to a panel of expert reviewers from the fields of general otolaryngology, otology, neurotology, neurology, family practice, advanced practice nursing, emergency medicine, radiology, and audiology who assessed the KASs to decide if they should be kept in their current form, revised, or removed and to identify new research that might affect the guideline recommendations. The reviewers concluded that the original guideline action statements remained valid but should be updated with minor modifications. Suggestions were also made for new KASs.

The recommendations in this CPG are based on systematic reviews identified by a professional information specialist using an explicit search strategy. Additional background evidence included RCTs as needed to supplement the systematic review or to fill gaps when a review was not available. An information specialist conducted a systematic literature search using a validated filter strategy to identify CPGs, systematic reviews, and RCTs published since the prior guideline (2012). Search terms used were: ("Hearing Loss, Sudden" [Mesh] OR "sudden hearing loss" [ti] OR "sudden deafness" [ti] OR

"sudden sensorineural hearing loss"[ti] OR "idiopathic sudden hearing loss"[ti]). These search terms were used to capture all evidence on the population, incorporating all relevant treatments and outcomes. In certain instances, targeted searches for lower-level evidence were performed to address gaps from the systematic searches identified in writing the guideline. The original search was updated from January 2011 to July 2017 to include MEDLINE, EMBASE, Web of Science, Cumulative Index to Nursing and Allied Health Literature, Cochrane Database of Systematic Reviews, National Guideline Clearinghouse, Allied and Complementary Medicine Database, Canadian Medical Association Infobase, and National Institute for Health and Care Excellence.

- 1. The initial search for CPGs identified 20 guidelines. After removing duplicates, irrelevant references, and non-English-language articles, 2 guidelines were reviewed for inclusion. Quality criteria for including guidelines were (a) an explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) an explicit system for ranking evidence, and (e) an explicit system for linking evidence to recommendations. Additional targeted searches were performed, which resulted in the inclusion of 10 CPGs to the CPG Update; this includes the prior version of this AAO-HNSF CPG.
- 2. The initial search for systematic reviews identified 127 systematic reviews or meta-analyses. After removing duplicates, irrelevant references, and non-English-language articles, 32 articles were reviewed for inclusion. Quality criteria for including reviews were (a) relevance to the guideline topic, (b) clear objective and methodology, (c) explicit search strategy, and (d) valid data extraction methods. After the public review process, 1 further systematic review and 1 further meta-analysis were included. The final data set retained was 29 systematic reviews or meta-analyses that met inclusion criteria.
- 3. The initial search for RCTs identified 83 RCTs that were distributed to GUG members for review. After removing duplicates, irrelevant references, and non-English-language articles, 30 articles were reviewed for inclusion. Quality criteria for including RCTs were (a) relevance to the guideline topic, (b) publication in a peer-reviewed journal, and (c) clear methodology with randomized allocation to treatment groups. The total final data set retained 36 RCTs that met inclusion criteria.

The AAO-HNSF assembled a GUG representing the disciplines of otolaryngology—head and neck surgery, otology, neurotology, family medicine, audiology, emergency medicine, neurology, radiology, advanced practice nursing, and consumer advocacy. The GUG had 3 conference calls and 1 in-person meeting, during which they defined the scope and objectives of updating the guideline, reviewed comments

from the expert panel review for each KAS, identified other quality improvement opportunities, and reviewed the literature search results.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with our current development standards.<sup>27</sup> Information was added to the action statement profiles regarding the quality improvement opportunity to which the action statement pertained, the guideline panel's level of confidence in the published evidence, differences of opinion among panel members, and the feasibility of measurability and implementability. New KASs were developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision support (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) software was used to facilitate creating actionable recommendations and evidence profiles.<sup>28</sup>

The updated guideline then underwent Guideline Implementability Appraisal (GLIA) to assess adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. The GUG received summary appraisals and modified an advanced draft of the guideline based on the appraisal. That modified draft of the updated CPG was again revised based on comments received during multidisciplinary peer review, open public comment, and journal editorial peer review, resulting in the final manuscript. A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

### Classification of Evidence-Based Statements

Guidelines are intended to produce optimal health outcomes for patients, to minimize harm, and to reduce inappropriate variations in clinical care. The evidence-based approach to guideline development requires the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that are anticipated when the statement is followed. The definitions for evidence-based statements are listed in **Table 2**<sup>30</sup> and **Table 3**.<sup>31</sup>

Guidelines are not intended to supersede professional judgment but rather may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with a "recommendation." "Options" offer the most opportunity for practice variability. Selinicians should always act and decide in a way that they believe will best serve their patients interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a

particular topic.<sup>31</sup> Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

## Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,<sup>33</sup> the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.34 Conflicts were again delineated at the start of the in-person meeting and at the start of each teleconference meeting, with the same caveats followed. All conflicts are disclosed at the end of this document.

# **Guideline Key Action Statements**

Each evidence-based statement is organized in a similar fashion: a KAS is in bold, followed by the strength of the recommendation in italics. Each KAS is followed by an "action statement profile" that explicitly states the quality improvement opportunity, aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, harms, risks, costs, and a benefits-harm assessment. In addition, there are statements of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence supporting the statement. An overview of each evidence-based statement in this guideline can be found in **Table 4**.

For the purposes of this guideline, *shared decision making* refers to the exchange of information regarding treatment risks and benefits, as well as the expression of patient preferences and values, which result in mutual responsibility in decisions regarding treatment and care.<sup>35</sup> The role of patient preferences in making decisions deserves further clarification. The GUG classified the role of patient preference based on consensus among the group as "none, small, moderate, or large." For some statements where the evidence base demonstrates clear benefit, although the role

Table 2. Aggregate Grades of Evidence by Question Type.<sup>a</sup>

	OCEBM				
Grade	Level	Treatment	Harm	Diagnosis	Prognosis
A	I	Systematic review <sup>b</sup> of randomized trials	Systematic review <sup>b</sup> of randomized trials, nested case-control studies, or observational studies with dramatic effect <sup>b</sup>	Systematic review <sup>b</sup> of cross- sectional studies with consistently applied reference standard and blinding	Systematic review <sup>b</sup> of inception cohort studies <sup>c</sup>
В	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 <sup>c</sup>
С	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; caseseries, 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	N/A	•	re validating studies cannot be per	· · ·	onderance of benefit over

Abbreviations: OCEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable.

of patient preference for a range of treatments may not be relevant (such as with tuning fork testing), clinicians should provide patients with clear and comprehensible information on the benefits to facilitate patient understanding and shared decision making, which in turn leads to better patient adherence and outcomes. In cases where evidence is weak or benefits unclear, the practice of shared decision making, where the management decision is made by a collaborative effort between the clinician and an informed patient, is extremely useful. Factors related to patient preference include (but are not limited to) absolute benefits, adverse effects, cost of medications or procedures, and frequency and duration of treatment, as well as certain less tangible factors such as religious and/or cultural beliefs or personal levels of desire for intervention. As with all counseling, documentation of the patient discussion and shared decision making should be entered into the patient chart.

### **Key Action Statements**

STATEMENT 1. EXCLUSION OF CHL: Clinicians should distinguish SNHL from CHL when a patient first presents with SHL. <u>Strong recommendation</u> based on systematic reviews and cross-sectional studies with a preponderance of benefit over harm.

## Action Statement Profile: I

- Quality improvement opportunity: Identifying patients who are appropriate for the guideline recommendations and those with CHL who may benefit from other therapies. (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- Aggregate evidence quality: Grade B, based on evidence that a common cause of CHL, cerumen impaction, can be treated effectively to improve hearing. Grade C, for evidence that CHL and SNHL can be distinguished by history, examination, and tuning fork tests
- Level of confidence in the evidence: High
- Benefits: Guide the choice of appropriate diagnostic tests, avoid misdiagnosis, improve diagnostic accuracy, ensure treatment is consistent with diagnosis, guide patient expectations, and identify CHL that can be treated and resolved.
- Risks, harms, costs: None
- Benefits-harm assessment: Preponderance of benefit over harm
- <u>Value judgments:</u> Panel consensus that despite a lack of systematic research evidence supporting

<sup>&</sup>lt;sup>a</sup>Adapted from Oxford Centre for Evidence-Based Medicine Work Group.<sup>30</sup>

<sup>&</sup>lt;sup>b</sup>A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

<sup>&</sup>lt;sup>c</sup>A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Table 3. Strength of Action Terms in Guideline Statements and Implied Levels of Obligation.

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

<sup>&</sup>lt;sup>a</sup>Adapted from the American Academy of Pediatrics classification scheme<sup>31</sup> (see **Table 2** for definitions of evidence grades).

this action, distinguishing SNHL was an essential first step in appropriate subsequent management.

- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

STATEMENT 2. MODIFYING FACTORS: Clinicians should assess patients with presumptive SSNHL through history and physical examination for bilateral SHL, recurrent episodes of SHL, and/or focal neurologic findings. Recommendation based on observational studies with a preponderance of benefit over harm.

#### Action Statement Profile: 2

- Quality improvement opportunity: Identify patients with potentially serious alternative conditions for whom the subsequent guideline recommendations do not apply. (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade C, based on observational studies and case series studies
- Level of confidence in the evidence: High

- Benefits: Identification of patients with a high likelihood of alternative and potentially serious underlying cause who require specialized assessment and management
- Risks, harms, costs: Time of assessment
- <u>Benefits-harm assessment:</u> Preponderance of benefit over harm
- Value judgments: None
- <u>Intentional vagueness:</u> None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 3. COMPUTED TOMOGRAPHY: Clinicians should not order routine computed tomography (CT) of the head in the initial evaluation of a patient with presumptive SSNHL. Strong recommendation against based on systematic reviews with a preponderance of benefit over harm for not obtaining CT.

#### Action Statement Profile: 3

• Quality improvement opportunity: Avoid unnecessary imaging. (National quality strategy: Patient Safety)

Table 4. Summary of Guideline Key Action Statements.

Statement	Action	Strength
Exclusion of conductive     hearing loss	Clinicians should distinguish sensorineural hearing loss (SNHL) from conductive hearing loss (CHL) when a patient first presents with SHL.	Strong recommendation
2. Modifying factors	Clinicians should assess patients with presumptive SSNHL through history and physical examination for bilateral SHL, recurrent episodes of SHL, and/or focal neurologic findings.	Recommendation
3. Computed tomography	Clinicians should <i>not</i> order routine computed tomography (CT) of the head in the initial evaluation of a patient with presumptive SSNHL.	Strong recommendation against
4. Audiometric confirmation of SSNHL	In patients with SHL, clinicians should obtain, or refer to a clinician who can obtain, audiometry as soon as possible (within 14 days of symptom onset) to confirm the diagnosis of SSNHL.	Recommendation
5. Laboratory testing	Clinicians should <i>not</i> obtain routine laboratory tests in patients with SSNHL.	Strong recommendation against
6. Retrocochlear pathology	Clinicians should evaluate patients with SSNHL for retrocochlear pathology by obtaining magnetic resonance imaging or auditory brainstem response (ABR).	Recommendation
7. Patient education	Clinicians should educate patients with SSNHL about the natural history of the condition, the benefits and risks of medical interventions, and the limitations of existing evidence regarding efficacy.	Strong recommendation
8. Initial corticosteroids	Clinicians may offer corticosteroids as initial therapy to patients with SSNHL within 2 weeks of symptom onset.	Option
9a. Initial therapy with hyperbaric oxygen therapy	Clinicians may offer, or refer to a clinician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy within 2 weeks of onset of SSNHL.	Option
9b. Salvage therapy with hyperbaric oxygen therapy	Clinicians may offer, or refer to a clinician who can offer, HBOT combined with steroid therapy as salvage within I month of onset of SSNHL.	Option
10. Intratympanic steroids for salvage therapy	Clinicians should offer, or refer to a clinician who can offer, intratympanic steroid therapy when patients have incomplete recovery from SSNHL 2 to 6 weeks after onset of symptoms.	Recommendation
11. Other pharmacologic therapy	Clinicians should <i>not</i> routinely prescribe antivirals, thrombolytics, vasodilators, or vasoactive substances to patients with SSNHL.	Strong recommendation against
12. Outcomes assessment	Clinicians should obtain follow-up audiometric evaluation for patients with SSNHL at the conclusion of treatment and within 6 months of completion of treatment.	Recommendation
13. Rehabilitation	Clinicians should counsel patients with SSNHL who have residual hearing loss and/or tinnitus about the possible benefits of audiological rehabilitation and other supportive measures.	Strong recommendation

- Aggregate evidence quality: Grade B, based on systematic reviews and appropriateness criteria from the American College of Radiology (ACR), plus observational studies clearly documenting the potential harms of radiation and side effects of intravenous contrast
- Level of confidence in the evidence: High
- Benefits: Avoidance of radiation, cost savings, reduced incidental findings, less inconvenience for the patient, avoiding false sense of security from false-negative scan
- Risks, harms, costs: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: None

- Intentional vagueness: The word *routine* in radiology parlance means a thick-cut CT of the head. In addition, this indicates that while a head CT to rule out intracranial bleed is not warranted in the absence of targeted neurologic findings, targeted imaging may be indicated if signs or clinical findings suggest an underlying etiology that is being explored. The panel recognizes that the term *initial evaluation* is vague, but the intent is to discourage the routine use of CT scanning of the head/brain when patients initially present with SSNHL.
- Role of patient preferences: Small
- Exceptions: Patients with focal neurologic findings
- <u>Policy level:</u> Strong recommendation
- <u>Differences of opinion:</u> None

STATEMENT 4. AUDIOMETRIC CONFIRMATION OF SSNHL: In patients with SHL, clinicians should obtain, or refer to a clinician who can obtain, audiometry as soon as possible (within 14 days of symptom onset) to confirm the diagnosis of SSNHL. <u>Recommendation</u> based on RCTs with a preponderance of benefit over harm.

# Action Statement Profile: 4

- Quality improvement opportunity: Ensure an accurate diagnosis. (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade C, based on criteria used in RCTs assessing the benefits and timing for intervention for SSNHL
- Level of confidence in the evidence: High
- Benefits: Guiding treatment, identifying urgent conditions that require prompt management, ensuring that interventions for SSNHL are offered to those patients who meet appropriate audiometric criteria for diagnosis
- Risks, harms, costs: Potential delay in treatment until audiometry is obtained; direct cost of audiometry
- <u>Benefits-harm assessment:</u> Preponderance of benefit over harm
- <u>Value judgments:</u> Treatments are more likely to be effective if offered early. The expediency of diagnosis is necessary to ensure that treatment can be offered within a reasonable therapeutic window.
- <u>Intentional vagueness:</u> Although most of the group felt that earlier is better, the words "as soon as possible (within 14 days of symptom onset)" were used, given that barriers to access to care may make it unreasonable to set an earlier time point.
- Role of patient preferences: None
- Exceptions: When audiometry is not available, clinical judgment should be used, based on history, examination, and tuning fork evaluation. Lack of audiometry should not preclude discussion and initiation of treatment.
- Policy level: Recommendation
- <u>Differences of opinion:</u> While everyone in the group agreed that audiometry is necessary, there were differences of opinion regarding how expediently the test should be obtained. Some members felt that it should be within 72 hours while others felt within 2 weeks was adequate. We agreed on the current language that sets an outside limit on how long it can be while encouraging earlier testing if feasible.

STATEMENT 5. LABORATORY TESTING: Clinicians should not obtain routine laboratory tests in patients

with SSNHL. <u>Strong recommendation against</u> based on 1 large cross-sectional study and a large number of other studies as well as a preponderance of benefit over harm.

## Action Statement Profile: 5

- Quality improvement opportunity: Avoid unnecessary testing. (National quality strategy: Making Quality Care More Affordable)
- Aggregate evidence quality: Grade B, based on cross-sectional studies and case series showing no benefit
- Level of confidence in the evidence: High
- Benefits: Cost containment, avoidance of stress and anxiety of patient, avoidance of false positives
- Risks, harms, costs: Missed diagnosis
- Benefits-harm assessment: Preponderance of benefit over harm
- <u>Value judgments:</u> Minimizing testing and the risks of false positives outweigh the value of finding a potential cause.
- <u>Intentional vagueness:</u> The word *routine* was to discourage a nontargeted approach to use of laboratory assessment. It is recognized that specific lab tests may be useful in assessing these patients based on specific individual patient conditions.
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

STATEMENT 6. RETROCOCHLEAR PATHOLOGY: Clinicians should evaluate patients with SSNHL for retrocochlear pathology by obtaining magnetic resonance imaging (MRI) or auditory brainstem response (ABR). Recommendation based on observational studies and a meta-analysis with a preponderance of benefit over harm.

### Action Statement Profile: 6

- Quality improvement opportunity: Identify an underlying cause of the hearing loss that may have other implications and treatment recommendations (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- Aggregate evidence quality: Grade B for MRI, grade C for ABR based on observational studies and a meta-analysis
- Level of confidence in the evidence: High
- Benefits: Identify vestibular schwannoma or other tumors in the internal auditory canal or cerebellopontine angle, identify conditions that might benefit from early treatment, patient peace of mind, supporting idiopathic diagnosis
- Risks, harms, costs: Procedure-specific risks/costs, anxiety, and stress

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- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Although the panel agreed that the MRI is the most sensitive means for diagnosing retrocochlear pathology, there was no consensus that identifying this pathology would in all cases influence outcomes. The panel therefore concluded that ABR (with follow-up MRI if abnormal) would be an acceptable alternative for initial assessment for retrocochlear pathology in SSNHL as long as there is appropriate counseling about the limitations of this modality.
- Intentional vagueness: The time frame and the health care professional responsible for ordering tests to assess for retrocochlear pathology are not specified. The panel felt that this should happen at some point in the care of the patient and that this would most likely be ordered by the treating otolaryngologist or otologist/neurotologist.
- Role of patient preferences: Small in deciding whether or not to assess for retrocochlear pathology; large in making shared decisions with the clinician for using MRI or ABR as the diagnostic test
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 7. PATIENT EDUCATION: Clinicians should educate patients with SSNHL about the natural history of the condition, the benefits and risks of medical interventions, and the limitations of existing evidence regarding efficacy. Strong recommendation based on systematic reviews with a preponderance of benefit over harm.

## Action Statement Profile: 7

- Quality improvement opportunity: Improve awareness of the natural history of SHL and the myriad treatment options to improve patient involvement in shared decision making. (National Quality Strategy domain: Health and Well-being of Communities; Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade B, based on systematic reviews
- Level of confidence in the evidence: High
- Benefits: Facilitate shared decision making, increase patient adherence to proposed therapy, empower patients, informed consent, link evidence to clinical decisions
- Risks, harms, costs: Time spent, miscommunication, patients get overwhelmed, patient anxiety
- Benefits-harm assessment: Preponderance of benefit over harm
- <u>Value judgments:</u> Based on the unclear benefit of primary treatments for SHL, patients should be

- informed regarding the uncertainty in treatment effectiveness in order to make an informed treatment decision.
- Intentional vagueness: None
- Role of patient preferences: Large
- Exceptions: None
- Policy level: Strong recommendation
- <u>Differences of opinion:</u> None

STATEMENT 8. INITIAL CORTICOSTEROIDS: Clinicians may offer corticosteroids as initial therapy to patients with SSNHL within 2 weeks of symptom onset. Option based on systematic reviews of RCTs and new RCTs and a balance of benefit and harm.

### Action Statement Profile: 8

- Quality improvement opportunity: More selective and appropriate use of a treatment option with modest potential benefit but only when used appropriately. (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade C, based on RCTs and systematic reviews of randomized trials downgraded for methodological limitations and again for inconsistent results
- Level of confidence in the evidence: Medium
- Benefits: Hearing improvement
- Risks, harms, costs:
  - Systemic steroids: Suppression of hypothalamicpituitary-adrenal axis and Cushing's-like syndrome (minimal with 10- to 14-day treatment); aseptic necrosis of the hip; hyperglycemia; low cost
  - IT corticosteroids: minimal systemic effect; local reactions of pain, tympanic membrane perforation, transient dizziness; high cost and multiple office visits
- Benefits-harm assessment: Balance of benefit and harm
- <u>Value judgments:</u> Even a small possibility of hearing improvement makes this a reasonable treatment to offer patients, considering the profound impact on QOL hearing improvement may offer.
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making with patients
- Exceptions: Systemic steroids: medical conditions affected by corticosteroids such as insulindependent or poorly controlled diabetes, tuberculosis, and peptic ulcer disease, among others
- Policy level: Option
- <u>Differences of opinion</u>: While all members of the GUG favored having steroids as an option as early as possible, several group members were reluctant to endorse the 2-week time frame due to concerns that patients presenting later may be denied

therapy. We ultimately agreed to leave the time frame of 2 weeks to encourage patients and clinicians to seek care early if they choose to be treated.

STATEMENT 9a. INITIAL THERAPY WITH HYPERBARIC OXYGEN THERAPY: Clinicians may offer, or refer to a clinician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy within 2 weeks of onset of SSNHL. Option based on systematic reviews of RCTs with a balance between benefit and harm.

STATEMENT 9b. SALVAGE THERAPY WITH HYPERBARIC OXYGEN THERAPY: Clinicians may offer, or refer to a clinician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy as salvage within 1 month of onset of SSNHL. Option based on systematic reviews of RCTs and new RCTs with a balance of benefit and harm.

## Action Statement Profile: 9

- Quality improvement opportunity: Allow the use of HBOT, which may have some limited benefit early after SHL as a potential option for primary or salvage therapy. (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination; Patient Safety)
- Aggregate evidence quality: Grade B, based on systematic review of RCTs with methodological limitations and new RCTs with limitations
- Level of confidence in the evidence: Medium
- Benefits: Hearing improvement
- Risks, harms, costs: Costs, patient time/effort, patient anxiety and stress, hyperbaric-associated complications such as barotrauma, oxygen toxicity, worsening of cataracts, fatigue, seizure, death
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: Although HBOT may not be readily available in all regions, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to include HBOT as an option for patients with SSNHL.
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

STATEMENT 10. IT STEROIDS FOR SALVAGE THERAPY: Clinicians should offer, or refer to a

clinician who can offer, IT steroid therapy when patients have incomplete recovery from SSNHL 2 to 6 weeks after onset of symptoms. <u>Recommendation</u> based on systematic reviews of RCTs with a preponderance of benefit over harm.

# Action Statement Profile: 10

- Quality improvement opportunity: Encourage the use of IT steroids, which may be effective to provide additional hearing recovery in patients with an incomplete response to initial therapy. (National quality strategy: Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- Aggregate evidence quality: Grade B, based on RCTs with limitations, and systematic reviews of RCTs with limitations
- Level of confidence in the evidence: High
- Benefits: Hearing recovery
- <u>Risks, harms, costs:</u> Perforation, discomfort, cost, patient anxiety
- <u>Benefits-harm assessment:</u> Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: Patients qualifying for salvage therapy have had an incomplete recovery of hearing after 2 weeks from onset regardless of initial therapy. Incomplete recovery is not clearly defined as there is limited guidance from the literature as to what level of residual hearing loss qualifies a patient for salvage. The GUG recognized that varying degrees of hearing loss will affect patients differently. This may govern the aggressiveness of the decision to pursue further therapy.
- Role of patient preferences: Large role for shared decision making
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 11. OTHER PHARMACOLOGIC THERAPY: Clinicians should not routinely prescribe antivirals, thrombolytics, vasodilators, or vasoactive substances to patients with SSNHL. <u>Strong recommendation against</u> based on systematic reviews of RCTs with a preponderance of harm over benefit.

### Action Statement Profile: 11

- Quality improvement opportunity: Avoid ineffective treatment(s) and associated risks, complications, side effects, costs, and potential adverse interactions with effective therapies. (National quality strategy: Patient Safety; Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- Aggregate evidence quality: Grade B, based on systematic reviews of RCTs

- Level of confidence in the evidence: High
- Benefits: Avoid unnecessary treatment, avoid adverse events of unnecessary treatment, cost saving
- Risks, harms, costs: None
- Benefits-harm assessment: Preponderance of harm over benefit
- Value judgments: None
- Intentional vagueness: The word routine is used to avoid setting a legal standard recognizing that there may be patient-specific indications for 1 or more of these therapies that may be reasonable to try on an individualized basis, with shared decision making.
- Role of patient preferences: None
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

STATEMENT 12. OUTCOMES ASSESSMENT: Clinicians should obtain follow-up audiometric evaluation for patients with SSNHL at the conclusion of treatment and within 6 months of completion of treatment. Recommendation based on observational studies with a preponderance of benefit over harm.

# Action Statement Profile: 12

- Quality improvement opportunity: Following patients with SHL may allow for identification of underlying causes not evident at presentation and will allow for appropriate rehabilitation of hearing loss in those that fail to recover hearing. (National quality strategy: Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: High
- Benefits: Assess outcome of intervention, identify patients who may benefit from audiologic rehabilitation, identify cause of hearing loss, identify progressive hearing loss, improve counseling
- Risks, harms, costs: Procedural cost
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: The patient perception of hearing recovery is not always completely accurate, and patients may be unaware of a residual hearing impairment that could be identified through audiometric assessment. Patients who report subjective hearing improvement may still derive additional benefits from objective testing.
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation

• <u>Differences of opinion:</u> While the entire group agreed that a hearing test at the conclusion of therapy is warranted, there was some disagreement about when a longer-term follow-up audiogram should be obtained.

STATEMENT 13. REHABILITATION: Clinicians should counsel patients with SSNHL who have residual hearing loss and/or tinnitus about the possible benefits of audiological rehabilitation and other supportive measures. <u>Strong recommendation</u> based on systematic reviews and observational studies with a preponderance of benefit over harm.

### Action Statement Profile: 13

- Quality improvement opportunity: Inform patients about strategies to help manage residual hearing loss and tinnitus. (National quality strategy: Effective Communication and Care Coordination; Prevention and Treatment of Leading Causes of Morbidity and Mortality; Health and Well-being of Communities)
- Aggregate evidence quality: Grade B, based on systematic reviews and observational studies
- Level of confidence in the evidence: High
- Benefits: Improved awareness of options that may improve QOL, functionality, hearing, and tinnitus and offer emotional support
- Risks, harms, costs: Time and cost of counseling
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Large
- Exceptions: None
- Policy level: Strong recommendation
- <u>Differences of opinion</u>: None, but 2 panelists were recused from the discussion regarding cochlear implants as rehabilitation for tinnitus and single-sided deafness as they are investigators on industry-funded studies of that technology.

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#### **Disclaimer**

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

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