Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Clinical practice guideline: sudden hearing loss.

Bibliographic Source(s)

Stachler RJ, Chandrasekhar SS, Archer SM, Rosenfeld RM, Schwartz SR, Barrs DM, Brown SR, Fife TD, Ford P, Ganiats TG, Hollingsworth DB, Lewandowski CA, Montano JJ, Saunders JE, Tucci DL, Valente M, Warren BE, Yaremchuk KL, Robertson PJ, American Academy of Otolaryngology-Head and Neck Surgery. Clinical practice guideline: sudden hearing loss. Otolaryngol Head Neck Surg. 2012 Mar;146(3 Suppl):S1-35. [251 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are defined at the end of the "Major Recommendations" field.

Statement 1. Exclusion of Conductive Hearing Loss

Clinicians should distinguish sensorineural hearing loss (SNHL) from conductive hearing loss (CHL) in a patient presenting with sudden hearing loss.

Strong recommendation based on evidence with a preponderance of benefit over harm.

Action Statement Profile

- 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 from history, examination, and tuning fork tests
- Benefit: Guide the choice of appropriate diagnostic tests, identify patients with more serious underlying conditions, avoid misdiagnosis, improve diagnostic accuracy, ensure treatment is consistent with diagnosis, guide patient expectations, identify conductive hearing loss that can be treated and resolved
- Risk, harm, cost: Adverse effects of cerumen removal, if required; time required for cerumen removal, if required; misdiagnosis
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Panel consensus that despite a lack of systematic research evidence supporting this action, distinguishing these types of

hearing loss was an essential first step in determining subsequent management
- Intentional vagueness: The panel intentionally decided not to specify the time frame to distinguish CHL from SNHL because of inconclusive evidence of the importance of early intervention but agreed that the distinction should be made as promptly as possible to allow intervention if a diagnosis of SSNHL is confirmed. Ideally, the determination should be made at the time of initial presentation.
- Role of patient preferences: No role
- Exclusions: None
- Policy level: Strong recommendation

Statement 2. Modifying Factors

Clinicians should assess patients with presumptive sudden sensorineural hearing loss for bilateral sudden hearing loss, recurrent episodes of sudden hearing loss, or focal neurologic findings.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, observational studies and case series
- Benefit: Identification of patients with a high likelihood of alternative and potentially serious underlying cause, who require specialized assessment and management
- Risk, harm, cost: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Limited
- Exclusions: None
- Policy level: Recommendation

Statement 3. Computed Tomography

Clinicians should not order computerized tomography of the head/brain in the initial evaluation of a patient with presumptive sudden sensorineural hearing loss (SSNHL).

Strong recommendation against based on systematic reviews with a preponderance of benefit over harm for not obtaining computed tomography (CT).

Action Statement Profile

- Aggregate evidence quality: Grade B, 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
- Benefit: Avoidance of radiation, cost savings, reduced incidental findings, less inconvenience for the patient, avoiding false sense of security from false-negative scan
- Risk, harm, cost: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: 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: Very limited
- Exclusions: Patients with focal neurologic findings
- Policy level: Strong recommendation against

Statement 4. Audiometric Confirmation of Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL)

Clinicians should diagnose presumptive ISSNHL if audiometry confirms a 30-decibel (dB) hearing loss at three consecutive frequencies AND an underlying condition cannot be identified by history and physical examination.

Recommendation based on randomized controlled trials (RCTs) with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on criteria used in RCTs assessing the benefits for intervention for SSNHL
- Benefit: Guiding treatment, identifying urgent conditions that require prompt management, ensuring that interventions for ISSNHL are limited to those patients who meet appropriate audiometric criteria for diagnosis
- Risk, harm, cost: Potential delay in treatment until audiometry is obtained; direct cost of audiometry
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although there is limited evidence as to the audiometric cut points for the definition of SSNHL, this definition has been used widely
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: 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 of, and initiation of, treatment.
- Policy level: Recommendation

Statement 5. Laboratory Testing

Clinicians should not obtain routine laboratory tests in patients with ISSNHL.

Strong recommendation against based on large cross-sectional studies showing a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on small cross-sectional studies showing no benefit as well as case series
- Benefit: Cost containment, avoidance of stress and anxiety of patient, avoidance of false positives, avoidance of delay of diagnosis, avoidance of delayed treatment
- Risk, harm, cost: Missed diagnosis
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Minimizing testing and the risks of false positives outweigh the value of finding a potential cause, especially when it has not been shown that early treatment affects prognosis
- Intentional vagueness: The word *routine* was to discourage a nontargeted approach to use of laboratory assessment. It is recognized that specific laboratory tests may be useful in assessing these patients based on specific individual patient conditions.
- Role of patient preferences: Limited
- Exclusions: None
- Policy level: Strong recommendation against

Statement 6. Retrocochlear Pathology

Clinicians should evaluate patients with ISSNHL for retrocochlear pathology by obtaining a magnetic resonance imaging (MRI), auditory brainstem response (ABR), or audiometric follow-up.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Identify brain tumors, identify conditions that might benefit from early treatment, patient peace of mind, supporting idiopathic diagnosis
- Risk, harm, cost: Procedure-specific risks/costs, anxiety, and stress
- Benefit-harm assessment: Preponderance of benefit
- 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 and follow-up audiometry would be acceptable alternatives for initial follow-up of SSNHL as long as there is appropriate counseling about the limitations of these modalities.
- Intentional vagueness: None
- Role of patient preferences: Limited in deciding whether or not to assess for retrocochlear pathology but substantial in making shared decisions with the clinician for using MRI, ABR, or audiology as the diagnostic test
- Exclusions: None
- Policy level: Recommendation

Statement 7. Patient Education

Clinicians should educate patients with ISSNHL 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

- Aggregate evidence quality: Grade B
- Benefit: Facilitate shared decision making, increase patient adherence to proposed therapy, empower patients, informed consent, link evidence to clinical decisions
- Risk, harm, cost: Time spent, miscommunication, patients get overwhelmed, patient anxiety
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Shared decision making is beneficial
- Intentional vagueness: None
- Role of patient preferences: Large
- Exclusions: None
- Policy level: Strong recommendation

Statement 8. Initial Corticosteroids

Clinicians may offer corticosteroids as initial therapy to patients with ISSNHL.

Option based on systematic reviews of RCTs with a balance between benefit and harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, systematic reviews of randomized trials with methodological limitations
- Benefit: Hearing improvement
- Risk, harm, cost: Oral corticosteroids: suppression of hypothalamic-pituitary-adrenal axis and Cushing-like syndrome, minimal with 10- to 14-day treatment; low cost. Intratympanic corticosteroids: Minimal systemic effect; local reactions of pain, tympanic membrane perforation, transient dizziness; high cost and multiple office visits
- Benefit-harm assessment: Balance of benefit versus harm
- Value judgments: Even a small possibility of hearing improvement makes this a reasonable treatment to offer patients, considering the profound impact on quality of life a hearing improvement may offer
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making with patients
- Exclusions: Oral steroids: medical conditions affected by corticosteroids such as insulin-dependent or poorly controlled diabetes, tuberculosis, and peptic ulcer disease, among others
- Policy level: Option

Statement 9. Hyperbaric Oxygen Therapy (HBOT)

Clinicians may offer HBOT within three months of diagnosis of ISSNHL.

Option based on systematic reviews of RCTs with a balance between benefit and harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, systematic review of RCTs with methodological limitations
- Benefit: Hearing improvement
- Risk, harm, cost: Costs, patient time/effort, patient anxiety and stress, barotraumas, otitis media, oxygen toxicity, worsening of cataracts, fatigue, death
- Benefit-harm assessment: Equilibrium
- Value judgments: Although HBOT is not widely available in the United States and is not recognized by many U.S. clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for ISSNHL
- Intentional vagueness: None

- Role of patient preferences: Large role for shared decision making
- Exclusions: None
- Policy level: Option

Statement 10. Other Pharmacologic Therapy

Clinicians should not routinely prescribe antivirals, thrombolytics, vasodilators, vasoactive substances, or antioxidants to patients with ISSNHL.

Recommendation against based on systematic reviews of RCTs with a preponderance of harm over benefit.

Action Statement Profile

- Aggregate evidence quality: Grade B
- Benefit: Avoidance of unnecessary treatment, avoid adverse events of unnecessary treatment, cost saving
- Risk, harm, cost: None as the recommendation is against the use of these therapies
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The word *routine* is used to avoid setting a legal standard, recognizing that patient-specific indications for one or more of these therapies may be reasonable to try on an individualized basis, with shared decision making
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation against

Statement 11. Salvage Therapy

Clinicians should offer intratympanic (IT) steroid perfusion when patients have incomplete recovery from ISSNHL after failure of initial management.

Recommendation based on RCTs with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, RCTs with limitations
- Benefit: Hearing recovery
- Risk, harm, cost: Perforation, discomfort, cost, patient anxiety
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: Patients qualifying for salvage therapy have failed to respond to initial management or have had an incomplete response. Failure of initial management 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 guideline panel 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: Significant role for shared decision making regarding treatment options depending on various perceived levels of hearing impairment
- Exclusions: None
- Policy level: Recommendation

Statement 12. Outcomes Assessment

Clinicians should obtain follow-up audiometric evaluation within six months of diagnosis for patients with ISSNHL.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observation studies
- Benefit: Assess outcome of intervention, identify patients who may benefit from audiologic rehabilitation, identify cause of hearing loss, identify progressive hearing loss, improve counseling
- Risk, harm, cost: Procedural cost
- Benefit-harm assessment: Preponderance of benefit
- 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: Some
- Exclusions: None
- Policy level: Recommendation

Statement 13. Rehabilitation

Clinicians should counsel patients with incomplete recovery of hearing about the possible benefits of amplification and hearing-assistive technology (HAT) and other supportive measures.

Strong recommendation based on systematic reviews and observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on systematic reviews and observational studies
- Benefit: Improved quality of life, improved functionality, emotional support, improved hearing
- Risk, harm, cost: Time and cost of counseling
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Patient may decline counseling
- Exclusions: None
- Policy level: Strong recommendation

Definitions:

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	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 that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (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 that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus 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.
No recommendation	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance

Statement	Definition	Implication
		of benefit versus harm; patient preference should have a substantial influencing role.

*See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnostic Tests	Evidence Quality for All Other Studies
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Sudden hearing loss (SHL), especially sudden sensorineural hearing loss (SSNHL)

Note: SHL is defined as a rapid onset, occurring over a 72-hour period, of a subjective sensation of hearing impairment in one or both ears. SSNHL is a subset of SHL that is sensorineural in nature and meets audiometric criteria, such as a decrease in hearing of ≥30 decibels (see the original guideline document for more explanation).

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Rehabilitation

Treatment

Clinical Specialty

Emergency Medicine

Family Practice

Geriatrics

Internal Medicine

Neurology

Otolaryngology

Radiology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide clinicians with evidence-based recommendations in evaluating patients with sudden hearing loss (SHL), with particular emphasis on managing sudden sensorineural hearing loss (SSNHL)

Target Population

Adult patients (aged 18 and older) who present with sudden hearing loss (SHL), especially sudden sensorineural hearing loss (SSNHL)

Interventions and Practices Considered

Diagnosis/Evaluation

1. Patient history and physical examination
2. Assessment with tuning fork tests and audiometry
3. Assessment for modifying factors
4. Audiometric confirmation of idiopathic sensorineural hearing loss (ISSNHL)
5. Evaluation of patients with ISSNHL for retrocochlear pathology

Counseling/Treatment/Rehabilitation

1. Patient education
2. Initial corticosteroids
3. Hyperbaric oxygen therapy
4. Other pharmacologic therapy including antivirals, thrombolytics, vasodilators, vasoactive substances, or antioxidants
5. Intratympanic steroid perfusion as salvage therapy for patients with incomplete recovery
6. Follow-up audiometric evaluation
7. Counseling

Major Outcomes Considered

- Appropriateness of diagnostic test
- Accuracy of diagnosis (rate of false-positive and false-negative test results)
- Timeliness of diagnosis and treatment
- Improved hearing and functionality

- Adverse effects of treatment
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

All literature searches were performed by an information specialist at the Cochrane Ear Nose and Throat (ENT) Disorders Group through November 27, 2010. Three initial searches were performed to identify clinical practice guidelines, systematic reviews, and randomized controlled trials (RCTs). In addition, a fourth search identified literature relating to the diagnosis of sudden hearing loss (SHL). The searches were performed in multiple databases, including the National Guidelines Clearinghouse (NGC; www.guideline.gov), The Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, PubMed, Web of Science, BIOSIS, the Cochrane Central Register of Controlled Trials (CENTRAL), CAB Abstracts, CMA Infobase, National Health Service (NHS) Evidence ENT and Audiology, National Library of Guidelines, National Institute of Clinical Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), New Zealand Guidelines Group (NZGG), Australian National Health and Medical Research Council, Tripdatabase, The Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment (HTA) Database, and Health Services Technology Assessment Texts (HSTAT).

1. Clinical practice guidelines were identified by a PubMed, EMBASE, CINAHL, Web of Science, CAB Abstracts, BIOSIS, Cochrane Library, DARE, HTA Database, and HSTAT search using guideline as a publication type or title word. The search identified 13 guidelines with a topic of SHL. After removing duplicates, clearly irrelevant references, and non-English-language articles, one guideline was selected for the panel's attention.
2. Systematic reviews were identified using a validated filter strategy that initially yielded 151 potential articles. The final data set included 29 systematic reviews or meta-analyses on SHL that were distributed to the panel members. Articles were excluded if they were not available in English and did not meet the panel's quality criteria (i.e., the review had a clear objective and method, an explicit search strategy, and a valid method of data extraction).
3. Randomized controlled trials were identified through PubMed, EMBASE, Web of Science, BIOSIS, CINAHL, and CENTRAL and totaled 339 trials. The results were then filtered by the guidelines chair and assistant chairs, removing articles that were not relevant to the work of the group. As a result, 136 articles were made available to the guideline panel.
4. Research articles related to the diagnosis of SHL were identified via PubMed. The search was conducted with the following Medical Subject Headings (MESH): "Hearing Loss, Sudden/etiology" and "Hearing Loss, Sudden/diagnosis" and identified 958 possible articles. Articles were removed that were non-English, did not report an abstract, and were tagged with a publication type of "case report." The results were then reviewed by the guidelines' chair and assistant chairs, who removed nonrelevant articles. As a result, 133 articles were made available to the guideline panel.

Results of all literature searches were distributed to guideline panel members, including electronic listings with abstracts (if available) of the searches for clinical guidelines, RCTs, systematic reviews, and other studies. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through June 2011.

Number of Source Documents

- 1 guideline
- 29 systematic reviews or meta-analyses
- 136 randomized controlled trials
- 133 original research studies

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnostic Tests	Evidence Quality for All Other Studies
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that 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 is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields. As much of the guideline dealt with evidence relating to diagnostic tests, the definitions for Evidence Quality for Grades of Evidence (see the "Rating Scheme for the Strength of the Evidence" field) was adapted to include current recommendations from the Oxford Centre for Evidence-Based Medicine.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline was 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. The guideline development panel comprised representatives from the fields of otolaryngology, otology, neurology, neurotology, family medicine, emergency medicine, audiology, and consumer groups.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in July 2011, the group met twice, with in-person meetings following the format previously described, using electronic decision support (BRIDGE-Wiz) software to facilitate creating actionable recommendations and action statement profiles. Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal

and Extractor (GLIA) to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in May 2011 and modified an advanced draft of the guideline.

Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

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Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	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 that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (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 that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus 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.
No recommendation	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final guideline draft underwent extensive external peer review. Comments were compiled and reviewed by the panel's chair, and a modified version of the guideline was distributed and approved by the guideline development panel.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

The recommendations contained in the guideline are based on the best available data published through June 2011. Where data were lacking, a combination of clinical experience and expert consensus was used.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate diagnosis and management of sudden hearing loss (SHL), particularly sudden sensorineural hearing loss (SSNHL)
- By focusing on opportunities for quality improvement, the guideline should 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.

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

Magnetic Resonance Imaging

- One disadvantage of magnetic resonance imaging (MRI) is the possibility of incidental findings not related to the hearing loss that may result in patient anxiety or additional evaluation. In one study of patients with sudden hearing loss (SHL), 57% of the MRI studies revealed some abnormality, but only 20% of these findings were directly related to the hearing loss. In another study, the overall rate of abnormal findings was 34.5%, with 36% of these directly related to the hearing loss. In general, the rate of incidental findings in patients with audiovestibular symptoms is significant (47.5%), but only a small fraction of these (2.5%) required additional referral or investigation. The cost and consequences of these incidental findings on MRI are difficult to assess.
- A second concern with MRI is the potential for rare immediate reactions to gadolinium (<1%) or gadolinium-induced nephrogenic systemic fibrosis. Fortunately, the latter is rare in patients without preexisting renal disease. These contrast-related risks can be avoided with fast-spin echo MRI.

Corticosteroids

- Potential side effects of systemic corticosteroid therapy are reported in many organ systems. Corticosteroids are hormones and have access to, as well as an effect on, all organ systems. The commonly used glucocorticoids, such as prednisone, have little mineralocorticoid, androgenic, or estrogenic effect, and the major systemic side effects are suppression of hypothalamic-pituitary-adrenal function and signs and symptoms of Cushing syndrome. An exhaustive list of side effects is beyond the scope of this guideline, but common side effects of prednisone include insomnia, dizziness, weight gain, increased sweating, gastritis, mood changes, photosensitivity, and hyperglycemia. Severe (but rare) side effects include pancreatitis, bleeding, hypertension, cataracts, myopathy, opportunistic infections, osteoporosis, and osteonecrosis manifesting as fractures and aseptic necrosis of the femoral and humeral heads. To minimize the risk of treatment, patients with systemic medical conditions such as insulin-dependent or poorly controlled diabetes, labile hypertension, tuberculosis, peptic ulcer disease, and prior psychiatric reactions to corticosteroids, among others, may not be able to receive systemic corticosteroids.
- Most serious side effects of systemic corticosteroids occur with chronic use, and adverse events are usually acceptable and manageable for the short 10- to 14-day course of steroids recommended for sudden sensorineural hearing loss (SSNHL). A study reviewed the safety of high-dose steroids taken for up to 22 weeks for autoimmune inner ear disease and found that most patients completed the course, with the most frequent adverse events being hyperglycemia and weight gain. There is also evidence that osteonecrosis and fractures occur more

commonly in patients with preexisting bone or joint problems in conditions such as systemic lupus erythematosus and rheumatoid arthritis.

- Although with less potential toxicity than systemic corticosteroid treatment, intratympanic (IT) corticosteroids can also have adverse effects. These are infrequent but include pain, transient dizziness, infection, persistent tympanic membrane perforation, possible vasovagal or syncopal episode during injection, cost, and multiple office visits. Adverse effects in one randomized controlled trial were reported by 88% of the oral steroid group, such as elevated blood sugar, increased thirst, and sleep or appetite changes, and 90% of the IT group, such as transient pain at the injection site and brief caloric vertigo. The adverse effects were the anticipated manageable side effects, most of which were resolved within 1 to 2 weeks, with rare outlying persistent tympanic membrane perforations lasting up to 6 months.
- The principal risk of IT steroids as salvage therapy appears to be a persistent tympanic membrane perforation at the injection site. This complication, however, is rare and frequently resolves spontaneously or with a paper patch myringoplasty in the office.

Hyperbaric Oxygen Therapy

- Although risk of serious side effects with hyperbaric oxygen therapy (HBOT) is small, some risks do exist. These include damage to ears, sinuses, and lungs from pressure changes; temporary worsening of short-sightedness; claustrophobia; and oxygen poisoning. Major adverse events were not reported in most of the studies reviewed.
- In a population of 782 patients with 11,376 sessions receiving HBOT for a variety of indications, the primary complication of HBOT was difficultly equalizing pressure in the middle ear, which occurred in 17% of patients. Another study found that 45% of patients undergoing HBOT for a variety of indications had eustachian tube dysfunction. Patients undergoing HBOT for SSNHL may have fewer complications as the use of concurrent systemic steroids is common and may decrease the inflammation or edema that may lead to difficulty in pressure equalization or eustachian tube dysfunction. In a study of 80 patients undergoing HBOT for SSNHL, five (6.25%) had ear or sinus barotrauma. In addition, patients may suffer from some degree of confinement anxiety while undergoing HBOT.

Contraindications

Contraindications

For patients in whom magnetic resonance imaging (MRI) is contraindicated (i.e., pacemakers, other metallic implants, claustrophobia), a fine-cut computed tomography (CT) of the temporal bones with contrast may be used.

Qualifying Statements

Qualifying Statements

- The recommendations outlined in this guideline 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 is not intended to replace individualized patient care or clinical judgment.
- Although the guideline focuses primarily on managing sudden sensorineural hearing loss (SSNHL), the panel recognized that patients enter the health care system with sudden hearing loss (SHL) as a nonspecific, primary complaint. Therefore, the initial recommendations of the guideline deal with efficiently distinguishing SSNHL from other causes of SHL at the time of presentation. The purpose of the guideline is not to present an exhaustive approach to managing SHL, in general, as only a limited number of causes are discussed.
- Guidelines are not intended to supersede professional judgment; rather, they 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. Clinicians 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.
- This clinical practice guideline is not intended as the sole source of guidance in managing patients with SHL. 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.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery*, which will facilitate reference and distribution. A full-text version of the guideline will also be accessible free of charge for a limited time at http://www.entnet.org. The guideline will be presented to the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) members as a miniseminar at the AAO-HNSF annual meeting and OTO EXPO. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

To distinguish sensorineural hearing loss (SNHL) from conductive hearing loss (CHL), the guideline panel recommends a combination of history, physical examination, tuning fork tests, and audiometry. To aid the clinician's implementation of this recommendation, a description of both the Weber and Rinne tests has been provided.

As a supplement to clinicians, the panel created a checklist of features associated with specific disorders underlying hearing loss. This checklist can be incorporated into future education materials developed by the AAO-HNSF.

The panel believes that patient education and shared decision making are an important component in the successful management of patients with idiopathic sudden sensorineural hearing loss (ISSNHL). As such, it is important for both clinicians and patients to be aware of the possible etiology of their hearing loss, available treatments and their associated benefits and risks, and rehabilitation services. A basic protocol has been developed for the management of patients with ISSHNL along with a list of discussion points. The panel believes these resources can be incorporated into a patient leaflet that can be made available through the AAO-HNSF.

To assist clinicians in determining an appropriate course of treatment, summary tables have been provided for corticosteroid therapy, hyperbaric oxygen therapy, and IT steroids as salvage therapy. As a reference aid, these summary tables, as part of the shared decision-making process, will help guide the clinician’s management of ISSNHL.

To aid patients in managing their sudden sensorineural hearing loss (SSNHL), Table 13 of the original guideline document (Counseling Issues Raised by Patients with Sudden Sensorineural Hearing Loss) will be adapted into a patient leaflet. The AAO-HNSF will seek the assistance of the consumer groups represented on the guideline panel when developing this tool.

Implementation Tools

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Stachler RJ, Chandrasekhar SS, Archer SM, Rosenfeld RM, Schwartz SR, Barrs DM, Brown SR, Fife TD, Ford P, Ganiats TG, Hollingsworth DB, Lewandowski CA, Montano JJ, Saunders JE, Tucci DL, Valente M, Warren BE, Yaremchuk KL, Robertson PJ, American Academy of Otolaryngology-Head and Neck Surgery. Clinical practice guideline: sudden hearing loss. Otolaryngol Head Neck Surg. 2012 Mar;146(3 Suppl):S1-35. [251 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

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Financial Disclosures/Conflicts of Interest

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 American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, 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.

Disclosures

Competing interests: Sujana S. Chandrasekhar—board of directors, office bearer, and stockholder: Scientific Development and Research; Surgical Advisory Panel: Cochlear Corporation. Seth R. Schwartz— research funding: Cochlear Corporation; instructor: Medtronic, temporal bone course, no personal funding. Denna B. Hollingsworth—speaker: Alcon Labs (Ciprodex). Debara L. Tucci—consultant: Otonomy; chair: Data Safety Monitoring Board (clinical trial of intratympanic steroids for Meniere disease). David M. Barrs—stockholder: Epic Hearing Health; stockholder: Otodyne. Theodore G. Ganiats—Advisory Panel: Tethys Bioscience.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the SAGE Journals Online Web site .

Availability of Companion Documents

A podcast of the guideline is available for download from the SAGE Journals Online Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on March 14, 2012. The information was verified by the guideline developer on April 5, 2012.

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