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INVITED ARTICLE

Clinical practice guideline: Cerumen impaction

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OBJECTIVE: This guideline provides evidence-based recommendations on managing cerumen impaction, defined as an accumulation of cerumen that causes symptoms, prevents assessment of the ear, or both. We recognize that the term "impaction" suggests that the ear canal is completely obstructed with cerumen and that our definition of cerumen impaction does not require a complete obstruction. However, cerumen impaction is the preferred term since it is consistently used in clinical practice and in the published literature to describe symptomatic cerumen or cerumen that prevents assessment of the ear. This guideline is intended for all clinicians who are likely to diagnose and manage patients with cerumen impaction.

PURPOSE: The primary purpose of this guideline is to improve diagnostic accuracy for cerumen impaction, promote appropriate intervention in patients with cerumen impaction, highlight the need for evaluation and intervention in special populations, promote appropriate therapeutic options with outcomes assessment, and improve counseling and education for prevention of cerumen impaction. In creating this guideline the American Academy of Otolaryngology–Head and Neck Surgery Foundation selected a panel representing the fields of audiology, family medicine, geriatrics, internal medicine, nursing, otolaryngology–head and neck surgery, and pediatrics.

RESULTS: The panel made a *strong recommendation* that 1) clinicians should treat cerumen impaction that causes symptoms expressed by the patient or prevents clinical examination when warranted. The panel made *recommendations* that 1) clinicians should diagnose cerumen impaction when an accumulation of cerumen is associated with symptoms, or prevents needed assessment of the ear (the external auditory canal or tympanic membrane), or both; 2) clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management, such as one or more of the following: nonintact tympanic membrane, ear canal stenosis, exostoses, diabetes mellitus, immunocompromised state, or anticoagulant therapy; 3) the clinician should examine patients with hearing aids for the presence of cerumen impaction during a healthcare encounter (examination more frequently than every three months, however, is not deemed necessary); 4) clinicians should treat the patient with cerumen impaction with an appropriate intervention, which may include one or more of the following: cerumenolytic agents, irrigation, or manual removal other than irrigation; and 5) clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should prescribe additional treatment. If full or partial symptoms persist despite resolution of impaction, alternative diagnoses should be considered. The panel offered as an *option* that 1) clinicians may observe patients with nonimpacted cerumen that is asymptomatic and does not prevent the clinician from adequately assessing the patient when an evaluation is needed; 2) clinicians may distinguish and promptly evaluate the need for intervention in the patient who may not be able to express symptoms but presents with cerumen obstructing the ear canal; 3) the clinician may treat the patient with cerumen impaction with cerumenolytic agents, irrigation, or manual removal other than irrigation; and 4) clinicians may educate/counsel patients with cerumen impaction/excessive cerumen regarding control measures.

DISCLAIMER: This clinical practice guideline is not intended as a sole source of guidance in managing cerumen impaction. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. It 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 diagnosing and managing this problem.

Cerumen, or "earwax," is a naturally occurring substance that cleans, protects, and lubricates the external auditory canal. Cerumen forms when glandular secretions from the outer one-third of the ear canal mix with exfoliated

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squamous epithelium.[1] Normally, cerumen is eliminated or expelled by a self-cleaning mechanism, which causes it to migrate out of the ear canal, assisted by jaw movement.[2]

Accumulation of cerumen, caused by failure of the self-cleaning mechanism, is one of the most common reasons that patients seek medical care for ear-related problems.[3,4] Excessive or impacted cerumen is present in one in 10 children, one in 20 adults, and more than one-third of the geriatric and developmentally delayed populations.[5-7] About 12 million people seek medical care annually for problematic cerumen in the United States, resulting in nearly eight million cerumen removal procedures.[8,9] Moreover, excessive or impacted cerumen in high-risk populations such as the elderly and developmentally delayed is underdiagnosed and likely undertreated.[6,10,11]

The target patient for this guideline is over six months of age with a clinical diagnosis of cerumen impaction:

- *Cerumen* is defined as a mixture of secretions (sebum together with secretions from modified apocrine sweat glands) and sloughed epithelial cells, and is a normal substance present in the external auditory canal. As cerumen migrates laterally, it may mix with hair and other particulate matter.
- *Cerumen impaction* is defined as an accumulation of cerumen that causes symptoms, prevents a needed assessment of the ear canal/tympanic membrane or audiovestibular system, or both.
- *Impaction vs obstruction:* Although "impaction" usually implies that cerumen is lodged, wedged, or firmly packed in the ear canal, our definition of cerumen impaction does not require a complete obstruction.

We have defined this term pragmatically to designate cerumen that requires management either because it is associated with symptoms or because it prevents a needed assessment of the ear.[1,4,7] Some patients will present with nonimpacted cerumen that does not cause symptoms and does not prevent assessment of the ear and is "asymptomatic." Asymptomatic cerumen often does not require active management. The guideline will discuss considerations relevant to watchful waiting and surveillance.

Symptoms associated with cerumen impaction include, but are not limited to: hearing loss, tinnitus, fullness, itching, otalgia, discharge, odor, or cough. Cerumen impaction can prevent diagnostic assessment by preventing complete examination of the external auditory canal and/or tympanic membrane or by interfering with diagnostic assessment.

The guideline does *not* apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; previous tympanoplasty/myringoplasty or canal wall down mastoidectomy.

GUIDELINE PURPOSE

The primary purpose of this guideline is to help clinicians identify patients with cerumen impaction who may benefit from intervention, and to promote evidence-based management. Another purpose of the guideline is to highlight needs and management options in special populations or in patients who have modifying factors. A guideline is necessary given the evidence of practice variation in medicine and the literature. The secondary goal includes creating a guideline suitable for deriving a performance measure on cerumen impaction.

The guideline is intended for all clinicians who are likely to diagnose and manage patients with cerumen impaction and applies to any setting in which cerumen impaction would be identified, monitored, or managed.

The guideline does *not* apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; previous tympanoplasty/myringoplasty or canal wall down mastoidectomy. However, the guideline will discuss the relevance of these conditions in cerumen management. The following modifying factors are not the primary focus of the guideline, but will be discussed relative to their impact on management: nonintact tympanic membrane (perforation or tympanostomy tube); ear canal stenosis; exostoses; diabetes mellitus; immunocompromised state; or anticoagulant therapy.

Existing guidelines[12,13] concerning cerumen impaction primarily address scope of practice issues or diagnosis, with no cross-specialty input. Moreover, there are no guidelines that contain explicit statements about management that are associated with evidence rankings. Our goal was to create a multidisciplinary guideline with a limited set of focused recommendations based on a transparent and explicit process that considers levels of evidence, harm-benefit balance, and expert consensus to fill evidence gaps. Moreover, the guideline should have a well-defined focus based on aspects of management offering the greatest opportunity for quality improvement.

BURDEN OF CERUMEN IMPACTION

Approximately 2% to 6% of the general population in the United Kingdom suffers from cerumen impaction at any given time.[7] Four percent of primary care patients will consult their clinician for cerumen impaction, and cerumen removal is the most common ear, nose, and throat procedure performed in the primary care setting in the United Kingdom.[7] Applying these rates to the United States population suggests a prevalence of cerumen impaction of 12 million individuals, ranging between six and 18 million. Further, approximately eight million ear irrigations are performed annually for this condition.[8]

Cerumen impaction is more common in the elderly and in patients with cognitive impairment. Estimates suggest that

from 19% to 65% of patients over 65 years old have cerumen impaction[10,11] and that elderly patients in nursing homes are likely at the upper end of this spectrum.[5,14] In the developmentally delayed adult population, 28% to 36% have excessive or impacted cerumen.[5,6] Moreover, the presence of cerumen impaction has been associated with hearing loss[15] and diminished cognitive function[11] in these populations.

The prevalence of cerumen impaction varies enormously. In a study of 1507 adults screened for hearing loss, 2.1% had occluding cerumen.[16] Another study found that almost 40% of nursing home patients had cerumen impactions.[17] Cerumen impaction is present in approximately 10% of children, 5% of normal healthy adults, up to 57% of older patients in nursing homes, and 36% of patients with mental retardation.[5]

Patients seek treatment for cerumen impaction for a host of symptoms. Pain, itching, sensation of fullness, tinnitus, odor, drainage, cough, and dizziness have all been reported, and complete occlusion can result in significant hearing loss.[7] Hearing loss can range from 5 to 40 dB depending on the degree of occlusion of the canal with cerumen.[3,5] While cerumen impaction may be asymptomatic in some cases, management may be necessary for diagnostic purposes so that the ear canal and/or tympanic membrane can be visualized or diagnostic assessment can be performed.[18]

Multiple treatment options exist for cerumen impaction, including observation; cerumenolytic agents; irrigation; or manual removal other than irrigation.[4,18] Combinations of these treatment options also exist (eg, cerumenolytic followed by irrigation; irrigation followed by manual removal). Manual removal other than irrigation may be performed with a curette, probe, hook, forceps, or suction under direct visualization with headlight, otoscopy, or microscopy.[1,7] The training, skill, and experience of the clinician play a significant role in the treatment option selected.[17] In addition, patient presentation, preference, and urgency of the clinical situation influence choice of treatment.

Though generally safe, treatment of cerumen impaction can result in significant complications. Complications such as tympanic membrane perforation, ear canal laceration, infection of the ear, or hearing loss occur at a rate of about one in 1000 ear irrigations.[3,19,20] Applying this rate to the approximate number of ear irrigations performed in the United States estimates that 8000 complications occur annually and likely require further medical services. Other complications that have been reported include otitis externa (sometimes secondary to external auditory canal trauma), pain, dizziness, and syncope.[4,21]

The primary outcome considered in this guideline is resolution or change in the signs and symptoms associated with cerumen impaction. Secondary outcomes include complications or adverse events. Cost, adherence to therapy, quality of life, return to work or activity, return physician visits, and effect on comorbid conditions (eg, sensorineural hearing loss, conductive hearing loss) were also considered. The high incidence and prevalence of cerumen impaction and the diversity of interventions available (Table 1) make this an important condition for an up-to-date, evidence-based practice guideline.

Table 1
Interventions considered in cerumen guideline development

Diagnosis
Targeted history
Physical examination
Otoscopy
Binocular microscopy
Audiologic evaluation
Treatment
Watchful waiting/observation
Education/information
Cerumenolytic agents
Ear canal irrigation
Manual removal other that irrigation (curette, probe, forceps, suction, hook)
Cotton-tip swabs
Ear candling
Prevention
Cerumenolytic agents
Hygiene
Education
Environmental controls

METHODS

General Methods and Literature Search

The 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.[22] The multidisciplinary guideline development panel was chosen to represent the fields of audiology, family medicine, geriatrics, internal medicine, nursing, otolaryngology–head and neck surgery, and pediatrics. Several group members had significant prior experience in developing clinical practice guidelines.

Several literature searches were performed through October 16, 2007. The initial MEDLINE search using "cerumen" or "earwax" or "ear wax" or "ear secretions" in any field yielded 1219 potential articles:

1) *Clinical practice guidelines* were identified by limiting the MEDLINE search using "guideline" as a publication type or title word. Search of the National Guideline Clearinghouse (www.guideline.gov) identified three guidelines with a topic of cerumen or earwax. After eliminating articles that did not have cerumen impaction as the primary focus, no guidelines met quality criteria of being produced under the auspices of a medical association or organization and having an explicit method for ranking evidence and linking evidence to recommendations.

2) *Systematic reviews (meta-analysis)* were identified by limiting the MEDLINE search to 10 articles using a validated

filter strategy for systematic reviews.[23] Search of the Cochrane Library identified one relevant title. After eliminating articles that did not have cerumen impaction as the primary focus, five systematic reviews met quality criteria of having explicit criteria for conducting the literature search and selecting source articles for inclusion or exclusion.

3) *Randomized controlled trials* were identified by search of the Cochrane Controlled Trials Register, which identified 33 trials with "cerumen" or "earwax" or "ear wax" in any field.

4) *Original research studies* were identified by limiting the MEDLINE search to articles on humans published in English since 1966. The resulting data set of 796 articles yielded 177 randomized controlled trials, 78 reviews, 10 systematic reviews, three guidelines, and 538 other studies. The literature was further narrowed using the standard literature review process including removal of: topics without sufficient evidence; nonoriginal research; letters; commentaries; narrative reviews; nonclinical research; case reports; or uncontrolled case series.[22]

Results of all literature searches were distributed to guideline panel members at the first meeting, including electronic listings with abstracts (if available) of the searches for randomized trials, systematic reviews, and other studies. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through December 14, 2007.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the nine months devoted to guideline development ending in June 2008, the group met twice, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.[24]

An independent review group used the Guideline Implementability Appraisal and Extractor (GEM-COGS)[25] to appraise adherence of the draft guideline to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in 2008 and modified an advanced draft of the guideline.

The final draft practice guideline underwent extensive external peer review. Comments were compiled and reviewed by the group chairpersons. The recommendations contained in the practice guideline are based on the best available published data through October 2007. Where data are lacking, a combination of clinical experience and expert consensus was used. A scheduled review process will occur at five years from publication or sooner if new compelling evidence warrants earlier consideration.

Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, to produce optimal health outcomes for patients, and to minimize harm. 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[26] are listed in Tables 2 and 3.

Guidelines are never 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.[27] Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.[26]

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 committee 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 American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past five years were compiled and distributed before the first conference call. After review and discussion of these disclosures,[28] 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. Lastly, 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.[29]

CERUMEN IMPACTION GUIDELINE EVIDENCE-BASED STATEMENTS

Each evidence-based statement is organized in a similar fashion: **evidence-based statement in boldface type,** followed by a statement on the strength of the recommendation. Several paragraphs then discuss the evidence base supporting the statement, concluding with an "evidence profile" of aggregate evidence quality, benefit-harm assessment, and statement of costs. Lastly, there is an explicit

Table 2
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 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.
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 vs harm; patient preference should have a substantial influencing role.

*See Table 3 for definition of evidence grades.

statement of the value judgments, the role of patient preferences, and a repeat statement of the strength of the recommendation. An overview of evidence-based statements in the guideline and their interrelationship is shown in Table 4.

The role of patient preference in making decisions deserves further clarification. For some statements the evidence base demonstrates clear benefit, which would minimize the role of patient preference. If the evidence is weak or benefits are unclear, however, not all *informed* patients might opt to follow the suggestion. In these cases, the practice of shared decision making, where the management decision is made by a collaborative effort between the clinician and the informed patient, becomes more useful. Factors related to patient preference include (but are not limited to): absolute benefits (number needed to treat); adverse effects (number needed to harm); cost of drugs or procedures; and frequency and duration of treatment. Comorbidity can also impact patient preferences by several mechanisms, including the potential for drug-drug interactions when planning therapy.

Statement 1a. DIAGNOSIS OF CERUMEN IMPACTION: Clinicians should diagnose cerumen impaction when an accumulation of cerumen 1) is associated with symptoms, or 2) prevents needed assessment of the ear, or 3) both. *Recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.*

Although impaction implies 100% occlusion to many clinicians, we elected to use an operational definition for this guideline such that only problematic cerumen is con-

Table 3
Evidence quality for grades of evidence

Grade	Evidence quality
A	Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case-control and cohort design)
D	Expert opinion, case reports, reasoning from first principles (bench research or animal studies)
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

sidered impacted. Clinicians should diagnose cerumen impaction when an accumulation of cerumen causes symptoms, prevents needed assessment of the ear, or both. It is emphasized that total occlusion is not necessary in this guideline definition. It should be noted that when an unobstructed ear canal or the view of the tympanic membrane is not essential to good care and is not associated with symptoms, cerumen in the ear canal is not considered "impacted" by this definition, and thus may not require any intervention other than observation.

Symptoms of cerumen impaction include: otalgia; tinnitus; fullness in the ear; pain; cough; hearing loss; and vertigo.[3,5,7] Presence of these symptoms should lead the clinician to examine the ear canal and, if cerumen is encountered, consider the diagnosis of impacted cerumen.

Physical examination of the external canal can be performed using a handheld speculum, an otoscope, or a binocular microscope. Cerumen impaction may impair a clinician's ability to visualize the tympanic membrane and assess the status of the middle ear.[30] In a study examining a cohort of children ranging in age from 2 to 60 months, cerumen was removed in 89 of 279 children (29%) subsequently diagnosed with acute otitis media. While the data are limited, they suggest that cerumen impaction can inhibit or prevent diagnosis of middle ear disease.

Cerumen impaction is appropriately diagnosed if cerumen in the ear canal prevents needed assessment even if the canal is only partially occluded. For example, if cerumen in the ear canal prevents visualization of all or part of the tympanic membrane in a patient suspected of having a perforation, the cerumen should be removed. Note that when visualization of ear canal anatomy or the tympanic membrane is not essential to good care and is not associated with symptoms, cerumen in the ear canal is not considered "impacted" by this definition.

If cerumen in the ear canal would compromise auditory or vestibular testing, cerumen impaction is also diagnosed. Several audiologic tests cannot be performed accurately because of complete or partial impaction; these tests include: audiometry; immittance testing; electrocochleography (ECochG); otoacoustic emissions (OAE); auditory brain stem responses (ABR); and real ear measurements during hearing aid fitting.

Evidence profile for 1a: Diagnosis of Cerumen Impaction.

- Aggregate evidence quality: Grade B, diagnostic studies with minor limitations regarding impact of cerumen on hearing and visualizations and Grade C with respect to signs and symptoms associated with cerumen impaction
- Benefit: Identify individuals with cerumen impaction who require intervention including those with otologic symp-

Table 4
Outline of evidence-based statements

Cerumen Impaction (*evidence-based statement number*)	Statement strength
I. Diagnosis	
a. Diagnosis (*Statement #1a*)	Recommendation
b. Modifying factors (*Statement #1b*)	Recommendation
II. Intervention	
a. Observation (*Statement #2*)	Option
b. Need for intervention (*Statement #3a*)	Strong recommendation
c. Need for intervention in special populations (*Statement #3b*)	Option
III. Hearing Aid Use (*Statement #4*)	Recommendation
IV. Treatment	
a. Therapeutic interventions (*Statement #5a*)	Recommendation
b. Cerumenolytic agents (*Statement #5b*)	Option
c. Irrigation (*Statement #5c*)	Option
d. Manual removal other than irrigation (*Statement #5d*)	Option
V. Outcomes assessment (*Statement #6*)	Recommendation
VI. Prevention (*Statement #7*)	Option

toms and those who require diagnostic assessment (raise awareness of the consequences of cerumen impaction—eg, cerumen impaction prevents caloric stimulation during electronystagmography)
- Harm: Overdiagnosis of cerumen impaction based on symptoms as a criterion resulting in failure to identify another cause of the symptoms
- Cost: no additional cost
- Benefits-harm assessment: preponderance of benefits over harm
- Value judgments: emphasis on clinical symptoms and signs for initial diagnosis; importance of avoiding unnecessary diagnostic tests; consensus on using the term "cerumen impaction" to imply cerumen that requires treatment
- Role of patient preferences: not applicable
- Policy level: Recommendation

Statement 1b. MODIFYING FACTORS: Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management such as one or more of the following: non-intact tympanic membrane, ear canal stenosis, exostoses, diabetes mellitus, immunocompromised state, or anticoagulant therapy. *Recommendation based on observational studies with a preponderance of benefit over harm.*

The management of cerumen can be influenced by host factors or anatomic abnormalities of the ear canal or tympanic membrane. The initial approach to the patient with cerumen impaction should include an assessment of these factors by history, physical examination, or both. Failure to identify such factors may lead to suboptimal care, harm, or inappropriate interventions.

Anatomic factors, either congenital or acquired, can modify the approach to treatment of cerumen impaction based on narrowing of the ear canal by either limiting visualization or increasing the likelihood of trauma. A narrow ear canal can make both irrigation and manual instrumentation difficult to perform. Narrow canals can be found in subjects with Down syndrome and other craniofacial disorders, chronic external otitis, and post trauma (including surgical).

Stenosis may be congenital or acquired. Congenital stenosis may involve both the lateral portion (cartilaginous) and the medial bony ear canal and can vary in severity from mild constriction of the external auditory canal (EAC) to complete atresia.

Diffuse exostoses and solitary osteomas of the external auditory canal are acquired bony growths that may severely limit the size of the ear canal and may trap cerumen and keratin debris in the bony canal and prevent adequate visualization of the tympanic membrane. Exostoses are broad-based hyperostotic lesions that tend to be multiple and bilateral and are associated with a history of cold-water swimming.[31] Osteomas are less common and are usually solitary, unilateral, and pedunculated.[32]

Safe and effective irrigation is not always possible in these patients; specialized equipment and procedures may be required to safely remove cerumen in these patients without undue risk. The clinician can usually remove the impaction by combining the magnification from the binocular microscope with micro-instrumentation.

A perforated tympanic membrane or patent tympanostomy tube limits the options available for cerumen removal. The presence of a nonintact tympanic membrane may be assessed by history and/or physical examination. Depending on the irrigation solution used, infection, pain, or ototoxic hearing loss could result. In addition, use of irrigation in the presence of a perforated tympanic membrane could produce caloric effects resulting in vertigo. Mechanical removal of cerumen is the preferred technique when the ear drum is not intact.

Irrigation with tap water has been implicated as an etiologic factor in several studies of malignant external otitis.[33-36] Given the reports of malignant otitis externa in immunocompromised AIDS patients, tap water ear irrigation may pose risks for that group as well.[37,38] Driscoll has demonstrated that the pH of diabetic cerumen is significantly higher than that in persons without diabetes, which may facilitate the growth of pathogens.[39] Clinicians who utilize irrigation in this patient population must be especially careful to minimize trauma, consider using ear drops to acidify the ear canal post irrigation, and provide close follow-up.

Patients who are on anticoagulant therapy are at higher risk for cutaneous hemorrhage or subcutaneous hematomas. Careful instrumentation is especially important if bleeding is to be avoided or minimized.

Evidence profile for 1b: Modifying Factors.

- Aggregate evidence quality: Grade C and D, observational studies
- Benefit: Reduce complications
- Harm: No harm
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: consensus that identifying modifying factors and modifying management will improve outcomes
- Policy level: recommendation

Statement 2. OBSERVATION OF NONIMPACTED CERUMEN: Clinicians may observe patients with nonimpacted cerumen that is asymptomatic and does not prevent the clinician from adequately assessing the patient. *Option based on randomized controlled trials with heterogeneity in diagnostic criteria and illness severity, and a relative balance of benefit and harm.*

Cerumen is a naturally occurring product of the ear canal. The normal lateral migration of epithelium in the external auditory canal is responsible for the ear's self-cleaning mechanism. Most cerumen is asymptomatic, and

does not impair necessary physical examination.[7] It is important that patients understand that cerumen does not always need to be removed. Cerumen may have beneficial effects; it serves as a self-cleaning agent with protective, emollient, and bacteriocidal properties.

Epithelial cells move off the tympanic membrane and then travel down the ear canal toward the meatus of the external canal. When Cerumen migrates toward the entrance of the canal foreign bodies such as dirt, dust, and other small particles adhere to it and are extruded with the cerumen when it is cast off from the canal.[5] This "conveyor belt" process has been shown to be an ongoing process in most individuals.[2]

Since cerumen is naturally removed from the ear canals of most people, observation over time can be offered as reasonable management. There have only been limited studies investigating the outcome of observing cerumen in the ear canal. Keane performed a small randomized controlled study of the use of solvents to disperse cerumen in the impacted ears of general practice patients in Dublin.[40] After five days, 5% of patients in the control group demonstrated complete cleaning of the ear and 26% demonstrated moderate cleansing, when managed with observation alone.

Moreover, residents at a privately owned intermediate care facility for the mentally retarded, who had 50% to 80% of their external canal occluded by cerumen but who did not have a related conductive hearing loss, had no intervention and were examined after a year.[6] At the follow-up exam, 44% had no cerumen, 53% still had the same amount but no conductive hearing loss, and only 3% progressed to impaction with associated hearing loss.

Evidence profile for 2: Observation of Nonimpacted Cerumen.

- Aggregate evidence quality: Grade D, one observational study, expert opinion, and first principles
- Benefit: avoid unnecessary treatment
- Harm: potential progression to impaction
- Cost: none
- Benefits-harm assessment: relative balance of harm vs benefit for nonimpacted cerumen
- Medical reasons for exceptions to this statement include, but are not limited to, history of recurrent cerumen impaction
- Value judgments: minimize unnecessary treatment, increase recognition of the benefits of cerumen
- Role of patient preferences: substantial role for shared decision making
- Policy level: option

Statement 3a. NEED FOR INTERVENTION: Clinicians should treat cerumen impaction that causes symptoms expressed by the patient or prevents clinical examination when warranted. *Strong recommendation based on randomized controlled trials with heterogeneity with a preponderance of benefit over harm.*

Cerumen impaction has been reported to cause symptoms that include itching and pain in the ear, discharge from the ear canal, ear fullness, cough, hearing loss, and tinnitus.

There are strong data that indicate removal of impacted cerumen can improve hearing;[3,11,15,41] however, there are limited outcomes data that describe the benefit of cerumen removal as it relates to improvement or resolution of other symptoms. If the patient has relevant symptoms (pain, tinnitus, hearing loss, aural fullness, vertigo) and the ear is impacted with cerumen, cerumen impaction may be presumed to be the etiology of the symptoms. Removal of the impaction is deemed efficacious if, after the Cerumen is removed, there is either improvement or complete resolution of the presenting symptoms.

While cerumen impaction may be a cause of reversible hearing loss, hearing acuity does not diminish until the cross-sectional area of the ear canal is reduced by at least 80%.[42] Consequently, it is difficult to predict whether or not a particular patient's cerumen impaction contributes to his or her hearing loss, and whether or not disimpaction will partially or completely correct the problem.

Screening studies in a variety of settings have shown that cerumen impaction is a frequent reversible cause of hearing loss.[6,43,44] A randomized community-based screening study in Oman determined that 2.7% of the population had a unilateral hearing impairment. Of those who were identified with a unilateral hearing loss, 54% were deemed to have a "mild" impairment (hearing threshold 26 to 40 dB), and half of that group had resolution of hearing loss after simply clearing the ear canal of cerumen at the time of screening.[43] In another study, residents at a privately owned intermediate care facility for the mentally retarded were examined annually over a 12-year period.[6] When examiners discovered patients with a new conductive hearing loss (greater than 10 dB air-bone gap at two or more frequencies) and a complete or near-complete ear canal occlusion by cerumen, the conductive hearing deficit resolved after the impactions were removed. In an uncontrolled study of 125 consecutive patients who had been referred by general practitioners to an ear syringing clinic in Bristol, UK, those who presented with difficulty hearing on the phone, ear pain, or "blocked ears" reported improvement or resolution of their symptoms 62% to 75% of the time after undergoing ear irrigation.[41] However, only 40% to 50% of those who complained of itching or dizziness reported improvement after ear lavage.

Older patients are often unaware that they have a cerumen impaction potentially impairing their hearing, or that removal of the impaction may improve their hearing.[10,14,15,45] In a random sample of 226 patients over the age of 65 who were admitted to the nonintensive care units of a hospital in the United States, 35% had cerumen impaction that blocked visualization of the tympanic membrane of either one or both ears. After lavage and otoscopic confirmation of clearing, repeat hearing tests showed subjects had improved hearing at several frequencies. There was no change in the control patients, who were not impacted.

Regardless of whether the subjects had cerumen impaction or not, the vast majority had been unaware of their hearing deficits and had rated their hearing ability as either "good" or "fair."[15]

The presence of cerumen may also hinder or prevent visual assessment of the ear canal and tympanic membrane. This is especially important as it relates to children who present with ear-related symptoms and in whom clinicians need to diagnose and treat acute otitis media and otitis media with effusion.[46] Unfortunately, most studies of interventions to remove cerumen impaction do not explicitly describe improved visualization of the tympanic membrane as an outcome, although ears may be described as "completely cleared."[9,40] One exception is a study of emergency room patients age 1 to 81 who presented with suspected ear problems and in whom visualization of the tympanic membranes was partially or totally obscured by cerumen. After instillation of docusate sodium followed by irrigation if necessary, there was full visualization 81% of the time.[47]

Evidence profile for 3a: Need for Intervention.

- Aggregate evidence quality: Grade B, randomized controlled trials with heterogeneity
- Benefit: improved hearing and symptom relief compared with no treatment
- Harm: potential complications related to treatment
- Benefits-harm assessment: preponderance of benefit over harm
- Role of patient preferences: some role for shared decision making
- Policy level: Strong recommendation

Statement 3b. NEED FOR INTERVENTION IN SPECIAL POPULATIONS: Clinicians may distinguish and promptly evaluate the need for intervention in the patient who may not be able to express symptoms but presents with cerumen obstructing the ear canal. *Option based on cohort and observational studies with a balance of benefit and harm.*

Elderly patients, young children, and the cognitively impaired are at high risk for cerumen impaction and may be unaware of it or unable to express the symptoms associated with cerumen impaction due to immaturity or cognitive impairment. The hearing loss associated with cerumen impaction may further impair cognitive function.

A higher incidence of cerumen impaction in these populations is well documented.[6,11,14,15,48-51] The specific reasons are not clear, but it may be related to the size of the external auditory canal in children and the cognitively impaired, or may stem from changes in the skin of the external auditory canal in elderly patients. A study of 107 children with Down syndrome who were referred to otolaryngologists showed that 39% had stenosis of the external auditory canal frequently complicated by cerumen impaction.[52] A longitudinal study of 117 developmentally delayed adult patients followed over a 12-year period demonstrated a high incidence of recurrent cerumen impactions in this population.[6] Data on recurrence rates are not available for children or elderly patients. Some elderly and developmentally delayed patients reside in nursing homes or institutions. Cerumen impaction rates appear higher for institutionalized patients.[11,53] Patients in these settings may also suffer more baseline cognitive impairment than similar, ambulatory populations.

Impaired cognitive function in the elderly may prevent them from recognizing hearing loss or other symptoms and may also impair their ability to bring symptoms to the attention of caregivers. A study screening asymptomatic elderly patients admitted to nursing homes[11] and another screening 755 asymptomatic developmentally delayed athletes[49] found relatively high levels of cerumen impaction and significant hearing loss in these populations. Small children may also lack the maturity to recognize hearing loss or to bring ear problems to the attention of their caregivers. A cross-sectional study of nearly 1000 South Indian children in South Africa found that conductive hearing loss from cerumen impaction caused over 10% of children to fail hearing screening.[54]

No randomized controlled trials compare hearing in patients in these populations who have or have not been evaluated and treated for cerumen impaction. A case-control study of 226 hospitalized elderly patients with each patient acting as his/her own control demonstrated an incidence of cerumen impaction of 35% and a statistically significant improvement in hearing in those patients who had an impaction removed.[15] A survey study of over 14,000 elderly people in England found that 10% of people who initially failed a hearing screening passed after cerumen removal.[55] A small cohort study by Moore et al of elderly patients admitted to nursing homes found that 65% of patients had cerumen impaction and removing the cerumen resulted in a statistically significant improvement in hearing and cognitive function as demonstrated by a mini mental status exam.[11] However, a strong conclusion cannot be made due to a small sample size (N = 29). In addition, there are no data on the impact of cerumen-induced hearing loss on cognitive function in children.

Evidence profile for 3b: Need for Intervention in Special Populations.

- Aggregate evidence quality: Grade C, cohort and observational studies
- Benefit: improved hearing and functional health status
- Harm: potential overtreatment of cerumen that is asymptomatic
- Cost: evaluation and treatment costs; substantial administrative burden in settings with a high prevalence of cognitively impaired individuals, such as nursing homes and institutional facilities
- Benefits-harm assessment: balance of benefit and harm

- Value judgments: importance of identifying and treating cerumen impaction in special populations
- Role of patient preferences: there is no role for patient preferences when the patient is unable to express preferences
- Policy level: Option

Statement 4. HEARING AID USE: The clinician should examine patients with hearing aids for the presence of cerumen impaction during a healthcare encounter. *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

The normal self-cleaning process of cerumen can be disturbed by the presence of objects such as hearing aids or earplugs.[5,56] Perry[57] has suggested that the presence of foreign objects such as hearing aids and earplugs can cause stimulation of cerumen glands, leading to excessive cerumen production, and he termed this process "mechanical milking." Therefore, hearing aid users are at increased risk for cerumen impaction.

The clinician should examine patients with hearing aids for impacted cerumen during a healthcare encounter, but this does not need to occur more frequently than every three months. Examination is accomplished by removing the hearing aid and inspecting the ear canal with a handheld otoscope. If the patient has bilateral hearing aids, the second ear is examined after replacing the first hearing aid to facilitate communication.

Cerumen impaction may change hearing aid performance. Irrespective of the type of hearing aids being worn, cerumen impaction can reduce the intensity of sound reaching the tympanic membrane by as much as 10 to 15 dB in the mid to high frequencies.[56] In addition, even a partial impaction can change the resonance properties of the ear canal, reducing mid and high frequency perception.[58]

Current estimates from various hearing aid manufacturers indicate that 60% to 70% of all hearing aids sent for repair are damaged as a result of contact with cerumen.[59] If an in-the-ear (ITE) instrument is utilized, cerumen can enter the vent or receiver. The resulting added mass of cerumen on the receiver diaphragm causes low-output distortion and loss of high-frequency response. A more insidious process occurs as the acidic compounds within the cerumen slowly deteriorate the diaphragm suspension, resulting in receiver failure.

Cerumen in the ear canal can cause the hearing aid to fit poorly and not seal properly. If the hearing aid fits poorly, sound produced by the aid passes around it and out of the ear canal, where it is picked up by the microphone and reamplified. A positive feedback loop is created and audible, high-pitched feedback results. Cerumen removal eliminates feedback when feedback is due to excess cerumen.

Evidence profile for 4: Hearing Aid Use.

- Aggregate evidence quality: Grade C, observational studies
- Benefit: prevent hearing aid dysfunction and associated repair costs
- Harm: overtreatment of asymptomatic cerumen
- Benefits-harm assessment: preponderance of benefit over harm
- Role of patient preferences: some role for shared decision making
- Policy level: Recommendation

Statement 5a. THERAPEUTIC INTERVENTIONS: Clinicians should treat the patient with cerumen impaction with an appropriate intervention, which may include one or more of the following: cerumenolytic agents, irrigation, or manual removal other than irrigation. *Recommendation based on randomized controlled trials and observational studies with a preponderance of benefit over harm.*

Appropriate interventions for cerumen impaction. In the symptomatic patient, the goal is to help alleviate or relieve the symptoms (pain, fullness, hearing loss, tinnitus, etc). In the asymptomatic patient with impacted cerumen, the goal is to allow visualization of the ear canal and the tympanic membrane or perform audiometric or vestibular evaluations. Several methods for achieving these goals are widely used. However, evidence in the literature that clearly identifies the superiority of one therapeutic option vs another is lacking.

The treatment method(s) used should depend on: 1) the available resources, 2) experience of the treating clinician with the available options, and 3) the ease with which the canal can be cleared. Clinically accepted standards include ear irrigation and manual disimpaction, although no comparative randomized clinical trials addressing benefit or harm have been conducted.[60]

Three effective therapeutic options are widely used: 1) cerumenolytic agents, 2) irrigation, and 3) manual removal other than irrigation. Combining one or more of these options, on the same day, or at intervals, is routinely used in everyday practice.[61] Irrigation or manual removal can be used alone or after softening the impacted cerumen. No direct comparison has been performed between same-day in-office softening followed by irrigation or disimpaction vs home softening followed by irrigation and manual disimpaction. Until more placebo-controlled data are generated, recommendations must be based on the relative safety of the treatment strategies, on the small number of direct comparison trials within each strategy, and on expert opinion.[60]

Irrigation or ear syringing involves flushing the wax out by a jet of warm water. Cerumenolytics, or wax-softening agents, are used to disperse the cerumen and reduce the need for syringing or for manual removal of the impaction. Cerumenolytics can be used alone or in combination with irrigation or manual removal. Manual removal includes the use of ear curettes, probes, hooks, forceps, or microsuction. Table 5 gives an overview of these methods.

Inappropriate interventions for cerumen impaction. According to expert opinion, interventions that are not appropriate for cerumen removal include home use of oral jet

Table 5
Therapeutic options: advantages, disadvantages

Option	Irrigation	Cerumenolytics	Manual removal
Advantages	Effective	Easy application Effectiveness not superior to saline or water	Effective
Complications/disadvantages	TM perforation Pain, vertigo EAC trauma Otitis externa Failure of wax removal Severe audio-vestibular loss	Otitis externa Allergic reactions Pain or vertigo if TM is not intact Transient hearing loss	Special skills required Skin laceration, pain Cooperation (especially with pediatric population)

TM, tympanic membrane; *EAC*, external auditory canal.

irrigators and cotton-tip swabs.[62] Removing cerumen with an oral jet irrigator has been described by Larsen.[63] Flared tip and OtoClear Tip are promoted as safer tips to eliminate overinsertion and direct the water away from the tympanic membrane, theoretically avoiding the risk of injury by reducing the build-up of pressure causing damage or pain. Research demonstrating the effectiveness of these home therapeutic options is lacking. Expert opinion favors the three clinician-administered methods discussed above as the most safe and effective options.

Expert opinion recommends against the use of cotton-tip swabs to remove cerumen from the ear canal, although the evidence against it is sparse. The product label of one of the leading manufactures of cotton-tip swabs specifically notes that the product should not be placed into the ear canal. The cotton buds at the end of cotton-tip applicators may separate, requiring removal as a foreign body.[62] Although only a case report, fatal otogenic meningitis and brain abscess due to retained cotton tips has been reported.[64]

In a prospective study, Lee et al showed that complications do arise from self-cleaning of the external auditory canal.[65] Thirty-six percent of the patients cleaned their ears by introducing a foreign object into the ear. The majority of the patients in that study were not willing to change their habits for a safer method of cleaning.

A nonrandomized comparison of earwax removal with a "do-it-yourself" ear vacuum kit vs the conventional manual method of removal with a Jobson-Horne probe concluded that the probe is significantly more effective than an ear vacuum for the removal of earwax.[66]

Complementary medicine is becoming more popular in the United States and use of alternative therapies has increased from 33% to 42%.[67] Otolaryngologists will therefore encounter patients who have tried one type or another of alternative practices. The most popular alternative practice for cerumen removal is ear candling, also known as "ear coning" or "thermo-auricular therapy." Ear candles are hollow tubes of fabric soaked with warm beeswax and subsequently hardened through cooling. The procedure of candling involves sticking such a candle into the ear, lighting the other end, and letting it burn for 15 minutes. Once the candle is extinguished, the near end is inspected. The patient is told that the waxy material at the end of the cone is cerumen from the ear, and has been drawn out through a "chimney effect" or capillary forces produced by the burning candle.[68]

In addition to cerumen removal, ear candling is sometimes recommended for common conditions such as headaches, rhinosinusitis, colds, and tinnitus.[69] No reliable prevalence data is available on candling, but data from wholesale distributors, thousands of Internet references to ear candling, and a survey of 122 US otolaryngologists showing that they were aware of ear candle use in at least one of their patients support the assumption that the prevalence of ear candle use is high.[70]

Adequate research on the effect of ear candling is limited. However, a series of experiments have concluded that candling does not eliminate wax from the ear, but rather the material deposited at the end of the cone is from the candle itself, and not wax from the external auditory canal.[70-72] Additionally, Seely et al concluded that the burning of the candle does not produce negative pressure.[70] Comparison of photographs from each subject's ear canals taken before and after the ear candling procedure revealed that no cerumen was removed from these ears. These investigators also surveyed a small sample of otolaryngologists regarding the use and safety of ear candles in their patient population. Fourteen out of 122 otolaryngologists who responded to the survey had treated 21 patients for complications from ear candles, which included: 13 burns of the auricle; 7 ear canal occlusions; and 1 tympanic membrane perforation. External otitis and temporary hearing loss were secondary complications in three and six patients, respectively.

In summary, these studies have shown that although ear candling is heavily promoted, the mechanism of action is implausible. Furthermore, it has no observable positive effects and ear candling use may be associated with considerable risks. The Food and Drug Administration (FDA) concluded that there is no validated scientific evidence to

support the efficacy of the ear candles and warns against their use.[73]

Evidence profile for 5a: Therapeutic Options.

- Aggregate evidence quality: Grade B and C, randomized controlled trials with limitations and cohort studies
- Benefit: improved cerumen removal by using effective therapies and to avoid harm from ineffective or untested therapies
- Harm: specific adverse effects related to treatments used
- Cost: no cost associated with the decision to use appropriate therapy
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: Therapy should be effective and minimize harm
- Role of patient preferences: Selection of office vs appropriate home treatment
- Policy level: Recommendation

Statement 5b. CERUMENOLYTIC AGENTS: Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction. *Option based on limited randomized trials with a balance of benefit and harm.*

Clinicians may use cerumenolytic agents or instruct patients in home use. Cerumenolytic agents include water. Topical therapy is regularly used to manage cerumen impactions either as a single therapeutic intervention or in combination with other techniques, including irrigation of the ear canal and manual removal of cerumen. Topical preparations exist in three forms: water-based; oil-based; and non–water-, non–oil-based (Table 6). Water-based agents have a cerumenolytic effect by inducing hydration and subsequent fragmentation of corneocytes.

Oil-based preparations are not true "cerumenolytics." They lubricate and soften cerumen without disintegrating cerumen.[74] The mechanism by which non–oil-, non–water-based ear drops manage cerumen has not been defined by in vitro studies.[75]

Cerumenolytic agents without irrigation. Cerumenolytic agents as a single intervention have been evaluated through studies comparing active agents to: 1) another active agent, 2) plain water, 3) saline, and 4) no intervention. The studies use various endpoints, including the need for subsequent irrigation and the ability to examine the tympanic membrane. The studies are heterogeneous with a diversity of treatment protocols and outcomes. One systematic review and meta-analysis evaluated 15 preparations, including saline and plain water, and concluded that without syringing, there was weak evidence that both water-based and oil-based ear drops were more effective than no treatment. Non–water-, non–oil-based preparations were more effective than oil-based preparations. Pooled data from this review suggest that longer treatment results in greater success in clearing of cerumen.[75]

A single study illustrates a comparison between control (no cerumenolytic), water, sodium bicarbonate, and an oil-based cerumenolytic.[40] Subjects were treated for five days prior to reassessment. There was no statistical difference in ears requiring irrigation to achieve complete clearance of the ear canal between the three cerumenolytic groups. Prior to syringing of the ear canal, moderate or complete clearance of the ear canal was achieved in 32% of the control group, 50% of the water group, 46% of the sodium bicarbonate group, and 60% of the oil-based group. The authors concluded that using any cerumenolytic is better than using no cerumenolytic.

The conclusion of a Cochrane review of water-based and oil-based preparations concluded that no specific agent was superior to another and none were superior to either saline or water.[1] One study of children compared a single 15-minute installation of: Cerumenex (10 percent triethanolamine polypeptide oleate condensate); Colace (docusate sodium), and saline drops.[76] There was no difference in the

Table 6
Topical preparations (Hand 2004)[75]

	Preparation	Active constituents
Water-based	Acetic acid	Aqueous acetic acid
	Cerumenex	Triethanolamine polypeptide oleate condensate
	Colace	Docusate sodium
	Hydrogen peroxide	Hydrogen peroxide solution
	Sodium bicarbonate	Sodium bicarbonate
	Sterile saline solution	Water
Oil-based	Almond oil	Almond oil
	Arachis oil	Arachis oil
	Earex	Arachis oil, almond oil, rectified camphor oil
	Olive oil	Olive oil
	Mineral oil/liquid petrolatum	Liquid petrolatum
Non–water-, non–oil-based	Audax	Choline salicylate, glycerine
	Debrox	Carbamide peroxide (urea–hydrogen peroxide)

clearance of cerumen with this protocol that included irrigation if the ears were not completely clear after the 15-minute period.

Children age 6 months to 5 years were treated with docusate, triethanolamine polypeptide, or saline with no statistical difference between groups after instillation of drops and following one or two attempts of irrigation.[77] The three treatment groups were similar with regard to age, sex, race, type of wax, and number of tympanic membranes partially or completely obstructed.

An in vitro study of multiple aqueous solutions and organic solvents demonstrated that a 10% solution of sodium bicarbonate was the most effective preparation for disintegration of a wax plug.[78]

In summary, the evidence indicates that any type of cerumenolytic agent tends to be superior to no treatment but lacks evidence that any particular agent is superior to any other. In vitro studies support using a true cerumenolytic rather than an oil-based lubricant for disintegration of cerumen, with a longer period of treatment tending to be more efficacious.

Cerumenolytic agents with irrigation. Variables evaluated with regard to cerumenolytics and irrigation include choice of ear drop and method of administration. Instilling water for 15 minutes prior to irrigation compared to immediate syringing reduced the number of syringing attempts in a study of 26 adult subjects.[79] A comparison of 15 minutes of water instilled in the ear to three days of using an oil-based product resulted in a non-statistical difference in the number of irrigation attempts to clear cerumen.[9] Ease of irrigation was one outcome for a study comparing Cerumol (turpentine oil 10%, chlorbutol 5%, paradichlorobenzene 2%, arachis oil 57.3%) with Otocerol (arachis oil, almond oil, rectified camphor oil), with no difference found between groups.[80]

A comparison of the prescription ear drop Cerumenex (10% triethanolamine polypeptide oleate condensate), Murine ear drops (6.5% carbamide peroxide), and a placebo consisting of BSS Sterile Irrigating Solution showed no statistical difference in clearance of cerumen.[81] This study allowed up to two 15-minute applications of the drops followed by water irrigation. Cerumenex and Murine are used only in combination with irrigation because leaving the ear drops in the ear canal for more than 30 minutes is contraindicated.

The systematic review by Hand concluded that there was equivalent success with irrigation after the instillation of oil-based and water-based preparations; dwell time of the ear drop was not a factor in determining success.[75] Instilling water prior to irrigation tended to be more successful than immediate irrigation.

Use of a cerumenolytic improves success of irrigation, but no cerumenolytic has been shown to be superior to another in this respect. Instilling a preparation immediately prior to irrigation has not been shown to be superior or inferior to using cerumenolytics for several days before irrigation.

Modifying factors. Factors to consider in evaluating cerumenolytics for managing cerumen are patient age, type of cerumen, and temperature of the cerumenolytic. One study of children between ages 6 months and 5 years comparing Docusate, triethanolamine polypeptide, and saline showed a trend toward a higher success rate for soft wax (68%) than for mixed wax (50%) or hard wax (43%).[77] Two studies suggest topical therapy is more effective in children than in adults.[47,82]

Study protocols and medication instructions variably recommend warming the cerumenolytic in the palm of the hand prior to instillation but do not provide data demonstrating better efficacy at higher temperatures. A laboratory study reported hydrogen peroxide was more successful dissolving cerumen if warmed to 37°C.[78]

Precautions. Instilling cerumenolytic agents can result in discomfort, transient hearing loss, dizziness, and skin irritation. Studies evaluating cerumenolytics exclude patients with otitis externa; therefore, cerumenolytics should be avoided in patients with active infections of the ear canal. Many commercially available cerumenolytics contain possible irritants. Subjects may have epidermal sensitivity to organic oils present in agents (ie, almond oil). Such agents should be applied for limited periods of time. For example, Cerumenex (10% triethanolamine polypeptide oleate) has a reported incidence of allergic dermatitis of 1%.

Risks and harms. The risk of a local skin reaction in response to a cerumenolytic appears to be lowest with non-organic solutions like saline.

Evidence profile for 5b: Cerumenolytic Agents.

- Aggregate evidence quality: Grade C, individual treatment arms of randomized trials showing beneficial outcomes, one randomized controlled trial suggesting better outcomes over no treatment
- Benefit: safe and effective removal of impacted cerumen
- Harm: potential external otitis, allergic reactions, and otalgia
- Cost: cost of cerumenolytic agents other than water or saline solution, cost of procedure if performed in an office setting
- Benefits-harm assessment: balance of benefit and harm
- Medical reasons for exceptions to this statement include, but are not limited to, persons with a history of allergic reactions to any component, persons with infection of the ear canal or active dermatitis, and persons with a nonintact tympanic membrane
- Value judgments: the panel values cost control and safety in view of limited data on absolute and comparative efficacy

- Role of patient preferences: substantial role for shared decision making
- Policy level: Option

Statement 5c. IRRIGATION: Clinicians may use irrigation in the management of cerumen impaction. *Option based on randomized controlled trials with heterogeneity and with a balance of benefit and harm.*

Aural irrigation is a widely practiced form of cerumen removal and can be performed with a syringe or electronic irrigator. While there are no randomized controlled clinical trials of aural irrigation vs no treatment, there is a consensus that aural irrigation is effective in removing cerumen. Manual irrigation, performed by using a large syringe typically made out of metal or plastic, is the most commonly employed method in general practice. Evidence has suggested that only a minority of general practitioners (19%) performed the procedure themselves. Most often, physicians delegated the task to practice nurses, some of whom received no instructions.[3]

Sorenson has assessed the pressure developed during routine ear syringing and found it safe for normal ears. But he did note that it may present a risk of perforation when the tympanic membrane is atrophic.[84]

A standard oral dental jet irrigator, with or without a specially modified tip, is commonly used. Electronic irrigators specially designed for aural irrigation are also available. These irrigators claim to have controlled pressures and specially modified tips which make them safer than standard oral jet irrigators, but comparative trials are not available to verify this assertion. A study by Dinsdale et al suggests that standard oral jet irrigators are safe if used at low pressure settings and if the jet of water is directed at the canal wall and not longitudinally down the canal toward the tympanic membrane.[85] The OtoClear safe irrigation system was found to be safe and effective in a small sample of children.[83]

There are no randomized controlled clinical trials comparing ear syringing to controls. However, clinical trials comparing earwax softeners to controls prior to syringing indicate that softeners enhance the efficacy of irrigations in removing earwax.[18]

A systemic review of the available evidence suggests that pretreatment with an otic drop improves the efficacy of aural irrigation, regardless of solution type. Therefore, saline and tap water may be as good as specially formulated products.[1,18]

In an unblinded study of 39 ears, Pavlidis et al found that considerably less water was required to completely remove a cerumen impaction if water had been instilled 15 minutes prior to syringing (87 mL vs 35 mL; $P = 0.043$).[79]

Meehan[76] and Singer[47] both compared the relative efficacy of liquid docusate sodium to triethanolamine with or without irrigation. In both studies, irrigation was performed because the otic drop alone did not remove the cerumen. Neither study found a statistically significant difference between the two pretreatment agents.

In one study, Roland et al compared pretreatment with either 10% solution of triethanolamine polypeptide oleate condensate or 6.5% carbamide peroxide or balanced salt solution prior to aural irrigation using an oral jet irrigator.[81] At the end of treatment there was no statistical significance; however, 29.2% of subjects treated with triethanolamine polypeptide, 15.4% of subjects treated with carbamide peroxide, and 41.7% of subjects treated with balanced salt solution experienced a resolution of occlusion.

A systematic review suggests that there are no significant differences between oil-based and water-based preparations for facilitating cerumen removal when administered prior to aural irrigation.[75] Pretreatment may be effective; however, evidence to this effect is limited. Data analysis suggests no significant difference between pretreatment followed by syringing within 15 to 30 minutes vs regular application of cerumenolytics for several days prior to syringing. Although the review included 18 randomized controlled clinical trials, only four were assessed as being of high quality. Fifteen different preparations were included across 18 clinical trials.

Hearing outcomes. In uncontrolled studies following aural irrigation of 28 ears with varying levels of occlusion, Mandel demonstrated, on average, that less than 5 dB improvement in hearing at all frequencies could be expected.[83] Other research also suggests an average 5-dB increase in hearing after aural irrigation.[3] In contrast, a randomized, single-blind, controlled trial found an average of 10 dB improvement in 34% of ears that had cerumen removed by aural irrigation vs only 1.6% of control ears.[41] Furthermore, hearing improvements up to 36 dB were observed.

Harms. The main complications reported after aural irrigation are pain, injury to the skin of the ear canal with hemorrhage, and acute otitis externa. Commonly reported significant complications are perforation (0.2% in Pavlidis series) and vertigo (0.2% in Pavlidis series).[79]

Complications were experienced by 38% of 274 practitioners who performed aural irrigation for cerumen removal.[3] Most complications either were relatively minor or responded promptly to initial management by the treating practitioner. Adverse events reported include pain, tinnitus, vertigo, otitis media, otitis externa, and perforation. Sharp et al estimated that only 1 in 1000 episodes of aural irrigation resulted in a complication significantly severe to require specialist referral.[3] Similarly, Bird asserts that major complications occur in 1 in 1000 ears syringed.[20] Roland et al reported a total of six adverse events in 74 patients who had cerumen removed with cerumenolytics followed by aural irrigation.[81] All were minor (3 puritis, 1 dermatitis, 1 vertigo, 1 discomfort) and resolved spontaneously.

Tympanic membrane perforation with serious injury to the middle and inner ear is rare but has been reported on a number of occasions.[3,19,85,86] Bapat et al[19] have reported fracture of the stapedial footplate with subsequent profound neurosensory hearing loss following aural irrigation using

an ear syringe, and Dinsdale et al[85] have reported a similar complication resulting in profound deafness following the use of an oral jet irrigator.

Modifying factors. Ear syringing should not be performed in individuals who have had ear surgery or who have a non-intact tympanic membrane. An intact tympanic membrane may be more vulnerable to perforation if a portion of the tympanic membrane is atrophic. Consequently, it is generally agreed that ears with a history of ear surgery should not be subject to aural irrigation. Since the eardrum is frequently not visualized due to cerumen impaction, clinicians sometimes must rely on history to establish that the eardrum is intact. If a small portion of the drum is visible and is mobile with pneumatic otoscopy, it is unlikely to be perforated. Similarly, if tympanometry can be performed and a low volume verified, tympanic membrane perforation is improbable.

A higher incidence of malignant otitis externa is found among patients with diabetes following aural irrigation with tap water, which may suggest that aural irrigation may have caused the disease in some number of these individuals.[34,36] Consequently, aural irrigation, especially with water, should be performed with caution in patients with diabetes. If patients with diabetes have cerumen removal by aural irrigation, they should be instructed to report the development of otorrhea and/or otalgia promptly. Consideration should be given to reacidifying the ear canal since the slightly acidic pH of the normal external auditory canal may be a significant factor in producing resistance to external otitis and/or malignant otitis externa.[39] Alternatively, consideration could be given to an irrigation solution other than water: hydrogen peroxide and solutions containing 50% white vinegar are reasonable alternatives. These considerations are based on expert opinion and made with a view to preventing the serious harm that can arise from temporal bone osteomyelitis (malignant otitis externa, necrotizing external otitis). Solutions containing alcohol should probably be avoided unless one can be certain that the tympanic membrane is intact. Alcohol in the middle ear space is both painful and potentially ototoxic.

Aural irrigation should be avoided in individuals with anatomic abnormalities of the canal (congenital malformations, osteomas, exostosis, scar tissue, etc) that might trap water in the external auditory canal after irrigation.

Evidence profile for 5c: Irrigation.

- Aggregate evidence quality: Grade B, one randomized controlled trial verifying absolute efficacy but multiple treatment arms of comparative studies verifying benefit over cerumenolytic alone
- Benefit: improved outcome of irrigation vs cerumenolytic alone
- Harm: external otitis, vertigo, tympanic membrane perforation, otalgia, temporal bone osteomyelitis
- Cost: cost of supplies and procedure
- Benefits-harm assessment: balance of benefit and harm
- Value judgments: panel enthusiasm was tempered by the lack of appropriate head-to-head trials comparing irrigation to manual removal or cerumenolytics
- Medical reasons for exceptions to this statement include, but are not limited to, persons with open tympanic membrane, active dermatitis or infection, or anatomic abnormalities of the ear canal
- Role of patient preferences: role for shared decision making
- Policy level: Option

Statement 5d. MANUAL REMOVAL: Clinicians may use manual removal other than irrigation in the management of cerumen impaction. *Option based on case series and expert opinion with a balance of benefit and harm.*

Advantages of manual removal are that it is often quicker, allows direct visualization of the external auditory canal, and does not expose the ear to moisture. Manual removal requires adequate illumination, visualization, and instrumentation. Examination of the ear throughout the process can determine when removal of the cerumen impaction is complete.[87]

A handheld speculum or otoscope, headlamp, or the binocular microscope are all appropriate instruments for visualization. The binocular microscope offers the advantage of stereoscopic magnification.[4] Instruments used for removal include a metal and plastic loop or spoon, alligator forceps, curette, right-angled hook, a straight applicator with applied wisps of cotton wool, angulated suction tips (French size 3,5,7), and a Jobson-Horne probe.[66] Wax that is of a softer consistency can sometimes be wiped out with cotton wool applied to an applicator or aspirated with the use of a suction tip attached to a negative-pressure pump.

Manual removal of cerumen is often considered in patients with abnormal otologic findings or systemic illness that may compromise immunity. Patients with perforation of the tympanic membrane are at risk for developing suppurative otitis media should irrigation or cerumenolytic agents enter the middle ear. The tympanic membrane may also be attenuated in patients who have had previous ear surgery, making them at greater risk of creating a pressure-induced perforation from irrigation.

Adequate training, experience, and the appropriate equipment will minimize the risk of adverse events and maximize the likelihood of successful cerumen removal.

Harms. Trauma to the external auditory canal, including pain and/or bleeding, perforation of the tympanic membrane, and, rarely, infection, has been reported. Suctioning the ear canal can produce noises that are quite loud and may startle the patient. Suctioning may create a cooling effect and elicit a caloric response from the inner ear, causing nystagmus and vertigo.

Modifying factors. Attempted manipulation of cerumen in a small external auditory meatus or canal stenosis may impede successful elimination of the cerumen impaction and may make it worse by pushing the cerumen further down the canal. The presence of exostoses in the ear canal may impair direct visualization and additional care is necessary to avoid contact with these bony lesions due to the sensitivity of the skin of the medial bony canal.

Evidence profile for 5d: Manual Removal.

- Aggregate evidence quality: Grade C and D, observational case series and expert opinion
- Benefit: removal of cerumen impaction under direct visualization
- Harm: bleeding, laceration, tympanic membrane perforation, otalgia
- Cost: procedural cost; equipment cost
- Benefits-harm assessment: balance of benefit and harm
- Value judgments: Recommendation acknowledges widespread practice of manual removal but this is tempered by the relative absence of evidence
- Role of patient preferences: role for shared decision making
- Policy level: Option

Statement 6. OUTCOMES ASSESSMENT: Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, alternative diagnoses should be considered. *Recommendation based on randomized controlled trials with limitations supporting a failure of clearance of cerumen in some cases and randomized controlled trials with limitations and a preponderance of benefit over harm.*

The symptoms of cerumen impaction include hearing loss, tinnitus, fullness, itching, otalgia, and occasionally cough. These symptoms overlap with those for many other conditions. Moreover, trials indicate that in-office treatment of cerumen impaction is variably effective.[75] In order to ascertain whether symptoms were in fact due to cerumen, one must evaluate the patient once the impaction has been resolved. Outcome assessment requires 1) examination of the ear and 2) patient assessment for symptom resolution. Both of these steps require collection and interpretation of clinical data and, depending on state laws governing scope of practice, the post-treatment evaluation may be performed by a physician, audiologist, advance practice nurse, physician assistant, or registered nurse. The laws governing scope of practice for medical assistants vary by state and therefore should be referenced before delegating the post-treatment assessment to a medical assistant.[88]

In addition, post-treatment evaluation for complications of the removal procedure is important for patient safety and medicolegal purposes.[89] While the techniques for cerumen removal are generally safe, these procedures have been associated with otitis externa, pain, dizziness, syncope, tinnitus, and tympanic membrane perforation.[3] For these reasons, the results of both the post-treatment otoscopic examination and symptom assessment should be documented in the medical record.

The impaction is resolved when 1) the clinician can examine the ear or perform the appropriate testing without the interference of cerumen and 2) associated symptoms have resolved. If this first condition is met but symptoms persist, the clinician should consider alternative diagnoses. Depending on the nature of the patient's symptoms, these might include: sensorineural hearing loss; otosclerosis; otitis media; medication side effects; head and neck tumors; temporomandibular joint syndrome; upper respiratory infections; eustachian tube dysfunction; or disorders of the skin of the canal.

If either of the above conditions is not met, suggesting persistent impaction, additional treatment should be prescribed (see the guideline section on Therapeutic Options).

Evidence profile for 6: Outcomes Assessment.

- Aggregate evidence quality: Grade C; observation in treatment arms of several randomized trials shows that retreatment is sometimes necessary and can be effective; first principles support evaluation for efficacy after treatment
- Benefit: detect complications, detect misdiagnosis, institute effective therapy
- Harm: see sections on individual treatments
- Cost: cost of additional treatment or evaluation
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: importance of clinician assessment after treatment; avoid misdiagnosis
- Role of patient preferences: limited
- Policy level: Recommendation

Statement 7. PREVENTION: Clinicians may educate/counsel patients with cerumen impaction/excessive cerumen regarding control measures. *Option based on survey and comparative studies with unclear balance of benefit vs harm.*

Although empirical evidence supporting measures to prevent cerumen impaction is limited, practitioners have the opportunity to counsel patients on the risks and potential benefits of specific control measures. Measures that may be beneficial in reducing cerumen impaction include 1) instilling prophylactic topical preparations, 2) irrigating the ear canal, or 3) routine cleaning of the ear canal by a clinician. Choices regarding topical preparations and devices for irrigating the ear should be discussed with the patient, allowing for substantial patient preference and cost factors in determining treatment options.

Patients should be counseled not to insert foreign objects, such as cotton-tip swabs or bobby pins, into the ear canal as

these objects can further contribute to impacting cerumen that is already present in the canal or even damage structures in the ear. Individuals who wear hearing aids are at increased risk for developing impactions; therefore, instructions on proper care and cleaning of these aids should be discussed with patients and caregivers.

Cerumen production is a normal physiologic process. Therefore, preventive measures should be focused towards those individuals who are at greatest risk for developing occlusion and those with a history of impaction. Individuals particularly susceptible to cerumen impaction are the elderly, the cognitively impaired, those with narrowed or anatomically deformed ear canals, and those with certain dermatologic conditions. Hearing aid users also have a higher incidence of impaction.[90] Several theories have been posed to explain this phenomenon, including overstimulation of cerumen production and impairment of normal cleaning mechanisms.[1,7]

Measures to prevent cerumen from accumulating and occluding the ear canal are based predominately on observations from clinical practice and anecdotal references, with limited research findings. A survey of general practitioners and nurses in the United Kingdom revealed that 84% supported the use of self-help measures by patients, including cerumenolytic drops and ear irrigations.[91]

One randomized prospective study evaluated the use of a prophylactic topical emollient preparation in preventing or reducing the recurrence of cerumen impaction.[92] Thirty-nine adults and children with completely impacted ear canals were randomly assigned to either an intervention group or a control group (regular care) following removal of the cerumen. The intervention group instilled a topical emollient preparation in their ears once a week for 12 months. Both groups were followed throughout the year and evaluated for recurrence of the impaction. Cerumen impaction recurred in one or both ears in only 23% of intervention patients vs 61% of the control patients, a significant difference between groups, suggesting benefits to using this prophylactic therapy. A high patient attrition rate, particularly in the intervention group, dampens enthusiasm for results of this study.

Although empirical data are quite limited, consensus opinion from clinicians is that cerumen impaction seems to be exacerbated by the use of hearing aids and cotton-tip swabs.[93] A descriptive study with older adults revealed that ear hygiene practices were often incorporated into the daily hygienic routine. Specific measures used to clean the ears ranged from washing the outer ear with soap and water to inserting objects into the ear canal (eg, bobby pins, cotton-tip swabs, paper clips). Some elders instilled topical alcohol or hydrogen peroxide drops to soften or prevent cerumen from accumulating in the ears.[94] Several surveys identified the use of cotton-tip swabs as a common method used by patients to clean the external auditory canal.[94-96]

In a survey of children and their parents aural toilet was found to be a common practice.[95] Methods used to clean the ears included wash cloth with soap and water, cotton-tip swabs, and ear drops. The patients' ears were examined for occlusion of the canal by cerumen. There was no association between washing, swimming, bathing, or using ear drops and the amount of cerumen in the child's external ear canal. In regard to recent use of cotton-tip swabs, there was a significant correlation between cerumen accumulation in the one ear canal but not on the contralateral side.

Another study noted a higher incidence of cerumen in children whose ears were cleaned with cotton-tip swabs.[96] In contrast, one descriptive study found no increased incidence of occluding cerumen in the ears of those using cotton-tip swabs.[97] One comparative study asked children with and without otitis externa to recall their use of cotton-tip swabs within 10 days of diagnosis and found a greater usage in those with otitis externa. The risk of developing otitis externa, suggested in this one study, requires further investigation. Based on the lack of well-designed controlled studies and the contradictory findings of these few descriptive studies, no clear relationship between use of cotton-tip swabs and increased accumulation of cerumen in the ear canal can be substantiated.

Alternative practices, which include ear candles, are sometimes used by patients in their attempt to remove excessive cerumen from the ear canal.[68] Research on the use of ear candles is limited, but published data do not support their efficacy and their use is not supported by the FDA.

It has been suggested that those with an increased propensity for cerumen production might benefit from regular ear care to reduce the risk of developing an impaction.[5] Regular cleaning of the ears performed every 6 to 12 months by professionals or routine self-care measures such as irrigating the ears or using topical preparations might prevent cerumen from accumulating in the ear canal and causing an impaction.[75] Studies evaluating the benefits as well as the harms associated with specific interventions designed to prevent or reduce cerumen impaction are very limited, and this area of research warrants further investigation.

Evidence profile for 7: Prevention.

- Aggregate evidence quality: Grade C; observational studies and expert opinion
- Benefit: prevent development of cerumen impaction
- Harm: side effects of preventive measures
- Cost: cost of control measures, minimal
- Benefits-harm assessment: balance benefit over harm
- Value judgments: importance of prevention in managing patients with cerumen impaction
- Role of patient preferences: substantial opportunities for shared decision making
- Policy level: Option

IMPLEMENTATION CONSIDERATIONS

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate refer-

ence and distribution. A full-text version of the guideline will also be accessible free of charge for a limited time at the www.entnet.org, the AAO-HNSF website. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

An anticipated barrier to diagnosis is distinguishing modifying factors for cerumen impaction in a busy clinical setting, which may be assisted by a laminated teaching card or visual aid summarizing important factors that modify management.

Anticipated barriers to using an "observation option" for nonimpacted cerumen are reluctance of patients and clinicians to consider observing cerumen, and misinterpretation by clinicians and lay press of the statement regarding observation of nonimpacted cerumen as a "recommendation" instead of an "option." These barriers can be overcome with educational pamphlets and information sheets that outline the favorable natural history of nonimpacted cerumen, moderate incremental benefit of removal on clinical outcomes, and potential adverse effects of treatment.

Prompt evaluation of special populations may be hindered by the high prevalence of cerumen impaction in these populations and additional treatment time that may be necessary in busy practice settings. Information sheets outlining the high prevalence and the potential morbidity of cerumen impaction in these populations may help clinicians to become more aware of this issue.

Performance of irrigation and instrument removal other than irrigation, when appropriate, may be hindered by access to equipment and by procedural cost. Lastly, successfully achieving an understanding of the lack of efficacy and potential harms of ear candling, a popular alternative therapy, will require patient and clinician access to educational materials. Pamphlets may help in dispelling myths about comparative efficacy.

RESEARCH NEEDS

While there is a body of literature from which these guidelines were drawn, significant gaps in our knowledge about cerumen impaction and its management remain. The guideline committee identified several areas where further research would improve the ability of clinicians to optimally manage patients.

The exact definition of cerumen impaction is variable and elusive. We used an operational definition for this guideline, but establishing a universal definition would lend standardization to all future studies and make comparison of management strategies more meaningful.

The natural history of impacted cerumen is also not well known. There is evidence that some impactions may clear spontaneously, but a longitudinal study documenting the likely outcome of cerumen managed by observation alone would guide clinicians as to the necessity of any intervention in the nonemergent setting. Similarly, the role of preventive measures such as emollients and ear hygiene merits further study in a controlled fashion. Additionally, these studies should stratify patients by age as the natural history and effect of preventive measures may vary by age.

The bulk of high-quality studies in the existing cerumen literature evaluated and compared different cerumenolytic agents alone or in combination with syringing. The committee saw significant room for further large and well-constructed randomized controlled trials comparing the different methods for cerumen removal alone or in combination. There are little data on manual removal other than syringing. While it was the opinion of the committee that this is an effective method with limited risk when performed by adequately trained practitioners, there were virtually no data to confirm this widely held conviction. Furthermore, the impact of different interventions on different age groups and special populations bears study. Cerumenolytic agents and irrigation might be more or less effective in children, the elderly, or other high-risk groups relative to adults. Relative cost data for the different treatment options are lacking and would be a useful addition to future guidelines. In addition, given that EAC trauma is a common complication of instrumentation, resulting in otitis externa, more information is needed on the efficacy of prophylactic topical antimicrobials when EAC trauma occurs.

Ear candling and other alternative medical approaches to cerumen removal are commonly practiced. There are very limited data on their effectiveness or lack thereof. There are reports of adverse events and limited effectiveness of these therapies, but prospective controlled studies are warranted to establish what role, if any, these therapies have in managing patients with otologic complaints and to better define the risks associated with their use.

All studies demonstrated limited outcomes data. Whether or not the impaction is cleared is an obvious outcome, but frequently cerumen is removed to alleviate symptoms such as pruritis, hearing loss, pain, fullness, tinnitus, or vertigo. An additional area of interest would be to determine if different types or consistencies of cerumen should be managed differently. The committee recommends that future studies of treatment effectiveness take these alternative outcomes into account. In the same regard, reports of the risks of cerumen removal are largely anecdotal. All trials of treatment effectiveness should clearly document adverse events.

Finally, in clinical practice, different levels of healthcare providers are involved in managing patients with cerumen impaction. Studies evaluating the safety and efficacy of one therapeutic option over another; resource use; and cost of cerumen management and post-treatment assessment by the various provider types are warranted.

DISCLAIMER

As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as condi-

tional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates, and they do not and should not purport to be a legal standard of care. The responsible physician, in light of all the 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 (AAO-HNS), Inc. emphasizes that these clinical guidelines should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results.

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