

CONSENSUS RECOMMENDATIONS OF THE FLORIDA ACADEMIC HEALTHCARE PATIENT SAFETY ORGANIZATION FOR THE

TREATMENT AND MANAGEMENT OF EAR IMPACTION





Consensus Recommendations of the Florida Academic Healthcare Patient Safety Organization for the Treatment and Management of Ear Impaction

hese consensus recommendations, developed by the Florida Academic Healthcare Patient Safety Organization (FAH PSO), are for informational purposes only and should not be construed or relied upon as the legal standards of care or a clinical practice guideline. The applicable standard for any particular patient is determined by many factors, including the patient-specific clinical data available, and is subject to change given developments in scientific knowledge, technological advances, and the evolution of healthcare. The ultimate decision regarding the appropriateness of any medical care and treatment for any individual patient is subject to that patient's clinical presentation and the reasonable judgment of the individual healthcare provider, in light of all information and circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.

The FAH PSO recommends institutions review these guidelines and accept, modify, or reject these recommendations based on their own institutional resources and patient populations. Any decision not to implement any of the recommendations herein, either fully or partially, should not be construed as evidence of negligence. Any recommendations, templates, proposed policies, or documents contained herein are solely illustrative. Additionally, institutions should continue to review and modify these recommendations as the science continues to evolve. Adherence to or adoption of the consensus recommendations do not include a comprehensive listing of all methods or models of ear impaction treatment and management. No statement or recommendation in this report should be construed as legal advice or as the official position of any of the institutions referenced in the report. It is anticipated that these recommendations will require updating as scientific information regarding ear impaction treatment and management evolves.



Participants

The following healthcare providers participated in the development of these consensus recommendations. This publication does not necessarily reflect the views or opinions of any particular healthcare provider, university institution, or healthcare organization. Again, these recommendations are not intended to create nor should they be construed as the legal standard or care or a clinical practice guideline. None of the participants has any affiliations or financial involvement that conflicts with the material presented in this report.

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About the Florida Academic Healthcare Patient Safety Organization

n 2005, Congress developed and enacted the Patient Safety and Quality Improvement Act (PSQIA) with the intent of cultivating a culture of safety and improving healthcare, by providing federal privilege and confidentiality protections for information that is reported to a Patient Safety Organization (PSO), developed by a PSO, or which represents the analyses and deliberations of patient safety events, for the conduct of patient safety activities. The PSQIA promotes the sharing of knowledge gleaned from these patient safety activities and the sharing of best practices and recommendations that seek to improve the quality of healthcare.

The Florida Academic Healthcare Patient Safety Organization (FAH PSO), listed by the Agency for Healthcare Research and Quality on April 22, 2014, represents a significant step toward improving patient safety in the third most populous state in the United States. The PSQIA and the associated federal confidentiality protections provide the required framework to allow the sharing of sensitive patient information among medical providers located at the six different State of Florida medical universities training the next generation of healthcare providers. The FAH PSO represents Florida Atlantic University, Florida International University, Florida State University, the University of Central Florida, the University of South Florida, and the respective institutions' healthcare providers working together to improve patient safety and healthcare.





Executive Summary

n 2020, at the behest of its membership, the FAH PSO convened an Ear Impaction Treatment and Management Work Group to arrive at an expert consensus of recommendations for effective treatment and management of ear impaction, including recommendations for training of health care providers, documentation of risks and benefits, and equipment. The FAH PSO sought to create these recommendations supported by a subject matter expert panel, review of the available literature, and identification of professional practices of healthcare providers actively involved in the provision of these services.

This Work Group began with a review of the latest scientific evidence, guidance, and opinion statements from relevant professional societies on the appropriate and effective treatment of ear impaction in the ambulatory setting. Further insights were gathered from subject matter experts in Medicine, Otolaryngology, and Student Health. The Group generated the following recommendations for the identification and management of ear impaction with the goal of developing a system that promotes successful treatment and the reduction and prevention of undesired outcomes. While the core focus is the treatment of foreign body or cerumen impaction of the ear, these recommendations also address several critical, related areas, including:

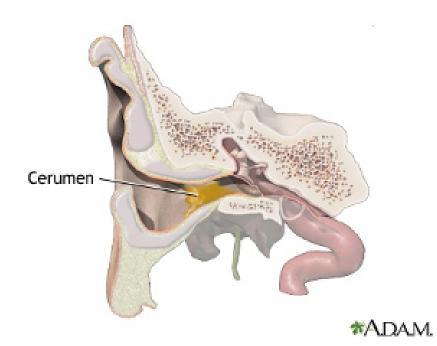
- Assessing proficiency of procedural skill for certification of the health care provider performing the procedure (RN/LPN/CMA) and documentation of same
- Training for providers and staff who are likely to perform this procedure
- Reviewing informed consent process and documentation
- Comparing and contrasting similar procedures across health systems of the FAH PSO

The following recommendations reflect the aim, mission, and consensus opinions of the Ear Impaction Treatment and Management Work Group. These recommendations offer guidance to healthcare providers and facilities in their efforts to provide safe, effective, and evidence-based healthcare. Student Health, Medicine, and Otolaryngology providers may be best informed and equipped to coordinate stakeholders to ensure that university students receive optimal healthcare and appropriate care. Specific resources will differ for and within each institution. These recommendations are supported by the literature available at the time of publication.



Ear Impaction Description and Therapeutic Options

the ear canal contains glands that produce cerumen, a wax-like oil that protects the ear by preventing dust and bacteria from entering and potentially damaging the ear. Cerumen also protects against irritation when water is presented into the canal and acts as a self-cleaning agent with protective, emollient, and bacteriocidal properties. Cerumen will usually fall out of the ear on its own or be removed by regular hygiene and washing. Some individuals, however, produce more cerumen than that which can be removed with regular washing. The excess cerumen may harden and block the ear canal, leading most commonly to hearing loss.



Patient Presentation and Examination

Cerumen impaction should only be diagnosed when the accumulation of excess cerumen is also associated with symptoms. Prior to the diagnosis of cerumen impaction, discussion with the patient regarding acceptable presence of cerumen in the ear canal is recommended, along with explanation that removal is not always necessary. Cerumen generally is removed from the ear canal naturally, so observation over time can be offered as a reasonable management strategy in asymptomatic patients with non-impacted cerumen and whose ear canal can be appropriately examined. Because self-ear cleaning is a common predisposing factor to cerumen impaction, discussion regarding proper ear hygiene is often appropriate as part of this examination. The patient should also be provided educational materials regarding the diagnosis and treatment of cerumen impaction. Educational materials created by the American Academy of Otolaryngology, and endorsed by the American Academy of Family Physicians and the American Academy

Plain Language Summary: Earwax (Cerumen Impaction)

AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY FOUNDATION

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

This plain language summary serves as an overview in explaining earwax (cerumen). The summary applies to patients older than 6 months with a clinical diagnosis of earwax impaction and is based on the 2017 update of the Clinical Practice Guideline: Earwax (Cerumen Impaction). The evidence-based guideline includes research that supports diagnosis and treatment of earwax impaction. The guideline was developed to improve care by health care providers for managing earwax impaction by creating clear recommendations to use in medical practice.

Keywords

cerumen, earwax, impaction, plain language summary

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How Was This Summary Developed?

This plain language summary is based on the American Academy of Otolaryngology-Head and Neck Surgery Foundation's (AAO-HNSF's) "Clinical Practice Guideline (Update): Earwax (Cerumen Impaction),"¹ which updates an earlier guideline developed in 2008 by the AAO-HNSF.² The purpose of the summary is to convey key concepts and recommendations from the guideline in clear, understandable, patient-friendly language. It was developed by consumers, clinicians, and AAO-HNS staff.

The earwax impaction guideline was developed using the methods outlined in the AAO-HNSF's "Guideline Development Manual, Third Edition."3 A literature search was performed by an information specialist to identify research studies (systematic reviews, clinical practice guidelines, and randomized controlled trials) published since the prior guideline (October 2007 to April 2015).

The AAO-HNSF assembled a guideline update group representing the disciplines of otolaryngology-head and neck surgery, otology/neurotology, family medicine, audiology, advanced practice nursing, and a consumer advocate. The group also included a staff member from the AAO-HNSF. Prior to publication, the guideline underwent extensive peer review, including open public comment.

Why Do I Have Earwax?

Earwax or "cerumen" (si-ROO-men) is a normal substance made by our bodies to clean, protect, and "oil" our ears. It acts as a self-cleaning agent to keep our ears healthy. Dirt, dust, and other small pieces of stuff stick to the earwax which keeps it from getting farther into the ear. Chewing, jaw motion, and growing skin in the ear canal help to move old earwax from inside our ears to the ear opening, where it then flakes off or is washed off when we bathe. This normal process of making wax and pushing the old wax out continues nonstop. Figure I shows where earwax occurs in the ear.⁴

What Does It Mean if My Earwax Is Impacted?

At times, your ear's self-cleaning process might not work very well and may lead to a buildup of earwax. When this happens, earwax can collect and block or partly block your ear canal. This is impaction. Impacted earwax can cause symptoms like hearing loss, itching, or ear pain. The impaction also makes it hard for your health care provider to see in your ears. You can have symptoms when your ear canal is completely blocked by earwax or only partly blocked.

What Are the Symptoms of Earwax Impaction?

- Ear pain
- Itching

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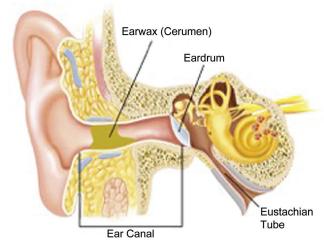


Figure 1. Cerumen is formed in the outer two-thirds of the ear canal and not the inner-third that ends at the eardrum. Impacted earwax (brownish mass) can completely obstruct the ear canal. Adapted and reproduced with permission.⁴

- Feeling of fullness in the ear
- Ringing in the ear (tinnitus)
- Hearing loss
- Discharge coming from the ear
- Odor coming from the ear
- Cough
- Change in hearing aid function

You should see your health care provider if you have symptoms and you are not sure if they are caused by earwax. You might have a different ear problem that needs medical care.

Who Is More Likely to Get Earwax Impaction?

It can happen to anyone but is more common in the following:

- \circ Elderly people
- People who use hearing aids or earplugs

How Is Earwax Impaction Diagnosed?

Earwax impaction is diagnosed through a physical examination and review of your medical history. Your health care provider may look in your ear canal with a tool called an otoscope (OH-t-OH-scope) or other device to see if you have impacted earwax. If you do, you may be treated for the impaction at that time or you may be sent to another provider for treatment.

How Is It Treated?

Impacted earwax can be treated in several ways. Some of the treatments can be done at home, but you may have certain medical or ear conditions that could make home options unsafe. You and your health care provider should discuss possible treatments and decide on the best treatment for you. **Figure 2** may help with your discussion.⁵ Available treatments are:

- Watchful waiting, or observation for a period of time. Earwax removal by the body is a natural process, and many impactions clear on their own. Your health care provider might offer the option to wait and see if the problem goes away or gets worse over time.
- Irrigation, or ear syringing. This involves clearing the wax out of the ear canal by a stream of warm water. Self-irrigation can be done at home. Irrigation is not recommended for patients who get a lot of ear infections, have ear tubes, or have a hole in the eardrum. Home use of oral jet irrigators is not effective and is not recommended as they can lead to damage in the ear.
- Wax softening agents (cerumenolytics). These are ear drops that soften or break up the wax to help in removal. These solutions can be used alone or together with irrigation or physical removal by a provider.
- Physical removal of wax with special instruments or a suction device. Physical removal of earwax should only be performed by a health care provider.

The updated Clinical Practice Guideline: Earwax (Cerumen Impaction) offers recommendations, also called key action statements, to improve the quality of care that people with impacted earwax receive. See **Table I** for a summary of the key action statements. These recommendations are not meant to provide comprehensive advice on managing all aspects of earwax but to find opportunities to align care with best research evidence and improve quality overall. Your doctor will provide care that is individualized to you, but you can still use the guideline recommendations as a source for discussion and shared decision making.

Can I Use Cotton Swabs to Clean inside My Ears?

You should avoid putting things in your ears. You may see some earwax come out on a cotton swab, bobby pin, paperclip, or other item you put in your ear canal, but you are really only pushing earwax back into your ear, which may cause problems. Putting things in your ears irritates them. You can also injure your ear by putting a hole in an eardrum, cutting or scratching the ear canal skin, or even causing an ear infection.

What about Ear Candling?

Ear candling or ear coning is NOT a safe option for earwax removal. Research shows that ear candling does NOT create

Table 1. Summary of Guideline Action Statements.	

Statement	Action	Strength
I. Primary prevention	Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen.	Recommendation
2A. Diagnosis of cerumen impaction	Clinicians should diagnose cerumen impaction when an accumulation of cerumen seen on otoscopy (1) is associated with symptoms, (2) prevents needed assessment of the ear, or (3) both.	Recommendation
2B. Modifying factors	Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management such as I or more of the following: anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, or nonintact tympanic membrane.	Recommendation
3A. Need for intervention if impacted	Clinicians should treat, or refer to another clinician who can treat, cerumen impaction, when identified.	Strong recommendation
3B. Nonintervention if asymptomatic	Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined.	Recommendation
3C. Need for intervention in special populations	Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults) and promptly evaluate the need for intervention.	Recommendation
4. Intervention in hearing aid users	Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter.	Recommendation
5A. Recommended interventions	Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include 1 or more of the following: cerumenolytic agents, irrigation, or manual removal requiring instrumentation.	Recommendation
5B. Contraindicated intervention (ear candling/coning)	Clinicians should recommend against ear candling/coning for treating or preventing cerumen impaction.	Recommendation
6. Cerumenolytic agents	Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction.	Option
7. Irrigation	Clinicians may use irrigation in the management of cerumen impaction.	Option
8. Manual removal	Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction.	Option
9. 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, the clinician should evaluate the patient for alternative diagnoses.	Recommendation
10. Referral and coordination of care	Clinicians should refer patients with persistent cerumen impaction after unsuccessful management by the initial clinician to a clinician with specialized equipment and training for cleaning and evaluating the ear canal and tympanic membrane.	Recommendation
II. Secondary prevention	Clinicians may educate/counsel patients with cerumen impaction/excessive cerumen regarding control measures.	Option

	PATIENT INFORMATION Shared Decision Making for Patients and Caregivers for Earwax Management			
FREQUENTLY ASKED QUESTIONS	OBSERVATION	EARWAX SOFTENING PRODUCTS	IRRIGATION	PHYSICAL REMOVAL
Are there any age limits?	No	Yes. Not recommended for ages below 3 years and in patients with non-intact ear drums.	No, but small children may be unwilling	No, but small children may be unwilling
What does it involve?	See provider every so often to check your ears.	Put a few drops of earwax softening products once or twice daily for 3 to 5 days.	Cleaning the ear canal with water to clear the earwax out of the inside of the ear	Earwax is physically removed by a provider in the office.
How long does the treatment take?	Time to look in the ear	Less than 5 minutes to put in drops	Should not take more than 30 minutes.	The treatment takes a few minutes and the patient will not be put to sleep.
What are the benefits?	Reduce unneeded treatment	Done at home, avoid clinician visits	Immediate improvement of symptoms caused by the earwax impaction Self-irrigation can also be done at home	Immediate improvement of symptoms caused by the earwax impaction
What are the risks and side effects?	Small amount of earwax could progress to impaction	None reported	Temporary dizziness, pain, and/or hole in ear drum	Injury to the ear skin leading to bleeding, infection, or discomfort
What usually happens in the long term?	Nothing	Earwax may return and require additional treatment	Earwax may return and require additional treatment	Earwax may return and require additional treatment
Are there any special safety measures?	None at this time.	Should seek medical attention if too much pain or discomfort or loss of hearing is noticed.	May not be recommended for some patients.	Discuss physical removal of earwax with health care provider
SOURCE: Adapted from Schwartz SR, Magit AE, Rosenfeld RM, et al; Clinical Practice Guideline (Update): Earwax (Cerumen Impaction). Otolaryngol Head Neck Surg. 2017;156:S1-S29.				
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Figure 2. Shared decision grid for patients and caregivers regarding therapeutic options for earwax management.

a vacuum to suck earwax from the ear. Any wax left on the ear candle is from the candle itself, not earwax. Some risks of the ear candling process are the following:

- Burns to the ear canal
- Ear blockage from candling wax
- Hole in eardrum
- Ear infection

Should I Do Anything to Prevent Earwax Buildup?

Not everyone needs prevention, but it is best for some groups. If you are elderly, use hearing aids, or have a history of making too much earwax, you may need regular treatment. It is important to remember that earwax is natural and helpful to the body. It does not always need to be removed. You do not have to do anything unless you have earwax buildup that causes symptoms or prevents your health care provider from examining your ears.

Figure 3, Dos and Don'ts of Earwax (Cerumen), gives some quick tips on earwax and what you should and should

not do about ear care and health. You can always talk to your health care provider about simple things you can do to keep your ears healthy.

Figure 4 includes some frequently asked questions about earwax prevention that might be helpful. You and your health care provider should talk about anything special you might need to do to prevent or lessen the buildup of earwax in your ears. **Figure 5**, Ways to Help Reduce Earwax, offers other options to help reduce earwax.

Where Can I Get More Information?

Health care providers should discuss all treatment options and find the best approach for the patient. There are printable patient handouts and materials that further explain earwax impaction and can help with decisions about care options. *For more information on earwax impaction, go to* http://www.entnet.org/CerumenCPG.

About the AAO-HNS

The American Academy of Otolaryngology—Head and Neck Surgery (www.entnet.org), one of the oldest medical associations in the nation, represents about 12,000



PATIENT INFORMATION Dos and Don'ts of Earwax (Cerumen)

DO	Know that earwax (cerumen) is normal. Earwax that does not cause symptoms or block the ear canal should be left alone.		
DO	Understand symptoms of earwax impaction (wax blocking the ear): decreased hearing, fullness, ringing in the ear (tinnitus), and distortion/changes to hearing aid function.		
DO	See your health care provider if you have symptoms of hearing loss, ear fullness or ear pain if you are not certain they are from earwax. Otitis media (fluid behind the ear drum), otitis externa (ear canal infection) and sudden inner ear hearing loss can seem like an earwax impaction.		
DO	Ask your provider about ways you can treat your earwax impaction at home. You may have certain medical or ear conditions which may make some options unsafe.		
DO	Seek medical attention if you have ear pain, drainage, or bleeding. These are not symptoms of earwax impaction, and need to be checked out by your health care provider.		
DON'T	Over-clean your ears. Too much cleaning may bother your ear canal, cause infection, and may even increase the chances of earwax impaction.		
DON'T	Put cotton swabs, hair pins, car keys, toothpicks, or other things in your ear. These can all injure your ear and may cause a cut in your ear canal, poke a hole in your ear drum, or hurt the hearing bones, leading to hearing loss, dizziness, ringing, and other symptoms of ear injury.		
DON'T	Use ear candles. Ear candles do not remove earwax and can cause serious damage to the ear canal and drum.		
DON'T	DON'T Ignore your symptoms if home remedies are not helping. Seek medical attention if your symptoms do not go away.		
DON'T	ON'T Irrigate or try earwax-removing/softening drops if you've had previous ear surgery or a hole in your ear drum unless cleared to do so by your ear, nose, and throat surgeon (otolaryngologist).		
DON'T	T Forget to clean your hearing aids as the manufacturer and your hearing health professional recommend.		
SOURCE: Adapted from Schwartz SR, Magit AE, Rosenfeld RM, et al; Clinical Practice Guideline (Update): Earwax (Cerumen Impaction). <i>Otolaryngol Head Neck Surg</i> . 2017;156:S1-S29.			
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The American Academy of Otolaryngology-Head and Neck Surgery (www.entnet.org), one of the oldest medical associations in the nation, represents about 12,000 physicians and allied health professionals who specialize in the diagnosis and treatment of disorders of the ears, nose, throat and related structures of the head and neck. The Academy serves its members by facilitating the advancement of the science and art of medicine related to otolaryngology and by representing the specialty in governmental and socioeconomic issues. The AAO-HNS Foundation works to advance the art, science, and ethical practice of otolaryngology-head and neck surgery through education, researach, and lifelong learning. The organization's vision: "Empowering otolaryngology-head and neck surgeons to deliver the best patient care."

Figure 3. Dos and don'ts of earwax (cerumen).



PATIENT INFORMATION Frequently Asked Questions: Earwax Prevention

FREQUENTLY ASKED QUESTIONS

Should I do anything to my ears to prevent a buildup of earwax?	Your body makes earwax to protect your ear canal skin and kill germs. It is normal to have it. Prevention is best for certain groups of people, but not everyone needs it. Among those who may be helped are the elderly, people with hearing aids, and those with a history of too much earwax. Discuss with your health care provider to determine if you need to have earwax removed.
What will happen if I don't clean my ears?	Most people do not need a regular schedule for preventing earwax buildup. Some people may need to have their ears cleaned at times. Your health care provider may find that you have too much earwax at your regular check-up. You may be treated at that time or sent to another provider for treatment.
What symptoms could be caused by too much earwax?	Common complaints include itching, hearing problems, or a sense of fullness in the ear canal. Other problems that might occur include discharge, odor, cough, or ear pain.
Does it hurt to remove earwax?	The procedures used to remove earwax should not cause any pain. If you are putting a type of liquid into the ear it may feel funny, but should not hurt.
If earwax is removed will my hearing get better?	The type of treatment used to prevent the buildup of wax in your ear should usually not affect your hearing. If your ear canal is completely, or almost completely blocked by too much earwax, then removing the wax will allow your hearing to return to pre-blocked levels.
How often should I remove wax from my ears?	There is no standard course of action for preventing earwax buildup. Most people do not have to do anything unless too much wax develops. Ask your health care provider if there is anything you should do to prevent or reduce earwax.
Is removing earwax costly?	Most procedures use over the counter materials and are not expensive. Your health care provider can help with the choices.
Do cotton swabs remove wax from the ear?	Cotton swabs can remove some wax, but they often just push the wax deeper into the ear and may worsen an impaction or injure the ear canal.
Who can I see to clean my ears?	Many primary care doctors have the ability to irrigate earwax in their clinics. An otolaryngologist (ear, nose, and throat doctor) can remove obstructed earwax.
	SOURCE: Adapted from Schwartz SR, Magit AE, Rosenfeld RM, et al; Clinical Practice Guideline (Update): Earwax (Cerumen Impaction). <i>Otolaryngol Head Neck Surg.</i> 2017;156:S1-S29.
AMERICAN ACADEMY OF OTOLARYNGOLOGY- HEAD AND NECK SURGERY FOUNDATION www.entnet.org	ABOUT THE AAO-HNS/F The American Academy of Otolaryngology-Head and Neck Surgery (www.entnet.org), one of the oldest med- ical associations in the nation, represents about 12,000 physicians and allied health professionals who spe- cialize in the diagnosis and treatment of disorders of the ears, nose, throat and related structures of the head and neck. The Academy serves its members by facilitating the advancement of the science and art of medicine related to otolaryngology and by representing the specialty in governmental and socioeconomic issues. The AAO-HNS Foundation works to advance the art, science, and ethical practice of otolaryngology-head and neck surgery through education, researach, and lifelong learning. The organization's vision: "Empowering otolaryn- gology-head and neck surgeons to deliver the best patient care."





PATIENT INFORMATION Ways to Help Reduce Earwax Buildup

HELPFUL PREVENTION CHOICES

Rubbing alcohol or hydrogen peroxide drops or irrigation

Earwax softening drops/agents

Irrigation with bulb syringe or irrigation kits

Checking of the ear canal for earwax by clinician in hearing aid users

Physically removing earwax by health care provider

NOT ADVISED

Daily olive oil drops or sprays

Ear Candling

Putting any objects in the ears (i.e. cotton-tipped swaps; pens/pen tops; paper clips)

SOURCE: Adapted from Schwartz SR, Magit AE, Rosenfeld RM, et al; Clinical Practice Guideline (Update): Earwax (Cerumen Impaction). Otolaryngol Head Neck Surg. 2017;156:S1-S29.



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Figure 5. Ways to help reduce earwax.

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Patient Presentation and Examination (continued)

A complete examination for presence of cerumen impaction will include the performance of an otoscopic examination to evaluate the condition of the ear, and note the presence, consistency, and accumulation of cerumen. The assessment will also include a discussion of any prior history of trauma or treatment of the ear canal or tympanic membrane. If the patient has a history of ear surgery or prior perforation, consideration should be given to referring the patient to an otolaryngologist for further evaluation and performance of the cerumen removal. If it is determined that cerumen removal is necessary to alleviate or prevent worsening of symptoms, and can be safely performed, removal may be accomplished by one or more of the following:

- Over-the-counter preparations (Debrox®)
- Manual removal with an instrument
- Irrigation with a large syringe or mechanical jet irrigators

Informed Consent for Procedure

A variety of approaches may be used to remove cerumen from the ear canal including softening agents, mechanical removal, suctioning, irrigation or a combination of these methods. Any procedure for removal of cerumen from the ear canal should be considered an invasive procedure with a risk of complication, pain and/or discomfort to the patient. Informed consent is the process of having a healthcare provider fully disclose to the patient: the type of procedure recommended; how it will be performed; known and recognized complications, risks, and side effects; reasonable alternatives to the recommended treatment; and the likely consequences of not receiving treatment. The patient should have an opportunity to have their questions and concerns addressed. This informed consent discussion should take place prior to the procedure and a detailed summary of that discussion documented in the patient's medical record. The patient should also be asked to sign and date, in the presence of a witness, an informed consent form that lists the specific procedure and its corresponding risks, benefits, and reasonable alternatives. The signed informed consent form should also be made part of the patient's medical record. A sample informed consent is attached as **Exhibit B**.

Exhibit B

Informed Consent for Treatment of Ear Impaction

I, the undersigned, consent to the following procedure(s) to the

🗆 Left Ear

🗆 Right Ear

manual removal of cerumen with an instrument
 irrigation with a large syringe or mechanical jet irrigator

to be performed by ______ and their assistants (including Registered Nurses, Licensed Practical Nurses, and Certified Medical Assistants), with knowledge that they will have primary responsibility for my care specific to the stated procedure. ______ has explained to me the nature and purpose of each procedure(s) as well as the substantial risks and possible complications involved, the benefits and the medically reasonable alternative methods of treatment. Alternative treatments, if applicable, were discussed. I have had the opportunity to ask questions and have had them answered to my satisfaction.

The **SUBSTANTIAL RISKS** include, but are not limited to: <u>incomplete removal of cerumen; mild to</u> <u>moderate discomfort during the procedure; bleeding; nausea; vertigo; tinnitus; hearing loss;</u> <u>puncture of the tympanic membrane; damage to the middle or inner ear.</u>

The **POTENTIAL BENEFIT(S)** include but are not limited to: <u>cerumen removal</u>; relief of symptoms.

The **MEDICALLY REASONABLE ALTERNATIVE(s)** options are: <u>over-the-counter cerumen softener;</u> <u>do nothing</u>.

- I understand that the information I have received about risks is not exhaustive and there may be other, more remote risks.
- I have had the opportunity to ask questions regarding the proposed procedure(s) and all my questions have been answered to my satisfaction.
- I have had explained to me and I understand the potential benefits and drawbacks, potential problems related to recuperation, the likelihood of success, the possible results of non-treatment, and any medically reasonable alternatives.
- I acknowledge that no promises, assurances or guarantees have been made to me concerning the results of these procedure(s)/treatment(s)/medication(s).
- I have had an opportunity to discuss/clarify the financial costs for these procedure(s)/treatment(s)/medication(s) and understand and agree to these costs.
- I know the relationship, if any, of my physician or other practitioners, to any teaching facility involved in my care.
- I have read or have had read to me, this Procedure(s) Informed Consent form.
- I hereby consent to receive this treatment and/or medication and I knowingly assume all risks in doing so.

•	I understand that certain significant tasks may be performed by qualified medical		
	practitioners who are not physicians, acting within their scope of practice as permitted by		
	State law and their clinical privileges granted by the hospital.		

CONSENT

I do hereby consent to the above described procedure(s).

By placing my initials at the end of this sentence, I also consent to having observers present during the procedure in accordance with the provider's approval and clinic policy.

Patient Signature	Date	Time
Patient Printed Name		
Staff Witness Signature		
Staff Witness Printed Name	-	
SIGNATURES FOR CONSENT WHEN GIVEN BY REPRESENTATIVE OF	PATIENT	
If patient is unable to consent, complete the following: Patient is a minor, or		
 Patient is a minor, of Patient is unable to consent because: 		
Patient's Representative's Signature		
Representative's Printed Name		Time
Relationship to Patient		
Staff Witness Signature		
Staff Witness Printed Name		
SIGNATURE OF PHYSICIAN WHO OBTAINED CONSENT I certify that the procedure(s) described above, including the subst complications, anticipated results, alternative treatment options (i their attendant risks and benefits, the likelihood of success and the recuperation, were explained by me to the patient or their legal rep	ncluding no possible pr	on-treatment) and oblems related to
Consent obtained with use of interpreter.	Name	of interpreter
Signature of Physician Who Obtained Consent		
Physician Identification Number	Date	Time



Informed Consent (continued)

Generally, manual removal of cerumen is performed on children or adults, who in the opinion of the health care provider would not tolerate irrigation. In the population of adults and young adults, irrigation is generally well tolerated by the patient. Manual removal of cerumen may be considered as a treatment option. If manual removal of the cerumen is attempted and unsuccessful, or the provider and/or the site lacks the specialized equipment and training to perform manual removal of the cerumen, then gentle irrigation may be used to loosen the cerumen, utilizing pressure and gravity to allow the cerumen to flow out of the ear canal. Though complications of cerumen removal are rare, there are some risks and side effects that may happen with curettage or irrigation. These include:

- Incomplete removal of cerumen
- Mild to moderate discomfort during the procedure
- Bleeding
- Nausea
- Vertigo
- Tinnitus
- Hearing loss
- Puncture of the tympanic membrane
- Damage to the middle or inner ear

No treatment is also an option. Though about a third of people with cerumen impaction find that the wax goes away on its own after about 5-7 days, existing symptoms may persist or worsen. Patients may also choose to utilize overthe-counter products, many of which contain cerumen softeners. Little research has been done to determine the effectiveness of these softeners.



Procedure Description and Equipment Used

Ear irrigation is the process of flushing the external ear canal with slightly warm tap water, saline, or a 50/50 solution consisting of warm water and hydrogen peroxide. Ear irrigation can be performed using a 10-60 cc/mL syringe or using an ear irrigation system, like the one pictured below, and commonly used in the ambulatory clinic setting. An irrigation system generally consists of a container or reservoir for irrigation solution with a handle and a tip placed in the affected ear that directs the gently pressurized irrigation solution into the ear canal. This allows the health care provider to regulate the pressure of the solution to reduce the risk of injury to the ear canal.

The patient is provided a basin to hold under the affected ear to capture the fluid and cerumen irrigated out of the ear canal. The temperature of the solution should be checked prior to initiating the irrigation; body temperature or slightly warmer (98.6-100°F [37-37.8°C]) is ideal. A cool irrigation solution is more likely to make the patient dizzy. If this occurs, irrigation should be discontinued and the patient monitored until dizziness subsides. The patient should be instructed to speak up if they experience pain or discomfort. If the irrigation is initially unsuccessful or does not completely remove the cerumen present, the health care provider may also consider instilling water in the external auditory canal for 15-30 minutes and attempt again to irrigate the cerumen. In the alternative, if the irrigation is initially unsuccessful, the health care provider may recommend the use of a cerumenolytic agent at home for 2-3 days, followed by another trial of irrigation with the health care provider. If the cerumen extraction, whether manual or by irrigation, has been performed by a Registered Nurse or Medical Assistant, the ordering health care provider should also examine the ear canal following completion of the procedure.





Documentation and Aftercare

Documentation in the medical record is critical to continuity of care. Thorough documentation related to cerumen extraction will include most or all of the following:

- · Patient's condition prior to any procedures performed
- Indications for performing the cerumen extraction
- Patient history and physical assessment
- Contraindications to the procedure
- Status of the ear canal and the tympanic membrane prior to the procedure
- Type of cerumen management procedure used, including any modifications made to the intervention plan based on any conditions present in the ear canal
- Symptoms or complaints reported by the patient during the procedure (or the absence of any symptoms or complaints)
- Outcome of the procedure, including the amount and characteristics of cerumen removed and the condition of the ear canal at the conclusion of the procedure

Additional documentation may be warranted depending upon the technique or procedure used; for example, if irrigation is the intervention performed, then the type, subjective temperature, and amount of irrigation solution used should be documented. In addition, complications (or the absence of complications) should be documented, along with any unusual findings, such as discovery of unexpected foreign items, including a description (e.g., type and size of foreign item encountered). At the conclusion of the procedure, after care information should be provided to the patient (See example at **Exhibit B**.)

If the initial management is unsuccessful, or the procedure must be aborted, the health care provider should document this, as well as any conversations with the patient in this regard. Health care providers should refer patients with persistent cerumen issues to health care providers who have specialized equipment and training to clean and evaluate ear canals and tympanic membranes. Any referrals, counseling, or recommendations provided to the patient should be documented with a process by which to follow up on the status of their condition within one week, if deemed necessary. Further, if the patient's symptoms persist despite resolution of impaction, the health care provider should consider evaluating the patient for an alternative diagnosis and the patient may be reexamined to determine whether the previously complained of symptoms were caused by the cerumen or some other underlying or overlapping issue. All of this information should be documented by the provider who is performing the procedure, whether the RN or the MA, and such documentation should be reviewed and co-signed by the ordering health care provider.



Sample Documentation

Chief Complaint: Hearing Loss

The patient is a 21 year old with a 3 day history of left-sided hearing loss. Patient denies discharge from the ear, denies fever, and denies history of impacted cerumen. Upon examination, the patient has bilateral cerumen impaction blocking the ear canals, for which ear lavage was offered. The procedure was explained to the patient, including all risks, benefits, alternatives and potential complications. A signed informed consent was obtained from the patient.

In the left ear, utilizing an ear curette/ear hook/forceps, a small/moderate/large amount of cerumen was removed by the provider. The external canal was lavaged with warm water. There was no trauma to the external ear canal during the procedure. Following the procedure, the patient's ear canal was clear and normal. The tympanic membrane was smooth, normal, with no bulging or retraction. The patient tolerated the procedure well and there were no complications.

In the right ear, utilizing an ear curette/ear hook/forceps, a small/moderate/large amount of cerumen was removed by the provider. The external canal was lavaged with warm water. There was no trauma to the external ear canal during the procedure. Following the procedure, the patient's ear canal was clear and normal. The tympanic membrane was smooth, normal, with no bulging or retraction. The patient tolerated the procedure well and there were no complications.

Written ear care instructions were given to the patient and patient was instructed to call the office if there are any problems or questions.

Staff Training and Education

In order to ensure that appropriate care is provided and procedures are appropriately performed, the health care providers performing the irrigation should have received education and training in the procedures, and have demonstrated adequate competency to perform the irrigation. Health care providers, including Registered Nurses, Licensed Practical Nurses, and Certified Medical Assistants, should receive an individual assessment and training to determine their proficiency. This may also be accomplished by a retrospective review of several of that provider's past ear irrigation procedures. Their proficiency is documented as part of their initial orientation and medical privileges. The proficiency of the health care provider should be assessed regularly.



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