Practice Guidance

Aural Care (Ear Wax Removal)

Date: April 2021

Due for review: April 2026

OD104-93

General foreword

This document presents Practice Guidance by the British Society of Audiology (BSA). This Practice Guidance represents, to the best knowledge of the BSA, the evidence-base and consensus on good practice, given the stated methodology and scope of the document and at the time of publication.

Although care has been taken in preparing the information supplied by the BSA, the BSA does not and cannot guarantee the interpretation and application of it. The BSA cannot be held responsible for any errors or omissions, and the BSA accepts no liability whatsoever for any loss or damage howsoever arising. This document is the first published BSA Practice Guidance document on this procedure and stands until superseded or withdrawn by the BSA.

Comments on this document are welcomed and should be sent to:

British Society of Audiology
Blackburn House
Redhouse Road
Seafield
Bathgate
EH47 7AQ
Tel: +44 (0)118 9660622

bsa@thebsa.org.uk
www.thebsa.org.uk

Published by the British Society of Audiology

Authors & Acknowledgments

Produced by: The Professional Guidance Group

Key Authors:
Miss Sarah Riches, Senior Audiologist and Senior Teaching Fellow (SFHEA), Aston University, Birmingham
Mr Martin Whitehouse, ENT Advanced Nurse Practitioner, Sandwell and West Birmingham Hospitals NHS Trust

Declaration of interests:
Sarah Riches: Course co-ordinator of the Basic Aural Care Course and Advanced Aural Care Course at Aston University
Martin Whitehouse: Course Leader of the Basic Aural Care Course and Advanced Aural Care Course at Aston University

Both authors have been involved in aural care training for ENT, other medical professionals, and Audiology professionals since 2003, initially providing this training at Birmingham School of Audiology before the courses were relocated to Aston University.

With thanks to:
All Audiology, ENT and medical professionals who participated in the consultation process. Colleagues in the Pharmacy, Optometry, and Engineering Department (Aston University, Birmingham).

Citation

Please cite this document in the following format:

BRITISH SOCIETY OF AUDIOLOGY (*2019*), Aural Care (Ear Wax Removal). [Online]. Available at: https://www.thebsa.org.uk/resources/ [Accessed *date*]

Contents

1. Introduction

This comprehensive BSA document provides best practice guidelines for safe removal of ear wax (aural care) by professionals trained to complete this activity.

1.1 Background and aims

The purpose of this document is to recommend **safe aural care using simple manual extraction instruments, water irrigation and suction under magnification.**

Ear wax removal is currently an extended scope of practice activity for Audiology professionals, with this activity having previously been undertaken by the nursing or medical profession. The current (2018) National Institute for Health and Care Excellence (NICE) Hearing Loss in Adults; assessment and management guidelines show that certain methods of wax removal are effective in primary and community care settings, and that others should not be used. The clinical evidence supporting current recommended procedures however is of either low or very low quality. NICE also found no robust health economic evidence supporting the use of one technique over another. Therefore, the BSA would advise that practitioners exercise due care and diligence in the adoption of this activity. The BSA advises that practitioners must therefore develop skills via training which meets the minimum training criteria described in BSA (2020) Minimum Training Guidelines in Aural Care Delivered by Hearing Care Professionals.

The term 'must' is used in this document to refer to essential practise, and 'should' is used to refer to desirable practise.

The document was developed with reference to the current (2018) National Institute for Health and Care Excellence (NICE) Hearing Loss in Adults; assessment and management guidelines. In addition, in 2017 a comprehensive Clinical Practice Guideline document was updated and published by The American Academy of Otolaryngology (Head and Neck Surgery) which the authors recommend as further useful reading on this subject.

Unless stated otherwise, this document represents the consensus of expert opinion and evidence as interpreted by the Professional Guidance Group of the British Society of Audiology (BSA) in consultation with its stakeholders.

1.2 Shared Decision-making

It is implied throughout this document that the service user should be involved in shared decision-making when undertaking audiological intervention, receiving subsequent information and understanding how it will impact on the personalisation of care. Individual preferences must be taken into account. The role of the professional is to enable a person to make a meaningful and informed

choice. Audiological interventions bring a variety of information for both the clinician and the service-user which can be used for counselling and decision-making regarding technology and anticipated outcomes. An accurate record must be made of all shared decision-making, intervention and treatment. Where available this must be a digital record.

2. Scope

2.0 Scope of guidance

Children under the age of 18 years are beyond the scope of this document and should only be treated by professionals who have undertaken further training and have the facility and insurance to provide paediatric care within their clinical premises.

Healthcare professionals are required to hold appropriate professional indemnity and public liability insurance. It is important to check with the insurer that the policy covers aural care. The insurance must be specific to the procedure being undertaken and the context in which it is being performed.

Some professionals may have appropriate experience such that their scope of practice may extend beyond the scope covered in this guidance document, under which circumstances they must not rely on this document alone as guidance in good practice. However, it is important aural care practitioners work within their scope of practice at all times.

2.1 Procedural scope

2.1.1 General scope

This document intends to describe methods of ear wax removal for adults and describes contra-indications to the methods covered. It does not extend to the treatment of ear conditions or the removal of foreign bodies.

BSA and the authors also make a further distinction in scope and advise only **necessary** ear wax removal in **routine** ears.

Necessary ear wax removal refers to the removal of ear wax which is:

- occluding the view of the tympanic membrane and external auditory meatus thus preventing their effective examination
- causing the subject to report a blocked/occluded sensation
- reducing the hearing beyond the usual baseline ability of the subject
- causing symptoms considered to be related to the presence of (or occlusion by) wax in the absence of detectable or discernible infection/abnormality

- preventing a required procedure or activity from safely or effectively taking place which may include a hearing test, tympanometry, impression-taking, caloric testing, or fitting of a hearing instrument including probe microphone measurements
- interfering with the performance of a hearing instrument when in situ

Routine as defined by this guidance document refers to ears which have none of the conditions described in the checklist in Appendix B and which, to the best of the practitioner's knowledge through otoscopy (or otherwise magnified view), history-taking and previous case notes (especially if unable to fully observe the tympanic membrane), contain a tympanic membrane which is intact and healthy.

Therefore these practice guidelines do not extend to cover non-routine cases such as:

- perforated ears
- post-surgery ears including provision of post-surgery care/treatment
- removal of foreign objects
- treatment of medical conditions
- removal of discharge or debris caused by acute or chronic ear infections, or which arise from skin conditions such as eczema or psoriasis

This list is not comprehensive. See Appendix B for the complete checklist of contra-indications, and conditions which require caution or an additional risk assessment.

Furthermore, NICE have based their contra-indications on irrigation and recognise that where irrigation is contra-indicated or has been unsuccessful for a subject or is unavailable, other methods such as microsuction or manual removal using simple extraction tools such as a curette may be considered (NICE 2018, NG98).

2.1.2 Methods of ear wax removal

This guidance includes wax removal using:

- simple extraction instruments such as loops, curettes and forceps
- electronic water irrigation machines
- suction devices

This guidance does not include wax removal by:

- manual syringing
- self-irrigation
- Hopi candles

Do not offer manual syringing to remove earwax (NICE 2018, NG98). This method is not considered to be safe based on evidence assessed by NICE. *(Please note that manual syringing and irrigation are not the same process – see Section 10).* NICE recommends further research into the safety of self-irrigation and therefore this should also not be offered. The use of Hopi candles is also considered by NICE to be inappropriate and should not be offered.

It is important to note that aural care practitioners should work within their scope of practice at all times and ensure they understand and communicate the risks associated with the specific procedure(s) they offer.

For example, if only irrigation is offered as a method, then the procedure should not be offered to subjects with the contraindications to irrigation in Appendix B. The individual should be referred to a colleague that provides microsuction or a specialist ear care service or ENT, if appropriate to the condition discovered.

2.2 Professional scope

2.2.1 Registered professionals

The audiology, nursing or medical professional usually undertaking this procedure will be registered with a statutory regulator (e.g. the HCPC, NMC or GMC) or registered on a PSA accredited register (AHCS or RCCP).

2.2.2 Other professionals

All non-registered healthcare professionals or practitioners (e.g. hearing and health care assistants - HCA) must undergo the required training in the wax removal procedure/s and understand the clinical governance arrangements that are in place regarding procedural and professional scope.

2.2.3 Supervision

Further to the points made in Section 2.2.2, those who are supervising staff undergoing training in this activity must ensure that they are available for advice and supervision as required.

Whilst undertaking training in aural care the student must not attempt to undertake aural care activities without the direct supervision of their supervisor until they have completed their training.

2.2.4 Training requirements

Those undertaking the procedure will have completed training in the removal of ear wax via a course which meets the training criteria described in BSA (2020) Minimum Training Guidelines in Aural Care Delivered by Hearing Care Professionals.

2.2.5 Fitness to Practise considerations

As well as being appropriately trained, those undertaking the procedure must ensure that they have sufficient visual ability and manual dexterity to undertake the procedure safely.

This extends to ensuring that the equipment they use (see Section 3.1) meets the correct quality and safety specifications to allow them to examine the ear confidently, and that it is set up correctly for their own vision. Magnification/viewing equipment should have clean lenses and a good light source and should be set up prior to the appointment to meet the practitioner's own visual requirements. This is especially important for shared equipment.

Practitioners must be aware that proceeding without being able to clearly see what they are doing, or proceeding without the required manual strength or dexterity to manipulate the equipment is a Fitness to Practise issue.

Fitness to Practise for this procedure also includes:

A. adherence to infection prevention and control policies and procedures
B. adherence to referral guidelines reflecting recognition of scope of practice
C. adherence to professional standards stipulated by any regulating body and/or employing organisation

3. Equipment and working environment

3.1 Equipment

3.1.1 Infection control related to equipment

Equipment must be kept clean in adherence to local infection control policies and according to the manufacturers' recommendations.

If equipment requires disinfection this must be carried out carefully according to the manufacturer's recommendations. If chlorine cleaning tablets or other decontamination agents are recommended by the manufacturer of the irrigation system or suction system, care should be taken that hands are washed thoroughly afterwards, fumes are not inhaled and contact with the eyes is avoided. If a soaking period is recommended, the system must be left in a safe place to avoid spills. Following the recommended soak time, the system must be thoroughly flushed with clean water and dried.

Single use consumables must not be disinfected or sterilised, and must be disposed of according to local infection control and disposal policies. Single use items must stay in their protective packaging until the point of use.

3.1.2 Fitness for purpose

When purchasing equipment, procurers must be advised that equipment must be *fit for purpose*, and recognised as appropriate for use for removal of bodily secretions and fluids in soft tissue orifices lined with skin or mucous membrane as encountered in the ear, nose or throat. Ideally this equipment should be an ENT grade medical product indicated for use in aural care if available.

3.1.3 Safety and quality specifications and standards

For otorhinolaryngology and endoscopic medical products such as suction units, warm water rinsing devices and nasopharyngoscopes the equipment must meet the following necessary minimum safety and quality standard specifications according to the International Organisation for Standardisation (ISO) and the **C**onformité **E**uropéene CE (translation = European Conformity):

1. The class II medical equipment must possess a CE certificate from an official certification body which confirms that it "meets the requirements of Annex IX, excluding section 4 of the directive 93/42/EEC. The manufacturer of the equipment must be able to prove that they have a quality assurance system which is subject to periodic surveillance, defined by Annex IX, section 5 of the aforementioned directive. For placing on the market of class III devices covered by the certificate a CE design-examination certificate according to Annex IX, section 4 is required." (Standard CE Certificate wording).
2. The equipment must also possess a certificate from an official certification body that it meets the requirements specified in EN ISO 9001:2008, and also EN ISO 13485:2012 and EN ISO 13485:2012/AC:2012

3.1.4 Conformity of equipment

Practitioners must seek to ensure the equipment they intend to use for aural care is appropriately designed and CE-marked as required, and meets the "Fit for purpose" requirements described in Section 3.1.2. The UK Government Medicines and Healthcare products Regulatory Agency (MHRA) guidelines provide comprehensive information about conformity of equipment. Practitioners and service-providing organisations are advised to keep up to date with changes in equipment requirements for aural care. Should they become aware of changes in equipment safety or quality legislation which could affect their practise, they should respond with a plan to phase out equipment and introduce replacement products which conform to the legislation within a reasonable timescale.

3.1.5 Equipment maintenance

A planned preventative maintenance (PPM) schedule must be in place to ensure that equipment is in good working order and checked and replaced regularly.

The aural care procedure must be abandoned immediately if it is suspected or identified that a machine has developed a fault whilst in the process of undertaking the procedure.

3.1.6 Risk assessments

Procedural risk assessments for wax removal must include appropriate use of equipment and should therefore also acknowledge as a potential risk the possibility of inappropriate use of the equipment.

3.2 Environment

Aural care must only be performed where room lighting levels allow safe illumination of the equipment and the ears being treated. This must be further supported by additional light sources e.g. head loupes, otoscopes etc.

For all wax removal methods the environment must be conducive to effective infection control.

There must be appropriate waste and sharps disposal facilities.

For irrigation, there should be easy access to a sink with hot and cold water. Where available, contaminated water from the ear or water infused with decontamination agents should be disposed in a designated sluice.

Infection control and waste management may be more difficult to manage in domiciliary and other settings so adequate appropriate risk assessments must be completed.

4. Preparation for the procedure

4.1 Subject preparation

4.1.1 Consent

Subjects must give informed consent for this procedure. This may be written or oral consent, and should be recorded in the clinical notes.

The risks and benefits of the procedure must be clearly explained to the subject. See Section 7 for details of risks.

Subjects must be advised to report to the GP immediately if discomfort, pain, swelling, discharge or odour, or disruption to the hearing is experienced following any procedure, and also inform the aural care practitioner. If the subject reports straight back to the aural care practitioner and not the GP the practitioner must advise and inspect as appropriate and provide a referral as soon as possible according to the type of symptom reported. See Section 12 regarding advice and aftercare.

See Appendix A for an example of a consent sign-off form. This currently contains all methods described in the guidance and will therefore need to be adapted to reflect the method/s selected or available.

4.1.2 Softening of ear wax prior to the procedure

The advice below assumes that the ear has already been identified by the aural care practitioner as routine according to this guidance document and as classified in Appendix B. This will require a health screen prior to the appointment.

Prior to ear wax removal by irrigation, subjects should be advised to use an ear wax softener unless on examination the wax already appears to be very soft. If pre-examination is not possible subjects must follow the softening advice. This is usually in the form of pharmaceutical olive oil spray or drops, or sodium bicarbonate drops but may also be water. This advice applies unless the subject or practitioner is aware of any known previous reactions to the proposed preparation, in which case additional caution shall be taken by the aural care practitioner when assessing the condition of the wax prior to the procedure. As no softener is considered by NICE to be more effective than another clinical judgement should be used to determine which softener is most appropriate for the subject (NICE 2019 NG98). The softener must be used for up to 5 days prior to the procedure following the manufacturer's guidelines on use which usually involves application between 2 to 4 times daily. If the ear wax remains very firm, water or olive oil can be applied 15 minutes prior to the irrigation procedure to assist the softening process. If wax removal is unsuccessful on the first visit, the softener may be applied for up to a further 5 days. Expert opinion varies regarding the use of olive oil prior to the microsuction procedure or use of simple extraction instruments such as curettes.

The subject must be advised that their ear may feel more occluded following application of an ear wax softener due to the expansion of the ear wax. For some it may also induce fluctuations in their hearing and mild discomfort or irritation. The subject should also be advised that sodium bicarbonate may effervesce in the ear as it comes in to contact with the wax, and may create a chalky deposit. In addition, for subjects who wear hearing instruments, particularly those with receiver in the ear/canal (RITE/RIC) and in the ear/canal (ITE/ITC/CIC) models, olive oil may adversely affect the function of the hearing instrument if it enters the hearing aid. It may be advisable to avoid wearing the hearing instrument when olive oil has recently been administered, therefore overnight use may be advisable.

4.1.3 Position of the subject and practitioner

The practitioner must be seated in a stable position for wax removal, no matter which method of wax removal is being employed. BSA Recommended Procedure for Ear Examination states "The examiner shall adopt a stable position and, unless unavoidable or inappropriate, should be seated when examining the ear using an otoscope". This is also applicable for any method of viewing the ear during aural care. If there are specific ergonomic reasons why this is not possible for an individual or for a particular room this should be investigated and if it cannot be resolved by modifications to the environment it may be more appropriate for the subject to be referred to an alternative provider.

The subject may be lying down on a raised couch, or may be sat upright on a stable chair. The use of a head support on the chair may be useful in some cases but is not essential. For some subjects the use of a head support may decrease rather than increase comfort, unless the chair can be reclined.

If a subject is unable to support their own head steadily in a stable upright position e.g. in the case of someone with Parkinson's disease, the practitioner needs to assess if the head can be supported in any other way to minimise movement of the head and allow safe completion of the procedure. The practitioner will need to assess the subject's neck control, and check for any neck pain before deciding the best course of action.

5. Procedure time

5.1 Routine cases

Adequate time should be allocated to allow the safe removal of the ear wax using whichever method is deemed most suitable by the practitioner. Sometimes a combination of removal methods may be required in order to remove the ear wax and time should be sufficient to allow for a switch in method if required. Providing that the ear wax has been softened sufficiently it should not take longer than half an hour on average to clear both ears. If a noisy procedure such as irrigation or microsuction is chosen, the risk of the potential adverse impact of the noise exposure on the individual should be assessed. Care should be taken to keep the duration of noise exposure to a minimum for all subjects.

It can sometimes be the case that the softener has not completely penetrated a long or very hard plug of ear wax and it may have only softened the outer layers. This means that it is not always possible to remove all of it. In this case it is important to be able to recognise when to cease the procedure and advise further application of the softener so that the remaining ear wax can be removed on a future appointment.

5.2 When a routine ear becomes non-routine

During ear wax removal it can sometimes be the case that an ear considered to be routine as defined by this guidance document is revealed as non-routine as the ear wax comes away. For example a foreign object may be uncovered, or an infection or trauma or other referable abnormality may become visible. If this occurs the procedure should be stopped and the subject must be informed. They should be referred for a medical opinion and for continued treatment according to the condition revealed and the professional referral guidelines, unless the individual has declined onward referral after being advised of the risk, under which circumstances, the advice given and such refusal must be noted in the record. See Appendix A for details.

6. Contra-indications and special care considerations

See Appendix B for a checklist to help identify if an ear is to be considered as routine as defined by this guidance document. Ear wax removal should not be attempted if the ear is identified prior to the procedure as non-routine. See Section 2 for more details on Scope.

As mentioned in Section 2.1.1 and 2.1.2 it is important to note that NICE based its guidance on contra-indications for the irrigation method only, as it was considered in the latest NICE guidelines (see Section 7) to be the primary method adopted in primary and community settings for the removal of wax in adult ears. These contra-indications are incorporated in the checklist in Appendix B. NICE acknowledged that other methods may be used in primary and community care settings if irrigation is unsuccessful or unavailable and recognised that the irrigation contra-indications may not always apply to these methods. Methods to be used or not used are stated in section 2.1.2.

Additional guidance in the checklist in Appendix B is provided by BSA and relates to irrigation, manual extraction using simple hand-held instruments such as loops and curettes, and suction. This additional contra-indications/special care considerations guidance takes into consideration current best practice guidance reviewed during the development of this document, including BAA (2016) and BSHAA (2017) referral criteria.

7. Risks and complications associated with ear wax removal

The following risks and complications are identified and discussed in the 2018 NICE Hearing loss in adults; assessment and management guidelines, the 2016 NICE Clinical Knowledge Summaries, and other practice guidance reviewed during the development of this document.

7.1 Physical trauma

7.1.1 Direct trauma

During any ear wax removal method there is the risk of physical trauma to the skin of the ear canal walls. Manual instruments such as loops, curettes, forceps and Cawthorne Hooks carry the greatest risk of abrasion to the skin, but suction tube appendages, Tumarkin and Rosen speculae, and endoscopes can also cause injury.

Some subjects may be at higher risk of bruising, abrasions and bleeding, such as older adults with thinning skin and individuals with conditions such as diabetes or blood-clotting disorders, those with an immunocompromised state, and those who have had head or neck radiotherapy. Certain types of medication also increase the risk, such as blood anticoagulants and anti-platelets, non-steroidal anti-inflammatory drugs (NSAID), steroids, medicines to treat cancer.

To minimise this risk it is important that the subject position is as stable as possible, either lying on a raised couch or sat in an upright position in a chair. No instrument should be introduced into the ear beyond the line of sight of the professional performing the procedure. Furthermore it is not recommended that instruments are used near the ear drum due to the increased risk of damage due to proximity. See Section 2.0 Scope of guidance, for further information.

7.1.2 Pain and discomfort thresholds

Although subjects should be encouraged to report any pain or discomfort during aural care, thresholds differ between individuals and this may affect how comfortable the aural care procedure is for a subject. For example, as well as an increased risk of bruising and bleeding subjects using blood anticoagulants can be more sensitive to pain as a side-effect (low pain threshold). In contrast, subjects with diabetes will sometimes have a higher pain threshold. Care must be taken to check that the subject remains comfortable throughout the procedure to minimise the risk of physical trauma or distress.

7.2 Pressure trauma

Risk of damage to the tympanic membrane due to pressure from an irrigation or suction device is possible. These are minimised by restricting the depth of insertion of the suction tube and assistive Tumarkin or Rosen speculae.

Risks from water pressure are minimised by ensuring that the irrigator pressure is kept regulated. High pressures from the irrigator are not necessary to remove ear wax from an ear which has been prepared well with softeners. In addition, the water jet from the irrigator should be directed superiorly at the ear canal wall or the wax itself and not at the tympanic membrane.

7.3 Infection

7.3.1 Risk of infection from the procedure

For any ear wax removal method there is the risk of infection developing after the procedure.

Risks can be minimised by ensuring adherence to infection control policies and manufacturer guidelines regarding equipment disinfection, and by ensuring that single use items are kept packaged until the point of use and not re-used. (See Section 3.1.1). Effective audit should be used to ensure that consumable stock is rotated and items are not used if out of date. It is not necessary to use sterilised water for water irrigation.

Infection from *Pseudomonas* or other microbial agents may occur following these procedures. Following water irrigation the ear should be dried using a curette wrapped in cotton wool or can be dried using microsuction if appropriate, to minimise the risk of a *Pseudomonas* bacterial infection forming as a result of water remaining trapped in the ear.

The development of necrotising otitis externa following wax removal, and following irrigation in particular, is possible. Evidence states that the risk is small but the possibility must be considered due to the severity of the impact of this condition.

Risk of infection increases when the skin of the ear canal is already disrupted which is why wax removal on ears with current active skin conditions and abrasions is not recommended.

7.3.2 Other infection risks

Awareness must be maintained regarding the risk of transmission of communicable skin, respiratory and blood conditions/infections. This can be through skin to skin contact, bodily fluid transmission by airborne aerosol droplets or via direct contact with the wax itself. Although only a small amount of studies have been conducted there has been some evidence to suggest the possibility of transmission of the Hepatitis B virus in ear wax, therefore in the interests of safety these findings should be considered. During the pre-aural care checks, all subjects must be asked if they have Hepatitis B, COVID-19, tuberculosis (TB) or MRSA. It is not advisable to proceed if these are reported. Due to the risk of non-disclosure of such conditions all practitioners must take steps to protect themselves and future service users from the risk of transmission. Infection control and clinical waste disposal policies must be adhered to, and the practitioners should consider the use of protective gloves, particularly if their own hands have cuts or abrasions, and consider other personal protective equipment (PPE) such as aprons, fluid resistant face masks which can be worn by the practitioner and/or subject, and eye protection. The practitioner must judge if the viewing method already affords them adequate eye protection and if wearing additional eye protection may actually impede their view of the ear (AIHHP et.al, 2020). It is

also recommended that the practitioner ensures that their vaccinations such as Hepatitis B are up to date.

7.4 Vertigo

Some subjects may experience dizziness as a result of wax removal. Dizziness due to caloric reactions can also arise in some subjects from temperature changes occurring in the ear canal and particularly at the tympanic membrane. Temperature variations can occur in the water used to irrigate the ear, or may arise from changes in temperature created by the suction device.

During the pre-aural care checks all subjects must be asked if they have diabetes (high or low blood sugar), or high or low blood pressure as light-headedness or dizziness associated with these conditions may contribute to dizziness experienced during the aural care procedure.

Although rare, in some subjects dizziness can be induced by the movement of the wax plug itself possibly due to resulting changes of air pressure. In very rare cases, fainting or vomiting may also occur.

If the subject is lying down or in a stable seated position during the procedure this may make these occurrences of dizziness easier to manage.

7.5 Noise exposure

Sound pressure levels created in the ear during irrigation but more particularly during suction have the potential to reach levels of greater than 85 dB A in some cases (Snelling et al. 2009).
Noise levels from this procedure therefore have the potential to exacerbate or trigger existing tinnitus and in rare cases trigger newly presenting tinnitus. These levels also have the potential to cause a temporary hearing threshold shift, or a permanent hearing loss.

Efforts should be made to minimise the time taken to complete the procedure so as to reduce the length of exposure to noise generated by the equipment and procedure, thereby reducing the risk of tinnitus and temporary threshold shift.

7.6 Risks arising from over-cleaning the ear canal

Removal of essential moisture can encourage dryness and irritation of the ear canal skin.

Skin layers may be physically disrupted resulting in the natural microbial flora of the skin surface entering the inner epidermal layers, and therefore possibly leading to the development of otitis externa.

As detailed in Section 2.1, only *necessary* ear wax removal should be performed.

7.7 Other risk considerations

NICE (2016) states confusion, agitation and inability to cooperate as contra-indications to irrigation in a primary or community setting. This could affect the subject's ability to sit still during the procedure. Those subjects with cognitive decline or learning difficulty may not be able to understand the risks and benefits of the procedure to give informed consent, and may be unable to understand or remember the safety instructions. This could also apply to the other wax removal methods described in this guidance and therefore it is not recommended to perform other methods of wax removal on this subject type but advise regarding softening agents instead.

NICE also states hearing in only one ear as a contra-indication to irrigation if that is the ear to be treated as there is a remote chance that irrigation could cause permanent deafness. In this instance it is appropriate to select the least invasive and least noise-generating procedure i.e. use of softeners and manual extraction via simple extraction instruments such as a loop or curette.

8. Methods of viewing the ear during wax removal

Ideally the ear canal should be viewed under magnification through a binocular microscope, or endoscope, either with its own light source or with an additional directional external light source. A more portable option is a head-worn binocular microscope, an electronic microscope, a head loupe, with its own light source, or a portable endoscopic system.

Otoscopy can be used regularly throughout the procedure. Video otoscopy creates a digital record of the appearance of the ear prior to and after the wax removal procedure, and can assist the process of onward referral.

Less commonly now, the viewing equipment may include a simple head torch or head mirror and lamp. This option offers a more limited view during the procedure and may therefore be more appropriate for irrigation and simple wax extraction near to the entrance of the canal.

All of these viewing methods require appropriate training to obtain competency in their use. See Section 2.2.4 regarding training requirements.

9. Manual removal using simple extraction instruments

Please note these are practice guidelines, not step-by-step recommended procedures.

9.1 Subject instruction

The subject must be instructed to remain as still as possible and to keep the practitioner informed of changes in comfort. The practitioner must also regularly visually and verbally monitor the comfort of the subject.

The subject may be lying down on a raised couch, or may be sat upright on a stable chair. The practitioner must also be seated during the procedure. The subject should be able to keep their head still for this procedure to be undertaken safely. The use of a head-rest or pillow may on some occasions be helpful but not essential. See Section 4.1.3 for more detail.

9.2 Method

Safe use of hand-held fine instruments such as loops, curettes and forceps must be demonstrated. When holding the instrument, bracing a finger on the subject's cheek is recommended to steady the hand where it is physically possible to do so, according to the practitioner's hand and finger span and where safety will be improved by doing so.

The pinna should be pulled backwards and upwards to open and straighten the ear canal and improve the line of sight.

The working end of the instrument must be directly applied to the wax itself. Contact of the working end of the instrument with the skin, and proximity and contact with the eardrum must be avoided.

The ear canal should be viewed at all times during this procedure. See Section 8 for methods of viewing the ear during wax removal.

9.3 Variations in method

Use of ear speculae, such as Tumarkin or Rosen speculae, may assist the process by keeping the ear-canal open and the skin protected.

9.4 Limitations of the procedure

This method must only be used to remove ear wax which is within easy reach in the outer regions of the ear canal, within a clear line of sight and of a consistency which is soft enough to extract without causing disruption to the ear structures or discomfort to the patient.

Ear wax may remain adhered to the ear canal walls if the softening preparation has only penetrated the outermost layers of the ear wax obstruction.

The procedure must be abandoned if the subject reports the procedure to be painful, if the ear wax remains too solid to move, is positioned too deeply in the ear canal to avoid close proximity of instruments with the ear drum, or if the usual procedure time has been significantly prolonged.

9.5 Complications of the procedure

Practitioners must not perform this procedure on ears which are not routine as defined by this guidance document unless it is within their current scope of practice. See Section 2.1 and 2.2 for details.

Infection is possible even when ears are routine due to the risk from abrasion by the wax removal instruments. Where the skin of the ear is already traumatised due to existing abrasions, cuts, bruising, inflammation, infection, or where skin conditions such as otitis externa, eczema and psoriasis are currently in their active state (e.g. causing pain, swelling, irritation or discharge), the risk may be increased, therefore these are contra-indications to the procedure. See Section 7.3 regarding risks.

Subjects who take anticoagulant medicines may be at more risk of abrasion, bruising and bleeding with this method if the wax removal instruments come into contact with the skin. Proceed with caution. See 7.1.1 for full list of those subjects at increased risk of physical trauma.

If a subject has a dry, irritable or tickly cough, this method may trigger or exacerbate it due to stimulation of the cough reflex. Proceed with caution.

10. Irrigation using electronic irrigation machines

Please note these are practice guidelines, not step-by-step recommended procedures.

10.1 Subject instruction

The subject must be instructed to remain as still as possible and to keep the practitioner informed of changes in comfort. The practitioner must also regularly visually and verbally monitor the comfort of the subject.

The subject must be sat upright on a stable chair as this procedure may be difficult to perform without getting the subject wet if they are lying down. The subject should be able to keep their head still for this procedure to be undertaken safely. The use of a head-rest may on some occasions be helpful but not essential. The practitioner must also be seated during the procedure. See Section 4.1.3 for more detail.

The subject's shoulder and clothes should be protected from water spillage using absorbent paper on the neck and shoulder, or a cape. They may be asked to hold the water-collecting receptacle securely under their ear during the procedure. A colleague or relative may need to hold this if the subject lacks the dexterity or strength to do this.

10.2 Method

An electronic water irrigator is used to gently circulate water in the ear canal.

The pinna should be pulled backwards and upwards to open and straighten the ear canal and improve the line of sight

The jet tip must rest gently in the inter-tragal notch while the water jet is directed superiorly at the ear canal walls or at the wax itself, and not at the tympanic membrane.

The water jet must enter the ear under regulated pressure according to the pressure gauge on the equipment.

Following water irrigation, the ear should be dry-mopped using a curette wrapped in cotton wool to minimise the risk of a *Pseudomonas* bacterial infection forming as a result of water remaining trapped in the ear. See Section 7.3.1.

10.3 Variations in method

For ear wax which proves difficult to remove, sodium bicarbonate powder may be added to the irrigation water to assist in the reduction of ear wax adherence to the ear canal walls.

10.4 Limitations of the procedure

Ear wax may remain adhered to the ear canal walls if the softening preparation has only penetrated the outermost layers of the ear wax obstruction.

The procedure must be abandoned if the subject reports the procedure to be painful, if the ear wax remains too solid to move, or if the usual procedure time has been significantly prolonged.

10.5 Complications of the procedure

Within the scope of this document, irrigation is not suitable for ears which are not routine as defined by this guidance document.

In particular, harm could occur if water is introduced into an ear where the ear drum is known (or is suspected) not to be intact, e.g. where the ear currently has (or has had) perforations, surgery, where grommets remain in situ, or where cleft palates are present (even if repaired) as water may enter areas of the cranium which would not normally admit water and may create a risk of infection.

Infection from *Pseudomonas* or other microbial agents is possible even when ears are routine and the skin presents originally as intact. Where the skin of the ear is already traumatised due to existing abrasions, cuts, bruising, inflammation, infection, or where skin conditions such as otitis externa, eczema and psoriasis are currently in their active state (e.g. causing pain, swelling, irritation or

discharge), the risk may be increased, therefore these are contra-indications to the procedure. See Section 7.3 regarding risks, and Appendix B.

Careful monitoring of the water temperature should be maintained to reduce the risk of dizziness, even in subjects who do not have existing or known vertigo. The water temperature should be at body temperature 37° C or within a variation tolerance of ideally less than 1 degree Celsius above or below body temperature.

If a subject has a dry, irritable or tickly cough, care must be taken as this method may trigger or exacerbate it due to stimulation of the cough reflex.

Efforts must be made to minimise the time taken to complete the procedure so as to reduce the length of exposure to noise generated by the equipment, and to reduce the risk of triggering new tinnitus or affecting existing tinnitus, or creating a temporary hearing threshold shift.

Care must be taken to keep the water pressure regulated to prevent discomfort or pressure trauma. Midway on a pressure gauge is usually sufficient to remove wax effectively but pressure control varies between devices so seek manufacturer's guidance.

11. Suction

Please note these are practice guidelines, not step-by-step recommended procedures.

11.1 Subject instruction

The subject must be instructed to remain as still as possible and to keep the practitioner informed of changes in comfort. The practitioner must also regularly visually and verbally monitor the comfort of the subject.

The subject may be lying down on a raised couch, or may be sat upright on a stable chair. The practitioner must also be seated during the procedure. The subject should be able to keep their head still for this procedure to be undertaken safely. The use of a head-rest or pillow may on some occasions be helpful but not essential. See Section 4.1.3 for more detail.

11.2 Method

A suction device should be used to extract the ear wax from the ear canal.

The pinna should be pulled backwards and upwards to open and straighten the ear canal and improve the line of sight. The ear canal may also be held open by the insertion of a Tumarkin or Rosen speculum which will also serve to protect the skin of the ear canal.

The working end of the suction instrument must be directly applied to the ear wax itself. Contact with the skin and proximity and contact with the eardrum must be avoided.

The ear canal should be viewed at all times during this procedure. See Section 8 for methods of viewing the ear during wax removal.

11.3 Variations in method

The subject must be able to keep the head still, or be assisted to do so, for the procedure to be undertaken safely. A chair head rest or pillow behind the head can therefore be of help.

11.4 Limitations of the procedure

This method should only be used to remove ear wax which is within a clear line of sight and of a consistency which is soft enough to extract without causing disruption to the ear structures or discomfort to the subject.

Ear wax may remain adhered to the ear canal walls if the softening preparation has only penetrated the outermost layers of the ear wax obstruction.

The procedure must be abandoned if the subject reports the procedure to be painful, if the ear wax remains too solid to move, is positioned too deeply in the ear canal to avoid close proximity of equipment with the ear drum, or if the usual procedure time has been significantly prolonged.

11.5 Complications of the procedure

An aural care practitioner must not perform this procedure on ears which are not routine as defined by this guidance unless it is within their current scope of practice. See Sections 2.1 and 2.2 for details.

Infection is possible even when ears are routine due to the risk from abrasion by the wax removal instruments. Where the skin of the ear is already traumatised due to existing abrasions, cuts, bruising, inflammation, infection, or where skin conditions such as otitis externa, eczema and psoriasis are currently in their active state (e.g. causing pain, swelling, irritation or discharge), the risk may be increased, therefore these are contra-indications to the procedure. See Section 7.3 regarding risks, and Appendix B.

If the subject has troublesome vertigo, this may be triggered or exacerbated by this procedure due to possible caloric effects caused by changing temperatures in the ear canal by the suction device, or by stimulation of local nerves.

Subjects who take anticoagulant medicines may be at more risk of abrasion, bruising and bleeding with this method if the wax removal instruments come into contact with the skin. Proceed with caution. See 7.1.1 for full list of those subjects at increased risk of physical trauma.

If a subject has a dry, irritable or tickly cough this method may trigger or exacerbate it due to stimulation of the cough reflex. Proceed with caution.

Efforts must be made to minimise the time taken to complete the procedure so as to reduce the length of exposure to noise generated by the equipment, and to reduce the risk of triggering new tinnitus, affecting existing tinnitus, or creating a temporary hearing threshold shift.

12. Advice and aftercare

12.1. Immediate aftercare

Immediately following the procedure the subject may feel unsteady and should be advised to avoid fast movements such as sitting up or standing up too abruptly.

Should the subject immediately report discomfort, dizziness, a new appearance of tinnitus or an increase in existing tinnitus, the practitioner must assess if the usual medical referral criteria should be applied. If the patient indicates that their hearing has not returned to their usual baseline once the wax has been removed, a hearing test should be offered and a comparison made to a previous audiogram, if one is available. Tympanometry may also be useful in these cases. If irrigation was used ensure water has drained away before completing any tests.

In the hours or days following the ear wax removal procedure patients must be advised to report to their GP as soon as possible if discomfort, pain, swelling, discharge or odour occurs, or if any disruption to hearing, balance or tinnitus is experienced. This will ensure that ear examination and referral can take place. The subject should also be told to report any symptoms to the aural care provider. All subjects should be given written details of possible post-aural care symptoms to be aware of to take away and given clear advice about how to seek medical advice and inform the aural care provider if symptoms do arise.

12.2. Educating subjects about ear wax management

There is limited advice and evidence available regarding how often ear wax should be removed and also whether regular removal actually encourages the production and accumulation of ear wax, therefore expert opinion varies on these matters.

Subjects should be advised following an ear wax removal episode that a build-up of ear wax may recur in the future and require further management.

Education regarding the prevention and reduction of ear wax levels should be encouraged. This may include advising regular use of softening preparations and regular check-ups. Subjects with non-routine ears should discuss softener options with their pharmacist or GP to ensure over-the-counter treatments are appropriate.

To reduce opportunities for service users to harm themselves, subjects should be advised not to use cotton buds or any other devices to manually remove the wax themselves, not to use self-irrigation methods and not to use Hopi candles (Nice 2018, NG98). Hopi candles do not remove wax from ears and should be strongly discouraged as they are inherently dangerous, as discussed by Ernst (2006) cited by Bandy (2017).

13. References

AIHHP, BAA, BSA, BSHAA (2020) Audiology and otology guidance during Covid-19 from the UK's Audiology Professional Bodies. Available at: https://www.flipsnack.com/bshaa/covid-19_audiology_and_otology_guidance_-_1_may_2020/full-view.html

British Academy of Audiology (2016). Guidelines for Primary Care: Direct Referral of Adults with Hearing Difficulty to Audiology Services [Online]. Available at: https://www.baaudiology.org/app/uploads/2019/07/OD1763_BAA_Primary_Care_Guidance_on_Direct_Referral_of_Adults_with_Hearing_Difficulty_to_Audiology_Services_2016.pdf

British Society of Hearing Aid Audiologists (2017) Referral guidelines for HCPC registered hearing aid dispensers – updated Sept 2017. Available: at https://www.bshaa.com/News/updated-guidance-on-onward-referral

Bandy, Veronica T. 2017. *Handbook of Non-prescription Drugs: An Interactive Approach to Self-Care, 19th Edition*.

Beatrice F, Bucolo S, Cavallo R. Earwax, clinical practice ACTA Otorhinolaryngologica Italica.2009;29 (Suppl 1):1–20

British Society of Audiology (2016) Procedure for processing documents for recommended procedures and guidelines. Available at: https://www.thebsa.org.uk/resources/

British Society of Audiology (2016) Recommended Procedure: Ear Examination. Available at: http://www.thebsa.org.uk/resources/

British Society of Audiology (2020) Minimum Training Guidelines for Aural Care**.** Available at: http://www.thebsa.org.uk/resources/

Clegg A.J. et.al (2010) The safety and effectiveness of earwax removal: a systematic review and economic evaluation. Health Technology Assessment (14) 28

Durand, M.L. (2018). 'Malignant Otitis Externa', in Durand, M.L. & Deschler, D.G. (eds.) Infections of the Ears, Nose, Throat, and Sinuses. Switzerland: Springer, Ch.10, pp.115-131. Available at: https://link.springer.com/content/pdf/10.1007%2F978-3-319-74835-1.pdf

Ernst. E. (2006) Ear candles – a triumph of ignorance over science. Available at: https://www.cambridge.org/core/journals/journal-of-laryngology-and-otology/article/ear-candles-a-triumph-of-ignorance-over-science/CECFD65315BB519D8F4AD491FC2CDDDA

Frisch, C.D., Beadle, B.M. & Gidley, P.W. (2018). 'Radiation Effects on the Temporal Bone', in Gidley, P.W. & DeMonte, F. (eds.) Temporal Bone Cancer. Switzerland: Springer, Ch.30, pp.379-402. Available at: https://link.springer.com/content/pdf/10.1007%2F978-3-319-74539-8.pdf

Gholami-Parizad E et al. (2011) Cerumen as a potential risk for transmission of Hepatitis B virus. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21715280

Guest. J.et al (2004) Impacted wax: composition, production, epidemiology and management QJM. 97:477-488

L. A. Fox (2015) Successful Removal and Complication rates for the Instrumented Wax Removal in the Audiology Clinic. BAA Magazine Summer 2015. 26-27

MRHA (2017) Medical Devices: EU Regulations for MDR and IVDR. What you need to know about the new EU regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR). Updated 24 April 2020. Available at: https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

NICE (2016) Clinical Knowledge Summaries. Available at: https://cks.nice.org.uk/earwax#!scenario:1

NICE (2018) Hearing loss in adults: assessment and management. Available at: https://www.nice.org.uk/guidance/ng98

Rubin, J., Yu, V.L., Kamerer, D.B. & Wagener, M. (1990). Aural irrigation with water: a potential pathogenic mechanism for inducing malignant external otitis? Annals of Otology, Rhinology, and Laryngology. 99, pp.117-119

Schwartz SR, Mait AE, Rosenfield RM, et.al. (2017) Clinical practice guideline (update): Earwax (cerumen impaction). Otolaryngol Head Neck Surg. 2017;156 (1):S1-S29

Snelling JD, Smithard A, Waddell A. (2009) Noise levels generated within the external auditory canal during microsuction aural toilet and the effect on hearing: a prospective controlled series. Clinical Otolaryngology 2009; 34:21-5

Wright T (2015) Ear wax. Systematic review 504.BMJ Clinical Evidence. Available at https://www.bmj.com/content/351/bmj.h3601.full

Appendices (see pages 29-33)

Appendix A

CONSENT FORM FOR EAR WAX REMOVAL

Your Aural Care Practitioner has discussed with you the need to remove wax from your ears.
In order to check that it is safe to proceed you will be asked some questions about the health of your ears and general health. It is also necessary to carry out a detailed visual inspection of your ear/s and the wax present. If safe to do so, wax will be removed from your ear/s using the safest and most appropriate method for the quantity and consistency of the wax discovered.

Three methods of wax removal may be used, and these are sometimes used in combination:

Removal of wax deposits using manual extraction instruments
Fine hand-held instruments are inserted carefully into your ear and used to gently extract the wax from the ear canal

Wax removal using suction
Wax is removed from the ear by suction from the tube. This procedure can be noisy.

Wax removal using irrigation
A fine jet of water is gently circulated around the ear canal to loosen and remove the wax deposit. This procedure can also be noisy.

Your Aural Care Practitioner has undertaken training in wax removal and will use best-practice procedures to minimise any risk of harm. However, even when performed with the utmost care, there are risks involved in wax removal. These risks include:

- damage to skin of the ear canal or the ear-drum during the procedure
- infection of the ear canal or other ear structures following the procedure
- temporary reduction in hearing
- permanent reduction in hearing
- temporary dizziness and (rarely) possible sickness or fainting
- triggering of new tinnitus or temporary aggravation of existing tinnitus
- temporary irritation to the throat, especially if already dry, tickly or sensitive

If the wax cannot be removed

Sometimes, depending on the amount and consistency of the wax and your own comfort, it may not be possible to remove all of the wax in one visit. If this situation occurs the Aural Care Practitioner will stop the procedure and you will be advised to continue to use a wax softener for a few days and return to have the remainder removed.

Reasons to refer you to another professional or service

Sometimes it may be necessary to reject you for this procedure. Most commonly this is because:

- medical referral conditions have been discovered in the health screen prior to undertaking the procedure which indicate it is unsafe to proceed

It may also be necessary to refer you to a medical professional for further management following this procedure. Most commonly this is because:

- evidence of a recent or previous infection has been discovered
- evidence of recent or previous damage or disruption to the ear has been discovered
- the wax removal procedure has made you feel unwell
- the wax is too difficult to remove without discomfort
- a foreign object has been discovered in the ear

Please tick the box to confirm:

☐ I have read the information above and understand there are risks involved. I give my consent to allow the Aural Care Practitioner to remove wax from my ear using the safest and most appropriate method for the amount and consistency of wax discovered.

☐ I understand that the removal may take more than one visit and that it may be necessary to refer me to a medical professional if any complications arise.

☐ I agree to have the image of my ear recorded by a video otoscope before and after the procedure, and give my consent for those images to be stored digitally in my clinical notes.

Name (please print): ……

Signed: ……

Date signed: ……

Appendix B

EAR WAX REMOVAL BY MANUAL EXTRACTION INSTRUMENTS, WATER IRRIGATION OR SUCTION

Checklist to ensure ears are **routine** as defined by BSA (2020) Practice Guidance - Aural Care (Ear Wax Removal)

Where † appears this is a contraindication to irrigation according to NICE.

Where * appears irrigation can be undertaken with caution according to NICE (NICE 2018, NG98)

Condition:	**Method this condition contra-indicates:**	**Condition not present or reported** **Proceed with aural care**	**Condition is present or reported** **Do not proceed** (***Refer for medical advice and/or to other services for aural care)***	**Further risk assessment required (see section below relating to this)**
Presence of a foreign object †	All			
Ear surgery (unless isolated to the pinna and in which case must not be within last 90 days) †	All			
Middle ear infection (current or within last 6 weeks) †	All			
Outer ear infection - current	All			
Outer ear infection – recurrent history*	N/A	NB: Irrigate with caution or use other method if available		
Acute otitis externa plus oedematous earcanal and painful pinna †	All			
A mucus discharge from the ear (within last 12 months) †	All			
Current active eczema or psoriasis (e.g. currently causing pain, swelling, irritation or discharge)	All			
Abrasions or inflammation of the ear-canal (current or within the last 90 days)	All			

Abnormal bony or skin growths, including polyps	All			
Significant ear pain (current or within last 90 days) considered to be un-related to the build-up of ear wax.	All			
Communicable blood or skin condition/infection such as Hepatitis B, MRSA.	All			
Communicable respiratory infection such as COVID-19 or tuberculosis (TB)	All			
Cleft palate even if repaired †	Irrigation	NB: Use manual extraction or suction only		
Perforations or recently healed perforations (current or within the last 90 days) †	Irrigation Suction	NB: Use manual extraction only		
Grommet (currently in situ or within last 90 days) †	Irrigation Suction	NB: Use manual extraction only		
Troublesome vertigo (current or recurrent history) *	Irrigation Suction	NB: Use manual extraction only		
Troublesome tinnitus affected by noise exposure *	Irrigation Suction	NB: Use manual extraction only		
Hearing in only one ear if it is the ear to be treated (remote chance that treatment could cause permanent deafness) †	Irrigation Suction	NB: Use manual extraction only		
Confusion, agitation, inability to cooperate †	All			
If the following conditions are present/reported, a further risk assessment is required:	**Conditions affected**			**Decision after further risk assessment:** **e.g. proceed or refer for medical advice and/or to other services for aural care**
History of any previous complications from wax removal procedures (e.g.	All			

pain, perforation, severe vertigo, appearance of new tinnitus, or a permanent worsening of existing tinnitus, or other)) †				
Poor head and neck control (unable to hold head in a stable position when sat or lying down)	All			
Current neck pain	All			
Dry, tickly or irritable throat	All			
Diabetes †	All			
Immunocompromised state †				
Anticoagulant or blood thinning medication such as warfarin, heparin, clopidogrel, dabigatran, rivaroxaban and apixaban	All			
Any condition which prevents or slows down the clotting of blood such as Haemophilia	All			
Head or neck radiotherapy	All			
High or low blood pressure unless effectively regulated by medication	All			

NB: The guidance below is for Aural Care Practitioners only. Separate the following information from the checklist above before use with individuals requiring wax removal.

Please refer to Section 2.1.1 and 2.1.2, Section 6 and Section 7 for further information when interpreting this checklist.

For those conditions indicated where a further risk assessment is required, it may be possible to proceed based on the clinical judgement of the aural care practitioner. The risk in proceeding in their own environment with their own equipment, training, competence, and experience should be self-assessed. Any additional risk will be discussed with the individual requiring wax removal in order to obtain further consent to proceed.

Practitioners must not proceed with aural care if they are in any way unsure about the procedure being safe for the individual that they are considering it for.