National Institute for Health and Care Excellence

Final version

Hearing loss

Hearing loss in adults: assessment and management

NICE guideline NG98

Methods, evidence and recommendations

June 2018

Final version

Developed by the National Guideline Centre, hosted by the Royal College of Physicians

Update information

October 2023: We updated the recommendation on considering suspected cancer pathway referral for adults of Chinese or south-east Asian family origin with hearing loss and a middle ear effusion not associated with an upper respiratory tract infection in line with NHS England's standard on faster diagnosis of cancer. People should have a diagnosis or ruling out of cancer within 28 days of referral.

See https://www.nice.org.uk/guidance/ng98 for all current recommendations and the evidence behind them.

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and, where appropriate, their carer or guardian.

Local commissioners and providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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1 Guideline summary

1.1 Full list of recommendations

Immediate, urgent and routine referral

1. Refer adults with sudden onset or rapid worsening of hearing loss in one or both ears, which is not explained by external or middle ear causes, as follows:
    - If the hearing loss developed suddenly (over a period of 3 days or less) within the past 30 days, refer immediately (to be seen within 24 hours) to an ear, nose and throat service or an emergency department.
    - If the hearing loss developed suddenly more than 30 days ago, refer urgently (to be seen within 2 weeks) to an ear, nose and throat or audiovestibular medicine service.
    - If the hearing loss worsened rapidly (over a period of 4 to 90 days) refer urgently (to be seen within 2 weeks) to an ear, nose and throat or audiovestibular medicine service.
2. Refer immediately (to be seen within 24 hours) adults with acquired unilateral hearing loss and altered sensation or facial droop on the same side to an ear, nose and throat service or, if stroke is suspected, follow a local stroke referral pathway. For information about diagnosis and initial management of stroke, see the NICE guideline on stroke and transient ischaemic attack in over 16s.
3. Refer immediately (to be seen within 24 hours) adults with hearing loss who are immunocompromised and have otalgia (ear ache) with otorrhoea (discharge from the ear) that has not responded to treatment within 72 hours to an ear, nose and throat service.
4. Consider making an urgent referral (to be seen within 2 weeks) to an ear, nose and throat service for adults of Chinese or south-east Asian family origin who have hearing loss and a middle ear effusion not associated with an upper respiratory tract infection. For information about recognition and referral for suspected cancer, see the NICE guideline on suspected cancer.
5. Consider referring adults with hearing loss that is not explained by acute external or middle ear causes to an ear, nose and throat, audiovestibular medicine or specialist audiology service for diagnostic investigation, using a local pathway, if they present any of the following:
    - unilateral or asymmetric hearing loss as a primary concern
    - hearing loss that fluctuates and is not associated with an upper respiratory tract infection
    - hyperacusis (intolerance to everyday sounds that causes significant distress and affects a person's day-to-day activities)
    - persistent tinnitus that is unilateral, pulsatile, has significantly changed in nature or is causing distress
    - vertigo that has not fully resolved or is recurrent
    - hearing loss that is not age related

6. Consider referring adults with hearing loss to an ear, nose and throat service if, after initial treatment of any earwax (see recommendations 15-19 on removing earwax) or acute infection, they have any of:

   - partial or complete obstruction of the external auditory canal that prevents full examination of the eardrum or taking an aural impression
   - pain affecting either ear (including in and around the ear) that has lasted for 1 week or more and has not responded to first-line treatment
   - a history of discharge (other than wax) from either ear that has not resolved, has not responded to prescribed treatment or recurs
   - abnormal appearance of the outer ear or the eardrum, such as:

   i. inflammation

   ii. polyp formation

   iii. perforated eardrum

   iv. abnormal bony or skin growths

   v. swelling of the outer ear

   vi. blood in the ear canal.

   - a middle ear effusion in the absence of, or that persists after, an acute upper respiratory tract infection.

MRI

7. Offer MRI of the internal auditory meati to adults with hearing loss and localising symptoms or signs (such as facial nerve weakness) that might indicate a vestibular schwannoma or CPA (cerebellopontine angle) lesion, irrespective of pure tone thresholds.

8. Consider MRI of the internal auditory meati for adults with sensorineural hearing loss and no localising signs if there is an asymmetry on pure tone audiometry of 15 dB or more at any 2 adjacent test frequencies, using test frequencies of 0.5, 1, 2, 4 and 8 kHz.

Subgroups

9. Consider referring adults with diagnosed or suspected dementia or mild cognitive impairment to an audiology service for a hearing assessment, because hearing loss may be a comorbid condition.

10. Consider referring adults with diagnosed dementia or mild cognitive impairment to an audiology service for a hearing assessment every 2 years if they have not previously been diagnosed with hearing loss.

11. Consider referring people with a diagnosed learning disability to an audiology service for a hearing assessment when they transfer from child to adult services, and then every 2 years.

Early versus delayed management of hearing loss

12. For adults who present for the first time with hearing difficulties, or in whom you suspect hearing difficulties:

   - exclude impacted wax and acute infections such as otitis externa, then
   - arrange an audiological assessment (for more information on audiological assessment see recommendation 13) and

- refer for additional diagnostic assessment if needed (see recommendations 1-6 on sudden or rapid onset of hearing loss and hearing loss with specific additional symptoms or signs).

Communications difficulties and limitations in function

13. Include and record the following as part of the audiological assessment for adults:
    - a full history including relevant symptoms, comorbidities, cognitive ability, physical mobility and dexterity
    - the person's hearing and communication needs at home, at work or in education, and in social situations
    - any psychosocial difficulties related to hearing
    - the person's expectations and motivations with respect to their hearing loss and the listening and communication strategies available to them
    - any restrictions on activity, assessed using a self-report instrument such as the Glasgow Hearing Aid Benefit Profile or the Client-Orientated Scale of Improvement
    - otoscopy
    - pure tone audiometry
    - tympanometry if indicated.
14. After the audiological assessment:
    - discuss with the person:
    i. the pure tone audiogram and the impact their hearing loss might have on communication
    ii. hearing deficits (such as listening in noisy environments) that are not obvious from the audiogram
    iii. options for managing their hearing needs, such as acoustic or bone conduction hearing aids, assistive listening devices and communication strategies, and the potential benefits and limitations of each option.
    iv. options for managing single-sided deafness if needed
    v. referral for implantable devices such as cochlear implants, bone-anchored hearing aids, middle-ear implants or auditory brain stem implants, if these might be suitable (see NICE's technology appraisal guidance on cochlear implants for children and adults with severe to profound deafness and interventional procedure guidance on auditory brain stem implants)
    vi. referral for medical or surgical treatments, if these might be suitable
    - agree and record a personalised care plan, taking into account the person's preferences, including goals, and give the person a copy.

Management of earwax

15. Offer to remove earwax for adults in primary care or community ear care services if the earwax is contributing to hearing loss or other symptoms, or needs to be removed in order to examine the ear or take an impression of the ear canal.

16. When carrying out ear irrigation in adults:

- use pre-treatment wax softeners, either immediately before ear irrigation or for up to 5 days beforehand
- if irrigation is unsuccessful:

i. repeat use of wax softeners or

ii. instil water into the ear canal 15 minutes before repeating ear irrigation

- if irrigation is unsuccessful after the second attempt, refer the person to a specialist ear care service or an ear, nose and throat service for removal of earwax.

17. Consider ear irrigation using an electronic irrigator, microsuction or another method of earwax removal (such as manual removal using a probe) for adults in primary or community ear care services if:

- the practitioner (such as a community nurse or audiologist):

i. has training and expertise in using the method to remove earwax

ii. is aware of any contraindications to the method

- the correct equipment is available.

18. Do not offer adults manual ear syringing to remove earwax.

19. Advise adults not to remove earwax or clean their ears by inserting small objects, such as cotton buds, into the ear canal. Explain that this could damage the ear canal and eardrum, and push the wax further down into the ear.

Sudden sensorineural hearing loss

20. Consider a steroid to treat idiopathic sudden sensorineural hearing loss in adults.

Information and support

21. Give the person and, if they wish, their family or carers, information about:

- the causes of hearing loss, how hearing loss affects the ability to communicate and hear, and how it can be managed
- organisations and support groups for people with hearing loss.

22. Follow the principles on tailoring healthcare services for each person and enabling people to actively participate in their care in the NICE guideline on patient experience in adult NHS services by, for example:

- taking into account the person's ability to access services and their personal preferences when offering appointments
- taking measures, such as reducing background noise, to ensure that the clinical and care environment is conducive to communication for people with hearing loss, particularly in group settings such as waiting rooms, clinics and care homes
- establishing the most effective way of communicating with each person, including the use of hearing loop systems and other assistive listening devices
- ensuring that staff are trained and have demonstrated competence in communication skills for people with hearing loss

- encouraging people with hearing loss to give feedback about the health and social care services they receive, and responding to their feedback.

Assistive listening devices

23. Give adults with hearing loss information about assistive listening devices such as personal loops, personal communicators, TV amplifiers, telephone devices, smoke alarms, doorbell sensors, and technologies such as streamers and apps.

24. Tell adults with hearing loss about organisations that can demonstrate and provide advice on how to obtain assistive listening devices, such as social services, the fire service, or the government through programmes such as Access to Work or Disabled Student Allowance.

Hearing aids

25. Offer hearing aids to adults whose hearing loss affects their ability to communicate and hear, including awareness of warning sounds and the environment, and appreciation of music.

26. Offer 2 hearing aids to adults with aidable hearing loss in both ears. Explain that wearing 2 hearing aids can help to make speech easier to understand when there is background noise, make it easier to tell where sounds are coming from, and improve sound quality.

27. For adults with hearing loss in both ears who chose a single hearing aid, consider a second hearing aid at the follow-up appointment.

Hearing aid microphone and noise reduction algorithms

28. When prescribing and fitting hearing aids, explain the features on the hearing aid that can help the person to hear in background noise, such as directional microphone and noise reduction settings.

29. Advise adults with hearing aids about choosing microphone and noise reduction settings that will meet their needs in different environments, and ensure that they know how to use them.

Monitoring and follow-up

30. Offer adults with hearing aids a face-to-face follow-up audiology appointment 6 to 12 weeks after the hearing aids are fitted, with the option to attend this appointment by telephone or electronic communication if the person prefers.

31. For adults with hearing loss who have chosen a management strategy other than hearing aids, such as assistive listening devices or communication strategies, offer a follow-up appointment when the effectiveness of the device or strategy can be evaluated.

32. Tell adults with hearing loss who have chosen not to have a hearing aid or other device how to contact audiology services in the future.

33. Consider having a system in place for recalling people with hearing devices for regular reassessment of hearing needs and devices.

Interventions to support the use of hearing aids

34. Consider using motivational interviewing or engagement strategies and goal setting when discussing hearing aids with adults for the first time, to encourage acceptance and use of hearing aids.

35. Show the hearing aids when they are first offered and discuss their suitability with the person.

36. At the follow-up audiology appointment for adults with hearing aids:

- ask the person if they have any concerns or questions
- address any difficulties with inserting, removing or maintaining their hearing aids
- provide information on communication, social care or rehabilitation support services if needed
- tell the person how to contact audiology services in the future for aftercare, including repairs and adjustments to accommodate changes in their hearing
- ensure that the person's hearing aids and other devices meet their needs by checking:

i. the comfort, sound quality and volume of hearing aids, including microphone and noise reduction settings, and fine-tuning them if needed

ii. hearing aid cleaning, battery life and use with a telephone

iii. use of assistive listening devices

iv. hours the hearing aid has been used, if shown by automatic data-logging

- review the goals identified in the personalised care plan and agree how to address any that have not been met (for information on the personalised care plan see recommendation 14).
- update the personalised care plan and provide them with a copy.

37. Give adults with hearing aids information about getting used to hearing aids, cleaning and caring for their hearing aids, and troubleshooting.

Key research recommendations

1. In adults with hearing loss, does the use of hearing aids reduce the incidence of dementia?
2. What is the prevalence of hearing loss among populations who under-present for possible hearing loss?
3. What is the clinical and cost effectiveness of microsuction compared with irrigation to remove earwax?
4. What is the most effective route of administration of steroids as a first-line treatment for idiopathic sudden sensorineural hearing loss?
5. What is the clinical and cost effectiveness of monitoring and follow-up for adults with hearing loss post-intervention compared with usual care?

For the full list of research recommendations please see appendix Q.

2 Introduction

Impact

Hearing loss is a major public health issue affecting about 9 million people in England. Because age-related hearing loss is the single biggest cause of hearing loss, it is estimated that by 2035 there will be around 13 million people with hearing loss in England – a fifth of the population.[86] Hearing loss ranks second in terms of prevalence of impairment globally and is third for disease burden in England (years lived with disability).[48]

Hearing loss has a significant impact on individuals leading to difficulty with communication at work, socially and at home. This can affect family relationships, employment or educational opportunities, enjoyment of leisure pursuits such as music and family gatherings, and independence. Hearing loss can cause feelings of isolation and low self-esteem and can lead to a significant reduction in people's quality of life.

Research shows that hearing loss doubles the risk of developing depression and increases the risk of anxiety and other mental health issues.[28, 34, 56, 113] Research also suggests that the use of hearing aids reduces these risks.[56] Although hearing loss affects all ages it is more prevalent in older people and there is an association between hearing loss and cognitive performance as well as dementia.[74] This association is more marked with more severe hearing loss.[73]

It is estimated that in 2013 the UK economy lost more than £28.4 billion in potential output because of high unemployment rates among people with hearing loss.[59] The cost may be higher if rates of underemployment are also taken into account. These high rates of unemployment and underemployment reflect the communication and participation difficulties experienced by people with hearing loss. One recent study estimated that the cost of hearing loss to society in 2013 was more than £136 million when considering the costs of GP and social services. In addition the cost of a reduced quality of life as a consequence of hearing loss was estimated at £26 billion.[7]

The vast majority of permanent hearing loss is bilateral (in both ears) and progresses slowly, with the most common complaint of adults with hearing loss being difficulty in hearing speech against a background of other noise. It can take time for people to accept they have a difficulty and studies have found that on average there is a 10 year delay in people aged 55 to 74 years seeking help for their hearing loss.[28, 38] Studies have identified that between 30% and 45% of adults who report hearing problems to their GP are not referred to NHS hearing services, with reports that they are advised to wait until their symptoms are more severe.[14, 34, 86] The figures are worse for those under 75 years of age. Only 1 in 3 adults who would benefit from hearing aids has had them prescribed and fitted.[28]

Pathways

The main referral pathway for an adult with hearing loss is directly from their GP to local audiology services, although some areas have adopted open access where people do not need a GP referral to access audiological care For those who require medical input, referral is direct to ear, nose and throat (ENT) or audiovestibular medicine services with referral coming from GPs or audiologists. In many cases the hearing loss can be managed by the local service in parallel with medical investigation or treatment, but in other cases, where audiological care is complicated, access to specialist audiology services is important. Each local area will have their own care pathway developed around the skills and expertise available within the different services.

Audiology services are provided in a number of NHS settings. In some parts of England this is through the AQP (any qualified provider) scheme, which means that people have a choice of providers ranging from traditional hospital or clinic-based audiology services, to independent high street

providers. Basic assessment for hearing loss includes, as a minimum, a history, examination of the ears, pure tone audiometry and, if required, tympanometry. In addition, it is important to establish if the individual recognises a hearing problem and if they are ready and willing to seek help. Primary management of hearing loss involves provision of hearing aids through the NHS by audiology services.

The findings on pure tone audiometry are often summarised using descriptors such as mild, moderate, severe or profound; however, this classification should not be used as the sole determinant for the provision of hearing support because this is not a reliable indicator of the difficulty experienced with communication in background noise. Although important, assessment of functional hearing and impact of the loss on the individual is variable and currently does not always occur routinely.

Management pathways for adults with disabling hearing loss vary. In general, if there is hearing loss in both ears, hearing aids are recommended for both ears, unless there are reasons why this is inappropriate. However, in some areas of the country, adults are not offered NHS hearing aids for disabling hearing losses where the pure tone audiogram findings are described as mild or moderate, while others are offered 1 hearing aid rather than 2. Low uptake of hearing aids and adherence to treatment are often dependent on the individuals' recognition of their loss as well as the support given. Hearing aids are sometimes trialled but discontinued because the person has not had advice about strategies to improve hearing and listening nor the aftercare necessary to enable effective use of the hearing aids.

Referral to secondary care allows access to a range of services which include ear nose and throat surgery, audiovestibular medicine, specialist audiology, hearing therapy and psychology. Referral into these services occurs for several reasons. It may be important to determine the cause of the hearing loss particularly in younger people and in those with sudden or progressive hearing losses. For some, surgery may offer treatment to improve hearing or prevent deterioration. For those whose hearing loss is too severe to benefit from hearing aids available through local audiology services there is the question of implantable devices such as cochlear implants, bone anchored hearing aids or middle ear implants. In addition, secondary care may provide additional specialist support for those with tinnitus and hyperacusis and those with complex needs.

Causes

Treatable difficulties in hearing can arise from problems such as occluding earwax or infection which can be managed in primary care. However, the identification and management of these causes of hearing difficulty is not always robust, leading to some people waiting a long time to see a specialist when they could have been treated successfully in primary care. When earwax or infection prevents the use of hearing aids it compounds the difficulties faced by those with hearing loss; delay in resolving the problem can have a significant impact.

In this guideline we consider 'diagnosis' to refer to the medical diagnosis of the underlying cause, or the aetiology, of the condition. When hearing is measured and a loss discovered, this is referred to as 'identification'. Identifying a hearing loss is not an end point in itself and it is important to consider what has caused the loss. For the majority, this will be permanent damage due to ageing, noise exposure or both, but for others there may be an underlying pathology, for example, middle ear disease, or hearing loss may be part of a significant systemic illness, such as autoimmune or renal disease, or the first symptom of neurological disease, or it may have a specific genetic cause. Addressing the diagnosis is beyond the scope of this guideline but is important because treatment will affect the eventual outcome for the individual and their family. It is for this reason that we have considered the symptoms and signs that should alert a GP or audiologist to the need for a medical assessment by an ENT surgeon or an audiovestibular physician, without wishing to limit discretion in other cases.

Summary

Variations in assessment and management pathways for hearing loss can have a major impact, adversely affecting individuals' outcomes and prognoses, and contributing to the overall financial and psychological burden of hearing loss. Encouraging people to seek help early, and identifying the correct routes of referral and optimal management pathways for people with hearing loss is therefore very important.

This guideline explores the most urgent questions about referral, assessment and management of hearing loss in adults in order to offer best practice advice. It cannot address the whole topic. One of the issues the guideline committee has encountered when preparing this guideline is that the quality of evidence on which to base recommendations is not high in many areas. There is scope for more robust research in all areas.

This guideline seeks to inform people with hearing difficulties, their families and carers, all healthcare professionals dealing with adults, social care professionals and commissioners of health and social care services about best practice in assessing and managing hearing loss. It is important that audiological care is patient-centred and that people should have the opportunity to make informed decisions about their care and treatment in partnership with their healthcare professionals (NICE guideline CG138) and this is reflected in the guideline.

3 Development of the guideline

3.1 What is a NICE guideline?

NICE guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS – from prevention and self-care through primary and secondary care to more specialised services. These may also include elements of social care or public health measures. We base our guidelines on the best available research evidence, with the aim of improving the quality of healthcare. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions.

NICE guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional.

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- A guideline topic is referred to NICE from NHS England.
- Stakeholders register an interest in the guideline and are consulted throughout the development process.
- The scope is prepared by the National Guideline Centre (NGC).
- The NGC establishes a guideline committee.
- A draft guideline is produced after the group assesses the available evidence and makes recommendations.
- There is a consultation on the draft guideline.
- The final guideline is produced.

The NGC and NICE produce a number of versions of this guideline:

- The 'full guideline' contains all the recommendations, plus details of the methods used and the underpinning evidence.
- The 'NICE guideline' lists the recommendations.
- 'Information for the public' is written using suitable language for people without specialist medical knowledge.
- NICE Pathways bring together all connected NICE guidance.

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk.

3.2 Remit

NICE received the remit for this guideline from NHS England. NICE commissioned the NGC to produce the guideline.

The remit for this guideline is: to produce a guideline on the assessment and management of hearing loss (adult presentation).

3.3 Who developed this guideline?

A multidisciplinary guideline committee comprising health professionals and researchers as well as lay members developed this guideline (see the list of guideline committee members and the acknowledgements).

The National Institute for Health and Care Excellence (NICE) funds the National Guideline Centre (NGC) and thus supported the development of this guideline. The committee was convened by the NGC and chaired by Katherine Harrop-Griffiths in accordance with guidance from NICE.

The group met approximately every 6 weeks during the development of the guideline. At the start of the guideline development process all committee members declared interests including consultancies, fee-paid work, shareholdings, fellowships and support from the healthcare industry. At all subsequent committee meetings, members declared arising conflicts of interest.

Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in appendix B.

Staff from the NGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, systematic reviewers (research fellows), health economists and information specialists. They undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate and drafted the guideline in collaboration with the committee.

3.3.1 What this guideline covers

The guideline covers the key areas of:

- Initial assessment (first presentation) and referral from primary care.
- Further assessment of hearing and communication needs.
- Management of hearing difficulties.

The following groups are covered:

- Adults (aged 18 years and older) with hearing loss, including those with onset before the age of 18 but presenting for the first time in adulthood.

For further details please refer to the scope in appendix A and the review questions in section **4.1**.

3.3.2 What this guideline does not cover

The guideline does not cover:

- Tinnitus (without hearing loss).
- Vertigo (without hearing loss).
- Acute temporary hearing loss caused by traumatic head injuries, for example perforated tympanic membranes or middle ear effusions.
- Management of disease processes underlying hearing loss.
- Surgical management of hearing loss.
- Screening programmes for hearing loss.

The following groups are not covered:

- Adults who presented with hearing loss before the age of 18.

3.3.3 Relationships between the guideline and other NICE guidance

Related NICE technology appraisals:

- Cochlear implants for children and adults with severe to profound deafness. NICE technology appraisal guidance 166 (2009).

Related NICE interventional procedures guidance:

- Auditory brain stem implants. NICE interventional procedure guidance 108(2005).

Related NICE guidelines:

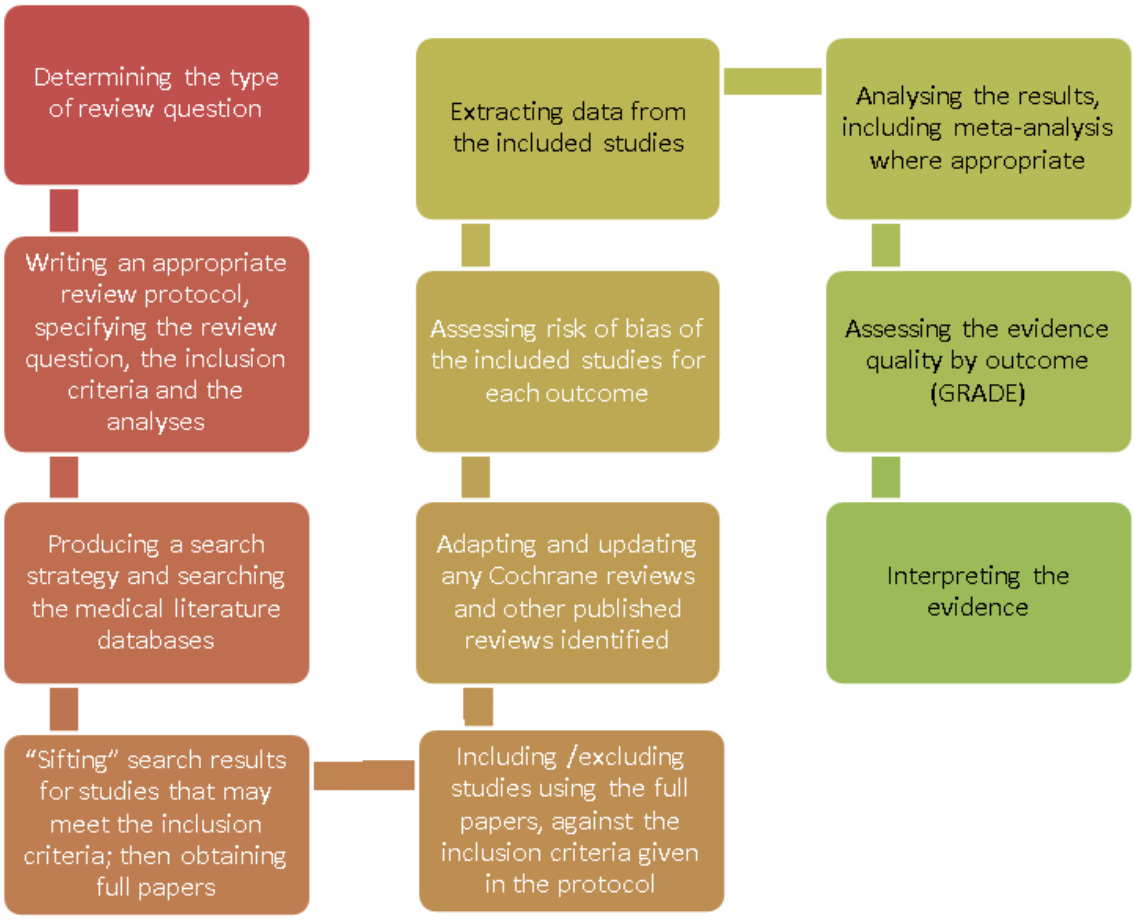
- Patient experience in adult NHS services. NICE guideline CG138 (2012)
- Service user experience in adult mental health. NICE guideline CG136 (2011)
- Medicines adherence. NICE guideline CG76 (2009)
- Tinnitus NICE guideline (in development)

4 Methods

This chapter sets out in detail the methods used to review the evidence and to develop the recommendations that are presented in subsequent chapters of this guideline. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2014 version.[82]

Sections 4.1 to 4.3 describe the process used to identify and review clinical evidence (summarised in Figure 1), sections 4.2 and 4.4 describe the process used to identify and review the health economic evidence, and section 4.5 describes the process used to develop recommendations.

Figure 1: Step-by-step process of review of evidence in the guideline



4.1 Developing the review questions and outcomes

Review questions were developed using a PICO framework (population, intervention, comparison and outcome) for intervention reviews; using a framework of population, index tests, reference standard and target condition for reviews of diagnostic test accuracy; using population, presence or absence of factors under investigation (for example prognostic factors) and outcomes for clinical prediction reviews; and using a framework of population, setting and context for qualitative reviews.

This use of a framework guided the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the guideline committee. The review questions were drafted by the NGC technical team and refined and validated by the committee. The questions were based on the key clinical areas identified in the scope (appendix A).

A total of 20 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

Table 1: Review questions

Chapter	Type of review	Review questions	Outcomes
Chapter 5	Clinical prediction	What are the symptoms and signs that allow early recognition of hearing loss needing immediate or urgent referral to a secondary care specialist?	• Severe infections: otitis media with facial nerve impairment, otitis externa (malignant or necrotising) • Sudden sensorineural hearing loss • Rapidly progressing cholesteatoma • Rapidly growing vestibular schwannoma • Nasopharyngeal cancer and intracranial tumours • Stroke • Long-term neurological damage • Autoimmune disease
Chapter 5	Diagnostic	Who should be routinely referred to audiovestibular medicine or ear, nose and throat (ENT) surgery for medical assessment?	• Sensitivity • Specificity • Positive predictive value • Negative predictive value • ROC curve or area under the curve • Adjusted odds ratios
Chapter 6	Diagnostic	In people who have been referred to secondary care with sensorineural hearing loss, who needs MRI to assess the underlying cause of hearing loss?	• Sensitivity • Specificity • Positive predictive value • Negative predictive value • ROC curve or area under the curve • Adjusted odds ratios
Chapter 7	Clinical prediction	Which groups of people are more likely than the general population to miss having hearing loss identified?	• Missed identification (no diagnosis prior to assessment and new diagnosis after assessment) • Identification rates
Chapter 8	Intervention	What is the clinical and cost effectiveness of early versus delayed management of hearing loss on patient outcomes?	• Hearing-specific health-related quality of life • Health-related quality of life • Listening ability • Usage of hearing aids (including data logging and self-report • Change in cognitive function (Mini-Mental State Examination, MMSE; Modified Mini-Mental State Examination (3MS) • Social functioning or employment • Sound localisation as measured by laboratory test • Speech in noise detection as measured by laboratory tests
Chapter 9	Intervention	What is the clinical and cost effectiveness of	**Critical** • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE)

Chapter	Type of review	Review questions	Outcomes
		communication needs assessment in adults with hearing loss?	or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ GHABP ○ CPHI ○ COSI ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale **Important** • Social functioning or employment
Chapter 10	Intervention	What is the most clinically and cost-effective method of removing earwax?	**Critical** • Health-related quality of life • Hearing (objective and patient reported) • Wax-related outcomes ○ amount and occlusion ○ ability / ease of removal ○ global impression of treatment efficacy (patient or clinician) • Adverse effects: perforation, infection, vertigo, bleeding, discomfort • Time to recurrence of wax **Important** • pure tone audiometry
Chapter 10	Intervention	What is the most clinically and cost-effective setting for the identification and treatment of earwax?	**Critical** • Success of earwax removal • Improvement in hearing • Adverse events ○ Earwax related - perforation - Infection - vertigo - bleeding - Discomfort • Hearing-specific health-related quality of life ○ Any patient-reported scale that has been validated to provide health utility measure, for example: - WHO DAS II - HUI2/HUI3

Chapter	Type of review	Review questions	Outcomes
			- Cambridge Otology QOL Questionnaire - Speech, Spatial and Qualities of Hearing (SSQ) Scale • Patient-reported disability or benefit • Measures validated to demonstrate changes with audiology care in the population under study, for example: ○ Device Orientated Subjective Outcome Scale ○ Glasgow Hearing Aid Benefit Profile ○ Hearing Handicap Inventory for the Elderly
Chapter 11	Intervention	What is the most clinically and cost-effective treatment for idiopathic sudden sensorineural hearing loss (SSNHL)?	**Critical** • Pure-tone audiometry • Speech discrimination • Health-related quality of life • Hearing-specific health-related quality of life **Important** • Adverse events for example, gastrointestinal bleeding, mood alteration or psychosis
Chapter 11	Intervention	What is the clinical and cost effectiveness of different routes of administration of steroids (for example oral or intratympanic) in the treatment of sudden sensorineural hearing loss (SSNHL)?	**Critical** • Pure-tone audiometry • Speech discrimination • Health-related quality of life • Hearing-specific health-related quality of life **Important** • Adverse events for example, gastrointestinal bleeding, mood alteration or psychosis
Chapter 12	Qualitative	What are the information, support and advice needs of people with hearing difficulty and their families and carers?	• Any type of information, support and advice described by studies. For example: ○ Content of information, support and advice required ○ How and by whom information, support and advice is delivered ○ Information for carers and family members as well as information for patients ○ Timing of information and support
Chapter 13	Intervention	What is the clinical and cost effectiveness of using patient-centred tools to help patients with hearing loss decide between different management strategies?	**Critical** • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ)

Chapter	Type of review	Review questions	Outcomes
			○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale ○ Any questionnaire not specified above that is relevant • Adherence to chosen strategy for example usage of hearing aids (including data logging and self-report (if applicable) **Important** • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment and education • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant
Chapter 14	Intervention	What is the clinical and cost effectiveness of assistive listening devices (such as loops) to support communication?	**Critical** • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale ○ Speech intelligibility (BKB, HINT, QuickSIN) ○ Ease of listening/listening effort

Chapter	Type of review	Review questions	Outcomes
			Important • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment (including voluntary work) and education
Chapter 15	Intervention	What is the clinical and cost effectiveness of hearing aids for mild to moderate hearing loss in adults who have been prescribed at least 1 hearing aid?	**Critical** • Hearing-specific health-related quality of life (key domain: participation) • Adverse effects: Pain **Important** • Health-related quality of life • Listening ability • Adverse effects: Noise-induced hearing loss
Chapter 15	Intervention	What is the clinical and cost effectiveness of fitting 1 hearing aid compared with fitting 2 hearing aids for people when both ears have an aidable hearing loss?	**Critical** • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Any questionnaire not specified above that is relevant • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) disability subscale ○ Any questionnaire not specified above that is relevant • Device Orientated Subjective Outcome Scale • Outcomes reported by carer or 'communications partner' • Patient preference
Chapter 16	Intervention	What is the clinical and cost effectiveness of directional versus omnidirectional	**Critical** • Speech recognition in noise • Ease of listening or listening effort (objective or self-reported)

Chapter	Type of review	Review questions	Outcomes
		microphones?	• Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant **Important** • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment and education ○ Health-related quality of life: ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) disability subscale ○ Any questionnaire not specified above that is relevant • Safety for example lack of awareness of environmental noise as an adverse effect • Adherence
Chapter 17	Intervention	What is the clinical and cost effectiveness of noise reduction algorithms?	**Critical** • Speech recognition in noise • Ease of listening or listening effort (objective or self-reported). *Note: there may not be measures to assess these but may be measured by self-report; behavioural measures of reduced processing load (for example, faster responses times when completing a listening task, or improved ability to multitask while listening; physiological measures such as lower skin conductance)* • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is

Chapter	Type of review	Review questions	Outcomes
			relevant **Important** • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment and education ○ Listening ability Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant • Safety (for example, lack of awareness of environmental noise as adverse effect) • Adherence
Chapter 18	Intervention	What is the most clinically and cost-effective method of delivery of monitoring and follow-up of people with hearing-related communication needs (including those with hearing aids)?	**Critical** • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale • Speech recognition in noise test

Chapter	Type of review	Review questions	Outcomes
			• Usage of hearing aids (including data logging and self-report (if applicable) **Important** • Social functioning or employment
Chapter 18	Intervention	When should people with hearing-related communication needs (including those with hearing aids) be monitored and followed up?	**Critical** • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale • Speech recognition in noise test • Usage of hearing aids (including data logging and self-report (if applicable) **Important** Social functioning or employment
Chapter 19	Intervention	What is the clinical and cost effectiveness of interventions to support continuing use of hearing aids?	**Critical** • Hearing aid use (measured as adherence or daily hours of use) • Adverse effects (inappropriate advice or clinical practice, or patient complaints) • Patient-reported outcomes including: ○ quality of life, ○ hearing handicap, ○ hearing aid benefit and communication • Outcomes reported by carers or relatives Outcomes measured over the short (≤12 weeks), medium (>12 to <52 weeks) and long term (≥1 year).

4.2 Searching for evidence

4.2.1 Clinical literature search

Systematic literature searches were undertaken to identify all published clinical evidence relevant to the review questions. Searches were undertaken according to the parameters stipulated within the NICE guidelines manual 2014.[82] Databases were searched using relevant medical subject headings, free-text terms and study-type filters where appropriate. Where possible, searches were restricted to papers published in English. Studies published in languages other than English were not reviewed. All searches were conducted in Medline, Embase, and The Cochrane Library. Additional subject specific databases were used for some questions: CINAHL, Current Nursing and Allied Health Literature and PsycINFO. Final searches were between 3 October 2016 and 21 June 2017, please see appendix G for specific dates.

Search strategies were quality assured by cross-checking reference lists of highly relevant papers, analysing search strategies in other systematic reviews, and asking committee members to highlight any additional studies. Searches were quality assured by a second information specialist before being run. The questions, the study types applied, the databases searched and the years covered can be found in appendix G.

During the scoping stage, a search was conducted for guidelines and reports on the websites listed below from organisations relevant to the topic.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearing House (www.guideline.gov)
- NHS Evidence Search (www.evidence.nhs.uk)
- TRIP, Turning Research Into Practice (www.tripdatabase.com).

All references sent by stakeholders were considered. Searching for unpublished literature was not undertaken. The NGC and NICE do not have access to drug manufacturers' unpublished clinical trial results, so the clinical evidence considered by the committee for pharmaceutical interventions may be different from that considered by the MHRA and European Medicines Agency for the purposes of licensing and safety regulation.

4.2.2 Health economic literature search

Systematic literature searches were also undertaken to identify health economic evidence within published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to hearing loss population in the NHS Economic Evaluation Database (NHS EED) and the Health Technology Assessment database (HTA) with no date restrictions (NHS EED ceased to be updated after March 2015). Additionally, the search was run on Medline and Embase using a health economic filter, from January 2014, to ensure recent publications that had not yet been indexed by the economic databases were identified. This was supplemented by additional searches that looked for economic papers specifically relating to Earwax on Medline, Embase, NHSEED and HTA as it became apparent that some papers in this area had not been identified by the first search. Where possible, searches were restricted to papers published in English. Studies published in languages other than English were not reviewed.

The health economic search strategies are included in appendix G. The search for quality of life was updated on 16 February 2016, the general hearing loss health economic search and the earwax health economic search were updated on 18 October 2017 and the hearing aids health economic search was updated on 4 September 2017. No papers published after these dates were considered.

4.3 Identifying and analysing evidence of effectiveness

Research fellows conducted the tasks listed below, which are described in further detail in the rest of this section:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts. Full papers were then obtained.
- Reviewed full papers against prespecified inclusion and exclusion criteria to identify studies that addressed the review question in the appropriate population, and reported on outcomes of interest (review protocols are included in appendix C).
- Critically appraised relevant studies using the appropriate study design checklist as specified in the NICE guidelines manual.[82] clinical prediction studies were critically appraised using NGC checklists. Qualitative studies were critically appraised using the GRADE CERQual approach for rating confidence in the body of evidence as a whole and using an NGC checklist for the methodological limitations section of the quality assessment.
- Extracted key information about interventional study methods and results using 'Evibase', NGC's purpose-built software. Evibase produces summary evidence tables, including critical appraisal ratings. Key information about non-interventional study methods and results was manually extracted onto standard evidence tables and critically appraised separately (evidence tables are included in appendix H).
- Generated summaries of the evidence by outcome. Outcome data were combined, analysed and reported according to study design:
  - Randomised data were meta-analysed where appropriate and reported in GRADE profile tables.
  - Data from non-randomised studies were presented as a range of values in GRADE profile tables or meta-analysed if appropriate.
  - Prognostic clinical prediction data were meta-analysed where appropriate and reported in GRADE profile tables.
  - Diagnostic data studies were meta-analysed where appropriate or presented as a range of values in adapted GRADE profile tables
  - Qualitative data were synthesised across studies and presented as summary statements with accompanying GRADE CERQual ratings for each review finding.
- A sample of a minimum of 10% of the abstract lists of the first 3 sifts by new reviewers and those for complex review questions (for example, clinical prediction reviews) were double-sifted by a senior research fellow and any discrepancies were rectified. All of the evidence reviews were quality assured by a senior research fellow. This included checking:
  - papers were included or excluded appropriately
  - a sample of the data extractions
  - correct methods were used to synthesise data
  - a sample of the risk of bias assessments.

4.3.1 Inclusion and exclusion criteria

The inclusion and exclusion of studies was based on the criteria defined in the review protocols, which can be found in appendix C. Excluded studies by review question (with the reasons for their exclusion) are listed in appendix L. The committee was consulted about any uncertainty regarding inclusion or exclusion.

The key population inclusion criterion was:

- Adults (aged 18 years and older) with hearing loss, including those with onset before the age of 18 but presenting for the first time in adulthood.

The key population exclusion criterion was:

- Adults who presented with hearing loss before the age of 18.

Conference abstracts were not automatically excluded from any review. The abstracts were initially assessed against the inclusion criteria for the review question and further processed when a full publication was not available for that review question. If the abstracts were included the authors were contacted for further information. No relevant conference abstracts were identified for this guideline. Literature reviews, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded.

4.3.1.1 Saturation of qualitative studies

Data extraction in qualitative reviews is a thorough process and may require more time compared with intervention reviews. It is common practice to stop extracting data once saturation has been reached. This is the point when no new information emerges from studies that match the review protocol. The remaining identified studies are, however, not directly excluded from the review as they nevertheless fit the criteria defined in the review protocol. Any studies for which data were not extracted due to saturation having been reached, but that fit the inclusion criteria of the protocol, were listed in the table for studies 'identified but not included due to saturation' in the appendix for the qualitative evidence review.

4.3.2 Type of studies

Randomised trials, non-randomised intervention studies, and other observational studies (including diagnostic or clinical prediction studies) were included in the evidence reviews as appropriate.

For most intervention reviews in this guideline, parallel randomised controlled trials (RCTs) were included because they are considered the most robust type of study design that can produce an unbiased estimate of the intervention effects. Crossover RCTs were considered if the studies reported data before cross over. If non-randomised intervention studies were considered appropriate for inclusion (for example, where no randomised evidence was available for critical outcomes) the committee stated a priori in the protocol that either certain identified variables must be equivalent at baseline or else the analysis had to adjust for any baseline differences. If the study did not fulfil either criterion it was excluded. Please refer to the review protocols in appendix C for full details on the study design of studies selected for each review question.

For diagnostic review questions, diagnostic RCTs, cross-sectional studies and retrospective studies were included. For clinical prediction review questions, prospective and retrospective cohort studies were included. Case–control studies were not included.

Where data from non-randomised studies were included, the results for each outcome were presented separately for each study or meta-analysed if appropriate.

4.3.3 Methods of combining clinical studies

4.3.3.1 Data synthesis for intervention reviews

Where possible, meta-analyses were conducted using Cochrane Review Manager (RevMan5)[100] software to combine the data given in all studies for each of the outcomes of interest for the review question.

4.3.3.1.1 Analysis of different types of data

Dichotomous outcomes

Fixed-effects (Mantel-Haenszel) techniques (using an inverse variance method for pooling) were used to calculate risk ratios (relative risk, RR) for the binary outcomes, which included:

- adverse events.
- missed diagnosis or misdiagnosis
- patient-assessed symptoms

The absolute risk difference was also calculated using GRADEpro[50] software, using the median event rate in the control arm of the pooled results.

For binary variables where there were zero events in either arm or a less than 1% event rate, Peto odds ratios, rather than risk ratios, were calculated. Peto odds ratios are more appropriate for data with a low number of events.

Continuous outcomes

Continuous outcomes were analysed using an inverse variance method for pooling weighted mean differences. These outcomes included:

- Heath-related quality of life (HRQoL) such as:
  - Health Utilities Index Mark 3 (HUI-3)
  - EQ-5D
  - SF-36
  - Glasgow Benefit Inventory (GBI)
  - WHO Disability Assessment Schedule (WHODAS)

- Hearing-related quality of life such as:
  - Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA)
  - Quantified Denver Scale of Communication (QDS)
  - Auditory Disability Preference – Visual Analog Scale (ADPI-VAS)

Where the studies within a single meta-analysis had different scales of measurement, standardised mean differences were used (providing all studies reported either change from baseline or final values rather than a mixture of both); each different measure in each study was 'normalised' to the standard deviation value pooled between the intervention and comparator groups in that same study.

The means and standard deviations of continuous outcomes are required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p values or 95% confidence intervals (95% CI) were reported, and meta-analysis was undertaken with the mean and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5[100] software. Where p values were reported as 'less than', a conservative approach was undertaken. For example, if a p value was reported as '$p \leq 0.001$', the calculations for standard deviations were based on a p value of 0.001. If these statistical measures were not available then the methods described in section 16.1.3 of the Cochrane Handbook (version 5.1.0, updated March 2011) were applied.

4.3.3.1.2 Generic inverse variance

If a study reported only the summary statistic and 95% CI the generic-inverse variance method was used to enter data into RevMan5.[100] If the control event rate was reported this was used to generate the absolute risk difference in GRADEpro.[50] If multivariate analysis was used to derive the summary statistic but no adjusted control event rate was reported no absolute risk difference was calculated.

4.3.3.1.3 Heterogeneity

Statistical heterogeneity was assessed for each meta-analysis estimate by considering the chi-squared test for significance at $p<0.1$ or an I-squared (I^2) inconsistency statistic (with an I-squared value of more than 50% indicating significant heterogeneity) as well as the distribution of effects. Where significant heterogeneity was present, predefined subgrouping of studies was carried out for the following subgroups where relevant:

- Severity of hearing loss
- Type of hearing aid
- Age
- Cognitive impairment
- Asymmetric hearing loss
- Visual impairment
- Tinnitus with hearing loss
- First-time users of hearing aids

Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. Any subgroup differences were interpreted with caution as separating the groups breaks the study randomisation and as such is subject to uncontrolled confounding. These additional subgrouping strategies were applied independently, so subunits of subgroups were not created. If all predefined strategies of subgrouping were unable to explain statistical heterogeneity within each derived subgroup, then a random effects (DerSimonian and Laird) model was employed to the entire group of studies in the meta-analysis. A random-effects model assumes a distribution of populations, rather than a single population. This leads to a widening of the confidence interval around the overall estimate, thus providing a more realistic interpretation of the true distribution of effects across more than 1 population. If, however, the committee considered the heterogeneity was so large that meta-analysis was inappropriate, then the results were described narratively.

4.3.3.2 Data synthesis for clinical prediction reviews

Odds ratios (ORs), risk ratios (RRs), or hazard ratios (HRs), with their 95% CIs, for the effect of the prespecified prognostic factors were extracted from the studies. Studies were only included if the confounders prespecified by the committee were either matched at baseline or were adjusted for in multivariate analysis.

Studies of lower risk of bias were preferred, taking into account the analysis and the study design. In particular, prospective cohort studies were preferred if they reported multivariable analyses that adjusted for key confounders identified by the committee at the protocol stage for that outcome.

4.3.3.3 Data synthesis for diagnostic test accuracy reviews

4.3.3.3.1 Diagnostic accuracy studies

For diagnostic test accuracy studies, a positive result on the index test was found if the patient had values of the measured quantity above or below a threshold value, and different thresholds could be

used. The thresholds were pre-specified by the committee including whether or not data could be pooled across a range of thresholds. Diagnostic test accuracy measures used in the analysis were: area under the receiver operating characteristics (ROC) curve (AUC), and, for different thresholds (if appropriate), sensitivity and specificity. The threshold of a diagnostic test is defined as the value at which the test can best differentiate between those with and without the target condition. In practice this varies amongst studies. If a test has a high sensitivity then very few people with the condition will be missed (few false negatives). For example, a test with a sensitivity of 97% will only miss 3% of people with the condition. Conversely, if a test has a high specificity then few people without the condition would be incorrectly diagnosed (few false positives). For example, a test with a specificity of 97% will only incorrectly diagnose 3% of people who do not have the condition as positive. -Coupled forest plots of sensitivity and specificity with their 95% CIs across studies (at various thresholds if available) were produced for each test, using RevMan5.[100] In order to do this, 2×2 tables (the number of true positives, false positives, true negatives and false negatives) were directly taken from the study if given, or else were derived from raw data or calculated from the set of test accuracy statistics.

Heterogeneity or inconsistency amongst studies was visually inspected in the forest plots and pooled diagnostic meta-analysis plots.

Heterogeneity or inconsistency amongst studies was visually inspected.

4.3.3.4 Data synthesis for qualitative study reviews

The main findings for each included paper were identified and thematic analysis methods were used to synthesise this information into broad overarching themes which were summarised into the main review findings. The evidence was presented in the form of a narrative summary detailing the evidence from the relevant papers and how this informed the overall review finding plus a statement on the level of confidence for that review finding. Considerable limitations and issues around relevance were listed. A summary evidence table with the succinct summary statements for each review finding was produced including the associated quality assessment.

4.3.4 Appraising the quality of evidence by outcomes

4.3.4.1 Intervention reviews

The evidence for outcomes from the included RCTs and, where appropriate, non-randomised intervention studies, were evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/). The software (GRADEpro[50]) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results.

Each outcome was first examined for each of the quality elements listed and defined in Table 2.

Table 2: Description of quality elements in GRADE for intervention studies

Quality element	Description
Risk of bias	Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect. Examples of such limitations are selection bias (often due to poor allocation concealment), performance and detection bias (often due to a lack of blinding of the patient, healthcare professional or assessor) and attrition bias (due to missing data causing systematic bias in the analysis).
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question.

Quality element	Description
Inconsistency	Inconsistency refers to an unexplained heterogeneity of effect estimates between studies in the same meta-analysis.
Imprecision	Results are imprecise when studies include relatively few patients and few events (or highly variable measures) and thus have wide confidence intervals around the estimate of the effect relative to clinically important thresholds. 95% confidence intervals denote the possible range of locations of the true population effect at a 95% probability, and so wide confidence intervals may denote a result that is consistent with conflicting interpretations (for example a result may be consistent with both clinical benefit AND clinical harm) and thus be imprecise.
Publication bias	Publication bias is a systematic underestimate or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. A closely related phenomenon is where some papers fail to report an outcome that is inconclusive, thus leading to an overestimate of the effectiveness of that outcome.
Other issues	Sometimes randomisation may not adequately lead to group equivalence of confounders, and if so this may lead to bias, which should be taken into account. Potential conflicts of interest, often caused by excessive pharmaceutical company involvement in the publication of a study, should also be noted.

Details of how the 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given below. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

4.3.4.1.1 Risk of bias

The main domains of bias for RCTs are listed in Table 3. Each outcome had its risk of bias assessed within each study first. For each study, if there were no risks of bias in any domain, the risk of bias was given a rating of 0. If there was risk of bias in just 1 domain, the risk of bias was given a 'serious' rating of −1, but if there was risk of bias in 2 or more domains the risk of bias was given a 'very serious' rating of −2. A weighted average score was then calculated across all studies contributing to the outcome, by taking into account the weighting of studies according to study precision. For example if the most precise studies tended to each have a score of −1 for that outcome, the overall score for that outcome would tend towards −1.

Table 3: Principle domains of bias in randomised controlled trials

Limitation	Explanation
Selection bias (sequence generation and allocation concealment)	If those enrolling patients are aware of the group to which the next enrolled patient will be allocated, either because of a non-random sequence that is predictable, or because a truly random sequence was not concealed from the researcher, this may translate into systematic selection bias. This may occur if the researcher chooses not to recruit a participant into that specific group because of: • knowledge of that participant's likely prognostic characteristics, and • a desire for one group to do better than the other.
Performance and detection bias (lack of blinding of patients and healthcare professionals)	Patients, caregivers, those adjudicating or recording outcomes, and data analysts should not be aware of the arm to which patients are allocated. Knowledge of the group can influence: • the experience of the placebo effect • performance in outcome measures • the level of care and attention received, and • the methods of measurement or analysis all of which can contribute to systematic bias.
Attrition bias	Attrition bias results from an unaccounted for loss of data beyond a certain level (a differential of 10% between groups). Loss of data can occur when participants are

Limitation	Explanation
	compulsorily withdrawn from a group by the researchers (for example, when a per-protocol approach is used) or when participants do not attend assessment sessions. If the missing data are likely to be different from the data of those remaining in the groups, and there is a differential rate of such missing data from groups, systematic attrition bias may result.
Selective outcome reporting	Reporting of some outcomes and not others on the basis of the results can also lead to bias, as this may distort the overall impression of efficacy.
Other limitations	For example: • Stopping early for benefit observed in randomised trials, in particular in the absence of adequate stopping rules. • Use of unvalidated patient-reported outcome measures. • Lack of washout periods to avoid carry-over effects in crossover trials. • Recruitment bias in cluster-randomised trials.

The assessment of risk of bias differs for non-randomised intervention studies, as they are inherently at high risk of selection bias. For this reason, GRADE requires that non-randomised evidence is initially downgraded on the basis of study design, starting with a rating of −2. This accounts for selection bias and so non-randomised intervention studies are not downgraded any further on that domain. Non-randomised evidence was assessed against the remaining domains used for RCTs in Table 3, and downgraded further as appropriate.

4.3.4.1.2 Indirectness

Indirectness refers to the extent to which the populations, interventions, comparisons and outcome measures are dissimilar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size, or may affect the balance of harms and benefits considered for an intervention. As for the risk of bias, each outcome had its indirectness assessed within each study first. For each study, if there were no sources of indirectness, indirectness was given a rating of 0. If there was indirectness in just 1 source (for example in terms of population), indirectness was given a 'serious' rating of −1, but if there was indirectness in 2 or more sources (for example, in terms of population and treatment) the indirectness was given a 'very serious' rating of −2. A weighted average score was then calculated across all studies contributing to the outcome by taking into account study precision. For example, if the most precise studies tended to have an indirectness score of −1 each for that outcome, the overall score for that outcome would tend towards −1.

4.3.4.1.3 Inconsistency

Inconsistency refers to an unexplained heterogeneity of results for an outcome across different studies. When estimates of the treatment effect across studies differ widely, this suggests true differences in the underlying treatment effect, which may be due to differences in populations, settings or doses. When heterogeneity existed within an outcome (chi-squared $p<0.1$, or $I^2>50\%$), but no plausible explanation could be found, the quality of evidence for that outcome was downgraded. Inconsistency for that outcome was given a 'serious' score of −1 if the I^2 was 50–74%, and a 'very serious' score of −2 if the I^2 was 75% or more.

If inconsistency could be explained based on prespecified subgroup analysis (that is, each subgroup had an $I^2<50\%$), the committee took this into account and considered whether to make separate recommendations on new outcomes based on the subgroups defined by the assumed explanatory factors. In such a situation the quality of evidence was not downgraded for those emergent outcomes.

Since the inconsistency score was based on the meta-analysis results, the score represented the whole outcome and so weighted averaging across studies was not necessary.

4.3.4.1.4 Imprecision

The criteria applied for imprecision were based on the 95% CIs for the pooled estimate of effect, and the minimal important differences (MID) for the outcome. The MIDs are the threshold for appreciable benefits and harms, separated by a zone either side of the line of no effect where there is assumed to be no clinically important effect. If either end of the 95% CI of the overall estimate of effect crossed 1 of the MID lines, imprecision was regarded as serious and a 'serious' score of −1 was given. This was because the overall result, as represented by the span of the confidence interval, was consistent with 2 interpretations as defined by the MID (for example, both no clinically important effect and clinical benefit were possible interpretations). If both MID lines were crossed by either or both ends of the 95% CI then imprecision was regarded as very serious and a 'very serious' score of −2 was given. This was because the overall result was consistent with all 3 interpretations defined by the MID (no clinically important effect, clinical benefit and clinical harm). This is illustrated in Figure 2. As for inconsistency, since the imprecision score was based on the meta-analysis results, the score represented the whole outcome and so weighted averaging across studies was not necessary.

The position of the MID lines is ideally determined by values reported in the literature. 'Anchor-based' methods aim to establish clinically meaningful changes in a continuous outcome variable by relating or 'anchoring' them to patient-centred measures of clinical effectiveness that could be regarded as gold standards with a high level of face validity. For example, a MID for an outcome could be defined by the minimum amount of change in that outcome necessary to make patients feel their quality of life had 'significantly improved'. MIDs in the literature may also be based on expert clinician or consensus opinion concerning the minimum amount of change in a variable deemed to affect quality of life or health. For binary variables, any MIDs reported in the literature will inevitably be based on expert consensus, as such MIDs relate to all-or-nothing population effects rather than measurable effects on an individual, and so are not amenable to patient-centred 'anchor' methods.

In the absence of values identified in the literature, the alternative approach to deciding on MID levels is the 'default' method, as follows:

- For categorical outcomes the MIDs were taken to be RRs of 0.75 and 1.25. For 'positive' outcomes such as 'patient satisfaction', the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm, whilst the RR of 1.25 is taken as the line denoting the boundary between no clinically important effect and a clinically significant benefit. For 'negative' outcomes such as 'bleeding', the opposite occurs, so the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant benefit, whilst the RR of 1.25 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm.
- For mortality any change was considered to be clinically important and the imprecision was assessed on the basis of the whether the confidence intervals crossed the line of no effect, that is whether the result was consistent with both benefit and harm.
- For continuous outcome variables the MID was taken as half the median baseline standard deviation of that variable, across all studies in the meta-analysis. Hence the MID denoting the minimum clinically significant benefit was positive for a 'positive' outcome (for example, a quality of life measure where a higher score denotes better health), and negative for a 'negative' outcome (for example, a visual analogue scale [VAS] pain score). Clinically significant harms will be the converse of these. If baseline values are unavailable, then half the median comparator group standard deviation of that variable will be taken as the MID.
- If standardised mean differences have been used, then the MID will be set at the absolute value of +0.5. This follows because standardised mean differences are mean differences normalised to the pooled standard deviation of the 2 groups, and are thus effectively expressed in units of

'numbers of standard deviations'. The 0.5 MID value in this context therefore indicates half a standard deviation, the same definition of MID as used for non-standardised mean differences.

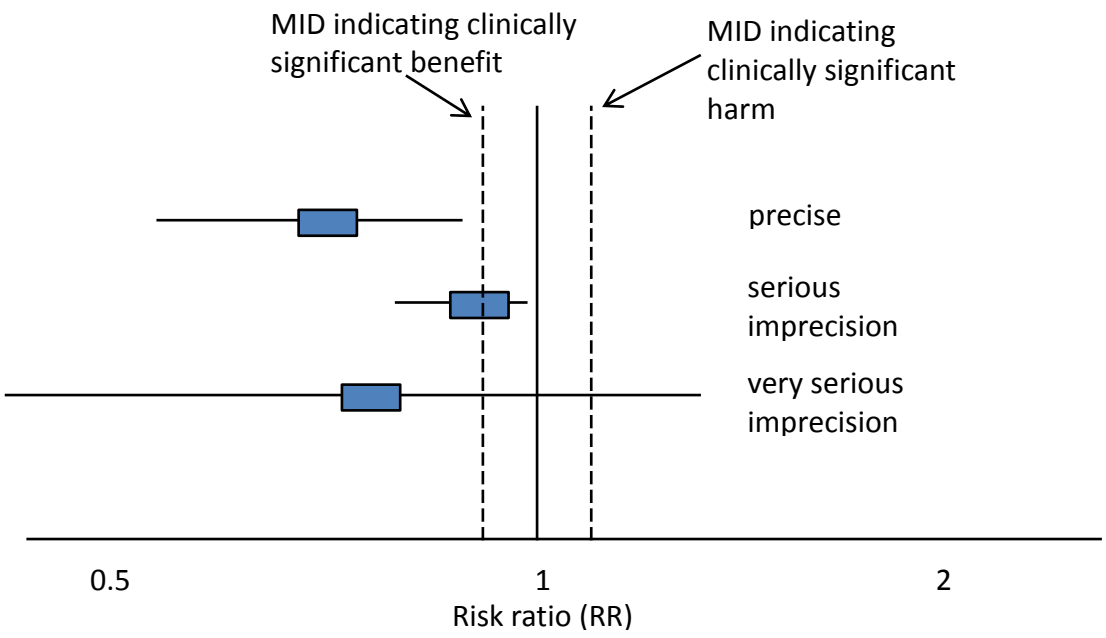
The default MID value was subject to amendment after discussion with the committee. If the committee decided that the MID level should be altered, after consideration of absolute as well as relative effects, this was allowed, provided that any such decision was not influenced by any bias towards making stronger or weaker recommendations for specific outcomes.

For this guideline, only the following MIDs for continuous outcomes were identified:

- The MID for HHIE scale is reported to be 18.7 for face-to face administration and 36 for pencil and paper[122]
- The MID for the verbal subscale of the CPHI is 0.93 at the 0.05 level[32]
- The MID for the IOI-HA is reported to be 1.75 for mild to moderate hearing loss
- The committee agreed that the MID for change in PTA score should be 10 dB

No other appropriate MIDs for continuous or dichotomous outcomes were found in the literature, and so the default method was adopted.

Figure 2: Illustration of precise and imprecise outcomes based on the 95% CI of dichotomous outcomes in a forest plot (Note that all 3 results would be pooled estimates, and would not, in practice, be placed on the same forest plot)



4.3.4.1.5 Overall grading of the quality of clinical evidence

Once an outcome had been appraised for the main quality elements, as above, an overall quality grade was calculated for that outcome. The scores (0, −1 or −2) from each of the main quality elements were summed to give a score that could be anything from 0 (the best possible) to −8 (the worst possible). However scores were capped at −3. This final score was then applied to the starting grade that had originally been applied to the outcome by default, based on study design. All RCTs started as High and the overall quality became Moderate, Low or Very Low if the overall score was −1, −2 or −3 points respectively. The significance of these overall ratings is explained in Table 4. The reasons for downgrading in each case were specified in the footnotes of the GRADE tables.

Non-randomised intervention studies started at Low, and so a score of −1 would be enough to take the grade to the lowest level of Very Low. Non-randomised intervention studies could, however, be upgraded if there was a large magnitude of effect or a dose-response gradient.

Table 4: Overall quality of outcome evidence in GRADE

Level	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

4.3.4.2 Prognostic clinical prediction reviews

A modified GRADE methodology was used for clinical prediction studies, considering risk of bias, indirectness, inconsistency and imprecision.

Risk prediction studies were evaluated according to the criteria given in Table 5. This table was adapted from the Quality In Prognosis Studies tool (QUIPS) [55]. If data were meta-analysed, the quality for pooled studies was presented. If the data were not pooled, then a quality rating was presented for each study.

Table 5: Description of quality elements for prospective studies (adapted from the QUIPS tool)

Domain	Risk of bias clinical prediction studies	Response and score
Selection bias	Was there a lack of reported attempts made to achieve some group comparability between the risk factor and non-risk factor groups? (ignore if 2 or more risk factors considered)	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
	Was there a lack of consideration of any of the key confounders, or was this unclear? [Note that if the study can show that a particular confounder was not at risk of causing bias (for example, by being well-matched at baseline between groups), then this confounder does not have to have been adjusted for in a multivariate analysis.]	Exclude.
	Was there a lack of consideration of non-key plausible confounders, or was this unclear? [Note that if the study can show that a particular confounder was not at risk of causing bias (for example, by being well-matched at baseline between groups), then this confounder does not have to have been adjusted for in a multivariate analysis.]	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
	If the outcome is categorical: Were there <10 events per variable included in the multivariable analysis? If the outcome is continuous: Were there <10 people per variable included in the multivariable analysis?	Consider if this was moderate, high or very high risk of bias if answer was 'yes' to either.
	Was it very clear that 1 group was more likely to have had more outcomes occurring at baseline than another group?	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
Detection bias	Was there a lack of assessor blinding AND the outcome was not completely objective?	Consider if this was moderate, high or very high risk of bias if answer

Domain	Risk of bias clinical prediction studies	Response and score
		was 'yes'.
	Were the risk factors measured in a way that would systematically favour either group?	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
	Were the outcomes measured in a way that would systematically favour either group?	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
	If there were multiple raters, was there lack of adjustment for systematic inter-rater measurement errors, or was inter-rater reliability unreported?	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
	Was there an excessively short follow-up, such that there was not enough time for outcomes to occur?	Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
Attrition bias	Was there >10% group differential attrition (for reasons related to outcome) and there was no appropriate imputation? (if 1 risk factor) or Was there >10% overall attrition (for reasons related to outcome) and there was no appropriate imputation? (if > 1 risk factor).	Consider if this was moderate, high or very high risk of bias if answer was 'yes'. Consider if this was moderate, high or very high risk of bias if answer was 'yes'.
	For each domain make a judgement of risk of bias (for example, very high if there are 2 moderate boxes and a high box). Sum these domain risks to form an overall rating of risk of bias (for example, no risk, serious risk or very serious risk).	

4.3.4.2.1 Inconsistency

Inconsistency was assessed as for intervention studies.

4.3.4.2.2 Imprecision

4.3.4.2.3 The criteria applied for imprecision were based on the confidence intervals around the estimate of association between the risk factor/predictor and the outcome (condition of interest). The decision to downgrade was discussed with the committee and was based on the interpretations of the width of the confidence intervals and how certain the Committee was in drawing a conclusion, that is, how certain that there is no association, or a positive association, or a negative association (protective) between the risk factor or predictor and the outcome (condition of interest).

4.3.4.2.4 Overall grading

Because clinical prediction reviews were not usually based on multiple outcomes per study, quality rating was assigned by study. However if there was more than 1 outcome involved in a study, then the quality rating of the evidence statements for each outcome was adjusted accordingly. For example, if one outcome was based on an invalidated measurement method, but another outcome in the same study was not, the second outcome would be graded 1 grade higher than the first outcome.

Quality rating started at High for prospective studies, and each major limitation brought the rating down by 1 increment to a minimum grade of Very Low, as explained for interventional reviews. For clinical prediction reviews prospective cohort studies with a multivariate analysis are regarded as the gold standard because RCTs are usually inappropriate for these types of review for ethical or pragmatic reasons. Furthermore, if the study is looking at more than 1 risk factor of interest then randomisation would be inappropriate as it can only be applied to 1 of the risk factors.

4.3.4.3 Diagnostic studies

Risk of bias and indirectness of evidence for diagnostic data were evaluated by study using the Quality Assessment of Diagnostic Accuracy Studies version 2 (QUADAS-2) checklists (see appendix H in the NICE guidelines manual 2014[82]). Risk of bias and applicability in primary diagnostic accuracy studies in QUADAS-2 consists of 4 domains (see Table 6):

- patient selection
- index test
- reference standard
- flow and timing.

Table 6: Summary of QUADAS-2 with list of signalling, risk of bias and applicability questions

Domain	Patient selection	Index test	Reference standard	Flow and timing
Description	Describe methods of patient selection. Describe included patients (prior testing, presentation, intended use of index test and setting)	Describe the index test and how it was conducted and interpreted	Describe the reference standard and how it was conducted and interpreted	Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2×2 table (refer to flow diagram). Describe the time interval and any interventions between index test(s) and reference standard
Signalling questions (yes/no/ unclear)	Was a consecutive or random sample of patients enrolled?	Were the index test results interpreted without knowledge of the results of the reference standard?	Is the reference standard likely to correctly classify the target condition?	Was there an appropriate interval between index test(s) and reference standard?
	Was a case–control design avoided?	If a threshold was used, was it pre-specified?	Were the reference standard results interpreted without knowledge of the results of the index test?	Did all patients receive a reference standard?
	Did the study avoid inappropriate exclusions?			Did all patients receive the same reference standard?
				Were all patients included in the analysis?
Risk of bias; (high/low/ unclear)	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct or its interpretation have introduced bias?	Could the patient flow have introduced bias?
Concerns regarding applicability (high/low/ unclear)	Are there concerns that the included patients do not match the review question?	Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Are there concerns that the target condition as defined by the reference standard does not match the review question?	

4.3.4.3.1 Inconsistency

Inconsistency was assessed by inspection of the sensitivity or specificity (based on the most important outcome for each particular review question) using the point estimates and 95% CIs of the individual studies on the forest plots. Particular attention was placed on values above or below 50% (diagnosis based on chance alone) and the threshold set by the committee (the threshold above which it would be acceptable to recommend a test). The evidence was downgraded by 1 increment if the individual studies varied across 2 areas [(for example, 50–90% and 90–100%)] and by 2 increments if the individual studies varied across 3 areas [(for example, 0–50%, 50–90% and 90–100%)]. Reasons for heterogeneity between studies included the populations which varied in the proportions of people presenting with hearing loss and other audiovestibular symptoms, different definitions of the target condition and different methods of testing.

4.3.4.3.2 Imprecision

The judgement of precision was based on visual inspection of the confidence region around the summary sensitivity and specificity point from the diagnostic meta-analysis, if a diagnostic meta-analysis was conducted. Where a diagnostic meta-analysis was not conducted, imprecision was assessed according to the range of point estimates or, if only one study contributed to the evidence, the 95% CI around the single study. As a general rule (after discussion with the committee) a variation of 0–20% was considered precise, 20–40% serious imprecision, and >40% very serious imprecision. Imprecision was assessed on the primary outcome measure for decision-making.

4.3.4.3.3 Overall grading

Quality rating started at High for prospective and retrospective cross-sectional studies, and each major limitation (risk of bias, indirectness, inconsistency and imprecision) brought the rating down by 1 increment to a minimum grade of Very Low, as explained for intervention reviews.

4.3.4.4 Qualitative reviews

Review findings from the included qualitative studies were evaluated and presented using the 'Confidence in the Evidence from Reviews of Qualitative Research' (CERQual) Approach developed by the GRADE-CERQual Project Group, a subgroup of the GRADE Working Group.

The CERQual Approach assesses the extent to which a review finding is a reasonable representation of the phenomenon of interest (the focus of the review question). Each review finding was assessed for each of the 4 quality elements listed and defined below in Table 7.

Table 7: Description of quality elements in GRADE-CERQual for qualitative studies

Quality element	Description
Methodological limitations	The extent of problems in the design or conduct of the included studies that could decrease the confidence that the review finding is a reasonable representation of the phenomenon of interest. Assessed at the study level using an NGC checklist.
Coherence	The extent to which the reviewer is able to identify a clear pattern across the studies included in the review.
Relevance	The extent to which the body of evidence from the included studies is applicable to the context (study population, phenomenon of interest, setting) specified in the protocol.
Adequacy	The degree of the confidence that the review finding is being supported by sufficient data. This is an overall determination of the richness (depth of analysis) and quantity of the evidence supporting a review finding or theme.

Details of how the 4 quality elements (methodological limitations, coherence, relevance and adequacy) were appraised for each review finding are given below.

4.3.4.4.1 Methodological limitations

Each review finding had its methodological limitations assessed within each study first using an NGC checklist. Based on the degree of methodological limitations studies were evaluated as having minor, moderate or severe limitations. The questions to be answered in the checklist below included:

- Was qualitative design an appropriate approach?
- Was the study approved by an ethics committee?
- Was the study clear in what it sought to do?
- Is the context clearly described?
- Is the role of the researcher clearly described?
- Are the research design and methods rigorous?
- Was the data collection rigorous?
- Was the data analysis rigorous?
- Are the data rich?
- Are the findings relevant to the aims of the study?
- Are the findings and conclusions convincing?

The overall assessment of the methodological limitations of the evidence was based on the primary studies contributing to the review finding. The relative contribution of each study to the overall review finding and of the type of methodological limitation(s) were taken into account when giving an overall rating.

4.3.4.4.2 Coherence

Coherence is the extent to which the reviewer is able to identify a clear pattern across the studies included in the review, and if there is variation present (contrasting or disconfirming data) whether this variation is explained by the contributing study authors. If a review finding in 1 study does not support the main finding and there is no plausible explanation for this variation, then the confidence that the main finding reasonably reflects the phenomenon of interest is decreased. Each review finding was given a rating of minor, moderate or major concerns about coherence.

4.3.4.4.3 Relevance

Relevance is the extent to which the body of evidence from the included studies is applicable to the context (study population, phenomenon of interest, setting) specified in the protocol. As such, relevance is dependent on the individual review and discussed with the guideline committee. Relevance is categorised in 3 ways: partial relevance, indirect relevance and no concerns about relevance.

4.3.4.4.4 Adequacy

The judgement of adequacy is based on the confidence of the finding being supported by sufficient data. This is an overall determination of the richness (depth of analysis) and quantity of the evidence supporting a review finding or theme. Rich data provide sufficient detail to gain an understanding of the theme or review finding, whereas thin data do not provide enough detail for an adequate understanding. Quantity of data is the second pillar of the assessment of adequacy. For review findings that are only supported by 1 study or data from only a small number of participants, the confidence that the review finding reasonable represents the phenomenon of interest might be decreased. As with richness of data, quantity of data is review dependent. Based on the overall judgement of adequacy, a rating of no concerns, minor concerns, or substantial concerns about adequacy was given.

4.3.4.4.5 Overall judgement of the level of confidence for a review finding

GRADE-CERQual is used to assess the body of evidence as a whole through a confidence rating representing the extent to which a review finding is a reasonable representation of the phenomenon of interest. The 4 components (methodological limitations, coherence, relevance and adequacy) are used in combination to form an overall judgement. GRADE-CERQual uses 4 levels of confidence: high, moderate, low and very low confidence. The significance of these overall ratings is explained in Table 8. Each review finding starts at a high level of confidence and is downgraded based on the concerns identified in any 1 or more of the 4 components. Quality assessment of qualitative reviews is a subjective judgement by the reviewer based on the concerns that have been noted. A detailed explanation of how such a judgement had been made was included in the narrative summary.

Table 8: Overall level of confidence for a review finding in GRADE-CERQual

Level	Description
High confidence	It is highly likely that the review finding is a reasonable representation of the phenomenon of interest.
Moderate confidence	It is likely that the review finding is a reasonable representation of the phenomenon of interest.
Low confidence	It is possible that the review finding is a reasonable representation of the phenomenon of interest.
Very low confidence	It is not clear whether the review finding is a reasonable representation of the phenomenon of interest.

4.3.5 Assessing clinical importance

The committee assessed the evidence by outcome in order to determine if there was, or potentially was, a clinically important benefit, a clinically important harm or no clinically important difference between interventions. To facilitate this, binary outcomes were converted into absolute risk differences (ARDs) using GRADEpro[50] software: the median control group risk across studies was used to calculate the ARD and its 95% CI from the pooled risk ratio.

The assessment of clinical benefit, harm, or no benefit or harm was based on the point estimate of absolute effect for intervention studies, which was standardised across the reviews. The committee considered for most of the outcomes in the intervention reviews that if at least 100 more participants per 1000 (10%) achieved the outcome of interest in the intervention group compared with the comparison group for a positive outcome then this intervention was considered beneficial. The same point estimate but in the opposite direction applied for a negative outcome. For the critical outcome of mortality any reduction represented a clinical benefit. For adverse events 50 events (20 for the ear wax review) or more per 1000 (5%) represented clinical harm. For continuous outcomes if the mean difference was greater than the minimally important difference (MID) then this represented a clinical benefit or harm. Where an SMD is used, this was converted back to mean difference into the units of one of scales (for example one that is most commonly used or more meaningful). Then the committee discussed whether the change in score represented a clinically important difference based on the change relative to the mean in the control group and to the number of points on the scale. For outcomes such as mortality any reduction or increase was considered to be clinically important.

This assessment was carried out by the committee for each outcome of interest, and an evidence summary table was produced to compile the committee's assessments of clinical importance per outcome, alongside the evidence quality and the uncertainty in the effect estimate (imprecision).

4.3.6 Clinical evidence statements

Clinical evidence statements are summary statements that are included in each review chapter, and which summarise the key features of the clinical effectiveness evidence presented. The wording of the evidence statements reflects the certainty or uncertainty in the estimate of effect. The evidence statements are presented by outcome and encompass the following key features of the evidence:

- The number of studies and the number of participants for a particular outcome.
- An indication of the direction of clinical importance (if one treatment is beneficial or harmful compared with the other, or whether there is no difference between the 2 tested treatments).
- A description of the overall quality of the evidence (GRADE overall quality).

4.4 Identifying and analysing evidence of cost effectiveness

The committee is required to make decisions based on the best available evidence of both clinical effectiveness and cost effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost effectiveness') rather than the total implementation cost. However, the committee will also need to be increasingly confident in the cost effectiveness of a recommendation as the cost of implementation increases. Therefore, the committee may require more robust evidence on the effectiveness and cost effectiveness of any recommendations that are expected to have a substantial impact on resources; any uncertainties must be offset by a compelling argument in favour of the recommendation. The cost impact or savings potential of a recommendation should not be the sole reason for the committee's decision.[82]

Health economic evidence was sought relating to the key clinical issues being addressed in the guideline. Health economists:

- Undertook a systematic review of the published economic literature.
- Undertook new cost-effectiveness analysis in priority areas.

4.4.1 Literature review

The health economists:

- Identified potentially relevant studies for each review question from the health economic search results by reviewing titles and abstracts. Full papers were then obtained.
- Reviewed full papers against prespecified inclusion and exclusion criteria to identify relevant studies (see below for details).
- Critically appraised relevant studies using economic evaluations checklists as specified in the NICE guidelines manual.[82]
- Extracted key information about the studies' methods and results into health economic evidence tables (included in appendix I).
- Generated summaries of the evidence in NICE health economic evidence profile tables (included in the relevant chapter for each review question) – see below for details.

4.4.1.1 Inclusion and exclusion criteria

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost–utility, cost-effectiveness, cost–benefit and cost–consequences analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially includable as health economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost effectiveness without disaggregated costs and effects were excluded. Literature reviews, abstracts, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded. Studies published before 2001 and studies from non-OECD countries or the USA were also excluded, on the basis that the applicability of such studies to the present UK NHS context is likely to be too low for them to be helpful for decision-making.

For more details about the assessment of applicability and methodological quality see Table 9 below and the economic evaluation checklist (appendix H of the NICE guidelines manual[82]) and the health economics review protocol in appendix D.

When no relevant health economic studies were found from the health economic literature review, relevant UK NHS unit costs related to the compared interventions were presented to the committee to inform the possible economic implications of the recommendations.

4.4.1.2 NICE health economic evidence profiles

NICE health economic evidence profile tables were used to summarise cost and cost-effectiveness estimates for the included health economic studies in each review chapter. The health economic evidence profile shows an assessment of applicability and methodological quality for each economic study, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from the NICE guidelines manual.[82] It also shows the incremental costs, incremental effects (for example, quality-adjusted life years [QALYs]) and incremental cost-effectiveness ratio (ICER) for the base case analysis in the study, as well as information about the assessment of uncertainty in the analysis. See Table 9 for more details.

When a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity.[93]

Table 9: Content of NICE health economic evidence profile

Item	Description
Study	Surname of first author, date of study publication and country perspective with a reference to full information on the study.
Applicability	An assessment of applicability of the study to this guideline, the current NHS situation and NICE decision-making:[(a)] • Directly applicable – the study meets all applicability criteria, or fails to meet 1 or more applicability criteria but this is unlikely to change the conclusions about cost effectiveness. • Partially applicable – the study fails to meet 1 or more applicability criteria, and this could change the conclusions about cost effectiveness. • Not applicable – the study fails to meet 1 or more of the applicability criteria, and this is likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from the review.
Limitations	An assessment of methodological quality of the study:[(a)] • Minor limitations – the study meets all quality criteria, or fails to meet 1 or more quality criteria, but this is unlikely to change the conclusions about cost effectiveness. • Potentially serious limitations – the study fails to meet 1 or more quality criteria, and this could change the conclusions about cost effectiveness. • Very serious limitations – the study fails to meet 1 or more quality criteria, and this is highly likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from the review.
Other comments	Information about the design of the study and particular issues that should be

Item	Description
	considered when interpreting it.
Incremental cost	The mean cost associated with a strategy minus the mean cost of a comparator strategy.
Incremental effects	The mean QALYs (or other selected measure of health outcome) associated with a strategy minus the mean QALYs of a comparator strategy.
Cost effectiveness	Incremental cost-effectiveness ratio (ICER): the incremental cost divided by the incremental effects (usually in £ per QALY gained).
Uncertainty	A summary of the extent of uncertainty about the ICER reflecting the results of deterministic or probabilistic sensitivity analyses, or stochastic analyses of trial data, as appropriate.

(a) Applicability and limitations were assessed using the economic evaluation checklist in appendix H of the NICE guidelines manual[82]

4.4.2 Undertaking new health economic analysis

As well as reviewing the published health economic literature for each review question, as described above, new health economic analysis was undertaken by the health economist in selected areas. Priority areas for new analysis were agreed by the committee after formation of the review questions and consideration of the existing health economic evidence.

The committee identified the following as the highest priority questions for original health economic modelling:

- What is the clinical and cost effectiveness of early versus delayed management of hearing loss on patient outcomes?
- What is the clinical and cost effectiveness of hearing aids for mild to moderate hearing loss in adults who have been prescribed at least 1 hearing aid?
- What is the clinical and cost effectiveness of fitting 1 hearing aid compared with fitting 2 hearing aids for people when both ears have an aidable hearing loss?

These questions were chosen due to the very large number of people in England using or who could benefit from hearing aids (and hence their high annual cost), and the existence of sufficient clinical and economic data for original analyses to be conducted on these questions.

The following general principles were adhered to in developing the cost-effectiveness analyses:

- case for interventions with health outcomes in NHS settings.[82, 84]
- The committee was involved in the design of the model, selection of inputs and interpretation of the results.
- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data were not available committee expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The model was peer-reviewed by another health economist at the NGC.

Full methods for the cost-effectiveness analysis for early versus delayed management of hearing loss are described in appendix N, and for the cost-threshold analysis are described in section 15.2.2.2.

4.4.3 Cost-effectiveness criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that committees should consider when judging whether an intervention offers good value for money.[83] In general, an intervention was considered to be cost effective (given that the estimate was considered plausible) if either of the following criteria applied:

- the intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- the intervention cost less than £20,000 per QALY gained compared with the next best strategy.

If the committee recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'Recommendations and link to evidence' section of the relevant chapter, with reference to issues regarding the plausibility of the estimate or to the factors set out in 'Social value judgements: principles for the development of NICE guidance'.[83]

When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless one strategy dominates the others with respect to every relevant health outcome and cost.

4.4.4 In the absence of health economic evidence

When no relevant published health economic studies were found, and a new analysis was not prioritised, the committee made a qualitative judgement about cost effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs, alongside the results of the review of clinical effectiveness evidence.

The UK NHS costs reported in the guideline are those that were presented to the committee and were correct at the time recommendations were drafted. They may have changed subsequently before the time of publication. However, we have no reason to believe they have changed substantially.

4.5 Developing recommendations

Over the course of the guideline development process, the committee was presented with:

- Evidence tables of the clinical and health economic evidence reviewed from the literature. All evidence tables are in appendices H and I.
- Summaries of clinical and health economic evidence and quality (as presented in chapters 5–19).
- Forest plots (appendix K).
- A description of the methods and results of the cost-effectiveness analyses undertaken for the guideline (appendix N and chapter 15).

Recommendations were drafted on the basis of the committee's interpretation of the available evidence, taking into account the balance of benefits, harms and costs between different courses of action. This was either done formally in an economic model, or informally. Firstly, the net clinical benefit over harm (clinical effectiveness) was considered, focusing on the critical outcomes. When this was done informally, the committee took into account the clinical benefits and harms when one intervention was compared with another. The assessment of net clinical benefit was moderated by the importance placed on the outcomes (the committee's values and preferences), and the confidence the committee had in the evidence (evidence quality). Secondly, the committee assessed whether the net clinical benefit justified any differences in costs between the alternative interventions.

When clinical and health economic evidence was of poor quality, conflicting or absent, the committee drafted recommendations based on its expert opinion. The considerations for making consensus-based recommendations include the balance between potential harms and benefits, the economic costs compared with the economic benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were agreed through discussions in the committee. The committee also considered whether the uncertainty was sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation (see section 4.5.1 below).

The committee considered the appropriate 'strength' of each recommendation. This takes into account the quality of the evidence but is conceptually different. Some recommendations are 'strong' in that the committee believes that the vast majority of healthcare and other professionals and patients would choose a particular intervention if they considered the evidence in the same way that the committee has. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. However, there is often a closer balance between benefits and harms, and some patients would not choose an intervention whereas others would. This may happen, for example, if some patients are particularly averse to some side effect and others are not. In these circumstances the recommendation is generally weaker, although it may be possible to make stronger recommendations about specific groups of patients.

The committee focused on the following factors in agreeing the wording of the recommendations:

- The actions health professionals need to take.
- The information readers need to know.
- The strength of the recommendation (for example the word 'offer' was used for strong recommendations and 'consider' for weaker recommendations).
- The involvement of patients (and their carers if needed) in decisions on treatment and care.
- Consistency with NICE's standard advice on recommendations about drugs, waiting times and ineffective interventions (see section 9.2 in the NICE guidelines manual[82]).

The main considerations specific to each recommendation are outlined in the 'Recommendations and link to evidence' sections within each chapter.

4.5.1 Research recommendations

When areas were identified for which good evidence was lacking, the committee considered making recommendations for future research. Decisions about the inclusion of a research recommendation were based on factors such as:

- the importance to patients or the population
- national priorities
- potential impact on the NHS and future NICE guidance
- ethical and technical feasibility.

4.5.2 Validation process

This guidance is subject to a 6-week public consultation and feedback as part of the quality assurance and peer review of the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website.

4.5.3 Updating the guideline

Following publication, and in accordance with the NICE guidelines manual, NICE will undertake a review of whether the evidence base has progressed significantly to alter the guideline recommendations and warrant an update.

4.5.4 Disclaimer

Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The National Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of this guideline and the literature used in support of this guideline.

4.5.5 Funding

The National Guideline Centre was commissioned by the National Institute for Health and Care Excellence to undertake the work on this guideline.

5 Immediate, urgent and routine referral

5.1 Introduction

The majority of hearing loss occurs as a consequence of ageing and excessive noise exposure; conditions for which there are no specific treatments that will change the outcome with respect to the hearing loss or the cause. There are, however, other causes of hearing loss where the underlying cause needs specific treatment, such as autoimmune diseases or Meniere's disease; or where surgery is required to correct an abnormality, such as conductive hearing loss in otosclerosis or a perforated ear drum; or to remove a tumour; or chronic infection. These cases are in the minority but for these patients timely medical care can make a significant difference to the prognosis of their hearing loss or of their underlying general medical problem. In rare cases, such as necrotising otitis externa, delay can result in death rather than recovery.

There are several clinical guidelines for GPs and audiologists outlining the circumstances in which they should consider referral for more specialist medical care – for example the British Academy of Audiology's Guidance for Audiologists and for Primary Care [16] and the British Society of Hearing Aid Audiologists[17] which reflect a broad clinical consensus.[16] However, there remains wide regional variation in both guidance and practice in the UK and unnecessary delay in care is frequently encountered.

The review questions in this chapter have been investigated with the aim of helping primary healthcare professionals and audiologists decide which symptoms and signs would indicate the need for more specialist medical assessment and with what degree of urgency. Clear national guidance may reduce disparities in care and improve the outcomes for people with causes of hearing loss that require specific treatment. Defining those who should be seen in secondary care, may also avoid people having several referrals before being seen by the correct team.

Not all criteria for referral to secondary care have been listed in this chapter. The scope of the guideline precludes mention of referral for consideration of an implantable device (cochlear implant, bone anchored hearing aid, middle ear implants and brain stem implants) and the referrer should consult other NICE guidelines (see 9.2.4).

5.2 Review question: What are the symptoms and signs that allow early recognition of hearing loss needing immediate or urgent referral to a secondary care specialist?

For full details see review protocol in appendix C.

The objective is to determine the diagnostic accuracy of specific symptoms and signs associated with hearing loss that may be indicative of serious underlying conditions such as stroke, autoimmune diseases or severe infections (see list in Table 10) and which require urgent referral for specialist care.

Table 10: Characteristics of review question

Population	Adults (18 years and over) presenting with hearing loss
Prognostic variables under consideration	• Sudden onset • Rapid progression • Cranial nerve involvement (or CNS symptoms), for example, facial paralysis, diplopia, speech and swallowing difficulties (bulbar paralysis) • Vertigo (sudden onset)

	• Recent-onset unilateral hearing loss • Additional systemic symptoms (skin, eye problems, joint problems, symptoms suggestive of autoimmune disease) • Severe pain with comorbid conditions, for example, diabetes • Spontaneous bleeding from ear (exclude malignancy)
Confounding factors	For studies reporting odds ratios, the following factors have been identified as key confounders and papers should include a multivariable analysis that adjusts for at least some of these confounders: • Earwax • Otitis externa (ordinary) • Ear infections • Middle ear effusion (due to infection, flight or diving) • Meniere's disease • Multiple sclerosis
Outcomes	• Malignant or necrotising otitis externa, otitis media with facial nerve impairment, • Rapidly progressing cholesteatoma • Rapidly growing vestibular schwannoma • Nasopharyngeal cancer and intracranial tumours • Stroke • Long-term neurological damage • Autoimmune disease
Study design	• Prospective and retrospective cohort studies, cross-sectional studies • Systematic reviews of the above

5.2.1 Clinical evidence

No relevant clinical studies were identified. See study selection flow chart in appendix E and the excluded studies list in appendix L.

5.2.2 Economic evidence

No relevant economic evaluations were identified.

See also the economic article selection flow chart in appendix F.

5.2.3 Evidence statements

Clinical

- No relevant published evidence was identified.

Economic

- No relevant economic evaluations were identified.

5.2.4 Recommendations and link to evidence

Recommendations	**1. Refer adults with sudden onset or rapid worsening of hearing loss in one or both ears, which is not explained by external or middle ear causes, as follows:** • **If the hearing loss developed suddenly (over a period of 3 days or**

	less) within the past 30 days, refer immediately (to be seen within 24 hours) to an ear, nose and throat service or an emergency department. • **If the hearing loss developed suddenly more than 30 days ago, refer urgently (to be seen within 2 weeks) to an ear, nose and throat or audiovestibular medicine service.** • **If the hearing loss worsened rapidly (over a period of 4 to 90 days) refer urgently (to be seen within 2 weeks) to an ear, nose and throat or audiovestibular medicine service.** **2. Refer immediately (to be seen within 24 hours) adults with acquired unilateral hearing loss and altered sensation or facial droop on the same side to an ear, nose and throat service or, if stroke is suspected, follow a local stroke referral pathway. For information about diagnosis and initial management of stroke, see the NICE guideline on stroke and transient ischaemic attack in over 16s.** **3. Refer immediately (to be seen within 24 hours) adults with hearing loss who are immunocompromised and have otalgia (ear ache) with otorrhoea (discharge from the ear) that has not responded to treatment within 72 hours to an ear, nose and throat service.** **4. Consider making an urgent referral (to be seen within 2 weeks) to an ear, nose and throat service for adults of Chinese or south-east Asian family origin who have hearing loss and a middle ear effusion not associated with an upper respiratory tract infection. For information about recognition and referral for suspected cancer, see the NICE guideline on suspected cancer.**
Relative values of different outcomes	Measures of diagnostic accuracy including sensitivity, specificity, positive predictive value, negative predictive value, ROC, AUC as well as adjusted odds ratios were all considered important outcomes to determine whether the symptoms and signs are indicative of a serious condition that requires immediate or urgent referral for a specialist assessment. The committee agreed that sensitivity is more important than specificity in this context because consequences may be missing a patient with serious conditions such as stroke, long-term neurological damage or rapidly progressing tumours. Specificity remains important because incorrectly diagnosing an individual may result in inappropriate administration of medications or treatments.
Quality of the clinical evidence	No clinical evidence was identified for this review.
Trade-off between clinical benefits and harms	As no evidence was found the recommendations were made by consensus of the committee. The committee agreed that good examples of referral criteria are set out in the British Academy of Audiology (BAA) guidance for audiologists and the British Society of Hearing Aid Audiologists (BSHAA).[61]This guidance lists onward referral criteria of patients by an audiologist, grouped by history, ear examination, tympanometry and audiometry. The committee reviewed and discussed some of the criteria and drew on this and its experience and clinical opinion in formulating recommendations. In the experience of committee members the criteria listed broadly reflect referral protocols and policies in place within their own areas of practice for immediate and urgent referral.

The committee agreed that the recommendation for referrals would not necessarily lead to more urgent referrals being made, but instead urgent referrals are more likely to be made earlier, thus possibly reducing harmful delays or unnecessary interim referrals and saving costs. The result should be more targeted referrals. The committee noted organisation of local services is very important in reducing unnecessary referrals between services. The committee noted that there is currently no nationally established pathway for community care to refer urgently to specialist services and the referral would be to GP services or A&E.

The consequence of delay in care varies dependent on the cause. For some this may mean that a hearing loss which could have responded to steroid treatment becomes permanent rather than recovering. For a few there are more severe possible consequences of delay: a stroke may be missed and further strokes could lead to permanent brain damage or death, autoimmune disease may not be treated promptly leading to serious sequelae such as aortitis or visual loss, if the cause of a sudden loss is bleeding into a vestibular schwannoma this could lead to brain stem compression and permanent neurological difficulties and , if the problem is necrotising otitis externa then delay usually results in death. Most of these problems are likely to be picked up eventually and treatment given but any damage could be worse than if early treatment is given.

Rationales for immediate or urgent referrals:

Most cases of hearing loss have no identifiable cause or specific treatment but some do and it is important to recognise the causes where treatment can be offered to prevent or limit morbidity. The committee considered and discussed the presentations where an urgent referral would be made and what time frames should be used to distinguish between different levels of urgency. The following definitions for referral times made in the recommendations were agreed:

- ' Refer immediately' means the person should be seen by the specialist service within 24 hours.
- 'Refer urgently' means the person should be seen by the specialist service within 2 weeks.
- 'Refer' means a routine referral.

It is expected that the GP will first exclude impacted wax, and acute infections such as otitis externa, otitis media or middle ear effusion (serous or mucoid fluid behind an intact ear drum) related to acute upper respiratory tract infections such as a cold, sinusitis or influenza as the cause of the hearing complaint and treat appropriately. It should be noted that wax removal may be an urgent requirement in order to exclude earwax as the cause of hearing loss and avoid delay in treatment of underlying pathology.

Sudden loss of hearing occurring over a period of 72 hours or less and presenting within 30 days.

This requires immediate or urgent investigation for treatable causes such as autoimmune disease, chronic infection, rapidly expanding vestibular schwannoma or stroke. Immediate treatment with steroids is current practice. Delay in management may lead to increased morbidity. If the sudden hearing loss occurred more than 30 days prior to presentation urgent investigation is still required but immediate care is not.

Rapid worsening of hearing loss over the last 90 days

Deteriorating hearing requires urgent investigation for treatable causes such as autoimmune disease, chronic infection, vestibular schwannoma or intracranial tumours. Delay in treating some causes can lead to increased morbidity.

	Unilateral hearing loss on the same side as altered sensation to face or facial droop These symptoms may indicate a vestibular schwannoma or CPA tumour, a viral infection, an aggressive cholesteatoma or a stroke. Immediate investigation is required and surgery may be needed. *Persistent otalgia and otorrhoea in immuno-compromised patients* This population is at risk of developing necrotising otitis externa (previously known as malignant otitis externa) in which an otitis externa infection extends inwards and affects the skull base and cranial nerves. Early and effective management is needed to prevent death. *Unilateral persistent middle ear effusion not associated with upper respiratory tract infection in people of Chinese and South-East Asian family origin* There is a high incidence of nasopharyngeal carcinoma in people of Chinese and South-East Asian family origin and presentation is often a middle ear effusion not associated with, or not resolving after, an upper respiratory tract infection. This pathology is also more common in other racial groups such as those from North Africa and Eskimos but is generally rare in people of European family origin. Early recognition and treatment of the tumour leads to a much better outcome. The committee agreed, based on its clinical experience and on epidemiological studies, that this presentation is strongly associated with nasopharyngeal cancer in this population, and was likely to be associated with a positive predictive value of 3% or above and would prompt the clinician to consider urgent referral. The presentations listed above require immediate or urgent medical management and referral should not be delayed in order to obtain an audiological assessment. It may be appropriate for local audiology services to manage any residual permanent hearing loss after initial treatment.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee judged that these recommendations reflect current best practice, though there is local variation and not all clinicians would currently be aware that all of these signs and symptoms should lead to urgent referral. The committee agreed that everyone with the symptoms listed in these recommendations would currently eventually receive specialist assessment and care. While some would currently be referred to receive this care urgently, others could face delay in receiving specialist care. They may be referred elsewhere (such as emergency departments) as an interim step, or be referred for non-urgent assessment, or may not be referred anywhere at first presentation, but then would later present again to primary care or at an emergency department before being referred to secondary care. As the assessment and care people will receive once they access specialist services will not vary based on how long it takes them to arrive there, there should not be a difference in costs from urgent or later referral to specialist care. However a direct urgent referral may reduce costs of unnecessary interim steps or repeat presentations. Crucially, seeing referred patients urgently is also likely to lead to better long-term health outcomes and possibly reduced later expenditure on avoidable complications. Delay in care increases morbidity and in some cases leads to death. This is a risk particularly for people with auto-immune disease, necrotising otitis externa, stroke or large intracranial tumours. Therefore, ensuring that people with the symptoms listed here are referred urgently will give rise to equivalent costs in specialist services, slightly reduced costs to other

	services, and the same or better health outcomes. The committee hence expects these recommendations to be cost effective or cost saving compared with current practice.
Other considerations	The committee agreed that having a checklist or table of symptoms and signs with the action and where to refer to and in what timeframe would be a useful quick guide for practitioners.

5.3 Review question: Who should be routinely referred to audiovestibular medicine or ear, nose and throat (ENT) surgery for medical assessment?

This review is to identify who needs to go to secondary or specialist medical care in addition to (non-medical) audiology, that is, they need audiological assessment but also medical care. It will look at most of the routine referral criteria for people with hearing loss who need to be referred to audiovestibular medicine or ear, nose and throat (ENT) surgery for medical assessment.

For full details see review protocol in appendix C.

Table 11: Characteristics of review question

Population	Adults (18 years and over)
Index tests	• Referral criteria • Risk assessment tools
Reference standard	Confirmed diagnosis of conditions requiring medical and audiological assessment, for example: • Vestibular schwannoma and cholesteatoma in the absence of sudden hearing loss • Perforated tympanic membrane • Ear infections
Statistical measures	• Sensitivity • Specificity • Positive predictive value • Negative predictive value • ROC curve or area under the curve • Adjusted odds ratios
Study design	• Diagnostic accuracy study (2-gate studies will be excluded unless no other data are available from single gate-studies) • Systematic reviews of diagnostic accuracy studies • Prospective cohort studies with multivariate analyses that adjust for age and medication • Systematic reviews of the above

5.3.1 Clinical evidence

No relevant clinical studies were identified investigating the diagnostic accuracy of routine referral criteria or risk assessment tools for people with hearing loss who need to be referred to audiovestibular medicine or ear, nose and throat (ENT) surgery for medical assessment. See study selection flow chart in appendix E and the excluded studies list in appendix L.

5.3.2 Economic evidence

No relevant economic evaluations were identified.

See also the economic article selection flow chart in appendix F.

5.3.3 Evidence statements

Clinical

- No relevant evidence was identified.

Economic

- No relevant economic evaluations were identified.

5.3.4 Recommendations and link to evidence

Recommendations	**5. Consider referring adults with hearing loss that is not explained by acute external or middle ear causes to an ear, nose and throat, audiovestibular medicine or specialist audiology service for diagnostic investigation, using a local pathway, if they present any of the following:** **• unilateral or asymmetric hearing loss as a primary concern** **• hearing loss that fluctuates and is not associated with an upper respiratory tract infection** **• hyperacusis (intolerance to everyday sounds that causes significant distress and affects a person's day-to-day activities)** **• persistent tinnitus that is unilateral, pulsatile, has significantly changed in nature or is causing distress** **• vertigo that has not fully resolved or is recurrent** **• hearing loss that is not age related** **6. Consider referring adults with hearing loss to an ear, nose and throat service if, after initial treatment of any earwax (see recommendations 15-19 on removing earwax) or acute infection, they have any of:** **• partial or complete obstruction of the external auditory canal that prevents full examination of the eardrum or taking an aural impression** **• pain affecting either ear (including in and around the ear) that has lasted for 1 week or more and has not responded to first-line treatment** **• a history of discharge (other than wax) from either ear that has not resolved, has not responded to prescribed treatment or recurs** **• abnormal appearance of the outer ear or the eardrum, such as:** **i. inflammation** **ii. polyp formation** **iii. perforated eardrum** **iv. abnormal bony or skin growths** **v. swelling of the outer ear** **vi. blood in the ear canal.**

	• **a middle ear effusion in the absence of, or that persists after, an acute upper respiratory tract infection.**
Relative values of different outcomes	Measures of diagnostic accuracy including sensitivity, specificity, positive predictive value, negative predictive value, ROC, AUC as well as adjusted odds ratios were all considered important outcomes to determine whether the symptoms and signs are indicative of a condition that requires onward routine referral for audiological assessment and medical care. The relative value of sensitivity compared with specificity would depend on the risk assessment tool or referral criteria being considered. Sensitivity was considered to be the most important outcome for assessment tools that aim to rule out patients that do not have the target condition and do not require onward referral and specificity was considered important for assessment tools that aim to identify patients with the target conditions who need onward referral. The guideline committee agreed that a risk assessment tool or referral criteria should have a sensitivity or specificity threshold of 90%. Only adjusted odds ratios from studies that had conducted a multivariate analysis including the clinical prediction factors of interest were considered.
Quality of the clinical evidence	No clinical evidence was identified for this review.
Trade-off between clinical benefits and harms	As no evidence was found the recommendations were based on consensus of the committee. The committee felt that these recommendations would not necessarily lead to an increase in the number of referrals, but are likely to lead to earlier referrals thus possibly reducing unnecessary interim referrals and saving costs. The result should be more targeted referrals. The committee noted that organisation of local services is very important in reducing unnecessary referrals between services. Most cases of hearing loss have no identifiable cause or specific treatment but some do and it is important to recognise the causes where treatment can be offered to prevent or limit morbidity. The symptoms and signs listed are those where it is very likely that medical or surgical investigation and treatment will be needed. The committee considered and discussed these outlining the rationale why these would usually be considered requiring a routine referral to specialist services. It is expected that the GP will first consider impacted wax, acute otitis externa, otitis media or middle ear effusion related to acute upper respiratory tract infections as the cause of the hearing complaint and treat appropriately. It should be noted that wax removal may be an urgent requirement in order to exclude this as the cause of hearing loss and avoid delay in treatment of underlying pathology. *Unilateral or asymmetric hearing loss* A unilateral or asymmetric hearing loss unrelated to earwax or an acute external or middle ear infection can indicate a possible vestibular schwannoma or CPA tumour, a cholesteatoma or conditions such as otosclerosis. Unless the hearing loss is sudden or rapidly progressive or accompanied by localising symptoms or signs, a routine referral is usual. It should be noted that on direct questioning someone may report a difference in hearing between the two ears with age or noise related hearing loss, therefore referral should be made if the individual presents with the problem of asymmetry. If there is doubt audiological assessment will determine if the asymmetry is sufficiently severe to warrant referral for diagnostic investigation, In some areas investigation for an asymmetric hearing loss can initially be taken forward by audiologists. The committee anticipated that audiologists would offer advice based on the referral guidelines of their professional organisation (BAA or BSHAA). *Hearing loss that fluctuates and is not associated with an upper respiratory tract infection*

Fluctuating hearing loss is commonly caused by Meniere's disease which needs careful evaluation and treatment. Other causes can include fluctuating middle ear effusion which could be linked with nasal pathology and in these cases it is important to exclude nasopharyngeal tumours.

Hyperacusis

Hyperacusis (intolerance to everyday sounds that causes significant distress and affects a person's day-to-day activities) can have a number of causes. When associated with hearing loss it is important to exclude causes that require specific treatment, such as a dehiscent superior semi-circular canal which may require surgery

Persistent tinnitus that is unilateral, or is pulsatile (in one or both ears) or has significantly changed in nature or is causing distress

A significant change in tinnitus is defined as one which the patient reports as significant. Examination should exclude other causes for change such as wax or infection.

Transient tinnitus which is short-lived (lasting for periods less than 5 minutes) or occurring after significant noise exposure or with upper respiratory tract infections or earwax occlusion does not require diagnostic referral. It is only when tinnitus becomes persistent that referral is indicated.

Tinnitus is a symptom that can change with time and the changes may not be associated with worrying pathology. However, these types of tinnitus with hearing loss need further investigation:

Unilateral tinnitus can be associated with conditions such as vestibular schwannoma, Meniere's disease or otosclerosis

Pulsatile tinnitus can be caused by intracranial vascular tumours, aneurysms or carotid atherosclerosis and by brainstem pathology (myoclonus).

A significant change in tinnitus may be caused by anxiety or stress but could be related to advancing pathology such as cholesteatoma.

Tinnitus that is causing distress will need management by specialist services and part of that care will include investigation of cause.

Vertigo which has not fully resolved or which is recurrent

Vertigo associated with hearing loss can indicate Meniere's disease, a perilymph fistula, a CPA tumour or brainstem pathology. Full assessment and investigation is needed.

Hearing loss that is not age related

Most hearing loss is age related and usually starts gradually in the 50s or 60s. It is a slowly progressive high frequency sensory hearing loss. If a GP or audiologist believes that a hearing loss is not due to ageing because of the history, including the age of onset, or the audiometric findings diagnostic investigation is recommended. Hearing losses that are not age related can be genetic in origin and can occur in isolation but can be associated with medical illness such as infection, renal disease or neurological disease or caused by ototoxic drugs or chemicals.

Partial or complete obstruction of the external auditory canal that prevents full examination of the eardrum or taking an aural impression

It is important to be able to examine the external ear and ear drum properly in people presenting with hearing or ear problems and if there is an obstruction that prevents examination a surgical opinion should be sought. This may be earwax that has been

	impossible to remove completely, a foreign body or a swelling or tumour. It is important to note that earwax remaining adherent to the ear drum, particularly if superior or posterior, can be an indication of cholesteatoma. *Pain affecting either ear (including in and around the ear) that has lasted for 1 week or more and has not responded to first-line treatment* Persistent pain around the ear can have a number of causes, for example, persistent infection, temporomandibular joint disorder or a malignant lesion in the ear or throat. The urgency of the referral is dependent on the presumed diagnosis with necrotising otitis externa being immediate and suspected malignancy on a 2 week cancer pathway with other cases being routine. Cases with shingles giving otalgia and hearing loss (Ramsay Hunt Syndrome) need immediate treatment and may need referral to ENT. *A history of discharge (other than wax) from either ear that has not resolved, has not responded to prescribed treatment or recurs* Persistent otorrhoea can indicate persistent infection due to otitis externa or chronic middle ear disease or cholesteatoma. Malignant tumours of the external ear can present with bloody discharge. If otorrhoea does not resolve with first line treatment specialist care and investigation is required. If malignancy is suspected a 2 week cancer pathway should be considered. Recurrent discharge may indicate a cholesteatoma needing surgical treatment. *Abnormal appearance of the outer ear or the eardrum* It is important for abnormal appearances to be properly diagnosed as some will require surgical treatment and delay can increase morbidity. These will include chronic middle ear disease or cholesteatoma, perforated tympanic membrane, malignant tumours or foreign bodies. If malignancy is suspected a 2 week cancer pathway should be considered. Proper identification and treatment of the cause is important and can be urgent. . *A middle ear effusion in the absence of, or that persists after, an acute upper respiratory tract infection.* Middle ear effusions are rare in adults. They can occur with an upper respiratory tract infection but should resolve soon after. A persistent effusion can be due to benign conditions such as chronic sinus disease, allergic rhinitis or nasal polyps, However it can also be caused by nasopharyngeal carcinoma. This is more common in people with Chinese, South East Asian, North African and Eskimo family origin, but can present at any age in any racial group. Delay in referral can lead to significant morbidity.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee judged that these recommendations largely reflect current practice. All those recommended to be referred for assessment by a specialist need this referral and would currently be expected to be referred. The committee agreed that any patients currently not referred in line with these recommendations by GPs at their

	first presentation, would in any case present again subsequently and would eventually be referred. Or, following referral to an audiologist for assessment, would be referred on to ear nose and throat services where that is appropriate. Referring directly to the right person in the first referral is much more efficient and will reduce morbidity. Timelier referral would not increase costs but would lead to faster treatment and so better health outcomes. In total the number of referrals is not expected to change, though some people may progress through a shorter patient journey involving fewer steps along the way. There should therefore be either no change or a small reduction in overall costs, and a probable small improvement in outcomes. Therefore, these recommendations will be very likely to be cost saving or cost effective compared with current practice.
Other considerations	The committee agreed that a good example of referral criteria was set out by the BAA guidance)[60] for audiologists based on history, examination and audiological assessment. Other similar documents include the BAA guidance for primary care and the referral criteria from British Society of Hearing Aid Audiologists (BSHAA). The committee referred to these documents when drawing up the recommendations above which were based primarily on experience and clinical opinion.. The above recommendations are for health professionals, such as GPs and audiologists, working within primary and community care. It is acknowledged that in some areas audiologists make direct referral into medical services and may investigate hearing loss directly. The committee mentioned persistent unilateral tinnitus associated with hearing loss in the recommendations, but notes that a comprehensive assessment on tinnitus is set out in the NICE clinical knowledge summary on tinnitus. The committee did not discuss referral for investigation into the cause of hearing loss when genetic or genomic aetiology is suspected. There is currently insufficient robust evidence to consider making a recommendation.

6 MRI

6.1 Introduction

Acquired audiovestibular symptoms may be an indicator of cerebellopontine angle (CPA), internal auditory meatus (IAM) or inner ear disorders, such as meningioma, vestibular schwannoma (VS), cholesterol granuloma or fibrosis of the labyrinth. Such pathologies may be accurately diagnosed with MRI. Hearing loss (asymmetric or unilateral) as a clinical symptom or as demonstrated on pure tone audiometry (PTA) is an important consideration when selecting patients for MRI.

Vestibular schwannoma (also known as acoustic neuroma) is a rare benign tumour of the cells that form the sheath around the nerve of balance (vestibular nerve). The vestibular nerves run with the nerve of hearing (cochlear nerve) in the internal auditory meatus. These tumours can cause hearing loss by compressing the cochlear nerve in this narrow bony channel or in the inner ear, or they can grow into the posterior cranial fossa and cause brain stem compression giving neurological symptoms and signs, and, in time, can be life-threatening if not treated. Small tumours may be very slow growing in older people, requiring observation only, but in younger people growth can be quicker and surgical removal may be needed.

Whilst the main focus of investigation with MRI is on the detection of vestibular schwannomas or similar tumours, other abnormalities may be demonstrated with a similar frequency.[117] In a paper by Vandervelde in 2009 looking at 881 consecutive MRI scans performed for audiovestibular symptoms 1.4% were positive for vestibular schwannomas, 0.4% identified other relevant pathology and in 1.4% incidental pathologies were found which were irrelevant to the presenting complaint.[117] MRI is increasingly performed in this clinical field due to wider availability of scanners, quicker scanning protocols, changes in diagnostic algorithms and easier access to audiological testing, as well as due to heightened patient awareness and expectations. It has been noted that up to 20% of new ENT referrals with audiovestibular symptoms are deemed appropriate for MRI.[54] This has contributed to an increased incidence of vestibular schwannoma detection in the past 30 years,[46, 106, 107, 114] and the average tumour size at detection has decreased from 3 cm to 1 cm.

When developing referral guidelines for MRI it is important to maximise diagnostic yield without missing pathologies which would benefit from earlier diagnosis, monitoring or treatment; however, it should be noted that vestibular schwannomas only grow in the medium term in 30–90% of cases[107] and are frequently managed conservatively. There is also a potential cost to the 'overdiagnosis' of asymptomatic vestibular schwannomas (or other abnormalities) which do not require intervention, in terms of increased resources required for clinical follow-up or MRI monitoring and increased patient anxiety. There is no clear consensus on the clinical and audiological parameters which should prompt MRI referral in order to optimise the diagnostic efficacy for clinically relevant pathology.

6.2 Review question: In people who have been referred to secondary care with sensorineural hearing loss, who needs MRI to assess the underlying cause of hearing loss?

For full details see review protocol in appendix C.

Table 12: Characteristics of review question

Population	Adults (18 years and over) presenting with hearing loss who have been referred to secondary care
Target condition	• Vestibular schwannoma (or other causative lesion) confirmed by MRI

Index tests	• Referral criteria • Risk assessment tools
Reference standard	• MRI
Statistical measures	• Sensitivity • Specificity • Positive predictive value • Negative predictive value • ROC curve or area under the curve • Adjusted odds ratios
Study design	Diagnostic accuracy study (2-gate studies will be excluded unless no other data are available from single gate-studies) Systematic reviews of diagnostic accuracy studies

6.2.1 Clinical evidence

We searched for prospective and retrospective studies assessing the diagnostic test accuracy of referral criteria or risk assessment tools to identify the presence (as indicated by MRI) of vestibular schwannoma (or other causative lesions) in people under investigation in secondary care for hearing loss (symmetric or asymmetric). We initially sought cohort (single-gate) studies, but if these were not available for a specific test, case–control (2-gate) studies were also considered. Studies were excluded if they included mixed populations (a mix of people with hearing loss and with other audiovestibular symptoms) and the proportion with hearing loss was unclear. Studies with mixed populations, but the majority having hearing loss at presentation were included but downgraded for indirectness.

Seven studies were included in the review; [20, 27, 66, 75, 102, 104, 111] these are summarised in Table 13 below. Evidence from these studies is summarised in the clinical evidence summary (Table 15). See also the study selection flow chart in appendix E, forest plots of sensitivity and specificity in appendix K, study evidence tables in appendix H and excluded studies list in appendix L.

The included studies covered a range of different clinical and audiological tests to triage those with hearing loss for further investigation with MRI. The MRI method also varied between studies as detailed in Table 13. A variety of thresholds or definitions of positive result were also used, which are shown in

Table **14**. One of the studies included some participants with symmetrical hearing loss.[66] Although the majority of studies did not state whether assessors were blinded, this was not considered as a source of bias because it is unlikely that prior knowledge significantly influences interpretation of the MRI findings in this setting. Due to the variability in the studies such as the MRI methods used and the definitions of the causative lesions, the study results have not been meta-analysed but have been presented as ranges of sensitivities and specificities for each outcome.

Table 13: Summary of studies included in the review

Study	n (incidence of VS/other lesion)	Study design	Population (country)	Target condition	Index test	Reference standard	Comments
Cheng 2012[20]	1751 (131)	Retrospective cohort	Sensorineural hearing loss (UK)	CPA lesion	15 pure tone audiometry protocols	MRI – High resolution non-enhanced FSE T2-weighted (n=217) or T1-weighted with gadolinium enhancement (n=1672); reason for different approaches unclear Slice thickness not stated Assessed by consultant radiologist (and a second assessor)	Sensitivity calculation based on taking non-acoustic tumours and non-pathological cases as negatives. See evidence table for specificity values based on taking only non-pathological cases as negatives.
Cueva 2004[27]	316 (4)	Prospective cohort	Asymmetric sensorineural hearing loss (USA)	Causative lesion	Auditory brainstem response	MRI – T1-weighted with gadolinium enhancement Slice thickness not stated Assessed by neuroradiologist	Blinded assessors
Kumar 2016[66]	756 (8)	Retrospective cohort	Suspected vestibular schwannoma (majority had either hearing loss or unilateral tinnitus) (UK)	Vestibular schwannoma	4 pure tone audiometry protocols	MRI of internal auditory meatus [no further details] Scanner and slice thickness not stated Assessor not stated	13–19% of sample did not have hearing loss at presentation (none of these had VS) Those with hearing loss had a mix of unilateral and bilateral, symmetrical and asymmetrical symptoms
Mandala 2013[75]	102 (49)	Prospective case–control	Confirmed vestibular schwannoma cases or controls with unilateral sensorineural	Vestibular schwannoma	Hyperventilation test Caloric irrigation	MRI – T1-weighted with gadolinium enhancement Scanner and slice thickness not stated Assessor not stated	PTA and ABR tests also presented but not analysed in this review as we have higher level data from other studies

Study	n (incidence of VS/other lesion)	Study design	Population (country)	Target condition	Index test	Reference standard	Comments
			hearing loss (Italy)				
Rupa 2003[102]	90 (4)	Prospective cohort	Asymmetric hearing loss and tinnitus (India)	Vestibular schwannoma	Auditory brainstem response	MRI – T1-weighted with gadolinium enhancement Scanner and slice thickness not stated Assessor not stated	18 patients (2 with VS) excluded because they had no response on ABR due to severe to profound sensorineural hearing loss. 14% of sample did not have hearing loss at presentation
Saliba 2011[104]	212 (84)	Retrospective cohort	Asymmetric sensorineural hearing loss (Canada)	Vestibular schwannoma	9 pure tone audiometry protocols	Posterior fossa MRI [no further details] Scanner and slice thickness not stated Assessed by a radiologist	High proportion (40%) with VS (referred tertiary care centre setting). Excluded patients without data at 3 kHz
Suzuki 2010[111]	500 (13)	Retrospective cohort	Asymmetric sensorineural hearing loss (Japan)	Vestibular schwannoma	Pure tone audiogram shapes	MRI – T2 without Gd-enhancement 1.5 Tesla scanner; 0.8 mm gapless slice Assessed by a radiologist/otolaryngologist	Included patients from 15 years of age

Abbreviations: VS: vestibular schwannoma

Table 14: Index test thresholds for included studies

Study	Index test	Thresholds/definitions of positive test	
Cheng 2012[20]	15 pure tone audiometry protocols	**Single-frequency comparison**	
		DOH-	≥20 dB at any single frequency between 0.5–4 kHz.
		Nashville	≥15 dB at any single frequency between 0.5–4 kHz.

Study	Index test	Thresholds/definitions of positive test	
		AMCLASS-B-Urben	≥15 dB at any single frequency.
		Rule 3000	≥15 dB asymmetry at 3 kHz.
		Rule 4000	≥20 dB asymmetry at 4 kHz.
		Two adjacent-frequency comparison	
		Sunderland	≥20 dB at 2 adjacent frequencies.
		AMCLASS-A-Urben	≥10 dB at 2 adjacent frequencies.
		Cueva	≥15 dB at 2 or more adjacent frequencies.
		Averaged multiple-frequency comparison	
		AAO-HNS	≥ 15 dB between ears averaging 0.5–3 kHz.
		Oxford	≥ 15 dB between ears averaging 0.5–8 kHz.
		Seattle	≥ 15 dB between ears averaging 1–8 kHz.
		Mangham	≥ 10 dB between ears averaging 1–8 kHz.
		Schlauch and Levine	≥ 20 dB between ears averaging 1–8 kHz.
		Sheppard	≥ 15 dB between ears averaging 0.25–8 kHz.
		Obholzer	≥ 15 dB if better ear is ≤ 30 dB hearing loss average at frequencies 0.25–8 kHz; or ≥ 20 dB if better ear is >30 dB hearing loss average at frequencies 0.25–8 kHz.
Cueva 2004[27]	Auditory brainstem response	Auditory brainstem response abnormal if: • Interaural IT5 inter-peak latency > 0.2 ms, • absolute wave V latency abnormal, or • absent/distorted waveform morphology.	
Kumar 2016[66]	4 pure tone audiometry protocols	≥20 dB at 2 adjacent frequencies; or ≤ 20dB with neurological signs. ≥15 dB between average of 0.5–8 kHz. ≥20 dB at any single frequency between 0.5–4 kHz. ≥15 dB at any single frequency between 0.5–4 kHz.	
Mandala 2013[75]	Hyperventilation test Caloric irrigation	Hyperventilation test: Hyperventilation-induced nystagmus (positive) Caloric irrigation deficit: paralysis or paresis	
Rupa 2003[102]	Auditory brainstem response	Auditory brainstem response suggestive of retrocochlear pathology if: • increased inter-peak latencies (I–III of ≥2.5 ms, III–V of ≥2.3 ms, I–V of ≥4.4 ms),	

Study	Index test	Thresholds/definitions of positive test
		• interaural latency difference of ≥0.3 ms, • poor waveform morphology and replicability, or • absent response despite normal/mildly elevated audiometric thresholds
Saliba 2011[104]	9 pure tone audiometry protocols	**Single-frequency comparison** DOH ≥20 dB asymmetry at any single frequency between 0.5–4 kHz. Nashville ≥15 dB asymmetry at any single frequency between 0.5–4 kHz. AMCLASS-B ≥15 dB asymmetry at any single frequency. Rule 3000 ≥15 dB asymmetry at 3 kHz. **Two adjacent-frequency comparison** Sunderland ≥20 dB asymmetry at 2 adjacent frequencies. AMCLASS-A ≥10 dB asymmetry at 2 adjacent frequencies. Cueva ≥15 dB asymmetry at 2 or more adjacent frequencies; or 15% difference in speech discrimination. **Averaged multiple-frequency comparison** AAO-HNS ≥ 15 dB asymmetry averaging 0.5–3 kHz. Oxford ≥ 15 dB asymmetry averaging 0.5–8 kHz. Seattle ≥ 15 dB asymmetry averaging 1–8 kHz.
Suzuki 2010[111]	Pure tone audiogram shapes	• **High frequency sloping loss**: normal threshold between 0.125 kHz and 2 kHz with a downward curve into the high frequencies (4, 6 and 8 kHz) and a 10 dB difference between 2 consecutive frequencies • **High frequency steep loss**: normal threshold between 0.125 kHz and 2 kHz with a loss of hearing of at least 40 dB at each measured high frequency (4, 6 and 8 kHz). • **Flat loss**: no difference of >20 dB between all frequencies • **Total deafness**: hearing loss of at least 90 dB at every frequency from 0.25 kHz to 8 kHz. • **Low frequency loss**: threshold reduced by at least 25 dB at the low frequencies (0.125 kHz and 0.25 kHz) with a rising curve into the speech range • **Basin-shaped loss**: good hearing at 0.125, 0.25, 0.5 and 8 kHz with elevated thresholds throughout the middle frequencies and >15dB difference between lowest and highest hearing thresholds. • **Mountain-shaped loss**: at least 2 consecutive frequencies between 0.25 kHz and 4 kHz that were better than 0.125 kHz and 8 kHz

Table 15: Clinical evidence summary: diagnostic test accuracy for non-imaging tests

Index Test	No of studies	n	Quality	Sensitivity % (95% CI)	Specificity % (95% CI)
Pure tone Hearing thresholds					
Hearing thresholds (DOH) [1]	3	2719	LOW[2,3] due to serious risk of bias, serious indirectness	Cheng: 83 (76–89) Kumar: 100 (63–100) Saliba: 87 (78–93)	Cheng: 63 (60–65) Kumar: 63 (60–67) Saliba: 59 (50–67)
Hearing thresholds (Nashville)[1]	3	2719	LOW[2,3] due to serious risk of bias, serious indirectness	Cheng: 88 (81–93) Kumar: 100 (63–100) Saliba: 93 (85–97)	Cheng: 52 (50–55) Kumar: 53 (49–56) Saliba: 44 (35–53)
Hearing thresholds (AMCLASS-B-Urben)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	88 (81–93)	45 (42–47)
Hearing thresholds (Rule 3000)	2	1963	VERY LOW[2,3,4] due to serious risk of bias, serious indirectness, serious inconsistency	Cheng: 88 (81–93) Saliba: 73 (62–82)	Cheng: 57 (55–60) Saliba: 76 (67–83)
Hearing thresholds (Rule 4000)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	82 (75–89)	63 (60–65)
Hearing thresholds (Sunderland)[1]	3	2719	LOW[2,3] due to serious risk of bias, serious indirectness	Cheng: 82 (75–89) Kumar: 88 (47–100) Saliba: 74 (63–83)	Cheng: 61 (59–63) Kumar: 79 (76–82) Saliba: 70 (62–78)
Hearing thresholds (AMCLASS-A-Urben)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	93 (87–97)	32 (29–34)
Hearing thresholds (AMCLASS)	1	212	LOW[2,3] due to serious risk of bias, serious indirectness	93 (85–97)	25 (18–33)
Hearing thresholds (Cueva)	2	1963	LOW[2,3] due to serious risk of bias, serious indirectness	Cheng: 85 (78–91) Saliba: 81 (71–89)	Cheng: 49 (46–51) Saliba: 60 (51–69)
Hearing thresholds (AAO-HNS)	2	1963	LOW[2,3]	Cheng: 87 (80–92)	Cheng: 65 (63–68)

Index Test	No of studies	n	Quality	Sensitivity % (95% CI)	Specificity % (95% CI)
			due to serious risk of bias, serious indirectness	Saliba: 90 (82–96)	Saliba: 55 (46–64)
Hearing thresholds (Oxford)[1]	3	2719	LOW[2,3] due to serious risk of bias, serious indirectness	Cheng: 85 (78–91) Kumar: 88 (47–100) Saliba: 93 (85–97)	Cheng: 61 (59–63) Kumar: 78 (75–81) Saliba: 44 (35–53)
Hearing thresholds (Seattle)	2	1963	LOW[2,3] due to serious risk of bias, serious indirectness	Cheng: 86 (79–92) Saliba: 92 (84–97)	Cheng: 60 (58–62) Saliba: 44 (35–53)
Hearing thresholds (Mangham)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	0.92 (85–96)	44 (42–47)
Hearing thresholds (Schlauch and Levine)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	81 (73–87)	66 (64–69)
Hearing thresholds (Sheppard)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	87 (80–92)	60 (58–63)
Hearing thresholds (Obholzer)	1	1751	LOW[2,3] due to serious risk of bias, serious indirectness	84 (77–90)	66 (64–69)
Audiometric shape					
High frequency sloping loss	1	500	LOW[2,5] due to serious risk of bias, and serious imprecision	8 (0–36)	93 (91–95)
High frequency steep loss	1	500	VERY LOW[2,5] due to serious risk of bias, and very serious imprecision	15 (2–45)	84 (80–87)
Flat loss	1	500	VERY LOW[2,5] due to serious risk of bias, and very serious imprecision	38 (14–68)	79 (75–83)

Index Test	No of studies	n	Quality	Sensitivity % (95% CI)	Specificity % (95% CI)
Total deafness	1	500	VERY LOW[2,5] due to serious risk of bias, and very serious imprecision	15 (2–45)	89 (85–91)
Low frequency loss	1	500	LOW[2,5] due to serious risk of bias, and serious imprecision	0 (0–25)	81 (77–84)
Basin-shaped loss	1	500	VERY LOW[1,5] due to serious risk of bias, and very serious imprecision	23 (5–54)	92 (89–94)
Mountain-shaped loss	1	500	LOW[2,5] due to serious risk of bias, and serious imprecision	0 (0–25)	88 (85–91)
Auditory brainstem response (accuracy for all pathology)					
IT5 inter-peak latency > 0.2 ms; absolute wave V latency abnormal; or absent/distorted waveform morphology.	1	316	LOW[2,5] due to serious risk of bias, and serious imprecision	71 (52–86)	74 (68–79)
Auditory brainstem response (accuracy for VS plus CPA meningioma)					
Increased interpeak intervals (I–III of ≥2.5 ms, III–V of ≥2.3 ms, I–V of ≥4.4 ms); interaural latency difference of ≥0.3 ms; poor waveform morphology and replicability, or absent response despite normal/mildly elevated audiometric thresholds [excluding the 'no responses' due to severe to profound sensorineural hearing loss]	1	72	VERY LOW[2,3,5] due to serious risk of bias, very serious imprecision, and serious indirectness	100 (54–100)	64 (51–75)
Caloric irrigation					

Index Test	No of studies	n	Quality	Sensitivity % (95% CI)	Specificity % (95% CI)
Canal paralysis or paresis	1	102	VERY LOW[2,3,5] due to very serious risk of bias, serious indirectness, and serious imprecision	43 (29–58)	91 (79–97)
Hyperventilation test					
Hyperventilation-induced nystagmus (positive)	1	102	VERY LOW[2,3,5] due to very serious risk of bias, serious indirectness, and serious imprecision	65 (50–78)	98 (90–100)

The assessment was conducted with an emphasis on test sensitivity as this was identified by the committee as the primary measure in guiding decision making. The committee used the sensitivity threshold of 90% as an acceptable level to recommend a test.

1. *Diagnostic meta-analysis has not been performed owing to differences between the three studies in the target condition definition, the population and the definition of the reference standard*
2. *Risk of bias was assessed using the QUADAS-2 checklist. The evidence was downgraded by 1 increment if the majority of studies were rated at high risk of bias, and downgraded by 2 increments if the majority of studies were rated at very high risk of bias*
3. *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability. The evidence was downgraded by 1 increment if the majority of studies are seriously indirect, and downgraded by 2 increments if the majority of studies are very seriously indirect*
4. *Inconsistency was assessed by inspection of the sensitivity/specificity plots. Particular attention was placed on the sensitivity threshold set as an acceptable level to recommend a test. In this case 90%. The evidence was:*
   - *downgraded by 1 increment if the individual study values varied across 2 areas, above/below the acceptable threshold of 90% [0–50% and 50–90%, or 50–90% and 90–100%]*
   - *downgraded by 2 increments if the individual study values varied across 3 areas, above/below the acceptable threshold of 90% [0–50%, 50–90% and 90–100%]*
5. *Imprecision was assessed according to the range of confidence intervals in the individual study. The evidence was downgraded by 1 increment when there was a 20-40% range of the confidence interval around the point estimate, and downgraded by 2 increments when there was a range of >40%*

6.2.2 Economic evidence

No relevant economic evaluations were identified.

See also the economic article selection flow diagram in appendix F.

6.2.3 Evidence statements

Clinical

Pure tone hearing thresholds

- Low to very low quality evidence from up to 3 studies with up to 2719 participants with sensorineural hearing loss showed that pure tone threshold protocols have sensitivities that range from 81% to 100% but this could be as low as 63%. The specificities ranged from 25% to 93% but this could be as low as 18%. The Nashville protocol had the highest sensitivity with an average of 94% across the 3 studies. However, this protocol had a very low specificity of only 50% average across the 3 studies. The Rule 3000 and the Sunderland protocols had the lowest sensitivities.

Audiometric shape

- Low to very low quality evidence from 1 study with 500 participants with asymmetric sensorineural hearing losses showed that different audiometric shapes have sensitivities that range from 0% to 38% and specificities that range from 79% to 93%. The flat loss shape had the highest sensitivity of 38% which was well below the threshold set by the committee. The low-frequency loss and mountain-shaped loss protocols were not sensitive at all at identifying vestibular schwannomas or other lesions. The highest specificity was seen when the high frequency sloping loss was used and the lowest with when the flat loss protocol was used.

Auditory brainstem response (accuracy for all pathology)

- Low quality evidence from 1 study with 316 asymmetric sensorineural hearing losses showed that ABR for all causative pathologies has a sensitivity of 71% (52, 86) and a specificity of 74% (68, 79).

Auditory brainstem response (accuracy for VS plus CPA meningioma)

- Very low quality evidence from 1 study (72 participants with asymmetric sensorineural hearing loss and tinnitus) showed that ABR for VS plus CPA meningioma has a sensitivity of 100% (54, 100) and a specificity of 64% (51, 75).

Caloric irrigation

- Very low quality evidence from 1 study with 102 participants with confirmed VS cases or controls with unilateral sensorineural hearing loss showed that caloric irrigation has a sensitivity of 43% (29, 58) and a specificity of 91% (79, 97).

Hyperventilation test

- Very low quality evidence from 1 study with 102 participants with confirmed VS cases or controls with unilateral sensorineural hearing loss showed that hyperventilation tests have a sensitivity of 65% (50, 78) and a specificity of 98% (90, 100).

Economic

- No relevant economic evaluations were identified.

6.2.4 Recommendations and link to evidence

Recommendations	**7. Offer MRI of the internal auditory meati to adults with hearing loss and localising symptoms or signs (such as facial nerve weakness) that might indicate a vestibular schwannoma or CPA (cerebellopontine angle) lesion, irrespective of pure tone thresholds.** **8. Consider MRI of the internal auditory meati for adults with sensorineural hearing loss and no localising signs if there is an asymmetry on pure tone audiometry of 15 dB or more at any 2 adjacent test frequencies, using test frequencies of 0.5, 1, 2, 4 and 8 kHz.**
Relative values of different diagnostic measures	The outcome prioritised for this review was diagnostic accuracy for vestibular schwannoma. Sensitivity was considered the most important measure of diagnostic accuracy by the guideline committee for this review question because a clinical decision rule should correctly identify all patients with suspected vestibular schwannoma for MRI scanning. The consequences of missing a patient with vestibular schwannoma could result in increased morbidity. The guideline committee used a sensitivity threshold of 90% as an acceptable level to recommend a test; this was considered to be close to the sensitivity of MRI, which is the best available reference standard.
Quality of the clinical evidence	The committee acknowledged the limited quality of studies for pure tone hearing thresholds and the limited quality and number of studies for other tests. It noted that a number of factors vary between the included studies, such as the populations, which had varying proportions presenting with hearing loss and other audiovestibular symptoms. The target condition was also defined differently amongst the studies, including any cerebellopontine angle (CPA) lesion or causative lesion and specifically vestibular schwannoma (VA), with the prevalence of these ranging from 1% to 40%. The MRI method varied and detail was commonly lacking regarding the scanner type and slice thickness. Therefore, the data were not meta-analysed. Pure tone hearing thresholds: Of the pure tone hearing thresholds investigated, the Nashville protocol had the highest sensitivity with an average of 94% across 3 papers, one of which had reported a sensitivity of 100%. However, the specificity for this protocol was very low and averaged only 50% across the 3 included papers. The least sensitive protocols were the Rule 3000 and the Sunderland protocols. Audiometric shapes: In general, audiometric shapes had very low sensitivities, well below the 90% threshold set by the committee with the highest only reaching 38% (flat loss shape). Some were not sensitive at all at identifying vestibular schwannomas or other lesions (low-frequency loss and mountain-shaped loss protocols). Auditory brainstem response: This test had a sensitivity of 71% for all cause pathology and this increased to 100% when looking at accuracy for VS plus CPA meningioma. Caloric irrigation and hyperventilation tests: Caloric irrigation and hyperventilation tests had very low sensitivities of 43% and 65% respectively. Despite the methodological differences in the studies and the uncertainty in the findings, these broadly aligned with clinical experience and so the uncertainty in the

	evidence did not preclude making a recommendation.
Trade-off between clinical benefits and harms	The committee considered the trade-off between using a test with a high sensitivity to select patients for MRI, while also not causing over-referral to imaging services, with the associated financial costs, patient waiting times and the inevitable risk of incidental findings that could cause unnecessary anxiety and follow-up for patients. Of the included tests, pure tone audiometric shapes, the hyperventilation test and caloric irrigation were agreed to have too low sensitivity to be useful. Of the many different protocols for pure tone hearing thresholds included in the studies, it was noted that a number of them achieved a sensitivity of at least 90% in 1 or more studies with varying specificities. The committee discussed the trade-off between sensitivity and specificity, being mindful that if the specificity was too low services could be overwhelmed. Therefore, it was agreed that the Cueva criteria of ≥15 dB asymmetry of sensorineural (bone conduction) hearing thresholds at two adjacent frequencies (using frequencies 0.5, 1, 2, 4, 8 kHz) may be the most appropriate protocol for referral for imaging. It was agreed that the difference in thresholds should be based on bone conduction thresholds (masked as appropriate) if these are available and if they are reliable. If bone conduction thresholds are not available, are unrecordable or unreliable then air conduction thresholds should be used. The evidence for auditory brainstem response (ABR) was from 2 studies, 1 of which reported on all causative lesions identifying a 71% sensitivity based on low quality evidence (an interaural difference of 0.2 ms for the I to V interval). It was noted that this study used the term inter-peak latency instead of inter-peak interval. The other study gave a sensitivity of 100%, based on very low quality evidence. The committee noted that this test is not often used and is additional to pure tone audiometry, with relative high cost and time demands. Therefore, there was insufficient evidence to change current practice from using pure tone thresholds as a criterion for requesting MRI scan, and ABR remains a useful test only in limited cases where scanning, either by MRI or CT, is impractical, and more evidence is required before making a decision about further investigation. The committee also discussed the importance of always referring for an MRI scan of the internal auditory meatus (IAM) when there are clinically apparent localising symptoms or signs indicating possible vestibular schwannoma or CPA lesions. Although this was not based on the evidence, the committee noted that this must be a strong recommendation based on the potential harms of not referring in these cases. Specific mention was made of unilateral tinnitus, which, if persistent, should prompt referral even if the hearing loss is symmetrical. Localising signs could include ipsilateral facial weakness, ipsilateral loss of corneal reflex, ipsilateral canal paresis or nystagmus, either lateral or vertical. Vestibular schwannoma can occur with normal hearing but this is outside the scope of this guideline.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The difficulties in balancing sensitivity and specificity, and hence the risks of over-referral or under-referral to MRI, are discussed above. Over-referral could lead to unnecessary overspending on MRI tests, whilst under-referral could lead to missing people with conditions that need treatment, leading to increased morbidity and more complicated procedures to treat conditions that could have been treated more easily, more effectively and more cheaply if identified earlier. In the absence of economic evidence and the limited nature of the clinical evidence the committee could not be certain of the optimal referral criteria, as discussed above. However, the committee noted that practice currently varies widely across the country and there are concerns about over-referral in some areas, with, consequently, stretched radiology resources. The committee was also aware of some referrals coming directly from primary care. Therefore, the systematic use of any defined protocol, such as that recommended by the committee, is likely to reduce referrals significantly in some areas, and is unlikely to increase referrals more than a

	small amount in other areas. Where referrals are increased, it may be the case that these areas are currently under-referring and so an increase in referrals may be clinically beneficial. Regarding England as a whole, the committee expect these recommendations, if fully adopted, to lead to the number of referrals remaining similar or decreasing, but being better focussed on those who need assessment. Therefore the recommendations are likely to be either cost saving or cost effective at a threshold of £20,000 per QALY gained compared with current practice. However, given that the exact impact, and downstream consequences, of any particular set of referral criteria for those with asymmetry are not certain due to limited clinical evidence, and so the best criteria are not certain, the committee recommended only that clinicians 'consider' referring on the basis of a specific measure of asymmetry.
Other considerations	People with red flag symptoms and signs, such as sudden-onset hearing loss, will be picked up earlier in the pathway. This question is looking purely at index tests that can be used as criteria for MRI scan to exclude a vestibular schwannoma. The committee noted that although the sensitivity of the Cueva criteria was not 100%, it is possible that some of the false negatives have other symptoms and would be identified and appropriately referred anyway. It was unclear from the studies whether this would have been the case in their samples. Current practice around MRI referral in this population is variable, with different PTA protocols or no protocols at all being used, and the extent of change in practice to implement this recommendation will also vary. The committee noted that caloric irrigation and hyperventilation tests are not used as part of routine practice. Caloric irrigation is time consuming and costly to do. Hyperventilation tests are not commonly done but may be a useful adjunct to audiometry. They are thought to be relatively quick and cheap to perform and when used in conjunction with PTA, they may provide a more accurate way of determining who needs MRI as they had a relatively high specificity. They do, however, require the use of Frenzel glasses. The shape of an audiogram has long been acknowledged as an unreliable criterion for further investigation for vestibular schwannoma. It was noted that although the review question specified people already referred to 'secondary care', currently patients are being referred for MRI in relevant clinical pathways from primary care. The committee was informed that the literature search and sifting process did not exclude studies based on the pathway of referral and so no studies should have been missed. However there is concern that this direct route of referral may lead to over-referral of cases. The committee emphasised the importance of careful clinical examination and robust audiological assessment prior to referral for MRI scan. The committee noted that tinnitus associated with hearing loss should be considered as a criterion for referral only if it is persistent. Cases of short-lived tinnitus (5 minutes or less), or transient tinnitus as a consequence of acute noise exposure, earwax impaction or acute infection are unlikely to need medical investigation.

7 Subgroups

7.1 Introduction

This chapter explores which people are at risk of having or developing hearing loss and in whom this might be missed because they have limited ability to seek help. Amongst this group we consider those with mild cognitive impairment, dementia and learning disability.

The link between hearing loss and learning disability is well recognised. One of the commonest causes of learning disability is Down's Syndrome and it is known that individuals with Down's Syndrome are at risk of developing a high frequency hearing loss from the second or third decade even if hearing has been good when younger. Chronic middle ear disease is also a common problem which starts in childhood but often fails to resolve. While monitoring of hearing is currently routine in childhood it is not clear what happens after transition to adult services. The Down Syndrome Medical Interest Group drafted guidelines in 2000 recommending that hearing assessment should be carried out every 2 years for adults with Down's Syndrome.[37] NHS England recommends that every adult with learning disabilities has an annual check which includes a check of hearing.[89] However, it is not clear how that assessment should be conducted.

A recent NHS Action Plan on Hearing Loss report[34] has highlighted the findings in a paper by Lin (2011) of the association between dementia and hearing loss reporting a 2-fold increased incidence of dementia in those with a mild hearing loss and a nearly 5-fold increase in those with severe hearing loss. There are also reports of hearing loss affecting the performance in cognitive function tests of people being assessed for dementia leading to misdiagnosis. Furthermore, a recent Lancet Commission on dementia prevention, intervention and care identified hearing loss as the largest modifiable risk factor for dementia in people who are middle aged.[74]

Those with mild cognitive impairment, dementia or learning disabilities may not be aware of their hearing loss or may not have the capacity to ask for help, and their families and carers may not consider that hearing loss is a compounding factor given their other health needs. However, hearing loss that is not addressed will significantly affect understanding and social interactions and will exacerbate underlying cognitive difficulties. It will contribute to increasing confusion and withdrawal. This can be misinterpreted as increasing cognitive decline, which is untreatable, rather than hearing difficulty, which can be helped by proper management.

The purpose of this chapter is to ensure that the needs of those who are unable to present the problem for themselves are considered. The review concentrates on 3 specific groups of individuals. The guideline committee is aware of other groups for whom presentation of hearing difficulties is difficult and hearing loss often missed, including those with depression and other mental health issues as well as those who are homeless or significantly disadvantaged and those who have a poor grasp of English. We hope that by raising awareness of the high prevalence of hearing loss generally and the need to consider this in every individual, these groups will also benefit. However, we have not focused on these groups in this guideline.

7.2 Review question: Which groups of people are more likely than the general population to miss having hearing loss identified?

For full details see review protocol in appendix C.

Table 16: PICO characteristics of review question

Population	Adults 18 years or older

Presence or absence of indicators	• Mild cognitive impairment • Dementia • Learning disabilities
Outcomes	• Missed identification (diagnosis) of hearing loss (no diagnosis prior to assessment and new diagnosis after assessment) • Identification (diagnosis) rates of hearing loss
Study design	Studies in which participants are divided into 2 groups by the presence or absence of 1 of the indicators listed above and all participants are formally assessed for the presence of hearing loss. Prevalence, incidence and epidemiology studies.

7.2.1 Clinical evidence

No relevant clinical studies reporting missed identification or identification rates in people with mild cognitive impairment, dementia and learning difficulties compared with people without the presence of those indicators were identified. See study selection flow chart in appendix E and the excluded studies list in appendix L.

7.2.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

7.2.3 Evidence statements

Clinical

- No relevant clinical evidence was identified.

Economic

- No relevant economic evaluations were identified.

7.2.4 Recommendations and link to evidence

Recommendations	**9. Consider referring adults with diagnosed or suspected dementia or mild cognitive impairment to an audiology service for a hearing assessment, because hearing loss may be a comorbid condition.** **10. Consider referring adults with diagnosed dementia or mild cognitive impairment to an audiology service for a hearing assessment every 2 years if they have not previously been diagnosed with hearing loss.** **11. Consider referring people with a diagnosed learning disability to an audiology service for a hearing assessment when they transfer from child to adult services, and then every 2 years.**
Research recommendation	**1. In adults with hearing loss, does the use of hearing aids reduce the incidence of dementia?** **2. What is the prevalence of hearing loss among populations who under-present for possible hearing loss?**

Relative values of different outcomes	The guideline committee agreed that the outcomes critical for decision-making were missed identification or identification rate in people who have hearing loss and dementia or cognitive impairment or learning difficulties.
Quality of the clinical evidence	No relevant clinical evidence was identified.
Trade-off between clinical benefits and harms	As no evidence was found the recommendations were based on consensus of the committee. The committee noted that people with learning difficulties, particularly those with Down's Syndrome, have an increased risk of hearing loss, which can deteriorate in early adult life. People in these subgroups also might not be able to report hearing loss themselves, therefore the committee agreed that it was important to conduct hearing assessment and review on a regular basis for these groups. The aim of the committee was to encourage inclusion of hearing assessment as part of the regular health check for these subgroups. The committee noted the importance of dementia and learning disability services being alert to hearing loss having an impact on communication needs of these groups of people. The committee discussed the particular vulnerability of people in residential settings whose hearing loss can remain unidentified or inadequately managed because of a lack of awareness and understanding of hearing loss amongst staff. This can result in poorer and less frequent social interaction for residents and impacts on their quality of life. The committee was aware that checking hearing is part of the baseline assessment in the GP's annual check for people aged 14 and over who have been assessed as having moderate, severe or profound learning disabilities, or people with a mild learning disability who have other complex health needs.[89] The document outlining this check makes it clear that the person should also see an audiologist for a full hearing assessment but does not recommend the frequency with which audiological review should occur. Hearing is commonly checked during childhood, but in this population the committee was not aware if hearing is currently routinely assessed on transition to adult services. Establishing hearing ability is an important part of assessment of this group at this stage because hearing can deteriorate early in adult life and it is important to establish a baseline and then retest regularly. The committee considered that for those with learning disabilities and those with dementia and mild cognitive impairment repeating the referral to audiology every 2 years would be good practice because of the high risk of developing hearing loss in these groups. It was agreed that there was no harm associated with repeated referrals and that the clinical benefits of early identification and management of hearing loss in these patients far outweigh the additional time involved in their assessment. This recommendation is in line with vision testing which is recommended every 2 years in this group. The committee noted that in addition to dementia masking hearing loss, hearing loss can also mask dementia. Misinterpreting symptoms of hearing loss as dementia and vice versa does occur.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee, however, noted that people with learning difficulties or cognitive impairment should already receive an annual general primary care health check as discussed above. This includes a hearing check with the GP, and also states that people should be seen by an audiologist, but does not suggest at what frequency. People with dementia also have frequent health checks but there are no national recommendations relating to assessing their hearing. Current practice is hence unclear, but it is unlikely all people with dementia are receiving a frequent full hearing assessment. People with dementia have been found to have a high prevalence of hearing loss, while people with mild cognitive impairment may have

	associated hearing loss. To assess the likely cost effectiveness of referring all people with dementia or mild cognitive impairment for a hearing assessment with an audiologist every 2 years, an additional sensitivity analysis was conducted as part of the original economic modelling comparing hearing aids with no hearing aids (see appendix N). This looked at a population of men aged 75 over a horizon of 10 years, and showed that if the proportion of the people referred for hearing assessment who in fact have an aidable hearing loss is decreased to 2% then this would still be cost effective at a threshold of £20,000 per QALY gained (ICER: £14,337 per QALY gained). Since annual incidence of hearing loss in people in these groups is at least 2–4% in younger age groups (rising with age), and it is more cost effective to treat younger people than older people, this indicates that referring all these groups for audiological assessment every 2 years would be cost effective.
Other considerations	The committee noted that for people who are unable to communicate by themselves that they have hearing difficulties, proactive provision of a hearing assessment will be the only way to identify hearing loss. This is an equality issue, meaning that such provision is necessary. The committee is aware of other subgroups with higher than average prevalence of hearing loss, who are less likely to report it themselves, or for whom the presence of hearing loss is less likely to be identified by clinicians. The committee agreed that the list of subgroups in the NHS Action Plan on Hearing Loss (2015)[34] was quite comprehensive and also included: older people, those with mental health conditions, including depression, care home residents and potential residents, those in other care and support settings, those with impaired vision, veterans and other exposed to noise in the workplace or socially, those having ototoxic drugs and those with brain tumours. The committee agreed that good awareness and surveillance of hearing problems is required to enable both people and health professionals to identify and raise concerns about hearing and communication problems on an individual and population basis. It is important that hearing assessment is carried out by a trained audiologist in an appropriately sound-attenuated environment. The hearing assessment of choice is pure tone audiometry, but the committee wished to emphasise that alternative methods of assessment should be used if clinical circumstances rule out standard methods, for example, if the person is not able to participate in the test. Testing using play techniques or visual reinforcement may be needed; this may require referral to a specialist service. It is expected, however, that the majority of people with mild cognitive difficulties could be catered for in local audiology services. The use of outdated clinical tests like a whisper test is inappropriate because these tests do not have the accuracy essential to identify hearing loss.

8 Early versus delayed management of hearing loss

8.1 Introduction

Hearing loss is usually insidious in onset with slow progression over a number of years. Early symptoms can be subtle but can have a significant impact on the individual, affecting their social functioning, work and quality of life.

There appears to be considerable variation across the country in the time taken between a patient presenting with hearing loss and receiving treatment, with no national guidance or standards available. Data suggest that most people with hearing loss have lived with their symptoms for 10 years before being referred for the most appropriate intervention.[28, 38] There is uncertainty around whether receiving audiological care earlier would result in improved outcomes for patients as well as financial savings for the NHS. This chapter examines the clinical and cost effectiveness of early versus delayed management of hearing loss.

8.2 Review question: What is the clinical and cost effectiveness of early versus delayed management of hearing loss on patient outcomes?

The focus of this question was to investigate the effectiveness of managing patients with early or mild hearing loss rather than waiting until their hearing loss is more severe in later-presenting patients, which is a common scenario in clinical practice. Therefore, studies of patients with sudden sensorineural hearing loss were excluded. For full details see review protocol in appendix C.

Table 17: PICO characteristics of review question

Population	Adults aged 18 and over presenting with hearing loss
Intervention	Early management – at first presentation or short history and mild/minimal symptoms
Comparison	Delayed identification – long history prior to management (as defined by the studies)
Outcomes	**Critical** • Hearing-specific health-related quality of life • Health-related quality of life • Listening ability **Important** • Usage of hearing aids (including data logging and self-report • Change in cognitive function (Mini-Mental State Examination, MMSE; Modified Mini-Mental State Examination (3MS) • Social functioning or employment • Sound localisation as measured by laboratory test • Speech in noise detection as measured by laboratory tests
Study design	RCTs or non-randomised comparative studies if no RCTS are identified

8.2.1 Clinical evidence

One study was included in the review;[28] this is summarised in Table 18 below. Evidence from this study is summarised in the clinical evidence summary below (Table 19). No randomised trials were identified and the available data were from a case–control study design, which starts at low quality in the GRADE rating system. See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

This study was part of a Health Technology Assessment and addressed the question of early versus delayed management of hearing loss with hearing aids using a case–control study design. The aim was to evaluate the benefit of prescribing and fitting hearing aids in those found to be eligible after early adult screening for hearing loss among 50–65 year olds. This was compared with people who were fitted after standard referral to a hearing aid clinic, who are generally older and have a longer history of hearing loss. Two control groups were selected to reduce the chance that any identified advantage was due to unpredictable bias, assuming that any benefit of early management via a screening programme was consistently present in comparison with both control groups. Note that the duration of hearing loss and the hearing level at hearing aid fitting is not reported for the control groups.

Table 18: Summary of studies included in the review

Study	Intervention and comparison	Early management population	Control group 1; delayed management population	Control group 2; delayed management population	Outcomes	Comments
Davis 2007[28] See also Davis 1992;[29] Stephens 1990[109]	Hearing aids fitted after early adult screening (50-65 year olds) versus after standard referral to a hearing aid clinic	Median **age at follow-up** (IQR): 70 (66-74) Median **age at fitting** (IQR): 58 (54-62) Median **duration of aid ownership**: 12 years n=50 identified from screening studies in Wales based on GP registers (original sample n=176; 43% of those traced still using their hearing aids). Those who reported hearing problems on a questionnaire had audiometric testing (others had home audiometric testing) and those with a hearing level >30 dB in the worse hearing ear were offered hearing aid fitting. The mean hearing level in the better ear at fitting was 30 dB	Median **age at follow-up** (IQR): 72.5 (68-77) Median **age at fitting** (IQR): 69 (64-72) Median **duration of aid ownership**: 4 years n=50 drawn from MRC IHR database of people referred to an NHS hearing aid clinic in Glasgow through standard NHS channels, but participating in other research studies and many being fitted with behind-the-ear digital hearing aids. Each subject matched to a subject in early management group for: • Gender • Socioeconomic group • Hearing threshold in better and worse ear at follow-up • Age at follow-up	Median **age at follow-up** (IQR): 69 (66-75) Median **age at fitting** (IQR): 69 (66-75) Median **duration of aid ownership**: approximately 3 months n=50 drawn from another MRC IHR database of people referred by GP to an NHS hearing aid clinic in Glasgow or Manchester and fitted with standard NHS analogue hearing aids (BE series). Each subject matched to a subject in early management group for: • Gender • Hearing level in aided ear • Age at follow-up And matching was attempted for: • Socio-economic group • Hearing levels in better and worse ear	**SHHI**: questionnaire on difficulties understanding speech in life situations (0-42; high worst) **ERS**: questionnaire on emotional effects of hearing loss (0-10; high worst) **Glasgow Health Status Inventory (GHSI)**: adapted to address hearing difficulties including participation restrictions, emotional effects, social support, and physical health (0-100; high best) **GHABP**: outcome of hearing aid fitting assessed for specific listening circumstances across 6 subscales, 4 of which are relevant – 'use' (0-100; high best), 'benefit'(0-100; high best), residual disability (activity limitation) (0-100; high worst); satisfaction with aid performance (0-100; high best) **EuroQol** thermometer:	• Only those still using the hearing aid at follow-up were included; 43% of original screening group • Controls fitted at an older age, which represents the delay in management (assuming their hearing loss began earlier) • Many fitted after early screening had subsequently stopped using the hearing aids (no ongoing post-fitting counselling or support was provided) • Control group 1 statistically significantly different from screening group for age at follow-up. But median difference of 2.5 years is unlikely to be clinically important

Study	Intervention and comparison	Early management population	Control group 1; delayed management population	Control group 2; delayed management population	Outcomes	Comments
		Pure tone hearing levels were measured, by air conduction, averaged over 0.5, 1, 2 and 4 kHz.			VAS of general health (0-100; high best)	• High proportion were male (74%); this was matched across all groups.

Table 19: Clinical evidence summary: early management group versus delayed management group 1

Outcomes	No of Participants (studies) Follow-up screening and control (median)	Quality of the evidence (GRADE)	Statistical comparison	Median (IQR) value in early group	Median (IQR) value delayed group	Difference in medians
SHHI Scale: 0-42; high worst	99 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	t=2.52 df=97 p=0.01	22 (19-28)	26.5 (21-31)	The median SHHI score was 4.5 points lower in the early intervention group
ERS Scale: 0-10; high worst	99 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	z=1.01 p=0.31	3 (1-6)	4 (1-8)	The median ERS score was 1 point lower in the early intervention group
GHSI general Scale: 0-100; high best	100 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	z=2.7 p=0.01	57 (41-68)	46.5 (24.5-59)	The median GHSI general score was 10.5 points higher in the early intervention group
GHSI social support Scale: 0-100; high best	100 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	z=0.19 p=0.85	67 (58-83)	67 (58-83)	The median GHSI social support score was the same in both groups
GHABP use Scale: 0-100; high best	99 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	z=2.57 p=0.01	67 (35.5-100)	38 (19-64)	The median GHABP use score was 29 points higher in the early intervention group
GHABP benefit Scale: 0-100; high best	99 (1 study)	VERY LOW[a,b] due to risk of bias,	z=3.80 p<0.01	56 (38-75)	38 (25-51.5)	The median GHABP benefit score was 18 points higher in the early intervention group

Outcomes	No of Participants (studies) Follow-up screening and control (median)	Quality of the evidence (GRADE)	Statistical comparison	Median (IQR) value in early group	Median (IQR) value delayed group	Difference in medians
	12 years and 4 years	indirectness				
GHABP residual disability Scale: 0-100; high worst	99 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	t=0.842 df=97 p=0.40	25 (13-38)	28 (13-39.5)	The median GHABP residual disability score was 3 points lower in the early intervention group
GHABP satisfaction Scale: 0-100; high best	99 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	z=4.69 p<0.01	63 (44-75)	40 (25-50)	The median GHABP satisfaction score was 23 points higher in the early intervention group
EuroQol thermometer Scale: 0-100; high best	100 (1 study) 12 years and 4 years	VERY LOW[a,b] due to risk of bias, indirectness	z=0.10 p=0.92	67.5 (50-80)	70 (50-80)	The median EuroQol thermometer score was 2.5 points lower in the early intervention group

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increments because the majority of evidence was from an indirect population/intervention (early versus delayed defined by mode of referral for hearing aid use – early screening or standard referral to hearing aid clinic at older age)

Table 20: Clinical evidence summary: early management group versus delayed management group 2

	Participants (studies) Follow-up screening and control (median)	(GRADE)	I comparison	(IQR) value in early group	Median (IQR) value delayed group	Difference in medians
GHSI general Scale: 0-100; high best	100 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	z=3.61 p≤0.001	57 (41-68)	42 (30.5-52.5)	The median GHSI general score was 15 points higher in the early intervention group
GHSI social support Scale: 0-100; high best	100 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	z=6.39 p<0.01	67 (58-83)	44 (31-51.5)	The median GHSI social support score was 23 points higher in the early intervention group
GHABP use Scale: 0-100; high best	99 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	z=2.78 p=0.01	67 (35.5-100)	48.5 (34-61.5)	The median GHABP use score was 18.5 points higher in the early intervention group
GHABP benefit Scale: 0-100; high best	99 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	z=4.15 p<0.01	56 (38-75)	42.5 (24-47)	The median GHABP benefit score was 13.5 points higher in the early intervention group
GHABP residual disability Scale: 0-100; high worst	99 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	t=2.34 df=97 p=0.02	25 (13-38)	34.5 (21-45)	The median GHABP residual disability score was 9.5 points lower in the early intervention group
GHABP satisfaction Scale: 0-100; high best	99 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	z=4.88 p<0.01	63 (44-75)	39 (28-50)	The median GHABP satisfaction score was 24 points higher in the early intervention group

Outcomes	No of Participants (studies) Follow-up screening and control (median)	Quality of the evidence (GRADE)	Statistical comparison	Median (IQR) value in early group	Median (IQR) value delayed group	Difference in medians
EuroQol thermometer Scale: 0-100; high best	100 (1 study) 12 years and 3 months	VERY LOW[a,b] due to risk of bias, indirectness	z=1.49 p=0.14	67.5 (50-80)	60 (50-70)	The median EuroQol thermometer score was 7.5 points lower in the early intervention group

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increments because the majority of evidence was from an indirect population/intervention (early versus delayed defined by mode of referral for hearing aid use – early screening or standard referral to hearing aid clinic at older age)

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8.2.2 Economic evidence

8.2.2.1 Published literature

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

8.2.2.2 Original cost-effectiveness analysis – summary

An original health economic model was constructed in order to conduct cost–utility analysis for this question and the review question regarding hearing aid use versus no hearing aids (see section 15.2). These questions were agreed by the guideline committee to be the highest priorities for original economic analysis in this guideline due to the very large number of people using or potentially eligible for hearing aids, and the lack of existing health economic research in this area.

Full details of the analysis can be found in appendix N. It includes a comparison between a cohort of people given a hearing assessment and offered hearing aids, if eligible, immediately after first presenting with hearing difficulties (early treatment) and a cohort who were not assessed or offered hearing aids until 10 years after they first reported hearing difficulties (delayed treatment).

The base case probabilistic results, reflecting the costs and outcomes for men aged 65 at the start of the analysis over a lifetime horizon, are in Table 21.

Table 21: Results of early versus delayed use of hearing aids, base case

Comparator	Cost	Incremental cost	QALYs	Incremental QALYs	ICER (£/QALY)
Delayed treatment	£738	-	7.75	-	
Early treatment	£1,576	£838	7.96	0.21	**£3,976**

Sensitivity analysis found these results to be robust to variations in all the parameters investigated in the analysis, including the age of the participants at the start of the analysis, their sex, the proportions not suitable for hearing aids or who decline to use hearing aids, rates at which participants stop using hearing aids, and the magnitude of improvement in quality of life caused by hearing aid use: the ICER was below £8,100 per QALY gained in every case.

The original health economic modelling is summarised in the health economic evidence profile below (Table 22).

Table 22: Health economic evidence profile: early management versus delayed management using hearing aids

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
NGC 2017 (UK) (see appendix N)	Directly applicable[(a)]	Minor limitations[(b)]	• Lifetime Markov model • Population: people reporting hearing problems. • Patients offered hearing aids at first report of hearing problems compared with those offered hearing aids after 10-year delay • Effectiveness: HRQoL benefit of hearing aids based on UK study using HUI3 (Barton 2004[11])	£838	0.21	ICER: £3,976 per QALY gained	The results were most sensitive to the quality of life benefit of hearing aids. When this was halved the ICER doubled to £8,079 per QALY gained, still well below £20,000 per QALY gained. Changing all other parameters had only very small effects on the ICER (below £5,400 per QALY gained in each case).

Abbreviations: HRQoL: health-related quality of life; HUI3: health utilities index mark 3; ICER: incremental cost-effectiveness ratio; QALYs: quality-adjusted life years

(a) Designed for this guideline using a UK NHS setting

(b) Some parameters estimated by expert consensus – conservative estimates were used. Model simplifies reality by reducing number of transitions between hearing aid use and non-use, but this has no significant effect on the results.

8.2.3 Evidence statements

Clinical

Early management group versus delayed management group 1

- There was a clinically important benefit of early management for SHHI, GHSI (general) and for GHABP use, benefit, and satisfaction (very low quality evidence, 1 study).
- There was no clinically important difference in ERS, GHSI (social support), GHABP residual disability and EuroQuol thermometer (very low quality evidence, 1 study).

Early management group versus delayed management group 2

- There was a clinically important benefit of early management for GSHI (general and social support), GHABP use, benefit and satisfaction (very low quality evidence, 1 study).
- There was no clinically important difference in GHABP residual disability and EuroQuol thermometer (very low quality evidence, 1 study).

Economic

- One original cost–utility analysis found that early provision of hearing aids was cost effective compared with delayed provision of hearing aids for managing hearing loss (ICER: £3,976 per QALY gained). This analysis was assessed as directly applicable with minor limitations.

8.2.4 Recommendations and link to evidence

Recommendations	**12. For adults who present for the first time with hearing difficulties, or in whom you suspect hearing difficulties:** • **exclude impacted wax and acute infections such as otitis externa, then** • **arrange an audiological assessment (for more information on audiological assessment see recommendation 13) and** • **refer for additional diagnostic assessment if needed (see recommendations 1-6 on sudden or rapid onset of hearing loss and hearing loss with specific additional symptoms or signs).**
Relative values of different outcomes	The following critical outcomes were included in this review: hearing-specific health-related quality of life, health-related quality of life, listening ability and outcomes reported by carer or 'communications partner'. The following important outcomes were also included: usage of hearing aids (including data logging and self-report), change in cognitive function, social functioning or employment, sound localisation as measured by laboratory tests and speech in noise detection as measured by laboratory tests.
Quality of the clinical evidence	One study assessing the benefits of early fitting of hearing aids was included and all outcomes were of very low quality due to the study design (case–control), the fact that not all of the potential confounders noted in advance by the guideline committee were controlled for and only those people still using their hearing aids at follow-up were included (<50% in the early management group). In addition, the definition of early versus delayed was based on the mode of referral or identification (proactive screening versus standard presentation through GP visits) with no data available about the time from onset to GP visit. Therefore, there was serious

	indirectness. No studies were available for other interventions, such as assistive listening devices, pharmacological or behavioural management.
Trade-off between clinical benefits and harms	Overall, the study showed evidence across a range of self-report questionnaires for a benefit of fitting hearing aids at an earlier age, compared with fitting at an older age. This was after controlling for age, hearing level, gender and socio-economic group using 2 control groups that differed on some important variables to minimise the chance of any findings being influenced by unidentified biases. Specifically, clinical benefits were found in comparison with both control groups related to: • fewer adverse effects of hearing loss in the person's life (general subscale of GHSI) • greater use of hearing aids (GHABP) • more self-perceived acoustical benefit (GHABP) • greater satisfaction (GHABP). • Benefits were found in comparison with only 1 of the control groups related to: • better ability to understand speech (SHHI; not administered in control group 2) • support from family and friends (social support subscale of GHSI versus control group 2). No clinically important differences between early and delayed groups were seen for: • ERS (measures emotional effects of hearing loss) • EuroQol thermometer scale (general health-related quality of life) • GHABP residual disability subscale (difficulty hearing in situations where people wore a hearing aid). However, there was a statistically significant benefit on this outcome compared with control group 2 although the absolute values did not cross the committee's threshold for clinical importance. The majority of the outcomes provided corroborative support for a benefit of early fitting of hearing aids. The EuroQol thermometer is part of a quality of life instrument (EQ-5D) thought to be insensitive to hearing loss and so the committee was not surprised that this outcome did not show a benefit of early fitting. It was also noted that it appears inconsistent for the residual disability subscale of the GHABP not to show a clinical difference when there is more hearing benefit and hearing aid satisfaction. However, there are a number of points that led the committee to believe that this apparent inconsistency does not discredit the other findings: • Across both comparisons the residual disability was less in the early group, although not reaching clinical significance. • The committee commented that there is a known phenomenon to explain this difference across the outcomes. Hearing aid users can be found to have an increased awareness of hearing disability once they have acclimatised to using an aid; however, they also have a better ability to cope with the difficulties of their condition. • The HTA study used analogue hearing aids but the additional flexibility and features on current digital hearing aids are likely to result in greater benefit. In summary, the evidence suggests a range of benefits for hearing ability, hearing aid use and quality of life, without any known harms. The committee noted that the clinical study identified focused on early screening for hearing loss and the committee discussed the risks and benefits of fitting a hearing aid for mild hearing loss when other management strategies such as listening tactics or communication training might be preferable to the person. The committee noted that current best practice is to offer active management, such as information and education, hearing aids, assistive listening devices or auditory training at presentation with hearing difficulties. However, there is variability across

	the country. The committee agreed that it is not good practice for a GP to delay referral for hearing difficulties until the problem is more severe. Not only could delay impact on everyday function at work and home but an older person is likely to have a greater number of additional health problems, less manual dexterity, and less brain plasticity and opportunity for perceptual learning. The committee agreed that all people with hearing difficulties presenting to a GP should, after exclusion of earwax or acute ear infections as the only cause, be referred to an audiology service for hearing assessment and advice in the first instance unless their need is for immediate or urgent medical care for hearing problems. The committee were aware of guidance from the BAA and BSHAA with regard to onward referral. They anticipated that should an individual require a subsequent referral for a medical opinion, the audiologist would follow this guidance and advise or refer accordingly.
Trade-off between net clinical effects and costs	No published health economic evaluations were identified for this question. Original health economic modelling was conducted for this question. It found that at a cost-effectiveness threshold of £20,000 per QALY gained, early treatment with hearing aids is highly cost effective compared with delayed treatment, with an ICER of £3,976 per QALY for lifetime treatment, or £4,591 per QALY for the first 10 years of treatment (based on men aged 65 at the start of the analysis). Sensitivity analysis found these results to be robust to all uncertainties investigated in the data used, including the age of the participants at the start of the analysis. The committee noted that assumptions and estimated data used in the model were chosen conservatively, that is, on balance they were likely to overestimate incremental costs and underestimate incremental effectiveness, favouring delayed treatment over early treatment. Notably, the model did not seek to include any advantages that the use of hearing aids might lead to in respect of improvements in any aspects of health other than hearing, or reduction in NHS costs as a result. The committee was hence satisfied that referring people who present with hearing difficulties for a hearing assessment at the earliest opportunity is cost effective, and so agreed that such people should be referred. The committee also noted that conducting a hearing assessment continued to be cost effective in the analysis even when the proportion of people without aidable hearing loss was increased very substantially. Given this, and the benefits of identifying people with hearing loss early, the committee agreed that proactively identifying people who appear to be showing signs of hearing loss and encouraging them to have a hearing assessment, even if they have not presented reporting hearing loss, would also be both clinically beneficial and cost effective.
Other considerations	The definition of ‘early intervention’ was discussed and it was suggested ‘early’ could be defined as ‘at the time of first presentation to the GP’ with an awareness of hearing problems. The committee highlighted the importance of education and training of health and social care professionals across all sectors in improving referral of people for hearing difficulties. It was felt that hearing loss is not always considered a priority in a GP’s appointment. While that may be as a consequence of short appointments and a lot to cover, it is acknowledged that there is a tendency to overlook sensory health in clinical practice. There was concern at reports of GPs being reluctant to refer .The committee also recognised that many people do not report hearing loss to their GP (or any other medical professional) until it has been present for a long time (around 10 years[28]). Given the advantages and cost effectiveness of managing hearing loss at an earlier stage, the committee agreed that in addition to referring people for assessment when they directly report hearing problems, GPs, other healthcare professionals and carers should actively consider the possibility of hearing problems in the course of routine consultations or care for other conditions. For example, if a patient appears to be having problems hearing the healthcare or social care

	professional when he or she is talking to them, they should specifically ask about hearing difficulties and recommend referral for audiological assessment.

9 Communication difficulties and limitations in function

9.1 Introduction

Communication difficulties experienced by a person with hearing loss cannot be judged just by a measurement of hearing thresholds on a pure tone audiogram. A pure tone audiogram is a measure of impaired ability to detect quiet tones when using headphones and this cannot capture the main complaint which is difficulty hearing speech in noisy backgrounds. Those with hearing loss depend on other cues such as lip-reading, facial expression and context to follow a conversation. Their listening environment can be challenging and other disabilities, such as visual loss or cognitive decline, can compound the effects of their hearing difficulties. It is important therefore to explore an individual's hearing and communication difficulties as well as their degree of functional impairment, quality of life and psychological distress in addition to measuring their hearing loss, in order to devise a meaningful individual management plan.

In this chapter, when considering and referring to communication needs this includes, not just difficulty with hearing and communication but also activity limitations and participation restrictions as a consequence of hearing difficulties. In addition the term encompasses the psychological distress and reduction in quality of life that hearing difficulties can bring about.

Communication needs will be different in different settings and the working environment can be particularly challenging. It is important to identify the practical difficulties faced by individuals in their work environment as advice about strategies that the individual, the employer and other employees can adopt, in addition to effective amplification can make the difference in keeping someone at work.

People with hearing difficulties are referred to audiology services for assessment. This assessment will almost always include measurement of hearing sensitivity or threshold (the quietest sounds that can just be heard) using pure-tone audiometry (PTA); tests that have well established procedure and practice guidance. However, assessment of hearing and communication needs, although just as important, is undertaken inconsistently across England.

Examples of recommended good clinical practice exist, such as those within the adult service model specification outlined within NHS England's 'Commissioning Services for People with Hearing Loss: A framework for clinical commissioning groups'.[86] However, there are no recommended procedures or practice guidance as to which methods of assessment of communication needs are most suitable, neither is there advice as to which tools to use.

The intention of this question is to examine the benefits of assessing communication needs, and to identify which are the most appropriate tools and approaches. The chapter will also consider how identified communication needs should be used to direct discussion of management options between patients and audiologists.

9.2 Review question: What is the clinical and cost effectiveness of communication needs assessment in adults with hearing loss?

For full details see review protocol in appendix C.

Table 23: PICO characteristics of review question

Population	Adults aged 18 and over presenting with hearing loss

Intervention	Fully comprehensive assessment of communication needs: • Measures of activity limitations (disability) for example GHABP (initial disability or disability pre-intervention) • Measures of participation restriction (handicap) HHIE (pre- intervention) • Measures of individual needs for example COSI • Individual managements plans
Comparison	• Pure tone audiogram before an intervention of hearing aids or auditory training • Speech and hearing in noise tests before an intervention of hearing aids or auditory training • Whisper voice test before an intervention of hearing aids or auditory training
Outcomes	**Critical outcomes** • Hearing-specific health-related quality of life - Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) - Quantified Denver Scale of Communication (QDS) - Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) - GHABP - CPHI - COSI - Device Orientated Subjective Outcome Scale - Any questionnaire not specified above that is relevant • Listening ability - Abbreviated Profile of Hearing Aid Benefit (APHAB) - Speech, Spatial and Qualities of Hearing (SSQ) - Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale **Important outcomes** • Social functioning or employment • Usage of hearing aids (including data logging and self-report (if applicable)
Study design	RCTs and systematic reviews of RCTs

9.2.1 Clinical evidence

No relevant clinical studies were identified that look at the effectiveness of conducting a fully comprehensive assessment compared with hearing tests to determine communication needs in people with hearing loss. See study selection flow chart in appendix E and the excluded studies list in appendix L.

9.2.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

9.2.3 Evidence statements

Clinical

- No relevant clinical evidence was identified.

Economic

- No relevant economic evaluations were identified.

9.2.4 Recommendations and link to evidence

Recommendations	**13. Include and record the following as part of the audiological assessment for adults:** • **a full history including relevant symptoms, comorbidities, cognitive ability, physical mobility and dexterity** • **the person's hearing and communication needs at home, at work or in education, and in social situations** • **any psychosocial difficulties related to hearing** • **the person's expectations and motivations with respect to their hearing loss and the listening and communication strategies available to them** • **any restrictions on activity, assessed using a self-report instrument such as the Glasgow Hearing Aid Benefit Profile or the Client-Orientated Scale of Improvement** • **otoscopy** • **pure tone audiometry** • **tympanometry if indicated.** **14. After the audiological assessment:** • **discuss with the person:** **i. the pure tone audiogram and the impact their hearing loss might have on communication** **ii. hearing deficits (such as listening in noisy environments) that are not obvious from the audiogram** **iii. options for managing their hearing needs, such as acoustic or bone conduction hearing aids, assistive listening devices and communication strategies, and the potential benefits and limitations of each option.** **iv. options for managing single-sided deafness if needed** **v. referral for implantable devices such as cochlear implants, bone-anchored hearing aids, middle-ear implants or auditory brain stem implants, if these might be suitable (see NICE's technology appraisal guidance on cochlear implants for children and adults with severe to profound deafness and interventional procedure guidance on auditory brain stem implants)** **vi. referral for medical or surgical treatments, if these might be suitable** • **agree and record a personalised care plan, taking into account the person's preferences, including goals, and give the person a copy.**
Relative values of different outcomes	The following critical outcomes were included in this review: hearing-specific health-related quality of life (for example HHIE, QDS and GHABP scales) and listening ability (for example APHAB SSQ GHABP residual disability scales). The following outcomes were identified as important for this review: social functioning or employment and usage of hearing aids (including data logging and self-report).
Quality of the clinical	No clinical evidence was identified for this review.

evidence	
Trade-off between clinical benefits and harms	As no evidence was found these recommendations were made by consensus of the committee. The committee agreed that an example of what comprises an audiological assessment is provided in the assessment guidance set out in the model adult service specification within the NHS England Commissioning Services for people with hearing loss report. The committee agreed that the components of the assessment listed in that document should be included as part of the initial assessment and reflect good practice, but noted that there is wide variation in the comprehensiveness of assessments undertaken in current practice and in the application of the NHS contracts across the UK. The components of a typical audiological assessment would include a clinical interview to assess the hearing and communication needs of the person. The audiologist would establish any relevant symptoms, cognitive ability, comorbidities, dexterity, lifestyle and the person's goals and expectations in order to work with the person in deciding which interventions would be appropriate to meet their needs, such as hearing aids, communication support or strategies or information about other communication devices available. Examination (for example, otoscopy) and measurements such as pure tone audiometry, tympanometry (when indicated), and assessment of activity restrictions and limitations to participation using a validated self-report instrument would also be carried out. The committee agreed that the most commonly used standardised self-report instruments to quantify a person's needs are the Glasgow Hearing Aid Benefit (GHABP) and the Client-Orientated Scale of Improvement. The committee acknowledged both tools have been subject to testing and comparison and considered them to be the most appropriate to quantify a person's activity restrictions and participatory limitations. The committee discussed people with complex needs, such as those with dementia, learning, or communication disabilities or who may need a different approach when carrying out an assessment and the committee noted an intermediary may be needed. The history may need to be simplified or obtained from the carer or intermediary. Most people with complex needs will be able to perform pure tone audiometry but for those who cannot, play techniques or visual reinforcement may be required and that may need referral to a specialist centre. Feedback and discussion will need to be tailored to the ability of the person to understand and contribute, with the carer or intermediary helping with hearing aid management and insertion depending on need. When discussing hearing aids most people will be offered acoustic hearing aids but there are situations when other types of hearing aids are more suitable. With conductive hearing losses the option of a bone conduction hearing aid should be discussed. In cases where the person is unable to gain adequate amplification from conventional hearing aids consideration should be given to alternative strategies including implantable devices such as cochlear implants, bone anchored hearing aids, middle ear implants or brain stem implants and referral for consideration of these should be discussed. National (see NICE's technology appraisal guidance on cochlear implants for children and adults with severe to profound deafness and interventional procedure guidance on auditory brain stem implants)and local referral criteria should be used as appropriate. Single-sided deafness can be difficult to manage but amplification should be based on needs, and CROS aids or implantable devices considered as appropriate. During assessment the audiologist may identify a hearing problem where secondary care is indicated. This may be for additional input from hearing therapy, psychology, specialist audiology or the need for medical investigation to look in more detail at the cause of a hearing loss. In some cases surgical treatment will be needed to prevent progression, such as with chronic suppurative otitis media or cholesteatoma,

	or to improve hearing thresholds such as ear drum perforation or otosclerosis. Discussion of the need for a further opinion within secondary care should form part of the audiological assessment. The committee were aware of guidance from the BAA and BSHAA with regard to onward referral. They anticipated that should an individual require a subsequent referral, the audiologist would follow this guidance and advise or refer accordingly. The committee members were in agreement that, in their experience, a comprehensive assessment of the person's needs, and opportunity to discuss the management options available to address their hearing loss achieves better health outcomes for the patient in the long term. It is important that the patient has the information with which to make informed decisions on what management options best suit their individual needs. An inadequate assessment may result in an inappropriate management strategy being selected and as a consequence poor compliance and reduced quality of life. A personal care plan is important as a record of the conclusions reached between the audiologist and the person, and is helpful at a future follow-up appointment to review the decisions reached and consider any changes that may be required.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee considered that an assessment of communication needs is principally a matter of both patients' rights and of necessity, as it will be impossible for a person's doctor(s) and other clinicians whom they may subsequently need to see to be able to interact with them successfully – and hence to be able to treat them effectively – if they cannot communicate well with the person with hearing loss. It is hence not primarily an economic issue. However, the committee also observed that there is currently often a waste of resources through people with hearing loss requiring additional appointments to resolve a health issue (often unrelated to hearing), because they did not fully hear and understand what was said in the first appointment. Therefore, the committee agreed that a modest amount of time (and hence money) invested in assessing a person's communication needs at an early stage would be very likely to save as much or more time by reducing future unnecessary use of health services. Thus the committee expects these recommendations as a whole to be neutral or cost saving for the NHS, whilst leading to improvements in quality of life and in experience of using NHS services. They will therefore be cost effective, and potentially cost saving.
Other considerations	See also the review of patient-centred decision tools in chapter 13, where the committee refers to recommendations made in NICE's guidance on patient experience. The committee believes it will only be possible to fulfil those recommendations if a comprehensive assessment of communication needs has first been conducted and advice and support given to enable the person to participate optimally.

10 Management of earwax

10.1 Introduction

Earwax (cerumen) is produced by cells lining the ear canal and works to protect the ear canal by keeping it clean and healthy. Wax is normally self-clearing but, if there is disruption to the normal movement of wax, it can build up in the ear canal. This build-up of wax can occur for many reasons, including using hearing aids, if cotton buds or other objects are inserted into the ear canal or if there has been previous surgery. Excessive hair in the ear canal can also prevent the easy flow of wax. Build-up of earwax can block the ear canal (impaction) giving a temporary hearing loss and discomfort and can contribute to outer ear infections (otitis externa). Hearing loss due to impacted wax can be frustrating and stressful and, if untreated, can contribute to social isolation and depression. Wax in the ear canal can also prevent adequate clinical examination of the ear, delaying assessment and management; for example, audiologists cannot test hearing or prescribe and fit hearing aids and doctors cannot examine the eardrum if the ear canal is blocked with wax.

The main approaches to removing earwax include the use of wax softeners (such as olive oil drops, sodium bicarbonate drops, or water) prior to mechanical removal using electronically controlled irrigation of the ear canal (flushing the wax out using water), or microsuction (using a vacuum to suck the wax out). It is not clear which earwax removal approach is the most effective and in which setting this should take place. Currently there is considerable variation in practice; people are inappropriately given ear drops for weeks without effect, irrigation in primary care may not be available and many are referred to ENT services for wax removal. Using secondary care services for earwax removal has considerable resource implications. There is a need for quick, efficient and cost-effective wax removal. This chapter examines the most effective method and the most appropriate setting for wax removal.

10.2 Review question: What is the most clinically and cost-effective method of removing earwax?

For full details see review protocol in appendix C.

Table 24: PICO characteristics of review question

Population	Adults, aged 18 and over, with impacted earwax that is causing hearing loss or discomfort

Interventions	• Earwax softeners
	  • restricted to preparations that are typically available in the UK
	• Irrigation
	• Mechanical removal
	  • manual or suction
	• Cotton buds
	• Combinations of treatment

Comparisons	• No treatment • Placebo treatment • Intraclass comparisons • Interclass comparisons
Outcomes	**Critical** • Health-related quality of life • Hearing (objective and patient reported)

	• Wax-related outcomes - amount and occlusion - ability / ease of removal - global impression of treatment efficacy (patient or clinician) • Adverse effects: perforation, infection, vertigo, bleeding, discomfort • Time to recurrence of wax **Important:** • Pure tone audiometry
Study design	Randomised control trials (RCT) Systematic reviews of RCTs Where there is no evidence from RCTs, quasi-RCT designs will be considered Crossover studies where data reported prior to crossover

10.2.1 Clinical evidence

One Cochrane systematic review was identified [18]. References from this review, and other identified systematic reviews and meta-analyses, were checked and studies included in these reviews were only included if they matched our protocol. The systematic reviews and meta-analyses were not included.

Eleven trials reported in 12 papers were included in the review;[19, 24, 25, 39, 45, 57, 63, 80, 94, 95, 101, 118] these are summarised in Table 25 below. Coppin 2008[24] reported short-term results and Coppin 2011[25] reported long-term results of the same trial. Seven studies compared earwax softeners alone, 11 compared earwax softeners followed by syringing or irrigation, and 2 primarily studied earwax softeners. No studies explicitly looked at hearing aid users as a special group, and we were therefore unable to use subgroup analysis.

The term 'irrigation' can be used to refer to irrigation of the external ear canal either using a syringe or using an electronic irrigator. Both methods adopt the principle of using water to flush out earwax and therefore, in this section on clinical evidence, the term 'irrigation' is used to refer to both or either method of wax removal. Most of the papers referred to were written at a time when manual syringing was an accepted method of irrigation and the principles they outline, in discussion of the attributes of cerumenolytics or wax-softening agents, are relevant to irrigation by both techniques.

No studies on mechanical removal other than by irrigation were identified.

Evidence from these studies is summarised in the clinical evidence summary below (Table 26). See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

Table 25: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Caballero 2009[19]	Chlorobutanol solution as wax softener applied 15 minutes prior to irrigation using a syringe (n=32) Saline (sodium chloride) as wax softener applied 15	Adults who had been referred to ENT clinic due to symptoms of cerumen in whom the tympanic membrane could not be visualised in clinic due to cerumen. (n=89)	Wax-based: Complete visualisation of tympanic membrane after immediate irrigation Adverse events: Patient-reported	A further potassium carbonate arm was not extracted as atypical for UK Intervention administered by healthcare professional.

Study	Intervention and comparison	Population	Outcomes	Comments
	minutes, prior to irrigation using a syringe (n=29)	Mean age (SD) 58 (13)	pruritus, pain, unsteadiness or other side-effect	Primary care ENT clinic setting, Spain
Coppin 2008[24] Coppin 2011[25]	Aural toilet (self) - Syringing (self-administered). provided with bicarbonate ear drops, bulb syringe and instructions on its use (n=118) Aural toilet (HCP) - provided with ear-drops (no bulb). Instructions to use the bicarbonate ear drops for at least two days then return for irrigation in clinic (n=119)	Adults presenting to GP with symptoms suggestive of occluding earwax and at least 1 ear canal occluded with wax and eligible for irrigation (n=237) Mean age (SD): Intervention 57 (14), control 55 (16)	Wax-based: (1) Wax clearance (tympanic membrane easily visible) at follow-up 1–2 weeks later; (2) presented again with wax symptoms in following two years. Adverse events: Otitis externa, perforation, discomfort, dizziness.	Seven GP practices in South England, UK Used electronic irrigation
Eekhof 2001[39]	Earwax softeners as 2nd line - Warm water ear drops 15 minutes immediately prior to repeat syringing. Duration 15 minutes (n=22) Earwax softeners as 2nd line - Oil (detail not specified) ear drops applied each night followed by returning to clinic for syringing. Duration Three days (n=20)	Individuals presenting to GP with complaints resulting from earwax **where first attempt at** syringing **had failed** to clear at least 25% of wax obstruction (5 attempts at syringing) (n=42) Mean age (SD) 51 (16)	Wax-based: (1) second syringing removes wax (2); number of syringing attempts needed for second irrigation	Out of 130 patients with wax complaints suitable for syringing, 42 (32%) were not cleared by first syringing Ear drops were self-administered GP practice, the Netherlands
Fraser 1970[45]	Comparison of earwax softeners, each applied once a day for three days, followed by syringing: Sodium bicarbonate solution ear drops, (n=124 ears) Olive oil ear drops (n=25 ears) Dioctyl sodium sulphosuccinate	Inpatients in general hospital (elderly wards) found by screening to have bilateral hard wax occluding both ears (n=142 participants, 284 ears) 800 elderly patients were screened. Mean age not given (elderly)	Wax-based: (1) syringing removes wax (2); ease of removal using author's scale Adverse outcomes: otitis externa (unilateral only, due to split-person design)	Three further arms not analysed – Cerumol arm uses old preparation of ear drop; Docusate capsules are no longer used for earwax in UK; TPO ear drops atypical in the UK. Within-person design, with sodium bicarbonate solution as control. Due to dropping arms, analysed here as

Study	Intervention and comparison	Population	Outcomes	Comments
	(Docusate) ear drops (brand: Waxsol) (n=26 ears)			between-person design. General hospital, UK Ear drops administered by HCP
Hinchcliffe 1955[57]	Comparison of earwax softeners, each applied into each ear 30 minutes prior to syringing Sodium bicarbonate solution ear drops, five drops (n=37) Hydrogen peroxide urea solution ear drops, five drops (n=37) Olive oil ear drops, five drops (n=37) No earwax softener. Syringing immediately (n=37)	Entrants to RAF training screened for wax occlusion Mean age not given (adult)	Wax-based: wax cleared by up to five minutes of syringing Adverse events: discomfort from ear drops (prior to syringing)	Further arms not analysed – Cerumol arm uses old preparation of ear drop no longer available Armed forces medical clinic, UK
Keane 1995[63]	Comparison of earwax softeners, each applied 4 drops twice daily for 5 day: Sterile water (n=38) Sodium bicarbonate solution ear drops (n=39) Chlorobutanol solution ear drops (brand Cerumol)(n=40) No earwax softener (n=38)	Impacted ears (n=97 people, 155 ears) Age not specified	Wax-related: No longer impacted at five days.	Seriously indirect population, as no detail about age, therefore may include children. Republic of Ireland, setting not given
Memel 2002[80]	Syringing of ear according to practice guidelines, following 3 days of unspecified 'oily' ear drops (n=55)	Patients referred to syringing clinic with ear drum completely obscured by wax (n=116)	Hearing: PTA improved by at least 10 dB HL (PTA averaged over four frequencies – 0.5 kHz, 1 kHz, 2 kHz and 4 kHz) in	Further outcomes, including subjective hearing, were measured before-and-after for all participants (not

Study	Intervention and comparison	Population	Outcomes	Comments
	No syringing (delayed until after follow-up hearing test), following 3 days of unspecified 'oily' ear drops (n=61)	Age median 63 (IQR 42–71) Baseline PTA in dB HL, median (IQR) syringing arm 34 (20–50) versus control 26 (14–41)	at least one ear. Mean improvement in hearing in dB HL (PTA averaged over four frequencies – 0.5 kHz, 1 kHz, 2 kHz and 4 kHz) for both groups	reported as not RCT) Three GP practices, UK
Oron 2011[94]	Auro ear drops containing carbamide peroxide, three drops, three times a day in each ear for a week (n=24 ears) Cerumol ear drops containing chlorobutanol solution, thee drops, three times a day for a week (n=26 ears)	Patients of the rehabilitation department of a geriatric hospital found to have cerumen impaction on routine screening otoscopy (n=41, 76 ears) Age mean 78 (67–92) No patients complained of hearing loss at baseline	Wax based: Ear has no occlusive wax, does not need further management at 1 week Wax based: Time to remove remaining cerumen at 1 week (could not be analysed) Adverse events: Participant reported side-effects (and continued treatment) at 1 week	Further arms not analysed – "Clean Ears", an oily spray including squalane and paraffin, not typically used in UK Intervention delivered by healthcare professional Hospital (not ENT) in Israel
Pavlidis 2005[95]	Water (warm tap water) as pre-syringe wax softener applied to fill the ear canal while lying for 15 minutes, prior to syringing (n=22 ears) No pre-syringe softener, immediate syringing (n=17 ears)	Adults with symptoms of wax occlusion, confirmed by visualisation (n=26 people, 39 ears) Mean age (SD): 63 (8)	Wax-based: number of attempts to syringe ear until visibly clear of wax (25ml at a time). Adverse events: Patient reported side-effect during and directly after the intervention	Intervention delivered by healthcare professional. GP setting, Australia.
Roland 2004[101]	Comparison of ear drops, which were instilled 15 mins prior to irrigation, followed by repeat instillation and irrigation if needed: Carbamide peroxide aka. Hydrogen Peroxide Urea solution (Brand:	Volunteers with excessive or impacted cerumen on screening (n=74) Mean age (range) 45 (22–66)	Wax related: Complete visualisation of tympanic membrane after first application and irrigation at 15 minutes Wax related: Complete visualisation of	Further arms not analysed – Triethanolamine polypeptide oleate condensate, as not typically used in the UK Unusual in including mild (<50%) occlusion. Also in repeating instillation if first irrigation unsuccessful

Study	Intervention and comparison	Population	Outcomes	Comments
	Murine ear drops 6.5%) (n=26 people) Saline (sterile saline solution with sodium chloride 0.64% and physiologic concentrations of multiple electrolytes) (n=24)		tympanic membrane after up to two applications and irrigation at 30 minutes Adverse events: Subject reported adverse events	Used electronic irrigation Industry funded research clinic
Vanlierde 1991[118]	Earwax softeners - Cerumol ear drops five drops twice a day for five days (n=35) Earwax softeners - Almond oil (generic), five drops twice a day for five days (n=34)	Stable patients in elderly ward with wax graded as excessive or occluding (n=41) 132 inpatients were screened (31%). Mean age not stated (elderly)	Wax significantly improved – no longer excessive or occlusive Adverse events: discontinued due to adverse effects	General hospital, South Africa Cerumol contains both chlorobutanol and arachis oil

10.2.1.1 Ear drops alone compared with no treatment

Table 26: Clinical evidence summary: water ear drops (repeated application) versus no treatment for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with water ear drops (repeated application) versus no treatment (95% CI)
No longer impacted wax	76 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 1.67 (0.96 to 2.91)	316 per 1000	212 more per 1000 (from 13 fewer to 604 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect population (age and other factors not defined, may include children)
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 27: Clinical evidence summary: sodium bicarbonate ear drops (repeated applications) versus no treatment for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with sodium bicarbonate ear drops (repeated applications) versus no treatment (95% CI)
No longer impacted wax	77 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 1.46 (0.82 to 2.6)	316 per 1000	145 more per 1000 (from 57 fewer to 506 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect population (age and other factors not defined, may include children)
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 28: Clinical evidence summary: chlorobutanol ear drops (repeated applications) versus no treatment for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with chlorobutanol ear drops (repeated applications) versus no treatment (95% CI)
No longer impacted wax at 5 days	78 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 1.11 (0.59 to 2.08)	316 per 1000	35 more per 1000 (from 130 fewer to 341 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect population (age and other factors not defined, may include children)
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

10.2.1.2 Ear drops (alone) compared with each other

Table 29: Clinical evidence summary: sodium bicarbonate ear drops versus water (repeated applications) for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with sodium bicarbonate ear drops versus water (repeated applications) (95% CI)
No longer impacted wax at 5 days	77 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 0.88 (0.56 to 1.38)	526 per 1000	63 fewer per 1000 (from 231 fewer to 200 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect population (age and other factors not defined, may include children)
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 30: Clinical evidence summary: chlorobutanol ear drops versus water (repeated applications) for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with chlorobutanol ear drops versus water (repeated applications) (95% CI)
No longer impacted wax at 5 days	78 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 1.14 (0.77 to 1.69)	526 per 1000	74 more per 1000 (from 121 fewer to 363 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect population (age and other factors not defined, may include children)
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 31: Clinical evidence summary: chlorobutanol ear drops versus sodium bicarbonate ear drops (repeated applications) for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with chlorobutanol ear drops versus sodium bicarbonate ear drops (repeated applications) (95% CI)
No longer impacted wax at 5 days	79 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 1.3 (0.85 to 1.98)	462 per 1000	139 more per 1000 (from 69 fewer to 453 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect population (age and other factors not defined, may include children)
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 32: Clinical evidence summary: chlorobutanol (Cerumol) ear drops versus almond oil (repeated applications) for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with chlorobutanol (Cerumol) ear drops versus almond oil (repeated applications) (95% CI)
No longer impacted wax at 5 days	69 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	RR 1.8 (0.82 to 3.97)	206 per 1000	165 more per 1000 (from 37 fewer to 612 more)
Adverse event: discontinued due to adverse effects	69 (1 study) 5 days	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision	Peto OR 7.18 (0.14 to 362.04)	0 per 1000	29 more per 1000 (from 48 fewer to 105 more)[d]

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 or 2 increments because the majority of evidence used intervention (Cerumol ear drops) that was not defined in terms of active ingredients
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
d Approximation taken from Cochrane RevMan calculator

Table 33: Clinical evidence summary: hydrogen peroxide urea solution ear drops compared with chlorobutanol ear drops (repeated applications) for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with chlorobutanol ear drops used repeatedly	Risk difference with hydrogen peroxide urea solution ear drops used repeatedly (95% CI)
No further management of wax needed	50 (1 study) 1 weeks	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.08 (0.55 to 2.14)	385 per 1000	31 more per 1000 (from 173 fewer to 438 more)
Adverse event: report side-effect	50	VERY LOW[a,b,d]	OR 0.14	77 per 1000	65 fewer per 1000

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with chlorobutanol ear drops used repeatedly	Risk difference with hydrogen peroxide urea solution ear drops used repeatedly (95% CI)
	(1 study) 1 weeks	due to risk of bias, imprecision	(0.01 to 2.32)[c]		(from 76 fewer to 85 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c Peto Odds Ratio used as no events in one arm
d Of particular concern, withdrawal due to side-effects not included

10.2.1.3 Earwax softeners compared with no intervention prior to irrigation

Table 34: Clinical evidence summary: water ear drops 15 minutes prior to syringing compared with no ear drops prior to syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with no ear drops prior to syringing	Risk difference with water ear drops 15 minutes prior to syringing (95% CI)
Attempts needed to syringe until visibly clear of wax Scale from: 0 to unstated.	39 (1 study) 15 minutes	LOW [a,b] due to risk of bias, imprecision		The mean attempts needed to syringe until visibly clear of wax in the control groups was 25 syringes	The mean attempts needed to syringe until visibly clear of wax in the intervention groups was 17.9 lower (36.88 lower to 1.08 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c Single event in both arms was in the same participant

Table 35: Clinical evidence summary: sodium bicarbonate ear drops 30 minutes prior to syringing compared with no ear drops prior to syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with no ear drops prior to syringing	Risk difference with sodium bicarbonate ear drops 30 minutes prior to syringing (95% CI)
Wax cleared by 5 minute irrigation	74 (1 study) 35 minutes	LOW [a,b] due to risk of bias, imprecision	RR 1.11 (0.88 to 1.4)	757 per 1000	83 more per 1000 (from 91 fewer to 303 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 36: Clinical evidence summary: hydrogen peroxide urea ear drops 30 minutes prior to syringing compared with no ear drops prior to syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with no ear drops prior to syringing	Risk difference with hydrogen peroxide urea ear drops 30 minutes prior to syringing (95% CI)
Wax cleared by 5 minute syringing	74 (1 study) 35 minutes	LOW [a,b] due to risk of bias, imprecision	RR 1.18 (0.95 to 1.46)	757 per 1000	136 more per 1000 (from 38 fewer to 348 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 37: Clinical evidence summary: olive oil ear drops 30 minutes prior to syringing compared with no ear drops prior to irrigation for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with no ear drops prior to syringing	Risk difference with olive oil ear drops 30 minutes prior to syringing (95% CI)
Wax cleared by 5 minute syringing	74 (1 study) 35 minutes	LOW [a,b] due to risk of bias, imprecision	RR 1.25 (1.03 to 1.52)	757 per 1000	189 more per 1000 (from 23 more to 394 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

10.2.1.4 Earwax softeners to facilitate immediate irrigation: comparing ear drops against each other

Table 38: Clinical evidence summary: chlorobutanol solution ear drops 15 minutes prior to syringing compared with saline ear drops 15 minutes prior to syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with saline ear drops 15 minutes prior to syringing	Risk difference with chlorobutanol solution ear drops 15 minutes prior to syringing (95% CI)
Complete visualisation of TM after syringing	60 (1 study) 15 minutes	LOW [a,b] due to risk of bias, imprecision	RR 1.53 (0.93 to 2.51)	429 per 1000	227 more per 1000 (from 30 fewer to 648 more)
Adverse events prior to syringing	64 (1 study) 15 minutes	VERY LOW [a,c] due to risk of bias, imprecision	Not estimable	0 per 1000	0 fewer per 1000 (from 59 fewer to 59 more)[d]

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with saline ear drops 15 minutes prior to syringing	Risk difference with chlorobutanol solution ear drops 15 minutes prior to syringing (95% CI)
risk of bias b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs c No events in either arms, therefore assumed to cross both MIDs d Estimated using Cochrane RevMan calculator					

Table 39: Clinical evidence summary: hydrogen peroxide urea solution ear drops 30 minutes prior to syringing compared with sodium bicarbonate 30 minutes prior to syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with sodium bicarbonate 30 minutes prior to syringing	Risk difference with hydrogen peroxide urea solution ear drops 30 minutes prior to syringing (95% CI)
Wax cleared by 5 minute syringing	74 (1 study) 35 minutes	LOW [a,b] due to risk of bias, imprecision	RR 1.06 (0.89 to 1.28)	838 per 1000	50 more per 1000 (from 92 fewer to 235 more)
Adverse events prior to syringing: discomfort	74 (1 study) 30 minutes	VERY LOW [a,b] due to risk of bias, imprecision	RR 1.5 (0.46 to 4.88)	108 per 1000	54 more per 1000 (from 58 fewer to 419 more)
a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs					

Table 40: Clinical evidence summary: hydrogen peroxide urea eardrops 30 minutes prior to syringing compared with olive oil (ear drops 30 minutes prior to syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with olive oil ear drops 30 minutes prior to syringing	Risk difference with hydrogen peroxide urea solution ear drops 30 minutes prior to syringing (95% CI)
Wax cleared by 5 minute syringing	74 (1 study) 35 minutes	MODERATE[a] due to risk of bias	RR 0.94 (0.82 to 1.08)	946 per 1000	57 fewer per 1000 (from 170 fewer to 76 more)
Adverse events prior to syringing: discomfort	74 (1 study) 30 minutes	VERY LOW [a,b] due to risk of bias, imprecision	RR 1.5 (0.46 to 4.88)	108 per 1000	54 more per 1000 (from 58 fewer to 419 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 41: Clinical evidence summary: hydrogen peroxide urea solution ear drops up to 2 applications with 15 minutes waits compared with sodium chloride (saline) ear drops up to 2 applications with 15 minute waits for earwax immediately prior to irrigation

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with sodium chloride (saline) ear drops up to 2×15 minute applications	Risk difference with hydrogen peroxide urea solution ear drops up to 2×15 minute applications (95% CI)
Complete visualisation of TM after irrigation (1st attempt)	50 (1 study) 30 minutes	LOW[a] due to imprecision	RR 1.38 (0.25 to 7.59)	83 per 1000	32 more per 1000 (from 62 fewer to 549 more)
Complete visualisation of TM after	50	LOW[a,b]	RR 0.37	417 per 1000	263 fewer per 1000

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with sodium chloride (saline) ear drops up to 2×15 minute applications	Risk difference with hydrogen peroxide urea solution ear drops up to 2×15 minute applications (95% CI)
irrigation (2nd attempt)	(1 study) 30 minutes	due to risk of bias, imprecision	(0.13 to 1.02)		(from 363 fewer to 8 more)
Adverse events: reported side-effects from ear drops	50 (1 study) 30 minutes	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.85 (0.18 to 19.08)	42 per 1000	35 more per 1000 (from 34 fewer to 753 more)

a Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
b Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

10.2.1.5 Earwax softeners to facilitate delayed irrigation: comparing ear drops against each other

Table 42: Clinical evidence summary: docusate solution ear drops (repeated applications) prior to delayed syringing compared with sodium bicarbonate solution ear drops (repeated applications) prior to delayed syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with sodium bicarbonate solution ear drops (repeated applications) prior to delayed syringing	Risk difference with docusate solution ear drops (repeated applications) prior to delayed syringing (95% CI)
Successful syringing at 3 days	149 (1 study) 3 days	HIGH	RR 0.99 (0.82 to 1.2)	847 per 1000	8 fewer per 1000 (from 152 fewer to 169 more)
Adverse event: otitis	150 (1 study)	LOW [a,b] due to risk of	RR 3.18 (0.56 to	24 per 1000	52 more per 1000

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with sodium bicarbonate solution ear drops (repeated applications) prior to delayed syringing	Risk difference with docusate solution ear drops (repeated applications) prior to delayed syringing (95% CI)
externa	3 days	bias, imprecision	18.09)		(from 11 fewer to 410 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 43: Clinical evidence summary: olive oil ear drops (repeated applications) prior to delayed syringing compared with sodium bicarbonate solution ear drops (repeated applications) prior to delayed syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with sodium bicarbonate solution ear drops (repeated applications) prior to delayed syringing	Risk difference with olive oil ear drops (repeated applications) prior to delayed syringing (95% CI)
Successful syringing at 3 days	149 (1 study) 3 days	MODERATE [a] due to imprecision	RR 1.09 (0.95 to 1.25)	847 per 1000	76 more per 1000 (from 42 fewer to 212 more)
Adverse event: otitis externa	149 (1 study) 3 days	VERY LOW [a,b] due to risk of bias, imprecision	Peto OR 0.3 (0.01 to 6.24)	24 per 1000	17 fewer per 1000 (from 24 fewer to 109 more)

a Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
b Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Table 44: Clinical evidence summary: docusate solution ear drops (repeated application) prior to delayed syringing versus oil ear drops (repeated applications) prior to delayed syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with docusate solution ear drops (repeated application) prior to delayed syringing versus oil ear drops (repeated applications) prior to delayed irrigation (95% CI)
Successful syringing at 3 days	50 (1 study) 3 days	MODERATE [a] due to risk of bias	RR 1 (0.85 to 1.18)	920 per 1000	0 fewer per 1000 (from 138 fewer to 166 more)
Adverse event: otitis externa	50 (1 study) 3 days	VERY LOW [a,c] due to risk of bias	No events in either arm	0 per 1000	0 fewer per 1000 (from 75 fewer to 75 more)[b]

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Estimated using Cochrane RevMan calculator
c No events in either arm, therefore confidence interval assumed to cross both MIDs, Downgraded by 2 increments as the confidence interval crossed both MIDs

Table 45: Clinical evidence summary: water 15 minutes prior to syringing compared with oil ear drops (repeated applications for 3 days) prior to delayed syringing for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with oil ear drops (repeated applications) prior to delayed syringing	Risk difference with water (single application) 15 minutes prior to syringing (95% CI)
Wax cleared at up to five syringes	42 (1 study) 0-3 days [a]	LOW [b] due to risk of bias	RR 1.04 (0.92 to 1.19)	955 per 1000	38 more per 1000 (from 76 fewer to 181 more)
Ease of syringing - number of	42	VERY LOW [b,c]		The mean ease of syringing - number of	The mean ease of syringing - number of

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with oil ear drops (repeated applications) prior to delayed syringing	Risk difference with water (single application) 15 minutes prior to syringing (95% CI)
syringes needed to clear Scale from: 1 to 6.	(1 study) 0-3 days [a]	due to risk of bias, imprecision		syringes needed to clear in the control groups was 2.4 syringes	syringes needed to clear in the intervention groups was 0.6 higher (0.32 lower to 1.52 higher)

a One arm had immediate irrigation, the other had after three days
b Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

10.2.1.6 Clinic irrigation versus other strategies

Table 46: Clinical evidence summary: ear drops plus home syringing kit versus ear drops plus irrigation in GP clinic for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ear drops plus irrigation in GP clinic	Risk difference with ear drops plus home syringing kit (95% CI)
No impacted wax at follow-up (one to two weeks)	206 (1 study) 1-2 weeks	LOW [a,b] due to risk of bias, imprecision	RR 0.77 (0.6 to 0.98)	628 per 1000	144 fewer per 1000 (from 13 fewer to 251 fewer)
Change in symptom score (scale 0-6, 6 worst)	218 (1 study) 1-2 weeks	VERY LOW [a,b,c] due to risk of bias, indirectness, imprecision		The mean change in symptom score (scale 0-6, 6 high) in the control groups was 1.26 points	The mean change in symptom score (scale 0-6, 6 high) in the intervention groups was 0.45 lower

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ear drops plus irrigation in GP clinic	Risk difference with ear drops plus home syringing kit (95% CI)
					(0.8 to 0.1 lower)
Consulted again with wax-related symptoms in next two years	234 (1 study) 2 years	VERY LOW [a,b] due to risk of bias, imprecision	RR 0.82 (0.68 to 0.99)	727 per 1000	131 fewer per 1000 (from 7 fewer to 233 fewer)
Adverse event: otitis externa at follow-up	191 (1 study) 1-2 weeks	VERY LOW [a,b] due to risk of bias, imprecision	RR 0.97 (0.06 to 15.27)	11 per 1000	0 fewer per 1000 (from 10 fewer to 157 more)
Adverse event: perforation at follow-up	191 (1 study) 1-2 weeks	VERY LOW [a,b,d] due to risk of bias, indirectness, imprecision	RR 0.97 (0.06 to 15.27)	11 per 1000	0 fewer per 1000 (from 10 fewer to 157 more)
Adverse event: discomfort during treatment	218 (1 study) 1-2 weeks	LOW [a,b] due to risk of bias, imprecision	RR 1.21 (0.84 to 1.73)	324 per 1000	68 more per 1000 (from 52 fewer to 237 more)
Adverse event: dizziness during treatment	218 (1 study) 1-2 weeks	VERY LOW [a,b] due to risk of bias, imprecision	RR 0.98 (0.49 to 1.96)	130 per 1000	3 fewer per 1000 (from 66 fewer to 125 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c Downgraded by 1 or 2 increments because the majority of evidence was based on a scale that had not been externally validated

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ear drops plus irrigation in GP clinic	Risk difference with ear drops plus home syringing kit (95% CI)
d Downgraded by 1 or 2 increments because the outcome was shown to be unreliable (inability to ascertain lack of ear drum perforation prior to intervention)					

Table 47: Clinical evidence summary: clinic irrigation following oily ear drops compared with oily ear drops alone for earwax

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ear drops alone	Risk difference with clinic irrigation following ear drops (95% CI)
Hearing improved by at least 10 dB HL PTA (0.5, 1, 2 and 4 kHz)	114 (1 study)	MODERATE [a] due to risk of bias	RR 20.72 (2.86 to 150.01)	16 per 1000	316 more per 1000 (from 30 more to 1000 more)
Improvement in hearing	114 (1 study)	LOW [a] due to risk of bias		Not given	The mean improvement in hearing in the intervention groups was 6.9 higher (3.8 to 10 higher)
a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias					

10.2.1.7 Summary of the clinical evidence:

Table 48: Summary of evidence for ear drops for treating earwax (i) alone

	Superior to (benefit ≥100 per 1,000):	No difference against (benefit between −100 and 100):
Water	No treatment (Very Low quality evidence)	Sodium bicarbonate (Very Low quality evidence) Chlorobutanol (Very Low quality evidence)

	Superior to (benefit ≥100 per 1,000):	No difference against (benefit between −100 and 100):
Sodium bicarbonate solution	No treatment (Low quality evidence)	Water (Very Low quality evidence)
Hydrogen peroxide urea solution		Chlorobutanol (Very Low quality evidence) – AEs favour peroxide
Chlorobutanol solution	Sodium bicarbonate (Very Low quality evidence) Almond oil (Very Low quality evidence) – AEs favour oil	No treatment (Very Low quality evidence) Water (Very Low quality evidence) Hydrogen peroxide urea (Very Low quality evidence) – AEs favour peroxide

Note: AEs: Adverse events or side effects, where reported. Favourable defined as absolute benefit of more than 19 fewer events per 1,000. All evidence on adverse events was rated Low or Very Low quality

Table 49: Evidence for ear drops for treating earwax (ii) directly before irrigation

	Superior to (benefit ≥100 per 1,000):	No difference against (benefit between −100 and 100):
Water	No treatment (Low quality evidence)	
Sodium Chloride (Saline)	Hydrogen peroxide urea when repeated (Low quality evidence) – AEs favour saline	
Sodium bicarbonate solution	Nil	No treatment (Low quality evidence) Peroxide (Low quality evidence) – AEs favour sodium bicarbonate
Hydrogen peroxide urea solution	No treatment (Low quality evidence)	Sodium bicarbonate (Low quality evidence), AEs favour sodium bicarbonate Oil (Moderate quality evidence) – AEs favour oil
Chlorobutanol solution	Saline (Low quality evidence)	
Oil	No treatment (Low quality evidence)	Peroxide (Moderate quality evidence) – AEs favour oil

Note: AEs: Adverse events or side effects, where reported. Favourable defined as absolute benefit of more than 1 fewer event per 1,000. All evidence on adverse events was rated Low or Very Low quality

Table 50: Evidence for ear drops for treating earwax (iii) for a number of days before irrigation

	Superior to (benefit ≥100 per 1,000):	No difference against (benefit between −100 and 100):
Sodium bicarbonate solution	Nil	Docusate (High quality evidence) – AEs favour sodium bicarbonate Oil (High quality evidence) – AEs no difference
Docusate solution	Nil	Sodium bicarbonate (High quality evidence) – AEs favour sodium bicarbonate Oil (Moderate quality evidence) – AEs no difference
Oil	Nil	Sodium bicarbonate (High quality evidence) – AEs no difference Docusate (Moderate quality evidence) – AEs no difference

Note: AEs: Adverse events or side effects, where reported. Favourable defined as absolute benefit of more than 1 fewer event per 1,000. All evidence on adverse events was rated Low or Very Low quality

10.2.2 Economic evidence

10.2.2.1 Published literature

One health economic study was identified that compared self-irrigation, irrigation at primary care and no treatment and has been included in this review.[23] This is summarised in the health economic evidence profile below (Table 51) and the health economic evidence table in appendix I.

See also the health economic study selection flow chart in appendix F.

Table 51: Health economic evidence profile: softeners followed by self-irrigation versus softeners followed by clinical irrigation versus no treatment

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Clegg 2010 [23] (UK)	Partially applicable[(a)]	Potentially serious limitations[(b)]	• Population: adults 35–44 with earwax, not necessarily with hearing loss • Comparators: ○ 1. no treatment ○ 2. use softeners for a week, self-irrigating (bulb irrigator) if wax does not clear	2 versus 1: £115.99 3 versus 1: £156.32	2 versus 1: 0.00474 QALYs 3 versus 1: 0.00486 QALYs	2 versus 1: £24,450 per QALY gained 3 versus 1: £32,136 per QALY gained	Using the base case results at a cost-effectiveness threshold of £20,000 per QALY gained neither treatment is cost effective compared with no treatment, however self-irrigation is cost effective compared with no treatment at a threshold of

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
			○ 3. use softeners (olive oil) for a week, returning to GP for irrigation if wax does not clear • Clinical effectiveness: from Keane 1995[63] and Coppin 2008[24] • Costs included out-of-pocket expenditure on softeners and irrigators as well as NHS expenditure • Utility: no data from earwax studies. −0.006 used (mild to severe hearing loss measured using EQ-5D), though −0.06 used in a sensitivity analysis (improvement resulting from hearing aid use, measured by HUI3) • The study describes its results as 'exploratory and should not be used as a basis for changing policy and practice'	3 versus 2: £40.33	3 versus 2: 0.00012 QALYs	3 versus 2: £336,000 per QALY gained	£30,000 per QALY gained. Under sensitivity analysis self-treatment became cost effective if the treatment effectiveness was increased; both treatments became highly cost effective (£2,444 or £3,211 per QALY gained) if the disutility caused by earwax was taken to be 0.06 rather than 0.006.

Abbreviations: ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life years

(a) Target population was not specifically people with hearing loss and earwax. The analysis perspective was wider than NHS and PSS. The utility values were not obtained from people with earwax but were indirect.

(b) Resource use is based on assumptions and not actual study data. Measurement of effectiveness was indirect (mild to severe hearing loss) not a direct measure of the effect of hearing loss; the value used in the base case was measured using EQ-5D which is known to be insensitive to the effect of hearing loss, rather than HUI3, which was used in a sensitivity analysis.

10.2.2.2 Unit costs

See appendix P.

10.2.3 Evidence statements

Clinical

Ear drops alone compared with no treatment

- There was a clinically important benefit for absence of impacted wax at 5 days when using water or sodium bicarbonate compared with no treatment (very low quality evidence, 1 study).
- There was no clinically important benefit when using chlorobutanol compared with no treatment (very low quality evidence, 1 study).

Ear drops (alone) compared with each other:

- There was a clinically important benefit for absence of impacted wax at 5 days when using chlorobutanol compared with almond oil but a clinically important benefit for discontinuation due to adverse events when using almond oil (very low quality evidence, 1 study).
- There was a clinically important benefit of chlorobutanol compared with sodium bicarbonate for absence of impacted wax at 5 days (very low quality evidence, 1 study).
- There was no clinically important difference for absence of impacted wax at 5 days when using sodium bicarbonate or chlorobutanol compared with water (very low quality evidence, 1 study).
- There was no clinically important difference in the need for further management of wax when using hydrogen peroxide urea solution compared with chlorobutanol but there was a clinically important benefit of hydrogen peroxide urea in reported side effects (very low quality evidence, 1 study).

Earwax softeners compared with no intervention 15 to 30 minutes prior to irrigation:

- There was a clinically important benefit of water before irrigation for number of attempts needed to syringe until visibly clear of wax (low quality evidence, 1 study).
- There was a clinically important benefit of hydrogen peroxide urea and olive oil compared with no intervention for wax clearance by 5 minute syringing (low quality evidence, 1 study).
- There was no clinically important difference in wax clearance by 5 minute syringing when using sodium bicarbonate (low quality evidence, 1 study).

Earwax softeners to facilitate immediate irrigation: comparing ear drops against each other

- There was a clinically important benefit of chlorobutanol compared with saline drops for complete visualisation of tympanic membrane after syringing and there were no reported adverse events prior to syringing (low quality evidence, 1 study).
- There was no clinically important difference in wax clearance by 5 minute syringing when using hydrogen peroxide urea compared with sodium bicarbonate (low quality evidence, 1 study) but there was a clinically important benefit of sodium bicarbonate for discomfort prior to syringing (very low quality evidence, 1 study).
- There was no clinically important difference in wax clearance by 5 minute syringing when using hydrogen peroxide urea compared with olive oil (moderate quality evidence, 1 study) but there was a clinically important benefit of oil for discomfort prior to syringing.

Earwax softeners to facilitate delayed irrigation: comparing ear drops against each other

- There was no clinically important difference in complete visualisation of the tympanic membrane after the first syringing attempt when using hydrogen peroxide urea compared with saline solution but there was a clinically important benefit of saline for complete visualisation of the tympanic membrane after the second syringing attempt and for reported adverse events from ear drops (low quality evidence, 1 study).
- There was no clinically important difference in successful syringing attempts at 3 days when using docusate compared with sodium bicarbonate (high quality evidence, 1 study) but there was a clinically important benefit of sodium bicarbonate for less adverse events (otitis externa; low quality evidence, 1 study).
- There was no clinically important difference in successful syringing at 3 days (moderate quality evidence, 1 study) and in adverse events (otitis externa) when using olive oil compared with sodium bicarbonate (very low quality evidence, 1 study)
- There was no clinically important difference in successful syringing at 3 days (moderate quality evidence, 1 study) and adverse events (otitis externa; very low quality evidence, 1 study) when using docusate solution compared with oil.
- There was no clinically important difference in wax clearance at up to 5 syringes (low quality evidence, 1 study) and ease of syringing (very low quality evidence, 1 study) when comparing water to oil.

Clinic irrigation compared with other strategies:

Ear drops plus home syringing kit versus ear drops plus irrigation in GP clinic for earwax

- There was a clinically important benefit of clinic irrigation compared with home syringing for absence of impacted wax at 1–2 week follow-up (low quality evidence, 1 study) and for adverse events (discomfort during treatment; low quality evidence, 1 study).
- There was a clinically important benefit of home syringing for repeated consultation for wax related symptoms within 2 years (very low quality evidence, 1 study).
- There was no clinically important difference in change in symptom score (very low quality evidence, 1 study), otitis externa and perforation at follow-up (very low quality evidence, 1 study), discomfort and dizziness during treatment (very low quality evidence, 1 study).

Clinic irrigation following ear drops compared with ear drops alone

- There was a clinically important benefit of clinic irrigation for hearing improvement by at least 10 dB HL pure tone average (0.5, 1, 2 and 4 kHz) (moderate quality evidence, 1 study) and for improvement in hearing (low quality evidence (low quality evidence, 1 study).

Economic

- One cost–utility analysis found that attending a GP for wax removal after using softeners was not cost effective compared with no treatment for treating earwax when the benefit was measured using EQ-5D (ICER: £32,136 per QALY gained) but was cost effective compared with no treatment when the benefit was measured using HUI3 (ICER: £3,211 per QALY gained). This analysis was assessed as partially applicable with potentially serious limitations.

10.2.4 Recommendations and link to evidence

Recommendations	**15. Offer to remove earwax for adults in primary care or community ear care services if the earwax is contributing to hearing loss or other symptoms, or needs to be removed in order to examine the ear or take an impression of the ear canal.**

	16. When carrying out ear irrigation in adults: • **use pre-treatment wax softeners, either immediately before ear irrigation or for up to 5 days beforehand** • **if irrigation is unsuccessful:** i. **repeat use of wax softeners or** ii. **instil water into the ear canal 15 minutes before repeating ear irrigation** • **if irrigation is unsuccessful after the second attempt, refer the person to a specialist ear care service or an ear, nose and throat service for removal of earwax.** **17. Consider ear irrigation using an electronic irrigator, microsuction or another method of earwax removal (such as manual removal using a probe) for adults in primary or community ear care services if:** • **the practitioner (such as a community nurse or audiologist):** i. **has training and expertise in using the method to remove earwax** ii. **is aware of any contraindications to the method** • **the correct equipment is available.** **18. Do not offer adults manual ear syringing to remove earwax.** **19. Advise adults not to remove earwax or clean their ears by inserting small objects, such as cotton buds, into the ear canal. Explain that this could damage the ear canal and eardrum, and push the wax further down into the ear.**
Research recommendation	**3. What is the clinical and cost effectiveness of microsuction compared with irrigation to remove earwax?**
Relative values of different outcomes	The outcomes identified as critical outcomes for this review were health-related and hearing-related quality of life, any outcomes related to wax removal, for example ability or ease of removal, and adverse events such as perforations or infections. Pure tone audiometry was identified as an important outcome.
Quality of the clinical evidence	The evidence found was very limited with mainly single studies made up of small numbers comparing interventions. The majority of the evidence ranged from low to very low quality. This was mainly due to risk of bias in patient selection and allocation where adequate descriptions were not provided and to indirectness as several papers do not include enough detail to determine whether children were included. The guideline committee noted the majority of the studies compared 2 alternative interventions or investigated the timing or combinations of interventions rather than comparing treatment with no treatment. Only 1 study compared the use of earwax softeners to no treatment. *Ear drops alone:* The evidence showed that there was a clinically important benefit in using ear drops, specifically water or sodium bicarbonate, compared with no treatment to remove impacted wax. Chlorobutanol did not show a clinically important benefit. When different ear drops were compared with each other, chlorobutanol was found

	to have a clinically important benefit compared with almond oil and to sodium bicarbonate. Both chlorobutanol and sodium bicarbonate showed clinically important benefits compared with water and hydrogen peroxide urea was more clinically beneficial than chlorobutanol. *Ear drops used to facilitate irrigation:* When compared with no treatment, water, hydrogen peroxide and olive oil had a clinically beneficial effect but there was no clinically important benefit of sodium bicarbonate in facilitating immediate irrigation. When comparing ear drops against each other, the only clinically important benefit observed was when chlorobutanol was compared with saline drops prior to immediate syringing. No clinically important differences were observed when ear drops were compared with each other prior to delayed irrigation. *Clinical irrigation compared with other strategies:* There was a clinically important benefit for successful removal of wax when this was performed by syringing in a clinic compared with removal using home kits. Adverse events were generally not well reported but there was mostly a small or no clinically important difference between the different ear wax softeners used and when comparing removal by syringing in a clinic to home kits. On the whole, the evidence does suggest that there is a clinical benefit in using an earwax softener such as water or sodium bicarbonate either as the sole treatment, or to facilitate irrigation. However, due to the limitations of the evidence, it was difficult to conclude that there is clear advantage of using one particular softener over another. The committee noted that earwax removal may be an urgent requirement in order to exclude this as a cause of hearing loss and avoid delay in treatment of underlying pathology. The committee noted the absence of comparative evidence regarding the method of earwax removal.
Trade-off between clinical benefits and harms	The committee discussed the importance of managing earwax in people with hearing loss. The presence of impacted wax prevents examination of the ear, and makes it impossible to perform accurate audiometry or take an ear mould impression. People who wear hearing aids are more likely to have impacted wax due to the hearing aid preventing wax from being excreted naturally. Although the committee agreed that the evidence was weak when considering one treatment over another, it was accepted that it is standard practice to treat earwax because it is not possible to manage a person's hearing loss clinically without removing earwax when present, nor is it safe to manage hearing loss without excluding conditions like chronic infection by examination of the eardrum. The committee considered it important to stress that the removal of earwax should be provided as part of basic management of patients, and made a consensus recommendation for the circumstances in which earwax should be removed. The committee agreed that wax can be removed under direct vision or a microscope using a probe in certain situations when wax build up is minimal and sited near the meatus rather than impacted earwax deep in the canal, but research and discussion should be focused towards situations where this would not be the case. The committee noted the clinical benefit of ear irrigation as opposed to ear drops

alone. In current practice, wax softeners are the standard intervention in primary care, followed by irrigation if unsuccessful.

Irrigation of the ear canal should be undertaken using warm water and an electronic ear irrigation machine with a variable pressure control. A jet tip is used to angle the flow of water along the top of the posterior wall. Historically ear syringing was used and this is evident in the papers reviewed. The effect is the same but irrigation is a much safer method and syringing is now contraindicated because of adverse effects, namely trauma.

Ear irrigation may be unsafe for some patients. The committee noted that the NICE clinical knowledge summary on ear irrigation includes contraindications for ear irrigation, and considered it important to signpost clinicians to this resource. Contraindications include perforation of the tympanic membrane, previous ear surgery, ear infection, previous problem with irrigation, and presence of a foreign body in the ear.

The evidence demonstrated the benefit of using earwax softeners before ear irrigation, however the evidence was not strong enough to recommend a specific type of softener between oil, sodium bicarbonate or water. The committee recognised that it is currently common practice to use sodium bicarbonate or olive oil, although there is wide variation in practice amongst clinicians and personal preference plays a strong role, as does the type of the earwax. The evidence indicated that water is as clinically effective as other types of softeners and could be used as an alternative. The committee considered that clinical judgement should be used to determine which softener is most appropriate for the patient. Clinicians should also consider cost as a factor in their decision-making.

Adverse events (such as irritation, otitis externa and perforation of ear drum) were reported in the evidence for hydrogen peroxide before irrigation, but the committee noted that the majority of studies did not report adverse events, so no conclusions could be drawn about adverse events of other treatments. The committee noted that sodium bicarbonate can also cause irritation. In contrast, there is some evidence that favours hydrogen peroxide alone (without irrigation). The committee noted the risk of potential confounding, for example if patients have used a cotton bud at the same time as the softener. The committee confirmed that hydrogen peroxide is no longer used in most clinical settings; however, it is available in pharmacies and is commonly used by the public in self-management. There is no evidence that hydrogen peroxide is more effective than other softeners before irrigation and there is evidence of a risk of adverse events, however overall the committee did not feel that there was sufficient evidence to justify making a negative recommendation about hydrogen peroxide.

There was no high quality evidence in favour of a specified time interval for administering a softener before ear irrigation, however the committee considered that this was a clinically significant issue. In the absence of evidence favouring longer periods of administration, and the impact on patients' quality of life caused by waiting, the committee agreed by consensus to recommend a timescale of either immediately before irrigation or up to 5 days prior to irrigation. The committee noted that health professionals may not be aware that administering ear drops on the same day as irrigation is an option, and wanted to highlight this for consideration. The impact on resources was noted as additional primary and community care appointments would not be required, but in some cases this would have to be balanced against appointments taking longer if the wax is difficult to remove. There may also be implications for clinic planning, particularly in remote rural areas where patients have limited travel options and may appreciate same day treatment.

Giving the patient advice or a leaflet on the correct method to instil ear drops is valuable to ensure they have effect. The committee also noted that giving advice on

	measures that may help prevent the build-up of wax is often welcomed by patients. The committee also noted issues around compliance and whether some patients with cognitive decline or physical limitations are able to administer earwax softeners effectively themselves. The committee suspected that some older patients in this category would not be able to self-administer this treatment, but would instead require instillation of drops by a healthcare professional in the clinic shortly before irrigation. The committee noted that no evidence was found comparing the clinical or cost effectiveness of irrigation with other mechanical methods, such as microsuction or physical removal with a probe. Microsuction is the method usually employed by ENT services because it is quick and efficient and allows the clinician a good view of the ear canal and drum. It is the method of choice if irrigation has failed or if the person has external or middle ear pathology. The technique, however, is gaining in popularity and is available in some ear care clinics. The committee wished to highlight that microsuction may be considered where available, and where appropriately trained staff can use this technique. The committee considered that ear syringing with a large metal syringe or similar obsolete equipment is potentially harmful. The design of the syringe and the inability to control the water pressure increases the risk of damage to the ear canal and tympanic membrane. This treatment should no longer be used in current practice. Irrigation using an electronic ear irrigation machine which pumps water into the ear at a controlled pressure is safer. The committee noted the lack of evidence on the harms associated with the use of cotton buds. The committee agreed cotton buds can present a potential hazard when used by patients or their carers to remove wax themselves, and the importance of highlighting this with a consensus recommendation to warn of the increased risk of infections and causing wax to become impacted by pushing it further into the ear canal. The general advice given is not to insert anything into the ear canal as it is self-cleaning and the only cleaning needed is to gently wipe the conch (bowl) of the external ear with a damp flannel over a finger in order to clean earwax away from the meatus (entrance to the ear canal).
Trade-off between net clinical effects and costs	One UK health economic evaluation was identified, which was carried out as part of an NIHR health technology assessment. This compared 3 options: no treatment; treatment using softeners for a week and self-irrigating (using a bulb irrigator) if the wax does not clear; using softeners for a week and returning to a GP if the wax does not clear. The study described its results as “exploratory and should not be used as a basis for changing policy and practice”. The committee noted that self-irrigation is not commonly recommended in the UK. There are concerns regarding the safety of self-irrigation, and recommending this approach would conflict with the separate recommendation to advise people not to insert objects into their ears. The committee noted that the ‘exploratory’ study showed that GP-administered irrigation was not cost effective compared with self-irrigation due to very little additional benefit to quality of life from increased effectiveness. However, the committee noted that only 1 clinical study was identified reporting adverse events for self-irrigation. The committee agreed that self-irrigation is a potential method that it needed to consider, but decided that at this stage there is too little evidence regarding its safety for the committee to be confident that such a significant change from current practice would be safe. The committee considered making a recommendation for further research. Although such research would be welcomed, the committee decided that the other questions identified in this guideline are currently higher priorities. Comparing earwax treatment to no treatment, the committee noted a significant difference in the ICERs depending on which quality of life measure is used: removal was highly cost effective at a threshold of £20,000 per QALY gained when quality of life was measured using HUI3 but not cost effective when EQ-5D was used. The

	committee agreed that HUI3 is a more appropriate measure of quality of life for people with hearing loss than EQ-5D (see appendix N for more discussion on this issue), and that it appears to be a more appropriate tool in this context, however the committee noted that this study had not found any measurement for a change in utility directly equivalent to the impact of having earwax, and so the results of this study cannot be relied upon. In addition to the low quality evidence that earwax removal could be cost effective, the committee also noted that current practice is to remove wax, and did not consider any treatment to be an option for consideration as this would not be acceptable to patients. Regarding the most cost-effective method of removing earwax, the committee was constrained by the lack of clinical evidence regarding methods other than irrigation (such as microsuction). Irrigation has been shown to be effective. The cost of the initial purchase of the machine (around £159) will be split over many hundreds of uses, and so is not significant. Consumables cost only £0.54 per use. Irrigation machines are currently found in some GP surgeries. The major cost involved is the healthcare professional's time, which is dependent on the number of appointments required to remove the earwax. Microsuction machines are considerably more expensive than irrigation machines. If purchased with a microscope the combined equipment can cost from £7,500 to as much as £14,000 if a high end microscope is used. However, if a loupe (a portable microscope with lower magnification) is used instead of a microscope then the combined cost would instead be between £1,350 and £3,350. The cost of consumables is however still low, expected to be slightly under £3 per use. In some areas there are alternative local ear care clinics providing irrigation to which people can be referred. It is not necessary and would not be appropriate to refer people with earwax, without complications, to a hospital service for earwax removal, as this would be unnecessarily more expensive than a primary or community care appointment. Consequently the committee recommended that earwax removal should be offered as it is likely to be cost effective, and that irrigation should be considered as the method of removal. Where irrigation is used, softeners should be used before irrigation to increase the rate of success of irrigation. The committee noted that various possible softeners are available that are cheap and similarly priced (all below £3 per bottle, with the cheapest below £1 per bottle). The committee therefore agreed that softeners that can be obtained at a low price and do not carry a risk of adverse effect should be preferred, such as water, sodium chloride or olive oil. Softeners such as water or sodium bicarbonate can be effective if instilled a few minutes before irrigation, or part-way through the irrigation appointment, thus reducing the need for further additional visits and also decreasing delays in care. The committee noted that no clinical or economic evidence was identified regarding microsuction compared with ear irrigation in either this review or the review of settings for earwax management, despite a common belief among clinicians that microsuction is more clinically effective. The committee also noted that, whereas ear irrigation is widely available, microsuction is less widely available and the equipment is more expensive. The committee therefore recommended that microsuction could be considered where it is already available, but that it cannot recommend that microsuction equipment be routinely purchased.
Other considerations	The committee also noted that there is a range of treatments available for treating earwax that are inappropriate and should not be used, for example ear candles. The committee discussed how great the impact of earwax on audibility would be. It was agreed that the measurable difference was probably not more than 10dB in most cases; a level which would give a perceived reduction in loudness of 50%. The committee however recognised that earwax can have a huge impact on quality of

	life, especially for certain occupations where safety is important. It is likely to have a much greater impact on those who wear hearing aids and find themselves unable to use their aids because of earwax. The committee is aware of the practice of using regular small quantities of olive or almond oil in order to keep earwax soft and in this way to try to avoid build-up of earwax. This use of oil was not researched and the committee know of no evidence to advise against this practice if it is found to help the individual.

10.3 Review question: What is the most clinically and cost-effective setting for the identification and treatment of earwax?

For full details see review protocol in appendix C.

Table 52: PICO characteristics of review question

Population	Adults aged 18 years and over who have difficulties hearing and earwax
Intervention and comparator	• Treatment in a primary care setting, for example a GP's surgery • Secondary care

Outcomes	**Critical**
	• Success of earwax removal
	• Improvement in hearing
	• Adverse events
	  ○ Earwax related
	  - perforation
	  - Infection
	  - vertigo
	  - bleeding
	  - Discomfort
	• Hearing-specific health-related quality of life
	  ○ Any patient-reported scale that has been validated to provide health utility measure, for example:
	  - WHO DAS II
	  - HUI2/HUI3
	  - Cambridge Otology QOL Questionnaire
	  - Speech, Spatial and Qualities of Hearing Scale (SSQ)
	• Patient-reported disability or benefit
	• Measures validated to demonstrate changes with audiology care in the population under study, for example:
	  ○ Device Orientated Subjective Outcome Scale
	  ○ Glasgow Hearing Aid Benefit Profile
	  ○ Hearing Handicap Inventory for the Elderly

Study design	RCT Systematic review of RCTs If not enough RCT evidence is identified, cohort studies will be considered

10.3.1 Clinical evidence

No relevant clinical studies were identified that compared the identification or treatment of earwax in primary or secondary care in adults who have difficulties hearing and earwax. See study selection flow chart in appendix E and the excluded studies list in appendix L.

10.3.2 Economic evidence

10.3.2.1 Published literature

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

10.3.2.2 Unit costs

See appendix P.

10.3.3 Evidence statements

Clinical

- No relevant clinical studies were identified for this review.

Economic

- No relevant economic evaluations were identified.

10.3.4 Recommendations and link to evidence

Recommendations	Please refer to recommendations in section 10.2.4 on earwax removal methods
Relative values of different outcomes	The committee agreed that the critical outcomes for decision-making were successful earwax removal; improvement in hearing; adverse events related to earwax including perforation, infection, vertigo, bleeding and discomfort; hearing-specific health-related quality of life as reported by validated scales including WHO DAS II, HUI2/HUI3, Cambridge Otology QoL Questionnaire and the SSQ. Further critical outcomes included patient reported disability or benefit; measures validated to demonstrate changes with audiology care in the population under study for example, the Device Orientated Subjective Outcome Scale, Glasgow Hearing Aid Benefit Profile and Hearing Handicap Inventory for the Elderly.
Quality of the clinical evidence	No relevant clinical studies were identified for this review.
Trade-off between clinical benefits and harms	As no evidence was found the recommendations were based on consensus of the committee. The committee discussed the most appropriate setting for routine earwax removal and acknowledged that there was delay in management of earwax and over-referral to secondary ENT services. The committee recognise the build-up of earwax is common, particularly in people who wear hearing aids, and removal of wax is necessary as part of managing the person's hearing loss. Management of earwax is usually carried out within primary care but there is variation in how and where physical removal by irrigation or microsuction takes place. In the absence of any evidence the committee made a consensus recommendation for management of earwax, including removal by irrigation or

	microsuction, to be carried out in a primary or community care setting, unless there are contraindications. Contraindications for ear irrigation would include cases where wax impaction accompanies the following conditions: • The person has (or is suspected to have) a perforation of the tympanic membrane, including grommets. • There is a past history of ear surgery. • There is a foreign body, including vegetable matter, in the ear canal. • There is obvious otitis externa Or if: • Ear drops have been unsuccessful and irrigation is contraindicated • Wax removal in primary or community care has been unsuccessful. In these situations referral should be made to an ENT service. Microsuction can be used in many cases where ear irrigation is contraindicated such as tympanic membrane perforation, some foreign bodies, mild otitis externa and in some cases of previous ear surgery. The training and experience of the person performing the procedure will dictate the cases they are competent to manage. The committee discussed the use of microsuction for earwax removal in a number of different environments including GP practices, audiology and community health services. It was noted that the availability of this service is variable, and in some areas people would be referred to ENT for this procedure. The committee agreed that as long as the correct equipment was available and there were health professionals trained to carry out this procedure, it would be appropriate to offer this service within primary or community care settings, and this should be encouraged. The committee noted that dedicated ear care clinic facilities are being set up in some areas. Ear care clinics provide ear irrigation and microsuction facilities for people with wax. They are usually staffed by audiologists or community nurses and have the additional function of providing hearing aid repairs, batteries and new moulds or tubing. Many offer a drop-in facility. They can offer a convenient one-stop facility for people with hearing aids. Referring people to ENT services for simple cases of wax removal would not be an appropriate use of ENT resources.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee noted that, in its experience, there is an increasing trend for GP surgeries not to treat patients with uncomplicated earwax in the surgery but to routinely refer them elsewhere or give them long courses of ear drops which, used on their own, are ineffective. This may be because of a misunderstanding of the difference between ear syringing (no longer advised) and ear irrigation (now the method of choice). If onward referral is to a community setting where a trained healthcare professional performs ear irrigation this can be a very efficient use of resources as the high volume of cases increases efficiency and expertise. However, in some cases people with uncomplicated earwax are being referred to secondary care ENT services. This is not a cost-effective pathway and is an inappropriate use of specialist services that have limited capacity. The committee hence recommended that, unless contraindicated, earwax removal should be conducted in primary care or community care – either GP surgeries or community settings specialising in this service, such as ear care clinics.
Other considerations	The committee noted the NICE clinical knowledge summary on earwax.

11 Sudden sensorineural hearing loss (SSNHL)

11.1 Introduction

Sudden sensorineural hearing loss (SSNHL) is an ENT emergency and is defined as a loss of hearing of 30 dB HL or more, over at least 3 contiguous frequencies, that develops within 3 days. Most cases are unilateral and the commonest age group affected are adults in their 40s and 50s. In 90% of cases no underlying cause is identified and it is considered idiopathic. Idiopathic SSNHL affects approximately 5–20 per 100,000 people per year in developed countries with an equal gender distribution. The hearing loss can range from mild to profound and can be temporary or permanent. Idiopathic SSNHL significantly impacts on individuals' lives, causing considerable disability, especially if there is a pre-existing hearing deficit in the other ear.

Hearing loss is confirmed by pure tone audiometry, and serious underlying causes are excluded by history, examination, MRI and blood tests. Additional investigations may be indicated depending on the presentation.

The mainstay of treatment currently consists of early initiation of steroids with antivirals as a possible adjunct. The effectiveness of these treatments is poorly understood and there is no national standard or guidance for the management of idiopathic SSNHL, with considerable variation in practices in terms of treatment regimen employed and routes of administration. This chapter examines the most clinically and cost-effective medical treatments for idiopathic sudden sensorineural hearing loss, including routes of administration.

11.2 Review question: What is the most clinically and cost-effective treatment for idiopathic sudden sensorineural hearing loss (SSNHL)?

For full details see the review protocol in appendix C.

Table 53: PICO characteristics of review question

Population	Adults aged 18 and over with idiopathic SSNHL
Interventions and comparators	**Interventions:** Steroids • Prednisolone • Dexamethasone • Hydrocortisone Antivirals • Acyclovir • Amantadine • Valacyclovir • Famciclovir • Ganciclovir **Comparisons:** Compared with each other, to placebo or to no treatment (if applicable) Combination (steroids and antivirals only) and different dosages will also be included

Outcomes	**Critical:** • Pure-tone audiometry • Speech discrimination • Health-related quality of life • Hearing-specific health-related quality of life **Important:** • Adverse events for example, gastrointestinal bleeding, mood alteration or psychosis
Study design	RCTs Systematic review of RCTs

11.2.1 Clinical evidence

Thirteen studies were included in the review: 8 first-line treatment comparisons [4, 12, 44, 91, 110, 115, 116, 123]; and 5 second-line treatment regimens [69, 70, 96, 127, 128,] these are summarised in Table 55 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 56, Table 57, Table 58, Table 59 and Table 60). See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

Two Cochrane systematic reviews were identified: Antivirals for idiopathic sudden-onset sensorineural hearing loss [8] and Steroids for idiopathic sudden sensorineural hearing loss.[121] References from these, and other identified systematic reviews and meta-analyses, were checked and studies were included in this review if they matched our protocol.

Some papers that were excluded by the Cochrane review on Steroids for idiopathic sudden sensorineural hearing loss[121] have been included in our review. The reasons for exclusion from the Cochrane review were as follows:

- Battaglia 2008[12] – "impossible to determine the true effects of steroid when there was no double placebo control (placebo intratympanic injections with placebo taper)"
- Lee 2011[69] – not randomised, double blind, or placebo controlled
- Li 2011[70] – not double blind or placebo controlled. "impossible to determine the true effects of steroid when there was no placebo control"
- Plontke 2009[96] – "Impossible to determine the true effects of steroid when there was no placebo control (participants without any systemic and local steroid treatment)"
- Wu 2011[127] – "Impossible to determine the true effects of steroid when there was no double placebo control of patients who received neither systemic nor intratympanic steroid"

Our protocol included studies that lacked a placebo comparison whereas the Cochrane review did not. In addition, we believe that the Lee 2011[69] study which was excluded from the Cochrane review, is in fact, randomised and has therefore been included in our review.

Two papers that were included in the Cochrane review on steroids[121] have been excluded from this review (Cinamon 2001[21] and Wilson 1980[125]) due to being quasi-randomised and having unclear methodology with mixed treatment doses, respectively.

One paper included in the Cochrane review on antivirals,[8] did not have any analysable data and was excluded (Westerlaken 2003).[124]

Of the included studies, all had a population with unilateral hearing loss. The methods for excluding underlying causes of hearing loss vary, with some studies excluding patients post randomisation where pathology was later identified. Five of the studies[4, 70, 91, 127, 128] did not explicitly state that patients with autoimmune disease were actively excluded. As this means any effect of steroids could

be due to their known benefits for autoimmune disorders, these studies were subject to sensitivity analysis to determine whether their findings differed from other studies within each comparison. No systematic differences were found between the results of these studies and the remaining studies that had excluded those with autoimmune disease.

The interventions that were included in the studies were prednisolone, methylprednisolone, dexamethasone, hydrocortisone, acyclovir and valacyclovir. Acyclovir was also used pre-randomisation in a second-line treatment study (Xenellis 2006[128]). The treatments were given intravenously (IV), orally or intratympanically (IT).

The studies reported pure tone audiometry (PTA) by change or final scores, author-defined improvement and recovery. In this report, PTA data are presented as the change or final scores as well as the author-defined recovery data as these were thought to be the most important outcomes for decision-making. Where these continuous and dichotomous outcomes are derived from the same dataset this has been highlighted to avoid double counting the data. If neither of these preferred definitions are presented by a given study, author-defined improvement was reported.

Speech discrimination was also recorded in some studies. Few studies reported adverse events, but these data have been extracted where possible. Only one study reported on quality of life, Tucci 2002,[115] but only an overarching summary comparing the population to the USA population was available.

The definitions used to describe recovery varied between the studies and some studies included more than one definition of recovery. The definitions included as outcomes within this report were those that were most representative of clinical recovery that is important to the patient (Table 54).

Table 54: Study definitions of improvement and recovery

Study	Recovery
Ahn 2008[4]	Final hearing better than 25 dB based on a four-tone average of thresholds at 0.5, 1, 2, and 4 kHz.
Battaglia 2008[12]	Recovery of hearing to within 5 percentage points of the contralateral speech discrimination score (SDS) or within 5 dB of the contralateral PTA. PTA measured by taking the 3-frequency average of the threshold value at 0.5, 1, and 2 kHz.
Filipo 2013[44]	PTA ≤25 dB or identical to the contralateral non-affected ear. PTA calculated as the mean of thresholds at 6 frequencies (0.25, 0.5, 1, 2, 4, and 8 kHz)
Nosrati-Zarenoe 2012[91]	Total recovery: recovery to within 10 dB (mean over 3 most affected contiguous frequencies) of prior audiogram of affected ear or, if not available, within 10 dB (mean over 3 most affected contiguous frequencies) of non-affected ear.
Plontke 2009[96]	Composite of complete and marked recovery: 6PTA≤25 dB and 6PTA improvement >30 dB respectively (6PTA is average of thresholds at 0.25, 0.5, 1, 2, 4 and 8 kHz)
Tucci 2002[115]	Within 10 dB of non-affected ear based on PTA measured by taking the 3-frequency average of the threshold value at 0.5, 1, and 2 kHz.
Westerlaken 2007[123]	Symmetrical hearing, interaural hearing difference of <20 dB HL based on a 4-tone average of thresholds at 0.5, 1, 2, and 4 kHz.

Another factor to consider is the mean time between the onset of hearing loss and start of treatment and whether this would affect the end of study outcomes as this varied between the studies (Table 55).

Table 55: Summary of studies included in the review

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
First-line treatment					
Ahn 2008[4] South Korea	6.5 (3.9) and 7.1 (4.1) days	Methylprednisolone (oral, 48mg per day for 9 days, 5 day tapering) versus methylprednisolone (oral, as above) plus dexamethasone (IT, 0.3-0.4ml of 5mg/ml 1st, 3rd and 5th day) 14 days of treatment, 3 months follow-up	n=120 No age restriction given in inclusion criteria. ITD group 48.6 (15.4) years, Control 45.9 (14.7) years.	PTA: complete recovery, slight hearing improvement	Risk that children were included as it was not stated that they were excluded.
Battaglia 2008[12] USA	11 (14), 7 (6), 4 (3) days (had to be within 6 weeks)	Prednisolone (oral) plus dexamethasone (IT) versus Prednisolone (oral) plus placebo (IT) versus Placebo (oral) plus dexamethasone (IT) Oral steroid dosing: 60mg/day for 7 days, 50mg for 2 days, 40mg for 2 days 30mg 1 day, 20mg 1 day, 10mg 1 day. Dexamethasone (IT) dosing: 0.5-0.7ml of 12mg/ml once a week for 3 weeks (unclear when first dose given). Stated to be a 2 year study. Capsules taken for 2 weeks, intratympanic injections over 3 weeks, audiogram stated to have been taken 4 weeks after the final injection. Also describes a 3 month follow-up after the last patient enrolled.	n=51 No standard deviations were reported. Placebo taper plus IT-Dex 60 years, HDPT plus IT saline 54 years, HDPT plus IT Dex 57 years.	PTA: scores, improvement, recovery Speech discrimination score	No age inclusion or ranges given. Risk of the inclusion of children.
Filipo 2013[44] Italy	Diagnosed within 3 days of onset. No data given.	Prednisolone (IT, 0.3ml at a dose of 62.5mg/ml/day for 3 days) versus placebo (IT) 3 days of intervention, follow-up at 1 month.	n=50 For the IT prednisolone group 49.9 (12.6) and IT saline group 50.8 (14.7) years	Adverse events PTA: improvement, recovery	Inclusion criteria was 15-85 years. Unclear how many children were included in the study.
Nosrati-zarenoe 2012[91] Sweden	Seeking care within 1 week after onset of HL. Range 0-7 days. Mean 3 (1.9) and 3.2 (2.3) days.	Prednisolone (oral, 60mg/day for 3 days, reduced by 10mg/day, total treatment time 8 days. If recovery was complete, treatment stopped, otherwise medication was continued at one capsule daily to a total of 30 days from beginning.) versus Placebo (oral) Up to 30 days of treatment with follow-up at 3 months.	n=103 Prednisolone 56.8 (12.7) range 26-80 years, Placebo 53.8 (13.5), range 26-79 years.	Adverse events PTA: mean change and recovery	

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
Stokroos 1998[110] The Netherlands	Seen on average 4 days after hearing loss began	IV prednisolone 1mg/kg day 1, to be diminished in equal increments over 7 days to 0mg. In addition, one group received 10mg/kg acyclovir 3 times a day for 7 days, the other group a placebo	n=44 11-71 years Mean age 42.5 years acyclovir group, 45.7 years placebo group	Adverse events	Age range was 11-71 years. Unclear how many children were included in the study.
Tucci 2002[115] USA	Patients seen within 10 days of hearing loss. No data given	Prednisolone (oral, Day 1-4: 80mg a day in divided doses (40,20,20mg), day 5-6; 60mg a day in divided doses (20,20,20mg), Days 7-9 40mg a day in divided doses (20,20mg), day 10-12; 20mg per day) plus valacyclovir (oral, 1g/day for 10 days) versus prednisolone (oral, dose as other treatment group) plus placebo (oral) 12 days of systemic steroids, 10 days antiviral or placebo, total duration of study 6 weeks.	n=105 55.8 years (range 18-82 years)	SF-12 PTA: scores, recovery Speech discrimination change score	
Uri 2003[116] Israel	Seen within 7 days of onset of hearing loss.	Hydrocortisone (IV, 100mg three times a day for 7 days followed by prednisolone tapering for 7 days) versus Hydrocortisone (IV, dose as above) plus acyclovir (IV, 15mg/kg/day) 14 days of intervention, 1 year follow-up	n=60 45.8 years, range 18-60 years, median 48 years.	Adverse events PTA: improvement Speech discrimination	
Westerlaken 2007[123] Netherlands	<14 days between onset and evaluation. 3 (3) and 4 (4) days delay in treatment from onset.	Prednisolone (oral, 70mg/day for 3 days, 40mg for 1 day, 30mg for 3 days) versus dexamethasone (oral, 300mg for 3 days followed by placebo 4 days) 12 month follow-up.	n=91 Prednisolone group: 49 (16), Dexamethasone group 46 (15)	PTA: scores, recovery Speech discrimination of 100%	
Second-line treatment					
Lee 2011[69] South Korea	Onset to initial treatment in the steroid group: 5.1 (5.6) and placebo group: 5.6	Previous treatment: 60mg/day oral steroids 5 days, tapering 5 days Dexamethasone (IT, 5mg/ml, 0.3-0.4ml instilled, twice a week for 2 weeks) versus no treatment. 2 week intervention followed	n=46 IT steroid group 44 (16.2) years, Control group 45.3 (13.5) years	PTA: improvement, scores	Initial failure definition: recovering ≤10 dB of affected ear PTA

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
	(5.3) days. Salvage therapy started within 2 days of initial steroid therapy	by 4 weeks follow-up.			
Li 2011[70] China	Onset to treatment ≤14 days. Initial treatment elicited no response after 2 weeks.	Previous treatment: IV steroids 1mg/kg for 5 days, division into 4 doses and tapered over the course of 9 days Prednisolone (IT, 1ml of 40mg/ml methylprednisolone in 1ml sodium bicarbonate, once every 3 days for 15 days) versus prednisolone (ear drops, 1ml of methylprednisolone, one every 3 days over 15 days) versus no treatment 15 days intervention, 2 month follow-up	n=65 IT methylprednisolone 53.5 years (18-72), ear drop methylprednisolone 50 years (21-69), blank control group 55.1 years (22-73)	PTA: improvement, scores Adverse events	Initial failure definition: Pure tone average of 4 frequencies (0.5, 1, 2 and 4 kHz) >30 dB for affected ear or >10 dB from affected ear Ear drops group not reported here as not a relevant treatment for this review
Plontke 2009[96] Germany	12–21 days from hearing loss to randomisation (during which time standard systemic therapy was received)	Previous treatment High dose prednisolone (IV, 250mg/day) for 3 days followed by a dose reduction of 50% every 2 days together with systemic rheological medication (pentoxifylline, 3 x 400mg/day) and an antioxidant drug (alphasliponic acid, 1 x 600mg/day). Dexamethasone (IT, 4mg/ml, daily dose 0.58mg, rate 6µL/h) versus placebo (IT, sodium chloride 0.9%, rate 6µL/h) delivered via a round window catheter. Intervention time: 2 weeks	n=23 IT dexamethasone 53 (21) years, Placebo 56 (15 years)	PTA: scores, improvement, recovery Speech discrimination (max. change)	Initial failure definition: hearing threshold in the contralateral ear of ≥20 dB worse in affected ear than contralateral ear in at least 3 frequencies between 0.5 and 4 kHz
Wu 2011[127] Taiwan 1 week	Initial systemic therapy started within 7	Previous treatment: IV steroid 5 days, tapered with oral prednisolone for 5 days. Dexamethasone (IT, 0.5ml of 8mg/2ml every 4 days for 2	n=60 IT steroid: 49.1 (14.2), IT saline 47.4 (15.7)	Adverse events PTA: scores, improveme	Initial failure definition: PTA difference between ears

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
post systemic treatment	days of hearing loss onset. Steroid group: 4.4 (1.6) and placebo group: 4.7 (1.9) days. Intervention began approximately 1 week after initial treatment ended	weeks) versus placebo (0.5mls normal saline every 4 days for 2 weeks) 2 week intervention plus 1 month follow-up (post treatment), total 6 week study		nt	of >20 dB
Xenellis 2006[128] Greece	Mean delay to initial IV treatment - steroid group : 11.8 (no SD) and placebo group: 8.1 (no SD) days. Interventions started after 10 days of IV treatment failed	Previous treatment: prednisolone IV, 1mg/kg per day for 10 days divided in 3 doses, gradually tapered for 5 days and acyclovir 4mg/day for 5 days divided in 5 doses, buflomedil hydrochloride 300mg, divided in 3 doses for 10 days and ranitidine during steroid treatment Methylprednisolone (IT, 1.5-2mls, 80mg/2ml, done 4 times in 15 days) versus no treatment Intervention 15 days, follow-up 1.5 months (total time 2 months)	n=37 Intratympanic treatment group 50.9 years, control group 50.3 years (no SD reported)	Adverse events PTA: scores, improvement	Initial failure definition: pure tone 4 frequency average (0.5, 1, 2 and 4 kHz) worse than 30 dB or ≥10 dB worse than the contralateral ear

PTA: pure tone average; IT: intra-tympanic; kg: kilograms; SD: standard deviation; mg: milligrams

11.2.1.1 First-line treatment for idiopathic sudden sensorineural hearing loss

Table 56: Clinical evidence summary: Steroid (oral/IT) versus placebo [Prednisolone versus placebo]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with First-line treatment: placebo	Risk difference with First-line treatment: steroid (95% CI)
Change in PTA - Day 8	93 (1 study) 8 days	LOW[a] due to risk of bias		The mean change in PTA in the control group was 26.4 dB	The mean change in PTA in the intervention group was 0.9 lower (11.73 lower to 9.93 higher)
Change in PTA - Day 90	93 (1 study) 90 days	LOW[a] due to risk of bias		The mean change in PTA in the control group was 35.1 dB	The mean change in PTA in the intervention group was 3.9 higher (8.57 lower to 16.37 higher)
Recovery - Day 8 (oral)[b]	103 (1 study) 8 days	VERY LOW[a,c] due to risk of bias, imprecision	RR 1.25 (0.56 to 2.75)	173 per 1000	43 more per 1000 (from 76 fewer to 303 more)
Recovery – 1 month (IT)	50 (1 study) 1 year	MODERATE, due to risk of bias	RR 3.8 (1.68 to 8.58)	200 per 1000	560 more per 1000 (from 136 more to 1000 more)
Recovery - Day 90 (oral)[b]	103 (1 study) 90 days	VERY LOW[a,c] due to risk of bias, imprecision	RR 1.02 (0.6 to 1.73)	346 per 1000	7 more per 1000 (from 138 fewer to 253 more)
Adverse events[d]	103 (1 study) 90 days	VERY LOW[a,c] due to risk of bias, imprecision	RR 1.39 (0.71 to 2.73)	212 per 1000	83 more per 1000 (from 61 fewer to 366 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with First-line treatment: placebo	Risk difference with First-line treatment: steroid (95% CI)

b The recovery data are based on the same dataset as the change in PTA, but presented as a dichotomous outcome

c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

d Gastrointestinal complaints were the most common adverse event reported. There were no severe adverse events.

Table 57: Clinical evidence summary: Steroid (oral/IT) versus steroid (oral) [Dexamethasone versus Prednisolone]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Prednisolone	Risk difference with Dexamethasone (95% CI)
PTA Final score	106 (2 studies) 12 months and 7 weeks (4 weeks after last injection)	LOW[a,b] due to risk of bias, imprecision		The mean PTA final score in the control groups ranged from 59-42 dB	The mean PTA final score in the intervention groups was 6.64 lower (17.58 lower to 4.3 higher)
Recovery - symmetrical hearing, interaural hearing difference of <20 dB HL	71 (1 study) 12 months	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.13 (0.75 to 1.68)	543 per 1000	71 more per 1000 (from 136 fewer to 369 more)
Recovery - Recovery of hearing to within 5% points of the contralateral SDS or within 5 dB of the contralateral PTA	35 (1 study) 7 weeks (4 weeks after last injection)	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.76 (0.5 to 6.28)	167 per 1000	127 more per 1000 (from 84 fewer to 882 more)
Speech discrimination of 100% (recognised all words at their optimum sound level)	71 (1 study) 12 months	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.12 (0.77 to 1.63)	571 per 1000	69 more per 1000 (from 131 fewer to 360 more)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Prednisolone	Risk difference with Dexamethasone (95% CI)
Mean speech discrimination (% words successfully discriminated)	35 (1 study) 7 weeks (4 weeks after last injection)	VERY LOW[a,b] due to risk of bias, imprecision		The mean speech discrimination in the control groups was 54%	The mean speech discrimination (% words successfully discriminated) in the intervention groups was 6 higher (20.88 lower to 32.88 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Table 58: Clinical evidence summary: steroid (oral) plus steroid (IT) versus steroid (oral/IT) [prednisolone plus dexamethasone versus prednisolone or dexamethasone plus placebo]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Single steroid (oral/IT)	Risk difference with Dual steroids (oral plus IT) (95% CI)
PTA Final score – oral plus IT versus **oral**	34 (1 study) 7 weeks (4 weeks after last injection)	LOW[a,b] due to risk of bias, imprecision		The mean PTA final score in the control groups was 59 dB	The mean PTA final score - oral versus oral plus IT in the intervention groups was 24 lower (42.39 to 5.61 lower)
PTA Final score - oral plus IT versus **IT**	33 (1 study) 7 weeks (4 weeks after last injection)	LOW[a,b] due to risk of bias, imprecision		The mean PTA final score in the control groups was 59 dB	The mean PTA final score - IT versus oral plus IT in the intervention groups was 16 lower (31.72 to 0.28 lower)
Recovery[c]	171 (2 studies)	VERY LOW[a,b,c,d] due to risk of	RR 1.37 (0.87 to 2.15)	248 per 1000	92 more per 1000 (from 32 fewer to 285 more)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Single steroid (oral/IT)	Risk difference with Dual steroids (oral plus IT) (95% CI)
	7-12 weeks	bias, inconsistency, imprecision			
Mean speech discrimination (% words successfully discriminated) - oral plus IT versus **oral**	34 (1 study) 7 weeks (4 weeks after last injection)	LOW[a,b] due to risk of bias, imprecision		The mean speech discrimination score in the control groups was 54%	The mean speech discrimination (% words successfully discriminated) - oral versus oral plus IT in the intervention groups was 31 higher (7.76 to 54.24 higher)
Mean speech discrimination (% words successfully discriminated) - oral plus IT versus **IT**	33 (1 study) 7 weeks (4 weeks after last injection)	LOW[a,b] due to risk of bias, imprecision		The mean speech discrimination score in the control groups was 54%	The mean speech discrimination (% words successfully discriminated) - IT versus oral plus IT in the intervention groups was 25 higher (4.11 to 45.89 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
c The recovery data are based on the same dataset as the final PTA, but presented as a dichotomous outcome
d Downgraded by 1 or 2 increments because of heterogeneity unexplained by subgroup analysis.

Table 59: Clinical evidence summary: Steroid (IV or oral) plus antiviral (IV or oral) versus steroid (IV or oral) [prednisolone or hydrocortisone plus acyclovir or valacyclovir versus prednisolone or hydrocortisone]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Steroid	Risk difference with Steroid plus antiviral (95% CI)
PTA Final score	68	VERY LOW[a,b]		The mean PTA final	The mean PTA final score in the intervention groups was

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Steroid	Risk difference with Steroid plus antiviral (95% CI)
	(1 study) 6 weeks	due to risk of bias, imprecision		score in the control groups was 38 dB	6.4 dB higher (9 lower to 21.8 higher)
Recovery - within 10 dB of non-affected ear[c]	68 (1 study) 6 weeks	VERY LOW[a,b] due to risk of bias, imprecision	RR 0.8 (0.46 to 1.38)	483 per 1000	97 fewer per 1000 (from 261 fewer to 184 more)
Improvement	60 (1 study) 6 weeks	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.02 (0.79 to 1.34)	774 per 1000	15 more per 1000 (from 163 fewer to 263 more)
Mean speech discrimination (% words successfully discriminated)	68 (1 study) 6 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean speech discrimination- final score in the control groups was 59.4%	The mean speech discrimination (% words successfully discriminated) in the intervention groups was 4.6% higher (15.51 lower to 24.71 higher)
Adverse events	43 (1 study) 7 days	VERY LOW[a,b] due to risk of bias, imprecision	RR 0.35 (0.08 to 1.54)	273 per 1000	177 fewer per 1000 (from 251 fewer to 147 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.

b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

c The recovery data are based on the same dataset as the final PTA, but presented as a dichotomous outcome

11.2.1.2 Second-line treatment for idiopathic sudden sensorineural hearing loss

Table 60: Clinical evidence summary: Steroid (IT) versus placebo (IT) /no treatment [Dexamethasone/prednisolone versus placebo/no treatment]

Outcomes	No of	Quality of the	Relative	Anticipated absolute effects

	Participants (studies) Follow-up	evidence (GRADE)	effect (95% CI)	Risk with Second-line treatment: placebo /no treatment	Risk difference with Second-line treatment: steroid (95% CI)
PTA Final score	148 (4 studies) 8 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean PTA final score in the control groups ranged from 59.9 to 90.5	The mean PTA final score in the intervention groups was 11.44 lower (19.47 to 3.41 lower)
Recovery[c]- Successful treatment according to Ho et al, complete and marked recovery: 6 PTA≤25 dB and 6PTA improvement >30 dB	20 (1 study) 2 weeks	VERY LOW[a,b] due to risk of bias, imprecision	OR 8.26 (0.48 to 142.43)	0 per 1000	200 more per 1000 (from 80 fewer to 480 more)
Improvement	55 (1 study) 6 weeks	HIGH	RR 4.15 (1.31 to 13.09)	107 per 1000	337 more per 1000 (from 33 more to 1000 more)
Speech discrimination (change in maximum % speech discrimination for monosyllables)	21 (1 study) 2 weeks	LOW[a,b] due to risk of bias, imprecision		The mean speech discrimination (max change) in the control groups was 4.5	The mean speech discrimination (change in maximum % speech discrimination for monosyllables) in the intervention groups was 19.9 higher (0.41 to 39.39 higher)
Adverse events: perforation of tympanic membrane	55 (1 study) 6 weeks	LOW[b] due to imprecision	POR 7.67 (0.15 to 386.69)	0 per 1000	40 more per 1000 (from 60 fewer to 130 more)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Second-line treatment: placebo /no treatment	Risk difference with Second-line treatment: steroid (95% CI)
3 The recovery data are based on the same dataset as the final PTA from this study, but presented as a dichotomous outcome					

11.2.2 Economic evidence

11.2.2.1 Published literature

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

11.2.2.2 Unit costs

See appendix P.

11.2.3 Evidence statements

Clinical

First line

Steroid (oral/IT) versus placebo [Prednisolone versus placebo]

- There was a clinically important benefit of prednisolone for recovery at 1 month (moderate quality evidence, 1 study).
- There was no clinically important difference in change in PTA at day 8 and day 90 (low quality evidence, 1 study), for recovery at day 8 and day 90 and for adverse events (very low quality evidence, 1 study).

Steroid (oral/IT) versus steroid (oral) [Dexamethasone versus Prednisolone]

- There was a clinically important benefit of dexamethasone for recovery of hearing to within 5% points of the contralateral SDS or within 5 dB of the contralateral PTA (very low quality evidence, 1 study).
- There was no clinically important difference in PTA final score (low quality evidence, 2 studies) and in symmetrical hearing recovery (interaural hearing difference of <20 dB HL) and speech discrimination of 100% (very low quality evidence, 1 study) and in mean speech discrimination (very low quality evidence, 1 study).

Steroid (oral) plus steroid (IT) versus steroid (oral/IT) [prednisolone plus dexamethasone versus prednisolone or dexamethasone plus placebo]

- There was a clinically important benefit of dual steroids (oral plus IT versus oral and versus IT) for PTA final score and mean speech discrimination (low quality evidence, 1 study).
- There was no clinically important difference in recovery (very low quality evidence, 2 studies).

Steroid (IV or oral) plus antiviral (IV or oral) versus steroid (IV or oral) [prednisolone or hydrocortisone plus acyclovir or valacyclovir versus prednisolone or hydrocortisone]

- There was a clinically important harm of prednisolone plus placebo (very low quality evidence, 1 study).
- There was no clinically important difference in PTA final score, recovery within 10 dB of non-affected, mean speech discrimination (very low quality evidence, 1 study) and improvement (very low quality evidence, 1 study).

Second line

Steroid (IT) versus placebo (IT) /no treatment [Dexamethasone/prednisolone versus placebo/no treatment]

- There was a clinically important benefit of steroids compared with placebo or no treatment for PTA final score (very low quality evidence, 4 studies), recovery and speech discrimination (low to very low quality evidence, 1 study) and for improvement (high quality evidence, 1 study).
- There was no clinically important difference in adverse events (perforation of tympanic membrane; low quality evidence, 1 study).
- There were no data on amantadine, famciclovir and ganciclovir.

Economic

- No relevant economic evaluations were identified.

11.2.4 Recommendations and link to evidence

Recommendations	20. Consider a steroid to treat idiopathic sudden sensorineural hearing loss in adults.
Relative values of different outcomes	The following critical outcomes were included in this review: pure tone average, speech discrimination or recognition, health-related quality of life and hearing-specific health-related quality of life. Adverse events were included as an important outcome.
Quality of the clinical evidence	The studies reported pure tone average (PTA) by change or final scores, author-defined improvement and recovery. We analysed the change or final scores as well as the author-defined recovery data as these were thought to be the most important outcomes for decision-making. If neither of these preferred definitions was presented by a given study, author-defined improvement was reported. The majority of the evidence was of low or very low quality and based on few studies with small sample sizes. There were no data on amantadine, famciclovir and ganciclovir. There were a range of limitations of the included evidence, most notably: • A lack of detail regarding how the diagnosis of 'idiopathic' SSNHL was determined. Some studies identified patients with causes of the SSNHL after randomisation and consequently excluded them from the study. • Many studies did not describe how the patients were randomised and how allocation was concealed. • Other reasons for downgrading related to blinding, attrition bias, and not specifying outcomes in the methods (post-hoc analysis). • Outcomes were also downgraded due to imprecision; many studies had relatively small numbers in each treatment group. • One study that provided the majority of the data about dual steroid (oral plus IT) treatments had significant baseline differences in time-to-treatment, speech discrimination score and PTA between the 3 treatment groups making the evidence difficult to interpret. • Some studies did not consider high frequency losses (above 2 kHz) within their analysis. • Some studies either included children but it was unclear how many, or gave no age inclusion criteria or age range to clarify whether any children had been included. However, given the mean ages and standard deviations it seems unlikely that any children were included in the later cases.
Trade-off between clinical benefits and	The guideline committee noted evidence for a lack of efficacy of oral steroids over placebo in first-line treatment of SSNHL, with associated adverse events. However,

harms	the adverse events were not clearly specified so it was not possible to determine the clinical importance of these. Oral steroids are currently the mainstay of treatment for this condition in clinical practice, but no evidence to support this practice was found. However, there was also insufficient evidence to change current practice. Conversely, 1 study gave moderate quality evidence that intratympanic steroids are clinically beneficial for recovery, but no other outcomes were available. When comparing dexamethasone and prednisolone for the first-line treatment of SSNHL, low and very low quality evidence showed no clinical difference for PTA final score, recovery or speech discrimination when both were given orally. However, IT dexamethasone was clinically beneficial compared with oral prednisolone for recovery and change in speech discrimination score (taking into account baseline differences). The committee noted that although there was some evidence that dual steroids (oral plus IT) were better than either alone, the majority of these data were from a study at very high risk of bias owing to baseline differences. Therefore, the committee did not have high confidence in these findings. However, they provided further evidence to support the emerging theme that IT steroids may be the most effective course of treatment in this patient group. When comparing treatment with steroid plus antiviral versus steroid alone there was no evidence of a clinical benefit of adding in the antiviral for any recorded positive outcome. There were fewer adverse events in the group given an antiviral in addition to the steroid; however, from looking at the specific adverse events reported, the committee did not believe there was a clinical explanation and it is likely to be a chance finding owing to the small sample size. There were 5 studies reporting the comparison of IT steroids versus placebo or no treatment for the second-line treatment of patients initially refractory to IV or oral steroid treatment. These all showed a clinical benefit of IT steroid in this group for PTA final score, recovery, improvement (1 study; high quality) and speech discrimination. The committee noted that it was interesting to see that second-line treatment with IT steroids is effective at a time in the natural course of the condition when spontaneous recovery would be less likely. Some studies reported individual cases of tympanic membrane perforation, but all either resolved spontaneously or were successfully repaired. As usual practice is to prescribe oral steroids, recommending IT would be a significant change in practice and would have an impact on service delivery due to the requirement of hospital-based treatment follow-up appointments and staff with expertise in this treatment. The committee discussed the possibility of a recommendation for IT steroids for second-line treatment, where there is evidence of benefit. However, it is not possible to determine whether IT steroids have a benefit by themselves or in combination with previous oral steroid treatment. Additionally, without sufficient evidence to be confident in the best route of administration for first-line treatment the committee could not specify the route of administration for second-line treatment. Therefore, it was unable to either fully support or change current treatment and the committee agreed to recommend steroid treatment without specifying the route of administration (see recommendation in following table).
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee considered the clinical evidence and unit costs for the alternative treatment options. The committee noted that the costs of the most likely steroids were low, being between £3 and £13 for a course lasting up to 2 weeks. Therefore the most important resource use and cost would be the cost of administering these drugs. If oral drugs are prescribed these can be taken at home and the patient may require only 2 outpatient appointments for investigation and review. Giving drugs intratympanically would give rise to greater costs as each time drugs are administered the patient would need to come into hospital for an outpatient

	appointment where this would be conducted by a suitably trained clinician. This could involve 3 or 4 outpatient appointments and the first such appointment may be outside routine hours adding to the expense. An outpatient appointment for a minor ear procedure has an NHS reference cost of £110. Adopting IT as the standard first-line treatment would be a change in practice and would require greater resources. Giving drugs intravenously, by contrast, would necessitate an inpatient stay, which would be even more expensive. Given that no clinical evidence was identified favouring IV drugs, the committee did not recommend this as an option. Given the limited evidence favouring steroid treatment and their low cost, but a lack of clear evidence from the clinical review comparing different oral and IT drugs, and considering the higher costs of IT treatment, the committee was not able to support any particular drug or route of administration, but advised that the use of steroids should be considered.
Other considerations	The committee highlighted the fact that hearing aid use, audiological rehabilitation and overall management strategies for SSNHL were not considered within this review.

11.3 Review question: What is the clinical and cost effectiveness of different routes of administration of steroids (for example oral or intratympanic) in the treatment of sudden sensorineural hearing loss (SSNHL)?

For full details see the review protocol in appendix C.

Table 61: PICO characteristics of review question

Population	Adults aged 18 and over with idiopathic SSNHL
Interventions and comparators	**Steroids** • Prednisolone • Dexamethasone • Routes of administration: Oral • Intratympanic • Other: for example IV compared with each other or to placebo or no treatment (if appropriate)
Outcomes	**Critical:** • Pure-tone audiometry or pure tone average • Speech discrimination • Health-related quality of life • Hearing-specific health-related quality of life **Important:** • Adverse events for example, gastrointestinal bleeding, mood alteration or psychosis
Study design	RCTs Systematic review of RCTs

11.3.1 Clinical evidence

For the sub-question addressing the route of steroid administration, 11 studies, reported in 13 papers were included in the review.[4-6, 12, 36, 40, 52, 53, 65, 71, 72, 99, 112] These are summarised in Table 63 below. Two of these studies were also included in the primary review.[4, 12] Evidence from these studies is summarised in the clinical evidence summary tables below (Table 63).

See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

Of the included studies, all but 1[112] had a population exclusively with unilateral hearing loss; in this study the majority had unilateral losses. The methods for excluding underlying causes of hearing loss vary; 2 of the studies[12, 99] explicitly stated that patients with autoimmune disease were actively excluded.

The interventions that were included in the studies were prednisolone, methylprednisolone, dexamethasone, and acyclovir. The treatments were given intravenously (IV), orally or intratympanically (IT).

The studies reported pure tone averages (PTA) by change or final scores, author-defined improvement and recovery. In this report, PTA data are presented as the change or final scores as well as the author-defined recovery data as these were thought to be the most important outcomes for decision-making. Where these continuous and dichotomous outcomes are derived from the same dataset this has been highlighted to avoid double counting the data. If neither of these preferred definitions are presented by a given study, author-defined improvement will be reported.

Speech discrimination or word recognition and adverse events were also recorded in some studies. None of the studies reported on quality of life.

The definitions used to describe recovery varied between the studies. The definitions included as outcomes within this report were those that were most representative of clinical recovery that is important to the patient (Table 54).

Table 62: Study definitions of improvement and recovery

Study	Recovery
Ahn 2008[4]	Final hearing better than 25 dB based on a four-tone average of thresholds at 0.5, 1, 2, and 4 kHz at 3 months
Battaglia 2008[12]	Recovery of hearing to within 5 percentage points of the contralateral speech discrimination score (SDS) or within 5 dB of the contralateral PTA. PTA measured by taking the 3-frequency average of the threshold value at 0.5, 1, and 2 kHz at 7 weeks.
Eftekharian 2016[40]	Complete recovery: return to within 10 dB HL of the unaffected ear and recovery of word recognition scores (WRS) to within 5%-10% of the unaffected ear at 3 months after treatment
Gundogan 2013[52]	Complete recovery: final hearing threshold better than 25 dB PTA at 4 weeks
Lim 2013[72]	Complete recovery: return to within 10 dB HL of the unaffected ear and WRS to within 5-10% of unaffected ear. PTA calculated across 4 frequencies: 0.5, 1, 2 and 3 kHz at 21 days
Swachia 2016[112]	Complete recovery or marked improvement: final 4-frequency PTA of ≤25 dB or PTA improvement >30 dB at 60 days

Another factor to consider is the mean time between the onset of hearing loss and start of treatment and whether this would affect the end of study outcomes as this varied between the studies (Table 63).

Table 63: Summary of studies included in the review

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
Ahn 2008[4] South Korea	Intervention group: 6.5 (3.9) and control group: 7.1 (4.1) days	Methylprednisolone (oral, 48 mg per day for 9 days, 5 day tapering) plus dexamethasone (IT, 0.3–0.4 ml of 5 mg/ml on first, third and fifth days), versus methylprednisolone (oral, as above) 3 months follow-up	n=120 Mean age ITD group 48.6 (15.4) years, control group 45.9 (14.7) years.	PTA: complete recovery, slight hearing improvement	Children not explicitly excluded. Does not state that underlying medical reasons for the sudden hearing loss were ruled out prior to inclusion.
Al-Shehri, 2016 [5]	Unclear, must have been <2 weeks	Methylprednisolone (IT; four 1-ml doses of 40 mg/ml over 2 weeks with a dose given every 3–4 days) versus prednisolone (oral; 60 mg/day tapering over 14 days)	n=39 Mean age Experimental group: 49.8±5.9; control group: 49.7±7.3 years	PTA: change score (based on the mean of hearing thresholds at 4 frequencies: 0.5, 1, 2 and 4 kHz) Adverse events	
Arastou, 2013 [6]	Intervention group: 18.97 (23.6); control group: 15.5 (22.6) days	Dexamethasone (IT; 0.4 ml of 4 mg/ml twice a week for 2 consecutive weeks) plus prednisolone (oral; 1 mg/kg/day for 10 days) plus acyclovir (oral; 2 g/day for 10 days, divided in 4 doses) plus triamterene H (oral; daily) plus omeprazole (oral; daily, during steroid treatment) versus Prednisolone (oral; 1 mg/kg/day for 10 days) plus acyclovir (oral; 2 g/day for 10 days, divided in 4 doses) plus triamterene H (oral; daily) plus omeprazole (oral; daily, during steroid treatment)	n=77 Mean age Intervention group: 45.4(14.8); control group: 49.2(14.4) years	PTA: change score (based on the mean of hearing thresholds at 4 frequencies: 0.5, 1, 2 and 4 kHz), improvement Adverse events	
Battaglia 2008[12] USA	IT: 11 (14), oral: 7 (6), oral plus IT: 4 (3) days (had to be within 6 weeks)	Prednisolone (oral) plus dexamethasone (IT) versus Prednisolone (oral) plus placebo (IT) versus Placebo (oral) plus dexamethasone (IT) Oral steroid dosing:	n=51 Mean age Placebo taper plus IT-Dex 60 years, HDPT plus IT saline 54 years, HDPT	PTA: scores, improvement, recovery (based on the mean of hearing thresholds at 3 frequencies 0.5,	Children not explicitly excluded. Baseline differences in speech discrimination

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
		60 mg/day for 7 days, 50 mg for 2 days, 40 mg for 2 days, 30 mg for 1 day, 20 mg for 1 day, 10 mg 1 day. Dexamethasone (IT) dosing: 0.5–0.7 ml of 12 mg/ml once a week for 3 weeks (unclear when first dose given). Stated to be a 2 year study. Capsules taken for 2 weeks, intratympanic injections over 3 weeks, audiogram stated to have been taken 4 weeks after the final injection. Also describes a 3-month follow-up after the last patient enrolled.	plus IT Dex 57 years.	1, and 2 kHz). Speech discrimination score	score: oral: 34±40% IT: 24±38% oral plus IT: 41±40% Baseline differences in PTA score: oral: 80±27 dB oral plus IT: 75±23 dB
Dispenza, 2011 [36]	Intervention group: 9.4 days and control group: 3.8 days	Dexamethasone (IT; 4 mg/ml injection repeated weekly for 4 weeks) versus prednisolone (oral; 60 mg/day tapered over 14 days)	n=51 Mean age 50 years	PTA: change score (based on the mean of hearing thresholds at 4 frequencies (0.5, 1, 2 and 4 kHz)) Adverse events	
Eftekharian, 2016 [40]	≤10 days	Methylprednisolone (IV; 500 mg daily for 3 consecutive days) followed by prednisolone (oral; 1 mg/kg, maximum 60 mg/day for 11 days) versus prednisolone (oral; 1 mg/kg, maximum 60 mg 14 days)	n=67 Mean age IV group: 42.2(12.6); oral group: 40.1(11.9) years	PTA: recovery, change score (based on the mean of hearing thresholds at 4 frequencies (0.5, 1, 2 and 4 kHz)) Word recognition score Adverse events	
Gundogan, 2013	Dual group: 4.7 (4.0); oral group: 5.14 (3.52) days	Methylprednisolone (IT; 0.4 ml of 62.5 mg/ml 4 times for 2 consecutive weeks (once every 3 days)) plus methylprednisolone (oral; 1 mg/kg and 10 mg taper every 3 days) versus methylprednisolone (oral; 1 mg/kg and 10 mg taper every 3 days)	n=79 Mean age Combination: 52.32 (12.94); oral: 51.6 (16.77) years	PTA: change score, recovery Speech discrimination score Adverse events	All patients were hospitalised for 1 week

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
Khorsandi Ashtiani, 2012 [65]	≤10 days	Prednisolone (oral; 1 mg/kg every day for 10 days) plus dexamethasone (IT; 2 mg for the first 3 days) versus prednisolone (oral; 1 mg/kg every other day for 10 days; no dose taper reported) plus dexamethasone (IT; 2 mg for the first 3 treatments) versus prednisolone (oral; 1 mg/kg every day for 10 days; no dose taper reported)	n=63 Mean age 50 (range: 20-70) years	PTA: change score (frequencies not stated) Speech discrimination score	
Lim, 2013 [71, 72]	Oral: 5.4 (3.1); IT: 10.1 (8.1), oral plus IT: 9.6 (7.5) days	Dexamethasone (IT; 0.3–0.4 ml of 5 mg/ml twice a week for 2 weeks, for a total of 4 times on days 0, 3, 7 and 10) versus prednisolone (oral: 60 mg/day for 5 days, 40 mg/day for 2 days, 20 mg/day for 2 days, and 10 mg/day for 1 day) versus prednisolone (oral – dosing as above) plus dexamethasone (IT – dosing as above)	n=60 Mean age Oral: 51.3 (14.4); IT: 53.3 (15.3), oral plus IT: 47.8 (14.2)	PTA: change score, recovery (based on the mean of hearing thresholds at 4 frequencies: 0.5, 1, 2 and 3 kHz)	
Rauch, 2011; Halpin, 2012 [53, 99]	Intervention group: 7.0 (6.4-7.6) and control group: 6.7 (6.1-7.4)	Methylprednisolone (IT; 4 doses every 3–4 days; 1 ml of 40 mg/ml) versus prednisolone (oral; 60 mg/day for 14 days, followed by a 5-day taper to 10 mg)	n=250 Mean age: 50 years	PTA: change score (based on the mean of hearing thresholds at 4 frequencies: 0.5, 1, 2 and 4 kHz) Word recognition score Adverse events	Pre-enrolment steroid usage of less than 10 days was acceptable as long as audiometric criteria were met on the day of enrolment.
Swachia, 2016 [112]	<14 days	Methylprednisolone (IT; 1 ml of 40 mg/ml solution injected into the middle ear cavity twice a week for 2 consecutive weeks) versus prednisolone (oral; 1 mg/kg body weight per day for first 10 days; 0.5 mg/kg per day on	n=42 Mean age: 44.3 years	PTA: change score, recovery (based on the mean of hearing thresholds at 4 frequencies: 0.5, 1, 2 and 4 kHz) Adverse events	83% unilateral

Study	Mean time from onset of HL to start of treatment	Intervention and comparison	Population	Outcomes	Comments
		days 11–12; 0.25 mg/kg per day on days 13–14)			

11.3.1.1 First-line treatment for idiopathic sudden sensorineural hearing loss

Table 64: Clinical evidence summary: Steroid (IT) versus steroid (oral) [IT prednisolone, methylprednisolone or dexamethasone versus oral prednisolone]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroid	Risk difference with IT (95% CI)
Pure Tone Average (PTA) improvement	417 (5 studies) 3 weeks - 6 months	VERY LOW[a,b] due to risk of bias, inconsistency		The mean PTA improvement in the control groups ranged from 18.2 to 30.2 dB	The mean PTA improvement in the intervention groups was 1.19 higher (3.41 lower to 5.78 higher)
Recovery[c]	82 (2 studies) 17-60 days	VERY LOW[a,d] due to risk of bias, imprecision	RR 0.84 (0.37 to 1.91)	241 per 1000	39 fewer per 1000 (from 152 fewer to 219 more)
Word recognition score change from baseline - 2 months	250 (1 study) 2 months	MODERATE[a] due to risk of bias		The mean word recognition score improvement at 2 months in the control groups was 34.2%	The mean word recognition score improvement at 2 months in the intervention groups was 0.4 lower (8.8 lower to 8 higher)
Word recognition score change from baseline - 6 months	250 (1 study) 6 months	LOW[a] due to risk of bias		The mean word recognition score improvement at 6 months in the control groups was 35.6%	The mean word recognition score improvement at 6 months in the intervention groups was 0.6 lower (9.29 lower to 8.09 higher)
Patients with adverse events	292 (2 studies) 2-6 months	HIGH	RR 1.03 (0.94 to 1.12)	876 per 1000	26 more per 1000 (from 53 fewer to 105 more)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroid	Risk difference with IT (95% CI)
Treatment-related serious adverse events	250 (1 study) 2 months	VERY LOW[a,d] due to risk of bias, imprecision	RR 0.31 (0.01 to 7.61)	8 per 1000	6 fewer per 1000 (from 8 fewer to 53 more)
Adverse events - Mood change	289 (2 studies) 2-6 months	MODERATE[a] due to risk of bias	RR 0.22 (0.13 to 0.37)	423 per 1000	330 fewer per 1000 (from 266 fewer to 368 fewer)
Adverse events - Blood glucose problem	289 (2 studies) 2-6 months	MODERATE[d] due to imprecision	RR 0.54 (0.35 to 0.85)	299 per 1000	138 fewer per 1000 (from 45 fewer to 194 fewer)
Adverse events - Sleep change	289 (2 studies) 2-6 months	MODERATE[a] due to risk of bias	RR 0.19 (0.1 to 0.36)	332 per 1000	269 fewer per 1000 (from 212 fewer to 299 fewer)
Adverse events - Increased appetite	289 (2 studies) 2-6 months	MODERATE[a] due to risk of bias	RR 0.2 (0.09 to 0.44)	241 per 1000	193 fewer per 1000 (from 135 fewer to 219 fewer)
Adverse events - Earache	289 (2 studies) 2-6 months	MODERATE[a] due to risk of bias	RR 15.68 (6.22 to 39.49)	17 per 1000	250 more per 1000 (from 89 more to 654 more)
Adverse events - Injection site pain	289 (2 studies) 2-6 months	MODERATE[a] due to risk of bias	RR 36.8 (4.99 to 271.62)	0 per 1000	250 more per 1000 (from 180 more to 320 more)
Adverse events - Mouth dryness/thirst	289 (2 studies) 2-6 months	MODERATE[a] due to risk of bias	RR 0.15 (0.06 to 0.35)	249 per 1000	212 fewer per 1000 (from 162 fewer to 234 fewer)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroid	Risk difference with IT (95% CI)
Adverse events - Weight gain	289 (2 studies) 2-6 months	LOW[a,d] due to risk of bias, imprecision	RR 0.28 (0.13 to 0.61)	166 per 1000	120 fewer per 1000 (from 65 fewer to 144 fewer)
Adverse events - Dizziness/vertigo	250 (1 study) 6 months	HIGH	RR 2.53 (1.41 to 4.54)	107 per 1000	164 more per 1000 (from 44 more to 379 more)
Adverse events - Ear infection	250 (1 study) 6 months	VERY LOW[a,d] due to risk of bias, imprecision	RR 3.28 (0.7 to 15.49)	17 per 1000	39 more per 1000 (from 5 fewer to 246 more)
Adverse events - Tympanic membrane perforation	250 (1 study) 6 months	VERY LOW[a,d] due to risk of bias, imprecision	POR 7.17 (1.22 to 42.01)	0 per 1000	40 more per 1000 (from 0 more to 80 more)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 or 2 increments because of heterogeneity, I2>50%, p<0.04, unexplained by subgroup analysis.
c The recovery data are based on a dataset that overlaps the change in PTA, but presented as a dichotomous outcome
d Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Table 65: Additional narrative information

Study	Intervention and comparison	Population	Outcomes	Risk of bias
Al-Shehri, 2016	Methylprednisolone (IT; four 1-ml doses of 40 mg/ml of over 2 weeks with a dose given every 3–4 days) versus	n=39	Total number of adverse events (could not be analysed because number of events exceeded number of participants in one	Very high

Study	Intervention and comparison	Population	Outcomes	Risk of bias
	prednisolone (oral; 60 mg/day tapering over 14 days)		group). IT steroid: 13 in 20 participants; oral steroid: 33 events in 20 participants.	
Dispenza, 2011	Dexamethasone (IT; 4 mg/ml injection repeated weekly for 4 weeks) versus prednisolone (oral; 60 mg tapered over 14 days)	n=51	No treatment-related complications	Very high

Table 66: Clinical evidence summary: Steroid (IV) versus steroid (oral) [IV methylprednisolone followed by oral prednisolone versus oral prednisolone]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroid	Risk difference with IV (95% CI)
PTA improvement	60 (1 study) 3 months	VERY LOW[a,b] due to risk of bias, imprecision		The mean PTA improvement in the control group was 54.6 dB	The mean PTA improvement in the intervention group was 5.4 higher (12.35 lower to 23.15 higher)
Recovery - Complete recovery: return to within 10 dB HL of the unaffected ear and recovery of WRS to within 5%-10% of the unaffected ear[3]	60 (1 study) 3 months	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.25 (0.47 to 3.28)	194 per 1000	48 more per 1000 (from 103 fewer to 442 more)
Word recognition score improvement (%)	60 (1 study) 3 months	VERY LOW[a,b] due to risk of bias, imprecision		The mean word recognition score in the control group was 63.1%	The mean word recognition score in the intervention group was 4.52 lower (25.69 lower to 16.65 higher)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroid	Risk difference with IV (95% CI)
Adverse events or complications	60 (1 study) 3 months	MODERATE[a] due to risk of bias	Not estimable	No events	No events

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
c The recovery data are based on the same dataset as the change in PTA, but presented as a dichotomous outcome

Table 67: Clinical evidence summary: Dual steroid (IT plus oral) versus steroid (oral) [IT dexamethasone plus oral prednisolone versus oral prednisolone]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroids	Risk difference with Dual (95% CI)
PTA change or final score - Oral every day	177 (4 studies) 10 days - 7 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean PTA final score in the control group was 59 dB from 1 study; the mean change score ranged from -18.7 to -25.9 dB	The mean PTA change or final score in the intervention groups was 15.39 lower (18.3 to 12.48 lower)
PTA change score - Oral every other day	31 (1 study) 10 days	VERY LOW[a,b] due to risk of bias, imprecision		The mean PTA change score in the control group was -25.9 dB	The mean PTA change score in the intervention groups was 2.45 dB lower (5.00 lower to 0.10 higher)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Oral steroids	Risk difference with Dual (95% CI)
Complete recovery[c]	267 (4 studies) 3-12 weeks	VERY LOW[a,b] due to risk of bias, imprecision	RR 1.4 (0.86 to 2.27)	272 per 1000	109 more per 1000 (from 38 fewer to 345 more)
Speech discrimination improvement or final score - Oral every day	137 (3 studies) 10 days - 7 weeks	VERY LOW[a,d] due to risk of bias, inconsistency		The mean final speech discrimination score in the control was 54% from one study; the mean change score ranged from 18.3 to 20.1%	The mean speech discrimination score improvement or final score in the intervention groups was 6.50 higher (1.78 to 11.23 higher)
Speech discrimination improvement score - Oral every other day	31 (1 study) 10 days	LOW[a] due to risk of bias		The mean speech discrimination change score in the control group was 18.3%	The mean speech discrimination score improvement score in the intervention groups was 7.29 lower (9.08 lower to 5.50 lower)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
c The recovery data are based on a dataset that overlaps the change in PTA, but presented as a dichotomous outcome
d Significant heterogeneity unexplained by pre-defined subgroups

Table 68: Additional narrative information: baseline, final and change scores

Outcome measure	Study	Mean baseline score (SD)	Mean final score (SD)	Mean change score (SD)	Comments

Outcome measure	Study	Mean baseline score (SD)	Mean final score (SD)	Mean change score (SD)	Comments
PTA score	Battaglia, 2008	Dual: 75 (23) dB Oral: 80 (27) dB	Dual: 35 (21) dB Oral: 59 (33) dB	Dual: 40 dB Oral: 21 dB	Baseline differences
	Gundogan, 2013	Dual: 80.7 (22.81) dB Oral: 76.3 (27.18) dB	Not available	Dual: 44.05 (21.53) dB Oral: 25.72 (19.77) dB	
	Khorsandi Ashtiani, 2012	Dual (with oral every day): 55.00 (8.38) dB Dual (with oral every other day): 60.33 (9.43) dB Oral: 60.47 (7.26) dB	Dual (with oral every day): 13.57 (4.37) dB Dual (with oral every other day): 34.70 (10.45) dB Oral: 34.58 (13.18) dB	Dual (with oral every day): 41.42 (4.01) dB Dual (with oral every other day): 28.33 (1.02) dB Oral: 25.88 (5.09) dB	
	Lim, 2013	Dual: 56.8 (28.3) dB Oral: 57.8 (28.5) dB	Dual: 34.9 (25.3) dB Oral: 39.1 (26.1) dB	Dual: 21.9 (26.2) dB Oral: 18.7 (19.1) dB	
Speech discrimination score	Battaglia, 2008	Dual: 41 (40)% Oral: 34 (40)%	Dual: 85 (23)% Oral: 54 (44)%	Dual: 44% Oral: 20%	Baseline differences
	Gundogan, 2013	Dual: 29.7 (20.96) % Oral: 43.3 (30.71) %	Not available	Dual: 41.08 (21.98) % Oral: 20.06 (22.69) %	Baseline differences
	Khorsandi Ashtiani, 2012	Dual (with oral every day): 79.33 (18.77)% Dual (with oral every other day): 80.64 (10.42)% Oral: 72.76 (8.50)%	Dual (with oral every day): 98.85 (8.86)% Dual (with oral every other day): 92.72 (9.85)% Oral: 90.58 (5.23)%	Dual (with oral every day): 19.33 (9.91)% Dual (with oral every other day): 11.01 (0.98)% Oral: 18.30 (3.50)%	

Table 69: Additional narrative information: adverse events

Study	Intervention and comparison	Population	Outcomes	Risk of bias
Battaglia, 2008	Prednisolone (oral) plus dexamethasone (IT) versus prednisolone (oral) plus placebo (IT) versus placebo	n=56	No long-term complications occurred	High

Study	Intervention and comparison	Population	Outcomes	Risk of bias
	(oral) plus dexamethasone (IT) Oral steroid dosing: 60 mg/day for 7 days, 50 mg for 2 days, 40 mg for 2 days, 30 mg for 1 day, 20 mg for 1 day, 10 mg for 1 day. Dexamethasone (IT) dosing: 0.5–0.7ml of 12 mg/ml once a week for 3 weeks (unclear when first dose given).			
Gundogan, 2013	Methylprednisolone (IT; 4 times for 2 consecutive weeks (once every 3 days)) plus methylprednisolone (oral; 1 mg/kg and 10 mg taper every 3 days) versus methylprednisolone (oral; 1 mg/kg and 10 mg taper every 3 days)	n=79	Total number of adverse events (could not be analysed because number per group not given). 3 cases of vertigo, 5 cases of otalgia after injection, no residual tympanic membrane perforation or otitis media.	Very high

Table 70: Clinical evidence summary: Dual steroid (IT plus oral) versus steroid (IT) [IT dexamethasone plus oral prednisolone versus IT dexamethasone]

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with IT steroids	Risk difference with Dual (95% CI)
PTA improvement or final score	73 (2 studies) 3-7 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean PTA improvement score in the control group in 1 study was 12.1% and the mean final score in 1 study was 51 dB	The mean PTA improvement or final score in the intervention groups was 12.35 lower (22.44 to 2.27 lower)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with IT steroids	Risk difference with Dual (95% CI)
Complete recovery[c]	73 (2 studies) 3-7 weeks	VERY LOW[a,b,d] due to risk of bias, indirectness, imprecision	RR 2.33 (1.18 to 4.62)	222 per 1000	295 more per 1000 (from 40 more to 804 more)
Speech discrimination final score	33 (1 study) 7 weeks	VERY LOW[a,b,d] due to risk of bias, indirectness, imprecision		The mean speech discrimination final score was 60 dB	The mean speech discrimination final score in the intervention groups was 25 higher (4.11 to 45.89 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
c The recovery data are based on a dataset that overlaps the change in PTA, but presented as a dichotomous outcome
d Intratympanic dosing not representative of UK practice

Table 71: Additional narrative information: baseline, final and change scores

Outcome measure	Study	Mean baseline score (SD)	Mean final score (SD)	Mean change score (SD)	Comments
PTA score	Battaglia, 2008	Dual: 75 (23) dB IT: 82 (28) dB	Dual: 35 (21) dB IT: 51 (25) dB	Dual: 40 dB IT: 31 dB	Baseline differences
	Lim, 2013	Dual: 56.8 (28.3) dB IT: 58.9 (31.2) dB	Dual: 34.9 (25.3) dB IT: 46.8 (28.2) dB	Dual: 21.9 (26.2) dB IT: 12.1 (14.6) dB	
Speech discriminatio	Battaglia, 2008	Dual: 41 (40)% IT: 24 (38)%	Dual: 85 (23)% IT: 60 (37)%	Dual: 44% IT: 36%	Baseline differences

Outcome measure	Study	Mean baseline score (SD)	Mean final score (SD)	Mean change score (SD)	Comments
n score					

Table 72: Clinical evidence summary: Dual steroid (IT plus oral) plus antiviral versus single steroid (oral) plus antiviral [IT dexamethasone plus oral prednisolone plus oral acyclovir versus oral prednisolone plus oral acyclovir] for poor prognosis cases

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Single steroid plus antiviral	Risk difference with Dual steroid plus antiviral (95% CI)
Improvement in PTA	77 (1 study) 1 month	LOW[a,b] due to risk of bias, imprecision		The mean improvement in PTA in the control group was 13.8 dB	The mean improvement in PTA in the intervention groups was 8.8 higher (0.91 lower to 18.51 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Table 73: Additional narrative information

Study	Intervention and comparison	Population	Outcomes	Risk of bias
Arastou, 2013	Dexamethasone (IT; 0.4 ml of 4 mg/ml twice a week for 2 consecutive weeks) plus prednisolone (oral; 1 mg/kg/day for 10 days) plus acyclovir (oral; 2 g/day for 10 days, divided in 4 doses) plus triamterene H (oral; daily) plus omeprazole (oral; daily, during steroid treatment) versus	n=77	Two cases of tympanic membrane perforation and two cases of sarcoidosis.	Very high

Study	Intervention and comparison	Population	Outcomes	Risk of bias
	Prednisolone (oral; 1 mg/kg/day for 10 days) plus acyclovir (oral; 2 g/day for 10 days, divided in 4 doses) plus triamterene H (oral; daily) plus omeprazole (oral; daily, during steroid treatment)			

11.3.2 Economic evidence

11.3.2.1 Published literature

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

11.3.2.2 Unit costs

See appendix P.

11.3.3 Evidence statements

Clinical

First line:

Steroid (IT) versus steroid (oral) [IT prednisolone, methylprednisolone or dexamethasone versus oral prednisolone]

- There was a clinically important benefit of oral steroids for ear ache and pain at injection site (moderate quality evidence, 2 studies) and for dizziness/vertigo (high quality evidence, 1 study).
- There was a clinically important benefit of IT steroids for mouth dryness/thirst (moderate quality evidence, 2 studies), weight gain (low quality evidence, 2 studies) and other adverse events (mood change, blood glucose problems, sleep change, and increased appetite; moderate quality evidence, 2 studies) and.
- There was no clinically important difference for PTA improvement (very low quality evidence, 5 studies), recovery (very low quality evidence, 2 studies), word recognition score at 2 months (moderate quality evidence, 1 study) and word recognition score at 6 months (low quality evidence, 1 study).
- There was no clinically important difference in the number of people with adverse events (high quality evidence, 2 studies), treatment-related serious adverse events (very low quality evidence, 1 study), and other adverse events (ear infection and tympanic membrane perforation; very low quality evidence, 1 study).

Steroid (IV) versus steroid (oral) [IV methylprednisolone followed by oral prednisolone versus oral prednisolone]

- There was no clinically important difference in PTA improvement, complete recovery, word recognition score improvement (very low quality evidence, 1 study) complications (moderate quality evidence, 1 study). There were no reported adverse events.

Dual steroid (IT plus oral) versus steroid (oral) [IT dexamethasone plus oral prednisolone versus oral prednisolone]

- There was a clinically important benefit of dual steroid (oral plus IT) for PTA change or final score when oral was used every day (very low quality evidence, 4 studies), for speech discrimination (low quality evidence, 1 study) when oral was given every other day and for complete recovery (very low quality evidence, 3 studies).
- There was no clinically important difference in PTA change score (very low quality evidence, 1 study) and no difference in speech discrimination when oral was given every day (very low quality evidence, 3 studies).

Dual steroid (IT plus oral) versus steroid (IT) [IT dexamethasone plus oral prednisolone versus IT dexamethasone]

- There was a clinically important benefit of dual steroids (oral plus IT) for PTA score and complete recovery (very low quality evidence, 2 studies) and for speech discrimination (very low quality evidence, 1 study).

Dual steroid (IT plus oral) plus antiviral versus single steroid (oral) plus antiviral

- There was no clinically important difference in improvement in PTA (low quality evidence, 1 study).

Economic

- No relevant economic evaluations were identified.

11.3.4 Recommendations and link to evidence

Recommendations	**Please see the recommendations in section 11.2.4.**
Research recommendation	**4. What is the most effective route of administration of steroids as a first-line treatment for idiopathic sudden sensorineural hearing loss?**
Relative values of different outcomes	The following critical outcomes were included in this review: pure tone average, speech discrimination or recognition, health-related quality of life and hearing-specific health-related quality of life. Adverse events were included as an important outcome.
Quality of the clinical evidence	The studies reported pure tone average (PTA) by change or final scores, author-defined improvement and recovery. We analysed the change or final scores as well as the author-defined recovery data as these were thought to be the most important outcomes for decision-making. If neither of these preferred definitions were presented by a given study, author-defined improvement was reported. The majority of the evidence was of low or very low quality and based on few studies with small sample sizes. There were some outcomes of moderate and high quality evidence, mostly relating to adverse events of IT steroids versus oral steroids. The studies were mainly downgraded were the following reasons: • A lack of detail regarding how the diagnosis of 'idiopathic' SSNHL was determined. Some studies identified patients with causes of the SSNHL after randomisation and consequently excluded them from the study. • Many studies did not describe how the patients were randomised and how allocation was concealed. • Other reasons for downgrading related to blinding, attrition bias, and not specifying outcomes in the methods (post-hoc analysis). • Outcomes were also downgraded due to imprecision; many studies had relatively small numbers in each treatment group. • Some studies did not consider high frequency losses (above 2 kHz) within their analysis.
Trade-off between clinical benefits and harms	The guideline committee noted that there was evidence of no clinical difference between IT and oral administration of steroids in the first-line treatment of idiopathic SSNHL, both for the positive outcomes and for the overall rates of adverse events. However, specific adverse events showed clinical differences between these routes of administration in line with clinical experience, with mood change and blood glucose problems being more frequent with oral steroids and injection site pain or dizziness and vertigo more common with IT administration. The committee highlighted the importance of avoiding residual or persisting tympanic membrane

	perforation during the IT procedure, as this should be a 'never event', and noted that finer needles could prevent this occurring. The committee saw no clinical difference between IV and oral steroids for any reported outcomes, and noted that IV steroids are not currently used owing to the requirement to be treated in a hospital setting and the more invasive nature of this route of administration. When administration of both oral and IT steroids was compared with either route alone the committee commented on the clinical benefit of dual administration for recovery, PTA scores and speech discrimination scores (after excluding 1 study with high baseline speech discrimination scores). However, 1 of the included studies used a much higher dose of IT dexamethasone than would be standard for UK practice and also had baseline differences that could bias the outcomes. The committee noted that when an antiviral was used in combination with either dual steroid routes or oral steroid alone no clinical difference was seen for the mean improvement in PTA. Overall, there was some evidence of benefit for steroid treatment. However, there was uncertainty about the optimal route and timing (first or second line) owing to the limited number and quality of the studies. This was particularly related to baseline differences and non-standard dosing of IT steroids.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee considered the clinical evidence and unit costs for the alternative treatment options. The committee noted that the costs of the most likely steroids were low, being between £3 and £13 for a course lasting up to 2 weeks. Therefore the most important resource use and cost would be the cost of administering these drugs. If oral drugs are prescribed these can be taken at home and the patient may require only 2 outpatient appointments for investigation and review. Giving drugs intratympanically would give rise to greater costs as each time drugs are administered the patient would need to come into hospital for an outpatient appointment where this would be conducted by a suitably trained clinician. This could involve 3 or 4 outpatient appointments and the first such appointment may be outside routine hours adding to the expense. An outpatient appointment for a minor ear procedure has an NHS reference cost of £110. Adopting IT as the standard first-line treatment would be a change in practice and would require greater resources. Giving drugs intravenously, by contrast, would necessitate an inpatient stay, which would be even more expensive. Given that no clinical evidence was identified favouring IV drugs, the committee did not recommend this as an option. Given the limited evidence favouring steroid treatment and their low cost, but a lack of clear evidence from the clinical review comparing different oral and IT drugs, and considering the higher costs of IT treatment, the committee was not able to support any particular drug or route of administration, but advised that the use of steroids should be considered.
Other considerations	The committee noted that the evidence was scarce, especially for oral steroids, which makes it difficult to draft a recommendation for routes of administration. The committee discussed current practice and pointed out this is varied; however, the committee agreed that the most common approach is using oral steroids, with IT steroids as a second-line treatment. The importance of full investigation (history, examination, MRI scan, blood tests for chronic infection and auto-immune disease) before offering treatment was discussed. However, there is an issue about delaying the treatment while waiting for the results. The committee discussed offering treatment while waiting for results for lack of a better option. The resource impact of IT steroids was discussed. Additionally, the regimens used in the studies were intensive, with 3 or 4 doses of IT steroid, which is more than the 1

	or 2 doses currently used in UK practice. For all the other areas the committee agreed to draft a research recommendation.

12 Information and support

12.1 Introduction

It is recognised that many people with hearing loss delay seeking professional help for up to 10 years after the hearing difficulty first becomes apparent,[28] leading to increasing difficulties for themselves, their families, carers and work colleagues. There are many possible reasons for this delay including denial of their difficulties and embarrassment at the thought of having to wear hearing aids, being unaware of the full impact of their hearing difficulties, and a lack of knowledge of the support and help available. Information and advice on the range of interventions to successfully manage hearing difficulties may not be readily available or easy to access. On the whole the general public has a poor knowledge of hearing-related issues, and in particular hearing aid users and their families and carers have a need for more information to help them cope with hearing loss.

Those who eventually seek support may not have the information they need in order to make informed choices about possible interventions including, but not restricted to, hearing aids. Also, once a care plan has been agreed, the person with hearing difficulties and their family or carers may not be able to access the advice required to ensure successful adherence to that plan.

Although clear, well-written and accessible information through a range of media is recommended (for example, Welsh Quality Standards for audiology services [90], Commissioning services for people with hearing loss[86]), provision of such information, support and advice is inconsistent throughout England. Charities and GP surgeries may provide pre-assessment information and advice but this is not universally available. NHS audiology information provision is also inconsistent. In some locations people with hearing difficulties who have been referred to an audiologist get at least 2 appointments with time for discussion of options, dissemination of information, answering questions and signposting to other sources of support. In other locations only 1 appointment is offered with limited scope for information dissemination.

This review was carried out to inform recommendations about the information, support and advice needs of adults with hearing loss, and their families and carers, that can enable them to adapt to, and successfully address, hearing difficulties.

12.2 Review question: What are the information, support and advice needs of people with hearing difficulty and their families and carers?

For full details see review protocol in appendix C.

Table 74: Characteristics of review question

Objective	To assess the information, support and advice needs of patients with hearing loss (adult presentation), their families, and carers.
Population and setting	Adults aged 18 and over with hearing loss Families, carers and 'communication partners' of people with hearing loss
Context	Any type of information, support and advice described by studies. For example, • Content of information, support and advice required • How and by whom information, support and advice is delivered • Information for carers and family members as well as information for patients • Timing of information and support
Review strategy	Synthesis of qualitative research. Results presented in narrative format. Quality of the

evidence will be assessed by a GRADE CerQual approach for each review finding.
Only studies that were based in the UK or OECD countries were included to ensure applicability and relevance of issues relating to the UK healthcare system.

12.2.1 Qualitative evidence

12.2.1.1 Methods

Eleven qualitative studies were included in the review;[3, 10, 13, 22, 35, 51, 64, 67, 68, 97, 98] these are summarised in Table 75 below. Key findings from these studies are summarised in Section 12.2.1.2 below. See also the study selection flow chart in appendix E, study evidence tables in appendix H, and excluded studies lists in appendix L.

12.2.1.2 Summary of included studies

The main findings for each included study were identified and synthesised to gain an insight into themes present across the body of evidence as a whole. Each review finding had its methodological limitations assessed within each study first using a risk of bias checklist. Based on the degree of methodological limitations studies were evaluated as having minor, moderate or severe limitations.

The overall assessment of the methodological limitations of the evidence was based on the studies contributing to the review finding. The relative contribution of each study to the overall review finding and the type of methodological limitations were taken into account when giving an overall rating. An explanation of the reasons for each overall quality rating is provided for each review finding (see section 12.2.1.4). Further information on appraising and synthesising qualitative studies is detailed in section 4 of the guideline).

Six of the included studies were based in the UK (Barlow 2007,[10] Bennion 2011,[13] Claesen 2012,[22] Kelly 2013,[64] Pryce 2012,[97] Pryce 2013[98]). All of these studies focussed on the patient perspective apart from 1, Pryce 2013,[98] that looked at the carer's perspective; the staff looking after those with hearing impairment in residential care homes.

Two studies (Laplante 2012,[68] Laplante 2013[67]) included UK participants as well as participants from other countries (Norway: Laplante 2012[68] & 2013[67]; Australia: Laplante 2012;[68] USA: Laplante 2012[68]). Three additional studies were based outside the UK (Aguayo 2001,[3] Detaille 2003,[35] Grenness 2014[51]).

There were no studies that reported the information, support and advice needs of families or carers of patients with hearing loss.

The majority of the studies used in-depth interviews or focus groups with the exception of 2 studies using ethnographic observation Pryce 2012[97] Pryce 2013.[98] The majority of included studies focused on the use of hearing aids in older people.

Table 75: Summary of studies included in the review

Study	Design	Population	Research aim	Comments
Aguayo 2011[3] Canada	In-depth individual interviews with semi-structured questions Qualitative analysis (type	People with acquired deafness Mean age 49 years (range 31–68 years)	To explore the psychological and social effects of becoming deaf as an adolescent or adult and the adequacy of rehabilitation services	Includes some patients with child onset (unclear n value) and surgical causes of deafness (n=3) No description of ethics approval

Study	Design	Population	Research aim	Comments
	not stated) n=8			Context not clearly described Author carries out all parts of the study (bias not discussed) Data analysis does not appear to be rigorous Severe limitations
Barlow 2007[10] UK	In depth semistructured interviews with framework analysis (5 topics) n=8	People with experience of late deafness living in the UK (33–60 years old)	To examine the views of people with experience of late deafness (severe to profound hearing loss acquired during adult life) living in the UK. Particular interest in participants' in-depth experiences of attending the LINK Intensive Rehabilitation programme and the experience of late deafness on emotions, family relationships, and employment given the prominence of these themes in the established literature.	Applicability issues as convenience sample used (tutors of LINK course) Specific focus on 5 aspects of living with deafness Minor limitations
Bennion 2011[13] UK	Semi structured interviews with thematic qualitative analysis n=9	Older people with hearing impairment (61–93 years old)	Explore and develop a greater understanding of the experience of living with age related hearing impairment from the perspectives of older people themselves to highlight possible recommendations for the improvement of hearing aid (HA) services and rehabilitations	Unclear setting, interviewer and data analyser background Recommendations restricted to older hearing impaired population Moderate limitations
Claesen 2012[22] UK	Interviews: 'conversation with purpose' Thematic analysis n=6	Adults referred to audiology by their GPs for hearing difficulties (65–77 years old)	Pilot study using qualitative methods to learn about the psycho-social needs of people who seek help with hearing loss	No description of researcher/experience and their relationship to study design Unclear interview content and structure 'conversational' No description of how the themes emerged Severe limitations
Detaille 2003[35] Netherlands	Focus group Concept mapping n=25 with	Moderate or severe hearing loss, lack of any other chronic illness that might affect work, paid job, age between 21-60 years	To determine factors that help currently employed people with rheumatoid arthritis, diabetes mellitus or hearing loss to continue working	Unclear context Unclear role of facilitator Unclear data richness Severe limitations

Study	Design	Population	Research aim	Comments
	hearing loss Mean 49 (range 36-58 years)			
Grenness 2014[51] Australia	Semi-structured interviews Content analysis n=10	Adults (aged 60+) who had owned hearing aids for at least one year; participants did not need to be current hearing aid users	To define patient-centred care specific to audiological rehabilitation from the perspective of older adults who have owned hearing aids for at least one year	Applicability to the UK Role of researcher/risk of bias No data saturation described Moderate limitations
Kelly 2013[64] UK	Mixed methods, 4 phases including semi-structured interviews, survey and focus groups Framework analysis n=31	At least 60 years old, any type of hearing loss, having no cognitive impairment, not having a terminal or life threatening illness and speaking English. (60–87 years old)	To explore older adults' perceptions of and experiences with new hearing aid use and to identify what they believed would enable them to successfully adjust to wearing a hearing aid	Mixed methods approach Minor limitations
Laplante 2012[68] Australia Denmark UK USA	In-depth interviews (n=34) Content analysis	At least 18 years old with hearing impairment (defined as at least one air-conduction threshold at 0.5, 1, 2, or 4 kHz greater than 25 dB HL in at least one ear. No age range given	Explore and describe hearing help-seeking and rehabilitation perspective of adults with hearing impairment	Applicability: 4 countries (includes UK 24%), mixed funding (68% eligible for funding) Authors conclusions not explicit/ clear Minor limitations
Laplante 2013[67] Norway, UK	Focus groups Inductive qualitative content analysis n=17 hearing aid users	at least 18 years of age Hearing aid user population and audiologists (23–90 years old, median 67)	To explore the meaning and determinants of optimal hearing aid use from the perspectives of hearing aid clients and audiologists To contrast the perspectives of the clients and audiologists	Minor limitations
Pryce 2012[97] UK	Ethnographic observation and in-depth interviews n=18	Residents from 2 residential care homes (76-99 years old)	To explore the factors affecting communicating with a hearing loss in residential care	Data collection and analysis not rigorous 11% of residents consider their hearing to be 'good' Moderate limitations
Pryce 2013[98] UK	Mixed method, 4 phases including ethnographic observation, interviews, qualitative survey,	Staff and residents at 3 residential care homes (Staff age range 22–58 years old)	To identify staff perspectives on hearing loss and their views about potential hearing service improvements	Mixed methods No description of researcher/experience No description about data saturation Moderate limitations

Study	Design	Population	Research aim	Comments
	stakeholder group discussions Constant comparative approach derived from grounded theory n=19			

12.2.1.3 Qualitative evidence synthesis

Table 76: Review findings

Main findings	Statement of finding
Poor verbal communication	Poor communication between healthcare providers, family, friends and individuals with hearing loss. Need for further education on improving communication techniques to support those with hearing impairment, prevent misunderstandings, confusion and potential adverse events.
Need for tailored, clear written information from healthcare providers	Patient desire for information varies and needs to be individualised and unbiased. Often felt to have insufficient information on management options.
Lack of support networks and rehabilitation services	Insufficient or lack of provision of social and emotional wellbeing support. Patients have limited knowledge and access to support groups for example; online, peer groups, community programmes.
Importance of follow-up	Patients acknowledged a lack of follow-up in which they had the opportunity for their questions/ issues to be addressed
Lack of hearing aid advice and support	Many patients felt there was a lack of advice and support relating to the use and maintenance of hearing aids and support with the stigma and cosmetic issues associated with their use.
Lack of awareness of practical and physical supportive interventions	Many patients were not aware of interventions that can be used to support their hearing in everyday activities.

12.2.1.4 Narrative summary of review findings:

Review finding 1: Poor communication.

In some cases there was a lack of sensitivity and knowledge on how to communicate with people with difficulty hearing by some healthcare professionals and residential home carers. Issues included shouting at the patient, speaking too quickly, not clearly, or in a rush, not listening to the patient, not conversing directly in front of the patient and poor understanding of how hearing aids work and function. The impact of background noise on the participants' ability to hear was poorly understood. This also had an impact in the workplace, where there was difficultly understanding the content of meetings and a lack of acknowledgment and understanding of the implications of having hearing loss by colleagues. Some of the consequences experienced due to miscommunication resulted in the

misunderstanding of medical information they had been told about their diagnoses. Good knowledge of the patient and their needs, friendly approach and use of interpreters allowed for better communication.

Explanation of quality assessment:

There were moderate methodological limitations in the contributing studies due to unclear roles of researchers, context and their potential bias, data collection and analysis not being rigorous. There were no concerns about relevance. There were minor concerns about inadequacy and minor concerns about coherence. There was a judgement of **moderate confidence** in this finding which was due to the concerns with moderate methodological limitations.

Review finding 2: Need for tailored, clear information from healthcare professionals

Some patients reported that the information that health professionals gave them was overwhelming and some did not remember it once they had got home. The amount of information required varies from patient to patient and this should be managed appropriately. It was important for patients to know that an audiologist's recommendations were not influenced by financial gain, whether they work in the public, charity or private sector. Patients also often relied on peers or family members for information.

Explanation of quality assessment:

There were moderate methodological limitations in the contributing studies due to unclear roles of researchers, their potential bias and the data analysis not being rigorous. There were no concerns about relevance. There were moderate concerns about inadequacy as the evidence provides different aspects of information needed by those with hearing loss (quantity of information, delivery of information) and did not have a depth to each contributing theme. There were minor concerns about coherence. There was a judgement of **low confidence** in this finding due to the concerns with moderate methodological limitations and moderate adequacy.

Review finding 3: Lack of support networks and rehabilitation services

There are limited emotional, mental and social support networks reported within the studies. Many people suffer from a variety of emotional reactions to the hearing loss including anxiety, frustration and depression, as well as feelings of isolation and lack of social acceptance which results in non-participation in hobbies or activities they previously enjoyed. There were mixed levels of family and friends support and in some cases people felt ignored, or abused by family members. In 1 study consensus proposed that family members should be given the chance to attend an audiology appointment with the patient and given written information and that family members should be involved in the decision making process.

There are a variety of medical professionals involved with the care of people who encounter hearing loss. However, there was no description of mental health professionals associated with the care pathway to address the patient's psychosocial needs. There were experiences, both positive and negative, in accessing rehabilitation support. Linking in with the poor communication, some patients found that healthcare professionals did not have the appropriate knowledge of rehabilitation services and resources that were available. There were other patients who did have a more positive experience.

Explanation of quality assessment:

There were moderate methodological limitations in the contributing studies due to unclear settings and roles of researchers and their potential bias, data analysis not being rigorous. There were no concerns about relevance. There were moderate concerns about inadequacy as the evidence describes limited depth to each contributing theme (social and psychological services, support

networks). There were minor concerns about coherence. There was a judgement of **low confidence** in this finding due to the concerns, with moderate methodological limitations and moderate adequacy.

Review finding 4: Importance of follow-up

Many patients thought that a follow-up audiology appointment would be beneficial and it was noticed if it was not available. This would enable any questions they later thought of, or information forgotten, to be addressed.

Explanation of quality assessment:

There were minor methodological limitations in the contributing studies. There were no concerns about relevance. There were moderate concerns about inadequacy as there was evidence for the need for follow-up. There were minor concerns about coherence. There was a judgement of **moderate confidence** in this finding due to the concerns, with moderate concerns about adequacy.

Review finding 5: Lack of hearing aid advice and support

Some patients found that there was a lack of information available on hearing aid options and NHS versus private dispensers. This may also influence patients' expectations to what a hearing aid can offer leading to unrealistic expectations and contributing to disappointment with the use of a hearing aid. Patients often experienced difficulties with their hearing aids and did not realise how they could be fixed or altered and how to use the controls. Issues consisted of day to day encounters (how long or when to wear it, whistling noises, interference with other electronic devices) and maintenance issues (changing the battery, cleaning). This was also found with staff caring for those who used hearing aids, who lacked knowledge on the use of hearing aids and did not have specific training. One study proposed the use of onsite audiological services to reduce logistical issues with the fitting and follow-up of hearing aids. The ability to trial the hearing aid or aids to see if the patient was happy with them and how they worked, was proposed by 2 studies. Major findings which limited hearing aid use was the stigma and cosmetic appearance of hearing aids. Some patients also felt pressurised to wear one.

Explanation of quality assessment:

There were severe methodological limitations in the contributing studies due to unclear settings and roles of researchers and their potential bias, data collection and analysis not being rigorous. There were no concerns about relevance. There were minor concerns about inadequacy. There were minor concerns about coherence. There was a judgement of **low confidence** in this finding due to the concerns with severe methodological limitations.

Review finding 6: Lack of awareness of practical and physical supportive interventions

Some patients had not experienced the loop system and lacked knowledge of other environmental aids, such as assistive devices, adapted telephones, doorbells, and safety devices such as vibrating smoke alarms. Participants in residential care found that they did not have access to some of the supportive interventions, for example, telephone or television aids. Those currently in employment found that if they were determined and persistent enough to ask for the necessary adaptations at work, these adaptations would enable them to continue with work. The role of occupational physicians (rehabilitation services) and their knowledge about hearing loss and ability to make the needed adaptations at work quickly was highlighted. This input allows those with hearing loss to continue at work.

Explanation of quality assessment:

There were moderate methodological limitations due to unclear context and roles of researchers and potential bias, and data collection and analysis not being rigorous. There were no concerns about

relevance. There were moderate concerns about inadequacy as there was insufficient data richness for environmental aids in individual settings. There were minor concerns about coherence. There was a judgement of **low confidence** in this finding due to the concerns with moderate methodological and adequacy concerns.

12.2.1.5 Qualitative evidence summary

Table 77: Summary of evidence

Study design and sample size			Quality assessment		
No of studies contributing to the finding	**Design**	**Finding**	**Criteria**	**Rating**	**Overall assessment of confidence**
Poor communication					
6 studies [10, 13, 35, 51, 97, 98] (n=80, 10 of which were carers)	Interviews n=3 Focus groups n=1 Ethnographic observation and focus groups n=1 Mixed methods n=1	Poor communication between healthcare providers, family, friends and individuals with hearing loss. Need for further education on improving communication techniques to support those with hearing impairment, prevent misunderstandings, confusion and potential adverse events.	Limitations	Moderate concerns	MODERATE
			Coherence	Minor concerns	
			Relevance	Minor concerns	
			Adequacy	Minor concerns	
Need for tailored information from healthcare providers					
2 studies[51, 64] (n=41)	Interviews n=1 Combination of interviews and focus groups n=1	Patient desire for information varies and needs to be individualised and unbiased. Often felt to have insufficient information on management options.	Limitations	Moderate concerns	LOW
			Coherence	Minor concerns	
			Relevance	Minor concerns	
			Adequacy	Moderate concerns	
Lack of support networks and services					
6 studies[3, 10, 13, 51, 64, 68] (n=100)	Interviews n=5Combination of interviews and focus groups n=1	Insufficient or lack of provision of social and emotional wellbeing support. Patients have limited knowledge and access to support groups for example; online, peer groups, community programmes.	Limitations	Moderate concerns	LOW
			Coherence	Minor concerns	
			Relevance	Minor concerns	
			Adequacy	Moderate concerns	
Importance of follow-up					

Study design and sample size		Finding	Quality assessment		
No of studies contributing to the finding	**Design**		**Criteria**	**Rating**	**Overall assessment of confidence**
3 studies[64, 67, 68] (n=82)	Interviews n=1 Focus groups n=1 Combination of interviews and focus groups n=1	Patients acknowledged a lack of follow-up in which they had the opportunity for their questions/ issues to be addressed	Limitations	Minor concerns	MODERATE
			Coherence	Minor concerns	
			Relevance	Minor concerns	
			Adequacy	Moderate concerns	
Lack of hearing aid advice and support					
9 studies[13, 22, 35, 64, 67, 68, 97, 98] (n=160, 10 of which were carers)	Interviews n=4 Focus groups n=2 Combination of interviews and focus groups n=1 Ethnographic observation and focus groups n=1 Mixed methods n=1	Many patients felt there was a lack of advice and support relating to the use and maintenance of hearing aids and support with the stigma and cosmetic issues associated with their use.	Limitations	Severe concerns	LOW
			Coherence	Minor concerns	
			Relevance	Minor concerns	
			Adequacy	Minor concerns	
Lack of awareness of practical and physical supportive interventions					
5 studies[10, 13, 35, 64, 97] (n=91)	Interviews n=2 Focus groups n=1 Interviews and focus groups n=1 Ethnographic	Many patients were not aware of interventions that can be used to support their hearing in everyday activities.	Limitations	Moderate concerns	LOW

Study design and sample size		Finding	Quality assessment		
No of studies contributing to the finding	**Design**		**Criteria**	**Rating**	**Overall assessment of confidence**
	observation and focus groups n=1				

12.2.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

12.2.3 Evidence statements

Clinical

See section 12.2.1.4

Economic

- No relevant economic evaluations were identified.

12.2.4 Recommendations and link to evidence

Recommendations	**21. Give the person and, if they wish, their family or carers, information about:** • **the causes of hearing loss, how hearing loss affects the ability to communicate and hear, and how it can be managed** • **organisations and support groups for people with hearing loss.** **22. Follow the principles on tailoring healthcare services for each person and enabling people to actively participate in their care in the NICE guideline on patient experience in adult NHS services by, for example:** • **taking into account the person's ability to access services and their personal preferences when offering appointments** • **taking measures, such as reducing background noise, to ensure that the clinical and care environment is conducive to communication for people with hearing loss, particularly in group settings such as waiting rooms, clinics and care homes** • **establishing the most effective way of communicating with each person, including the use of hearing loop systems and other assistive listening devices** • **ensuring that staff are trained and have demonstrated competence in communication skills for people with hearing loss** • **encouraging people with hearing loss to give feedback about the health and social care services they receive, and responding to their feedback.**
Findings identified in the evidence synthesis	Six findings were identified in the review: 1. Poor communication 2. Need for tailored clear information from healthcare professionals 3. Lack of support networks and rehabilitation services 4. Importance of follow-up 5. Lack of hearing aid advice and support

	6. Lack of awareness of practical and physical supportive interventions. There was no evidence on the information and advice needs of the families of those with hearing loss. The studies used a mixture of interviews, focus groups and ethnographic observation. The majority of the studies had negative findings, indicating the needs of those with hearing loss and their carers were not being met. The main finding revolved around communication issues (verbal and written) and the problems that those with hearing loss faced, and the consequences of misunderstandings. There was no evidence to suggest that support networks and rehabilitation groups were adequate, and indicated a greater need for psychosocial support. Several studies highlighted the lack of awareness amongst healthcare and social care staff on how to communicate with people with hearing loss and demonstrated a need for more education and training to improve communication techniques. Observations of poor practice included using raised voices or shouting during consultations, not considering background noise or communication difficulties when conversing in group situations. Two studies conducted in care homes reported on how environmental factors affected participation activities by residents. Noise levels from background music or televisions resulted in limited interactions between residents, and staff tended to limit conversation to tasks or needs, leading to residents with hearing loss withdrawing from participation activities. Many of the studies focused on older people and their use of hearing aids. It was found that those with hearing loss had not been fully informed of the different types of hearing aids available to them, they were not given the opportunity to trial different devices, or shown how to use hearing aids to their maximum ability. People lacked knowledge on general maintenance and fine-tuning of their hearing aids, and on the availability and use of environmental aids. Patients acknowledged a lack of follow-up opportunities in which they could have their questions addressed. One study considered the different advice and support required by first-time users of hearing aids prior to fitting and after fitting, and the ongoing psychological and practical support needed for people to successfully adjust to using a hearing aid. A survey of audiologists reported poor information retention and misunderstandings by patients that was potentially detrimental to optimal hearing aid use. Audiologists who repeated information, provided written information, or gave access to an ongoing source of information, for example, newsletters or follow-up information, were particularly appreciated. The importance of monitoring and follow-up for patients with hearing loss has been reviewed in more detail in chapters 17 and 18 where specific recommendations have also been included in sections 17.3.4 and 18.2.4.
Quality of the evidence	Overall, there was low to moderate confidence in the evidence. The evidence was primarily downgraded due to methodological limitations in the studies (ranging from low to severe limitations). Many of the studies did not describe the context, researcher role and their risk of bias and did not have rigorous data collection or analysis. The other main reason for downgrading was due to concerns relating to the adequacy of the data. Although many of the papers portrayed the same findings, it was felt that sub-findings within them were insufficiently evidenced in most cases to be classed as ‘data rich’. This, combined with the minimal evidence relating to carers and lack of evidence relating to families of those with hearing loss, results in the findings that are highlighted in this systematic review not necessarily being generalisable across the protocol population. Areas of need for carers and families of those with hearing loss were not identified. The committee also noted the following differences in international healthcare systems which were provided in 1 of the papers:

	• Denmark and UK have predominantly public hearing services • Australia: only some people are eligible for public hearing services • USA: main public hearing service provider is the Department of Veterans' Affairs, but the vast majority of the population is ineligible for public hearing services
Trade-off between net effects and costs	No health economic evidence was identified for this question. The committee agreed that staff training and suitable environments are necessary to enable staff to be able to communicate with and hence provide healthcare (of all kinds) for people with hearing loss in an equivalent manner to people without hearing loss. Therefore it is important to find ways to put such environments in place, to prevent people with hearing loss from being discriminated against by being unable to access healthcare services. In light of the qualitative evidence that poor communication with patients leads to misunderstanding, confusion and potential adverse events, the committee noted that this may lead to additional downstream costs later both in dealing with adverse events and in providing increased care for (non-hearing-related) conditions that have worsened due to not being dealt with properly at an earlier stage due to miscommunication. At a more modest level, the committee reported from experience that people with hearing loss commonly present for an additional appointment in primary care because they did not hear or understand what they were told at their previous appointment – giving rise to unnecessary costs. As such, better training of staff may lead to consequential later cost savings, though these cannot be quantified in the absence of objective evidence. In considering the organisation of staff training the committee recommended that for new staff members training should be incorporated into their basic medical or role-specific training. For existing staff members who have not previously been trained one-off additional training would be required. This cannot be accurately costed, as it would be provided in different ways depending on the local organisation of training. This could be along the lines of other mandatory training, either face-to-face or online according to local preference, and could be combined with other training as part of routine in service training or continuing professional development, for which all members of staff should have some time available each year. As such there would either be no cost above the time and resources already allocated to training each year, or there would be a small additional cost per staff member, which may be offset by subsequent savings as discussed above. Therefore, the committee agreed that staff training is very likely to be cost saving or cost effective at a threshold of £20,000 per QALY gained in the medium to long term. The NICE guideline on patient experience in adult NHS services considered the cost effectiveness of providing information and support to patients and agreed that the provision of low-cost information materials is a cost-effective intervention.
Other considerations	The committee highlighted some ways of communicating which are particularly helpful to people with hearing loss: • Choosing an appropriate room which has good lighting and is as quiet and private as possible (so that louder than average voices would not be overheard). • Not shouting at the person when speaking to them. • Not speaking too quickly, and avoiding exaggerated lip patterns. [92] • Not covering your mouth when speaking and making sure you are facing the person when speaking. Making sure your face is visible, for example, by avoiding a light source behind you. This list does not cover all strategies which can be helpful and stressed the need for training so that the person with hearing loss is empowered and not patronised. Healthcare and social care staff includes all staff members who communicate with patients, for example reception staff and care assistants. Training should include

general principles of good communication given in the NICE Patient experience in adult NHS services guidance (CG138), as well as simple and often overlooked strategies specific to people with hearing loss, for example lip reading and clarifying that what has been said has been heard and understood.

The committee noted that the evidence does not include explicit discussion of the communication needs of people with hearing loss who are also blind, have dementia, special educational needs, or English as a second language.

The committee stated that in its experience, residential and care homes are settings where training and education of staff about how to communicate with people with hearing loss is often inadequate. Care staff members also need training in how hearing aids work and how to fix common problems with them. Improvements in this area are therefore a priority, and good communication is required between healthcare services to ensure that good practice is disseminated.

It is important that monitoring staff communication training and education is undertaken to ensure that it is effective and tailored to meet the needs of patients, carers and family members. The committee noted that auditing patient perspectives is the most effective way to do this.

The committee also considered that specialised equipment (for example personal communication devices and loop systems) should be available in healthcare settings to enable staff to communicate more effectively with people with hearing loss. Personal communication devices involve a hand-held microphone, amplifier and earphones; they can be used to talk directly with a person with hearing loss ensuring that the speaker's voice is amplified and background noise reduced. They are invaluable in situations where hearing is compromised because the person does not have their aids (such as accident and emergency departments), aids have not been provided or cannot be used (out-patient appointments, care homes). Loop systems are useful in the presence of background noise and are often used at reception desks, waiting rooms, for telephones and for watching television or theatre performances. They require that the individual is wearing hearing aids. For further information see chapter 14 on assistive listening devices.

It is important when giving information to people with hearing loss to ensure that the information is in an accessible format. This is particularly so for people with cognitive difficulties, dual sensory loss and those for whom English is a second language.[88]

When discussing the management of hearing loss the audiologist needs to consider whether social services would be a valuable contact.

The committee noted the comments about provision for work, and the importance of having advice and support to ensure that adaptations are made to enable someone with a hearing loss to continue at work. In England employers have to make reasonable provision in the workplace for people with impairments, and advice and equipment can often be sourced through the Access to Work programme.[33]

See also chapter 17 on monitoring and follow-up and chapter 18 on interventions to support the use of hearing aids.

13 Decision tools

13.1 Introduction

People who become aware of hearing-related difficulties do not report their hearing loss until an average of 10 years after it began;[28, 38] often only when the problem becomes unmanageable and impacts greatly on the person or those around them. The reasons for this delay are described in other sections. Many people referred to audiology have little idea of what to expect and can be anxious. They may not be in an optimal state to make decisions and may acquiesce to whatever is advised or offered by an audiologist in deference to professional expertise.

An audiologist's main aim with new referrals is to assess the extent of hearing and communication difficulties, determine the degree and type of hearing loss and recommend the appropriate intervention to address those difficulties – usually 1 or 2 hearing aids (NHS England commissioning framework[86]). However research studies indicate that some people issued with hearing aids fail to use them as prescribed. The Health Survey for England 2014 [56] found that 28.6% of those who had tried a hearing aid no longer used one but did not address suboptimal use.[77] A number of people only wear hearing aids when they need them and this can be categorised as non-use if less than the sought for number of hours in a survey. These figures demonstrate equivalent or better adherence than is found for other forms of medical treatment; nevertheless the question of improving adherence does need addressing. Whilst there is a range of practical reasons for discontinued or suboptimal use this non-adherence may also reflect that audiologists do not always take full account of the individual's motivation, drivers, fears and priorities as part of the decision-making process – often because of time constraints. There is an increasing volume of evidence that demonstrates a clear association between increased involvement in decision-making by the individual and better outcomes, better health status, and greater self-reliance; and this association is independent of social class or economic status. Equally, a better understanding of individuals' motivation for seeking help enables the audiologist to deliver person-centred care in a way that suits the client.

Engaging the patient in decisions about hearing interventions, that is, "no decision about me without me", is a key component of contemporary health policy and critical in matching the intervention to the client in order to maximise effective use of healthcare interventions. This NICE guideline reviews the evidence about the effectiveness of motivational interviewing and decision tools in improving the uptake and optimal use of hearing aids.

13.2 Review question: What is the clinical and cost effectiveness of using patient-centred tools to help patients with hearing loss decide between different management strategies?

For full details see review protocol in appendix C.

Table 78: PICO characteristics of review question

Population	Adults aged 18 and over presenting with hearing loss
Interventions/ Comparisons	**Interventions:** Tools specific to hearing for example Ida Institute motivational tools Option grids, shared decision-making, decision aids **Comparators:** No decision aid, no patient choice, professional decision
Outcomes	**Critical outcomes**

	• Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities of Hearing (SSQ) ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale ○ Any questionnaire not specified above that is relevant • Adherence to chosen strategy for example usage of hearing aids (including data logging and self-report (if applicable) **Important outcomes** • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment and education • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ HRQoL ○ Any questionnaire not specified above that is relevant
Study design	RCTs and systematic reviews of RCTs

13.2.1 Clinical evidence

No relevant clinical studies were identified investigating the clinical effectiveness of using patient-centred tools to help patients with hearing loss decide between different management strategies in adults presenting with hearing loss. See study selection flow chart in appendix E and the excluded studies list in appendix L.

13.2.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

13.2.3 Evidence statements

Clinical

- No relevant clinical evidence was identified.

Economic

- No relevant economic evaluations were identified.

13.2.4 Recommendations and link to evidence

Recommendations	See recommendation 14 in communication needs chapter 9.
Research recommendation	**What is the clinical and cost effectiveness of person-centred, decision-making tools when agreeing the preferred management strategy for hearing loss in adults?**
Relative values of different outcomes	The following outcomes were identified as critical outcomes for this review: hearing-specific health-related quality of life and adherence to chosen strategy. Outcomes reporting health-related quality of life were identified as important for this review.
Quality of the clinical evidence	No clinical evidence was identified for this review.
Trade-off between clinical benefits and harms	The committee discussed the importance of having validated tools to support the decision-making process. The committee was aware of decision aids being marketed for use in the field of hearing loss but noted that these tools have not been validated for this particular use and for this specific patient group and therefore may not be optimal. The committee was aware of a research study currently being carried out looking at the Ida Institute motivational tools, but further research is needed for other types of tool such as option grids. The committee agreed that decision aids could be helpful in supporting people when they are considering their goals and the range of management options available to them. A decision tool could be used in addition to information and advice provided by the practitioner at the time of the audiological assessment.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The committee agreed that the recommendations made for the NICE guideline on patient experience are appropriate for people with hearing loss. These were found to be cost effective for a general population in the patient experience guideline, and the committee agrees that this will be equally so in people with hearing loss. In particular, taking the time to offer appropriate support to a person with hearing loss and their carers or family members at an early stage has the potential to save time in future. In the committee's experience, people with hearing loss frequently require additional appointments when consulting health practitioners, such as GPs, due to not being able to hear the clinician or to participate fully in decision-making at the first appointment. There could therefore be a cost saving from ensuring that clinicians engage fully with people with hearing loss on all occasions.
Other considerations	The committee considered the recommendations for shared decision-making in the NICE guideline on patient experience to be relevant and applicable to people with hearing loss. This outlines supporting the person when considering different options which is directly applicable when discussing the different interventions available for hearing difficulties and making decisions on the most appropriate strategy. The committee noted the emphasis placed there on supporting decisions around treatment options, however the principles outlined remain relevant to hearing loss.

14 Assistive listening devices

14.1 Introduction

The primary management option for permanent hearing loss is hearing aids. However, there are other devices, known as assistive listening devices (ALDs), that can help an individual detect sounds or understand speech. ALDs can be used in conjunction with hearing aids, or instead of hearing aids.

Assistive listening devices such as loop systems, FM/RM radio aids, personal communicators and newer devices such as streamers and apps, are designed to improve access to speech and help individuals to communicate. Some of these devices facilitate access to music and enhance recreational pursuits such as streamers or TV amplifiers. These ALDs function by improving the signal to noise ratio, thus enhancing speech. Other ALDs alert the person with hearing loss to environmental sounds and these include alarm clocks, doorbell sensors, baby alarms and smoke detectors, which use flashing lights, vibrators or loud sounds.

ALDs are sometimes provided by the NHS, social care services or the fire service, and amongst these devices are those that are important for safety such as smoke alarms. Provision will vary across England and the individual needs to approach the local services for advice. Those in work may be able to get necessary equipment through Access to Work while students are frequently supported by the Disabled Student's Allowance. Other ALDs, such as streamers or apps, are purchased by the hearing aid user as required.

There is uncertainty about the effectiveness of ALDs, when they should be recommended, and how individuals should access them as part of management of their hearing difficulties. This chapter examines the clinical and cost effectiveness of assistive listening devices to support communication.

14.2 Review question: What is the clinical and cost effectiveness of assistive listening devices (such as loops) to support communication?

For full details see review protocol in appendix C.

Table 79: PICO characteristics of review question

Population	Adults aged 18 and over with hearing loss
Interventions	Assistive listening devices: • FM / RF radio frequency modulators • telephone/television amplifiers • amplifiers for telephone/doorbell/smoke detector • loop system (personal or in-built) or telecoils • hearing aid apps • Bluetooth devices • PSAPs (personal sound amplification products)
Comparisons	• ALDs compared with each other • ALDs compared with hearing aids • Conventional hearing aids compared with hearing aids in conjunction with amplification devices such as FM and smartphone apps
Outcomes	**Critical:** Hearing-specific health-related quality of life

	• Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) • Quantified Denver Scale of Communication (QDS) • Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) • Device Orientated Subjective Outcome Scale • Any questionnaire not specified above that is relevant Health-related quality of life • Health Utilities Index Mark 3 (HUI-3) • EQ-5D • SF-36 • Glasgow Benefit Inventory (GBI) • WHO Disability Assessment Schedule (WHODAS) • Self-Evaluation of Life Function (SELF) • Any questionnaire not specified above that is relevant Listening ability • Abbreviated Profile of Hearing Aid Benefit (APHAB) • Speech, Spatial and Qualities of Hearing (SSQ) • Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale • Speech intelligibility (BKB, HINT, QuickSIN) • Ease of listening/listening effort **Important:** Any outcomes reporting: • Restricted participation or activity limitation • Social interactions, employment (including voluntary work) and education
Study design	Systematic review of RCTs and RCTs

14.2.1 Clinical evidence

A systematic review of RCTs was conducted to search for evidence on the effectiveness of assistive listening devices that can help support communication of patients with hearing loss. The interventions of interest included stand-alone devices as well as add-on devices that provide additional features to conventional hearing aids.

One study was included in the review: McInerney 2013.[78] This is summarised in Table 80 below. Evidence from this study is summarised in the clinical evidence summary below (Table 81). See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

Table 80: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
McInerney 2013[78]	Assistive listening device (Sonic Ear: a wired assistive listening system composed of headphones, an amplifier and a microphone wired to	Elderly patients recruited from retirement homes. Patients with hearing impairment were randomised and allocated into one of two groups (with and	Communication efficiency measured as the number of observed communication breakdowns	USA study Funding not stated

Study	Intervention and comparison	Population	Outcomes	Comments
	each other) Compared with no assistive listening device	without ALD) and those without hearing impairment were randomised into one of two groups (with and without ALD). Groups consisted of: HL with ALD: 7 HL without ALD: 5 No HL with ALD: 5 No HL without ALD: 5 n=27 (1 excluded due to MMSE score <24, 4 excluded due to impacted cerumen) Overall: Age - Mean (range): 82.45 years (70-93). Gender (M:F): 86.4% Female In the hearing loss with/without ALD-Age (SD), %female: **HL/ALD**: n=7 82 (9.3), 58 % F **HL/no ALD** n=5 85 (7.8), 100% F		

Table 81: Clinical evidence summary: assistive listening devices compared with no assistive listening devices

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No assistive listening devices	Risk difference with Assistive listening devices (95% CI)
Number of communication breakdowns	12 (1 study)	LOW[a] due to risk of bias		The mean number of communication breakdowns in the control groups was 12.6	The mean number of communication breakdowns in the intervention groups was 11.03 lower (16.77 to 5.29 lower)

[a] Downgraded 2 increments because the evidence was at very high risk of bias

14.2.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

14.2.3 Evidence statements

Clinical

- There was a clinically important benefit of ALDs for reducing the number of communication breakdowns (low quality evidence, 1 study).

Economic

- No relevant economic evaluations were identified.

14.2.4 Recommendations and link to evidence

Recommendations	**23. Give adults with hearing loss information about assistive listening devices such as personal loops, personal communicators, TV amplifiers, telephone devices, smoke alarms, doorbell sensors, and technologies such as streamers and apps.** **24. Tell adults with hearing loss about organisations that can demonstrate and provide advice on how to obtain assistive listening devices, such as social services, the fire service, or the government through programmes such as Access to Work or Disabled Student Allowance.**
Research recommendation	**What is the clinical and cost effectiveness of assistive listening devices (ALDs) compared with other devices, combination of devices or no intervention to support adults with hearing loss?**
Relative values of different outcomes	The guideline committee considered the following outcomes as critical: hearing-specific health-related quality of life including the Hearing Handicap Inventory for the Elderly (HHIE), Health-related quality of life including the Health Utilities Index Mark 3 (HUI-3), and listening ability including the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale. Outcomes reporting restricted participation or activity limitation and social interactions, employment (including voluntary work) and education were considered important outcomes.
Quality of the clinical evidence	One study was included in this review. This study compared the use of Sonic Super Ear (an ALD composed of headphones, an amplifier and a microphone wired to each other) to no ALD in a US care home population, with mild or moderate hearing loss. The outcome reported in this study was communication efficiency as indicated by the number of communication breakdowns. This was considered an outcome that informs the participation or activity limitation outcome prioritised by the committee. The quality of the evidence for this outcome was at very high risk of bias mainly due to the small sample size and to the selection of participants. The committee understood that while there are significant differences between UK and US care homes in that in the US people enter retirement homes at an earlier age and are generally more active and in better health than those entering care homes in

	the UK, nevertheless the results of this research has relevance to older people in the UK who find communication difficult because of hearing difficulties and do not wear hearing aids. Provision of ALDs as described in this paper would be most useful for older people in care homes, GP or out-patient consultations or emergency settings, to improve communication between the patient and the healthcare provider.
Trade-off between clinical benefits and harms	The only evidence available was from 1 small study. Although this showed that there was a clinical benefit to using an assistive device, it was in a US retirement home setting looking at one specific device. There was no evidence on any of the other potentially useful devices that the committee was interested in. Therefore, the committee also used its clinical experience and knowledge and co-opted a social worker in order to make more generalisable recommendations. The committee noted that it is a legal requirement for provision to be made such that those with a disability have equality of access to medical services, where possible. Consequently loop systems are generally provided in hospital reception areas. However there is not always suitable provision in clinical areas where loops may be impractical. This is of particular concern in emergency situations, but is also an issue on wards and in clinics when patients are unable to hear what is said to them. Personal listening devices are invaluable in these situations but it is not clear if they are widely provided and, if provided, used when needed. Where the person's safety is assessed as being at risk, audiology services can refer the person to social services for further assessment for assistive listening devices to be provided in the person's home. The committee agreed that currently liaison between health and social services does not happen routinely and, as a consequence, services are not joined up. The committee noted the lack of evidence for ALDs in the workplace. However, based on professional experience, the committee highlighted the value of schemes such as Access to Work and the Disabled Student Allowance that fund assistive listening devices to enable equality of access in work and educational settings. The committee agreed it would not be usual to prescribe a device like the Sonic Ear (described in the evidence review) for an individual with hearing loss, although such devices could be purchased by an NHS organisation and used by healthcare and social care professionals in a variety of settings. However technology is developing rapidly and personal amplification systems are becoming more accessible, for example, apps on mobile phones, and it is important that people are given information on what is available. Most audiology services would demonstrate and explain what assistive listening devices are available and how to access them. The committee noted that an appropriate time to explore continuing communication or listening difficulties would be at follow-up appointments following hearing aid provision and ALDs could be reconsidered at this time.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The recommendations made for this review concern giving advice to people with hearing loss regarding the benefits of ALDs, their availability and how to access them. Difference in the content of the advice will not give rise to any difference in cost but would improve quality of life for some people if they go on to obtain and benefit from an ALD. It is assumed that such advice can be given relatively briefly during the course of routine appointments that a person with hearing loss will already be having with healthcare professionals, and so this will not require additional appointments. ALDs are not normally given to patients by the NHS, and so these recommendations do not have any direct economic impact on the NHS. If people with hearing loss wish to follow up this advice and obtain relevant ALDs then these would need to be paid for either by social care services, or the user, or shared between the user and social care services. This guideline does not make any recommendations on what devices

	(if any) social care services should provide, and whether these should be provided free or for a fee. It is for social care providers (or other relevant bodies, such as fire services) to consider the cost effectiveness of providing each ALD, and they will need to take into account the lack of evidence on this subject. The committee does not encourage people with hearing loss to self-purchase devices, although the committee recognises that some may wish to do so and this would impose direct costs upon them. The committee cannot comment on the value that users would receive from such purchases due to the lack of clinical and economic evidence for this review. The committee is hence content that the recommendations made in this review to advise people with hearing loss regarding ALDs will have no additional cost to the NHS compared with not giving such advice.
Other considerations	It was noted that there is a limit to the equipment that can be provided by the NHS. Social services or the fire service provide equipment as safety measures in people's own homes such as flashing or vibrating smoke detectors or provide information and advice on other useful ALDs, for example personal loops, doorbell and telephone amplifiers and baby monitors. Charging for devices varies. The committee is aware of innovations in this field with modern technology in particular FM, AI and Bluetooth, and is unable to comment on effectiveness in the absence of evidence.

15 Hearing aids

15.1 Introduction

Hearing loss affects a large portion of the general population. In the majority of cases, hearing loss in adults affects both ears and is permanent. The primary management option for permanent hearing loss is hearing aids. All hearing aids consist of a microphone, an amplifier powered by a battery, a receiver, and a means to route the amplified sound into the ear canal.

The general goal of prescribing and fitting hearing aids is to improve functional auditory capacity and restore good communication skills and participation in everyday life. Hearing aids partially overcome the deficits associated with hearing loss by restoring the audibility of sound and improving the intelligibility of speech. Because hearing aids cannot improve deficits in frequency, temporal resolution and spatial resolution that generally accompany the most common causes of permanent hearing loss, an adult with hearing loss may continue to experience some difficulties, even when wearing hearing aids.

Prescribing and fitting hearing aids to both ears (bilateral fitting) has the potential to provide binaural stimulation. The benefits of binaural stimulation include improved intelligibility of speech in background noise, sound localisation, and sound quality. It also has the potential to avoid deficits that may develop over time if only 1 hearing aid is fitted and the unaided ear is deprived of stimulation. On the other hand, potential disadvantages of bilateral fitting include additional cost (to the NHS), a perception that 2 devices may be too complex for some people to use, and binaural interference (reduced speech intelligibility compared with performance with a single device). Quantifying the advantages and disadvantages of fitting 2 hearing aids is not straightforward. For this reason, it is not always clear who will benefit from (and accept) 2 hearings aids. Although the provision and fitting of bilateral hearing aids is considered the norm, this is based largely on theoretical benefits and efficacy studies in research laboratories. The intention of this chapter is to review the evidence on the clinical and cost effectiveness of providing hearing aids and to develop recommendations for their use in adults with hearing loss.

15.2 Review question: What is the clinical and cost effectiveness of hearing aids for mild to moderate hearing loss in adults who have been prescribed at least 1 hearing aid?

For full details see review protocol in appendix C.

Table 82: PICO characteristics of review question

Population	Adults age 18 years and over who have mild to moderate hearing loss Hearing loss defined either: • Qualitatively as ‘mild’ or ‘moderate’, OR • Quantitatively following WHO definitions of mild and moderate hearing loss (mild: 26–40 dB HL inclusive; moderate: 41–70 dB HL inclusive)
Intervention	Acoustic hearing aids, irrespective of the type of technology (analogue or digital)
Comparisons	• Passive control (placebo; no intervention; or waiting list) OR • Active control (information or education only, listening tactics and communication training; assistive listening devices; or auditory training)
Outcomes	**Critical outcomes:** 1. Hearing-specific health-related quality of life (key domain: participation)

	2. Adverse effects: Pain **Important outcomes:** 3. Health-related quality of life 4. Listening ability 5. Adverse effects: Noise-induced hearing loss
Study design	RCT Systematic review of RCTs

15.2.1 Clinical evidence

A recent Cochrane review [43] was identified that addressed our clinical question. The Cochrane review aimed to identify the clinical effectiveness of hearing aids versus no hearing aids for mild to moderate hearing loss. Five studies were included in the review.[2, 58, 76, 79, 81] Two of these studies were deemed to be inappropriate for inclusion within the meta-analysis but otherwise met the review protocol and are summarised narratively below. It was not possible to include the Scaling Assessment reported by Melin 1987[79] in the meta-analysis as no usable data were reported for either the intervention or the comparator groups. However, the study reported a significant improvement for the hearing aid versus unaided comparator for the Scaling Assessment for easy to difficult hearing situations. In addition to this, the data on health-related quality of life reported by Adrait 2017[2] was not included in the meta-analysis due to the indirectness of the population, which was exclusively adults with Alzheimer's disease. The committee agreed that this population was a distinctly different clinical population from typical first-time hearing aid users. However, this study was the only study that measured adverse effects and therefore was reported in the clinical evidence table.

The studies with data suitable for meta-analysis are summarised in Table 83 below. Evidence from these studies is summarised in the clinical evidence summary (Table 84). See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

The Cochrane review [43] was incorporated into this guideline in the following ways:

- Article selection and risk of bias assessment per study were directly adopted without further checking.
- GRADE assessments for risk of bias, imprecision and inconsistency per outcome were checked. If differences with the standard methodology used within this guideline were found, GRADE ratings and subgroup analyses were amended accordingly to ensure consistency across the reviews within this guideline.

Table 83: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Humes 2017[58]	Intervention (n=108): Active hearing aids, behind-the-ear, fully digital. Bilateral fits. Two service delivery models combined. Control (n=51): placebo hearing aids, behind-the-ear, . Bilateral fits.	n=164 randomised n=154 completed People aged 55 to 79 years with no prior hearing aid experience with pure-tone audiometry consistent with age-related bilaterally	• Hearing-specific health-related quality of life • Listening ability	Multiple outcomes reported but only hearing-specific HRQoL and listening ability relevant.

Study	Intervention and comparison	Population	Outcomes	Comments
		symmetrical hearing loss Age (mean (SD): 69.1 (6.1) Gender (m/f): 92/72 Country: USA		
McArdle 2005[76]	Intervention (n=189): hearing aids, in-the ear, analogue or fully digital. Control (n=191): waiting list controls, no hearing aids up to 10 weeks post baseline	n=380 randomised n=362 completed People with PTA≥30 dB HL in better ear. No prior HA experience. Eligible for HAs through VA Age (mean (SD)): 69.4 (9.0) Gender (m/f): 374/16 Country: USA	• Hearing-specific and general health-related quality of life • Listening ability	Setting was Veterans' Administration (VA) medical centres in the USA. Overwhelmingly male sample.
Mulrow 1990[81]	Intervention (n=95): hearing aids, in-the-ear, unilateral fits, typically to the worst hearing ear Control (n=99): waiting list controls, no hearing aids	n=194 randomised n=188 completed People with PTA at 2 kHz, ≥40 dB in better hearing ear Aged>64 years Gender (% m): intervention: 100%; control: 99% Country: USA	• Hearing-specific and general health-related quality of life	Setting was Veterans' Administration medical centres in the USA. Overwhelmingly male sample.

Table 84: Clinical evidence summary: Hearing aids versus no hearing aids

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Hearing aids versus no/placebo hearing aids (95% CI)
Hearing-specific health-related quality of life assessed with HHIE (range 0-100, lower is better)	722 (3 studies) 6 weeks to 4 months	MODERATE[a] due to risk of bias		The mean hearing-specific health-related quality of life in the control groups was 39	The mean hearing-specific health-related quality of life in the intervention groups was 26 lower (42 to 11 lower)
Health-related QoL assessed with: WHO-DAS II (range 0 to 100) and the SELF (range 54 to 216) Lower is better	568 (2 studies) 2 months to 16 weeks	MODERATE	-	-	SMD **0.38 lower** (0.55 lower to 0.21 lower) Lower score indicates better HRQoL. The SMD corresponds to a small effect size favouring hearing aids, which is equivalent to a 6-point decrease (9- to 3-point decrease) on the 0 to 100 scale of the WHO-DAS II[4].
Listening ability assessed with: PHAP (range 0 to 1) and APHAB (range 0 to 100) Lower is better	534 (2 studies) 6 weeks to 2 months	MODERATE	-	-	SMD **1.88 lower**(3.24 lower to 0.52 lower) Lower score indicates improved listening ability. The SMD corresponds to a large effect size favouring hearing aids, which is equivalent to a 29-point decrease (50- to 8-point decrease) on the 0 to 100 scale of the APHAB[5].
Adverse effect - pain	48 (1 study)	VERY LOW[3]		No adverse events reported	There was too little information to estimate the risk of pain.
Adverse effect - noise-induced hearing loss	48 (1 study)	VERY LOW[3]		No adverse events reported in	There was too little information to estimate the risk of noise-induced hearing loss.

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Hearing aids versus no/placebo hearing aids (95% CI)
risk of bias [b] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs [3]Very serious imprecision as the sample size was very small. There was serious indirectness because only people with mild to moderate Alzheimer's disease were included in the study [4]Equivalent change calculated assuming a standard deviation of 15.99 in WHO-DAS II scores in the no hearing aid group. [5]Equivalent change calculated assuming a standard deviation of 15.30 in APHAB scores in the no hearing aid group.					

15.2.2 Economic evidence

15.2.2.1 Published literature

One health economic study was identified with the relevant comparison[62] and has been included in this review along with the original health economic modelling conducted in appendix N. These are both summarised in the health economic evidence profile below (Table 85) and the former is summarised in a health economic evidence table in appendix I.

One health economic study relating to this review question was identified but was excluded due to the availability of more applicable evidence.[15] This is listed in appendix M, with reasons for exclusion given.

See also the health economic study selection flow chart in appendix F.

Table 85: Health economic evidence profile: hearing aids versus no hearing aids

Study	Applicability	Limitations	Other comments	Incremental cost[(e)]	Incremental effects	Cost effectiveness	Uncertainty
Joore 2003[62] (Netherlands)	Partially applicable[(a)]	Potentially serious limitations[(b)]	• Lifetime Markov model based on single Netherland study • Before-and-after study design, no control group (n=78) • Population: patients receiving	£571	EQ-5D: 0.05 QALYs	EQ-5D: ICER: £11,555 per QALY gained	The results were highly sensitive to the quality of life benefit of hearing aids. The 95% confidence intervals for this crossed 0, and so the intervention could be not

Study	Applicability	Limitations	Other comments	Incremental cost[(e)]	Incremental effects	Cost effectiveness	Uncertainty
			first hearing aid(s) • Effectiveness: HRQoL measured using EQ-5D (both questionnaire and VAS) before hearing aid fitting and at 4 months. This was used as benefit of hearing aids		EQ-5D VAS: 0.03 QALYs	EQ-5D VAS: ICER: £17,358 per QALY gained	effective or cost effective, or at the other end of the range the ICER could be £4,339 per QALY gained. Varying other parameters had only a moderate effect on the ICER.
NGC 2017 (UK) (see appendix N)	Directly applicable[(c)]	Minor limitations[(d)]	• Lifetime Markov model • Population: people reporting hearing problems. Patients offered hearing aids compared with those not offered aids • Effectiveness: HRQoL benefit based on UK before-and-after study using HUI3 (Barton 2004[11])	£1,539	0.37	ICER: £4,167 per QALY gained	The results were most sensitive to the quality of life benefit of hearing aids. When this was halved the ICER doubled to £8,465 per QALY gained, still well below £20,000 per QALY gained. Changing all other parameters had only very small effects on the ICER (below £5,700 per QALY gained in each case).

Abbreviations: EQ-5D: EuroQol 5 dimensions (scale: 0.0 [death] to 1.0 [full health]); HRQoL: health-related quality of life; HSQoL: hearing-specific quality of life; HUI3: health utilities index mark 3; ICER: incremental cost-effectiveness ratio; QALYs: quality-adjusted life years; VAS: visual analogue scale (scale 0.0 to 1.0)

Abbreviations: ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life years

(a) Study conducted in Netherlands. Hearing assessment pathway similar but with some differences to UK. Payment methods different (patients responsible for some costs) but analysis includes all costs that would be covered by UK NHS.

(b) Costs are based on 1998 Dutch costs, in particular hearing aids were very much more expensive than currently in the UK; however the model also assumes hearing aids are replaced much less frequently (8-15 years) than currently in the UK, and that only 25% of people will have 2 hearing aids fitted and paid for. Benefit of hearing aids was measured by an in-trial analysis of 78 patients, using EQ-5D which is known to be insensitive to the effect of hearing loss of quality of life. This gave a benefit of hearing aids greater than that measured in the UK using EQ-5D but half to a third of the benefit measured in the UK using HUI3. Part-funded by hearing aid manufacturers.

(c) Designed for this guideline using a UK NHS setting

(d) Some parameters estimated by expert consensus – conservative estimates were used. Model simplifies reality by reducing number of transitions between hearing aid use and non-use, but this has no significant effect on the results.

(e) 1998 Euros, presented here as 1998 UK pounds, converted using 1998 purchasing power parities[93]

15.2.2.2 Original cost-effectiveness analysis – summary

An original health economic model was constructed in order to conduct cost–utility analysis for this question and the review question regarding early versus delayed management of hearing loss (see chapter 8). These questions were agreed by the guideline committee to be the highest priorities for original economic analysis in this guideline due to the very large number of people using or potentially eligible for hearing aids, and the lack of existing health economic research in this area.

Full details of the analysis can be found in appendix N. It included a comparison between a cohort of people given a hearing assessment and offered hearing aids, if eligible, immediately after first presenting with hearing difficulties (early treatment) and a cohort who never undertook a hearing assessment and were never offered hearing aids (no treatment).

The base case probabilistic results, reflecting the costs and outcomes for men aged 65 at the start of the analysis over a lifetime horizon, are in Table 86.

Table 86: Results of hearing aids (early) versus no hearing aids, base case

Comparator	Cost	Incremental cost	QALYs	Incremental QALYs	ICER (£/QALY)
No treatment	£37	-	7.59	-	
Early treatment	£1,576	£1,539	7.96	0.37	**£4,167**

Sensitivity analysis found these results to be robust to variations in all the parameters investigated in the analysis, including the age of the participants at the start of the analysis, their sex, the proportions not suitable for hearing aids or who decline to use hearing aids, rates at which participants stop using hearing aids, and the magnitude of improvement in quality of life caused by hearing aid use: the ICER was below £8,500 per QALY gained in every case.

15.2.3 Evidence statements

Clinical

- There was a clinically important benefit of hearing aids for hearing-specific health-related quality of (HHIE; moderate quality evidence, 3 studies), overall health-related quality of life as measured by the WHO Disability Assessment Schedule II scale and the Self-evaluation of Life Function (moderate quality evidence, 2 studies), for overall listening ability as measured by the profile of hearing aid performance and the APHAB (moderate quality evidence, 2 studies).
- There was no clinically important difference in health-related quality of life as measured by self-evaluation of life function (low quality evidence, 1 study).
- No evidence was found comparing hearing aids to an active control (information or education only, listening tactics and communication training; assistive listening devices; or auditory training) or for the outcomes of pain or noise-induced hearing loss.

Economic

- One cost–utility analysis found that hearing aids were cost effective compared with no hearing aids for managing hearing loss (ICER: £11,555 per QALY gained). This analysis was assessed as partially applicable with potentially serious limitations.
- One original cost–utility analysis found that hearing aids were cost effective compared with no hearing aids for managing hearing loss (ICER: £4,167 per QALY gained). This analysis was assessed as directly applicable with minor limitations.

15.2.4 Recommendations and link to evidence

Recommendations	**25. Offer hearing aids to adults whose hearing loss affects their ability to communicate and hear, including awareness of warning sounds and the environment, and appreciation of music.**
Relative values of different outcomes	The following outcomes were identified as critical outcomes for this review: hearing-specific health-related quality of life (key domain: participation) and the specific adverse event of pain. Important outcomes included health-related quality of life, listening ability and the specific adverse event of noise-induced hearing loss.
Quality of the clinical evidence	The quality of the evidence was moderate for hearing-specific health-related quality of life and for health related quality of life and very low for the outcomes relating to adverse events (pain and noise induced hearing loss). All of the outcomes were downgraded for a high risk of bias. This was mainly due to a high risk of selection, performance or detection biases. These biases are widely acknowledged to be problematic within hearing aid intervention studies as the blinding of patients and outcome assessors can be difficult to achieve. [30, 31] One of the studies had a follow-up period of 6 weeks but the committee agreed that the evidence should not be downgraded for indirectness as there is unlikely to be a significant clinical difference between a 6 week follow-up and an 8 week follow-up as specified in the protocol. For the outcome of hearing-specific health-related quality of life where participation is the key domain, moderate quality evidence showed that hearing aids had a large beneficial effect in reducing participation restrictions. There were significant differences in the size of effects across studies. The effects reported by 2 studies in Veterans' Administration settings were similar but more than twice the size of the effect reported by the third study which was set in a university hospital clinic. However, all 3 studies individually reported large beneficial effects that favoured hearing aids, meaning that while further evidence may change the size of the overall effect on hearing-specific health-related quality of life, there is high confidence in the magnitude and direction of the effect. For the outcome of health-related quality of life as measured by the WHO Disability Assessment Schedule II (WHO-DAS II) scale 1 study showed a significant benefit of hearing aids compared with placebo or no hearing aids. Using the Self-evaluation of Life Function, another study found no significant beneficial effect of hearing aids. Overall, moderate quality evidence showed a small overall beneficial effect of hearing aids. For listening ability, moderate quality evidence showed a large beneficial effect of hearing aids compared with unaided/placebo conditions based on 1 study that used the APHAB and another study that used the PHAP. The planned subgroup analyses (age, sex, and degree of hearing loss) could not be performed as data from these subgroups were not reported. No evidence was found comparing hearing aids to an active control (information or education only, listening tactics and communication training; assistive listening devices; or auditory training) or for the outcomes of pain or noise-induced hearing loss.
Trade-off between clinical benefits and harms	The committee noted the limitations of the studies but agreed that the evidence demonstrated that people with mild to moderate hearing loss benefitted from having hearing aids as this improved their listening ability and quality of life. The committee acknowledged the difference hearing aids can make by enabling people to participate in everyday situations and the impact this can have in improving the quality of life for people with hearing difficulties. The committee agreed that having hearing aids at an early stage of their hearing loss enables people to adjust more easily to using the aids. The committee is aware that people are often reluctant to seek help or are slow at identifying a difficulty. There is

	evidence that people have not been referred for further assessment when hearing loss is first suspected (see also chapter 8 on early versus delayed management of hearing loss).[28] The committee noted that reporting for mild and moderate hearing loss had not been clearly separated in the studies.
Trade-off between net clinical effects and costs	One published economic evaluation was identified for this question. This measured the benefit to quality of life in 78 patients given hearing aid(s) for the first time and used this benefit in a lifetime model of hearing aid use. It found that hearing aid use was cost effective compared with no hearing aids at a cost-effectiveness threshold of £20,000 per QALY gained (ICER: £11,555 per QALY gained). However, the committee noted that the costs used in the study differed from current UK costs: in particular the cost used for hearing aids was much higher than UK costs. It also assumed a much longer time between replacement of hearing aids (at least 8 years), and a lower rate of fitting of 2 hearing aids (only 25%) than currently expected in the UK. Consequently the results of this analysis cannot be relied upon to relate to the current UK context. The committee therefore also considered the relevance of the original economic modelling conducted for the early versus delayed management question in this guideline. By comparing both of the intervention arms ('early' and 'delayed') against the no treatment arm, the benefit of referring for assessment and, where suitable, prescribing and fitting hearing aids is demonstrated. This analysis showed that either early or delayed fitting of hearing aids would be highly cost effective compared with no treatment at the NICE cost-effectiveness threshold of £20,000 per QALY gained, with ICERs of £4,167 per QALY and £4,421 per QALY respectively. The original modelling was not able to look into the effect of using different hearing loss thresholds, as there is no comparative evidence on the benefit to quality of life of improving hearing for people with different levels of hearing loss. However, sensitivity analysis which dramatically reduced the benefits of hearing aids for the whole population, and sensitivity analysis that increased the proportion of people either not suitable for hearing aids or dropping out after being fitted with hearing aids indicate that even if those people with lower levels of hearing loss benefit by a smaller amount than the average benefit expected in the model, the intervention would still be very cost effective overall. In addition, the committee noted that there is no standard universal definition of hearing loss. While the BSA criteria fit best with current understanding and practice in the UK, in the Cochrane review the international WHO classification was used. The committee agreed that decision-making on whether to fit hearing aids should not be based on a threshold measurement alone but on a combination of hearing measurement and communication difficulties. The committee therefore agreed that audiologists should be able to use their expertise to assess whether a person would benefit clinically from using hearing aid(s) due to their hearing loss, and if so they should offer hearing aid(s) and discuss this with the person. The committee agreed that provision of hearing aids to all who would benefit from them will be cost effective at a cost-effectiveness threshold of £20,000 per QALY gained.
Other considerations	The committee acknowledged that there is variation across the UK in whether people with mild to moderate hearing losses receive hearing aid(s) and consider that the decision to fit should be based on need rather than on hearing thresholds. Furthermore, as amplification has been shown to have benefit and is cost effective, hearing aids should be offered at the first opportunity if the individual is likely to benefit. The committee expressed concern that not providing hearing aids, and the care needed to use them effectively, to a person with an aidable hearing loss, raises serious questions of inequality of access. Hearing aids can make a difference to the ability of a person with hearing loss to communicate effectively and can thus reduce the impact of their impairment. Their impairment is permanent and even a mild

	hearing loss can have a significant effect on day-to-day functioning. The NHS England commissioning framework for adult hearing loss provides guidance on how high quality audiology services and pathways can be designed.[86]

15.3 Review question: What is the clinical and cost effectiveness of fitting 1 hearing aid compared with fitting 2 hearing aids for people when both ears have an aidable hearing loss?[a]

For full details see review protocol in appendix C.

Table 87: PICO characteristics of review question

Population	Adults age 18 years and over with bilateral hearing loss, where both ears would be suitable for amplification
Intervention	2 hearing aids (bilateral)
Comparison	1 hearing aid, aid fitted to either the right or left ear (unilateral)

Outcomes	**Critical outcomes:**
	• Hearing-specific health-related quality of life
	  ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA)
	  ○ Quantified Denver Scale of Communication (QDS)
	  ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS)
	  ○ Any questionnaire not specified above that is relevant
	• Health-related quality of life
	  ○ Health Utilities Index Mark 3 (HUI-3)
	  ○ EQ-5D
	  ○ SF-36
	  ○ Glasgow Benefit Inventory (GBI)
	  ○ WHO Disability Assessment Schedule (WHODAS)
	  ○ Self-Evaluation of Life Function (SELF)
	  ○ Any questionnaire not specified above that is relevant
	• Listening ability
	  ○ Abbreviated Profile of Hearing Aid Benefit (APHAB)
	  ○ Speech, Spatial and Qualities (SSQ) Hearing Scale
	  ○ Glasgow Hearing Aid Benefit Profile (GHABP) disability subscale
	  ○ Any questionnaire not specified above that is relevant
	• Device Orientated Subjective Outcome Scale
	• Outcomes reported by carer or 'communications partner'
	• Patient preference
	
	Important outcomes:
	• Usage of hearing aids (including data logging and self- report)
	• Adverse effects, such as pain, infection
	• Annoyance scale in patient reported outcome measures
	• Sound localisation as measured by laboratory test
	• Speech in noise detection as measured by laboratory tests

[a] This review was developed in collaboration with Cochrane.

Study design	RCT Systematic review of RCTs If no RCTs or systematic reviews of RCTs are identified we will include prospective or retrospective (data bases) cohort studies and case–control studies with multivariate analyses that adjust for the following key confounders: • Age • Hearing (loss) level • Types of devices • Degree of asymmetry

No minimum duration of hearing aid use or follow-up was applied as an inclusion criteria to consider studies for review. However, evidence was downgraded for indirectness of evidence if participants had used the hearing aids for 6 weeks or less. The rationale is a period of adjustment is important before the full effects of hearing aid fitting can be properly observed and evaluated.

15.3.1 Clinical evidence

Four studies (5 papers) were included in the review[26, 41, 108, 119 47] these are summarised in Table 88 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 88). See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

Table 88: Summary of studies included in the review

Study	Population	Intervention and comparison	Outcomes	Comments
Cox 2011[26] (n=94/100)[(a)]	• Symmetrical bilateral [(b)] hearing loss pure tone average (0.5, 1, 2 kHz) 30–80 dB HL • No preference, most were new patients • 51–83 years old • No exclusion for tinnitus	Bilateral versus unilateral (either side) – digital hearing aids	Preference	• Crossover study – USA • "subjects were paid for their participation"
Vaughan-Jones1993[119] (n=55/64)	• Mean pure tone thresholds (0.25, 0.5, 1, 2, 4, 8 kHz) worse than 25 dB HL • Never used hearing aids • 45% had tinnitus • 40–83 years old	Bilateral versus unilateral (either side) – "standard range of NHS hearing aids"	Preference	• Crossover study • UK – Scotland
Stephens1991[108] (n=29/38)	• Pure tone average (0.5, 1, 2, 4 kHz) ≥30 dB in better ear – Never used hearing aids • 50–65 years old • No exclusion for tinnitus	Bilateral versus unilateral (preferred side) – UK NHS BE18 post-aural HA	Preference	• Crossover study - Wales
Erdman1981 (n=30/30) [41]	• Noise induced hearing loss in 23 subjects, 7 had a flat hearing loss	Bilateral versus unilateral, hearing aids used not	Preference	• US Military personnel • Washington DC

Study	Population	Intervention and comparison	Outcomes	Comments
	• 23–58 years old • No exclusion for tinnitus	described		• Quasi alternation • Crossover study

(a) (n=x/y) denotes that x participants completed/provided data from analysis out of y participants recruited
(b) "Symmetric bilateral" not defined in study. The other studies had not excluded patients with asymmetric hearing loss, but it is unclear what percentage of patients had asymmetric hearing loss and the magnitude of asymmetry was not reported.

Table 89: Clinical evidence summary: Bilateral versus unilateral hearing aids

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with one hearing aids	Risk difference two hearing aids
Patient preference	178 (4 studies) 1 day to 10 weeks for each phase.	VERY LOW[a,b,c] due to risk of bias, indirectness and imprecision		Preference for bilateral HA Study 1: 54% (51/94) – crossover, 2:1 randomised to monoaural Study 2: 40% (22/55) – crossover, 2:1 randomised to monoaural Study 3: 55% (16/29) – crossover Study 4: 77% (23/30) – crossover	
Usage of hearing aids (including data logging and self- report)	56 (1 study) 10 weeks in each phase (total 30 weeks)	VERY LOW[a,b,c] due to risk of bias, indirectness and imprecision		"often or all the time": 84% of responses in monoaural hearing aid phase	"often or all the time": 28% of responses
Sound localisation as measured by patient questionnaire (improved, no difference, worse)	56 (1 study) 10 weeks in each phase (total 30 weeks)	VERY LOW[a,b,c] due to risk of bias, indirectness and imprecision		"better when monoaurally aided"	"18% found localisation worse when binaurally aided than when unaided"
Speech in noise detection as measured patient questionnaire (improved, no difference, worse)	56 (1 study) 10 weeks in each phase (total 30 weeks)	VERY LOW [a,b,c] due to risk of bias, indirectness and imprecision		65% reported "improvement" in monoaural HA	43% reported "worse than when unaided"

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with one hearing aids	Risk difference two hearing aids
b Downgraded by 1 or 2 increments because the majority of evidence was from an indirect time-point c Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs					

Table 90: Summary of preferences results

Study	Prefer bilateral	Reasons for preference	Comments
Cox 2011[26]	54% (51/94)	Bilateral – Balance, quality, comfort ("more capable, secure, relaxed and safe")	2:1 randomisation to unilateral. Study investigated predictors using logistic regression. Four factors can predict with 66% accuracy.
		Unilateral – Comfort ("feeling more normal and free, not closed in, plugged or cut off"), quality, meets need (good enough);	
Vaughan-Jones 1993[119]	39% (22/56)	Not reported.	2: 1 randomisation to unilateral No "association" was found between age, sex, pure tone audiometry and tinnitus. Appropriateness of statistical test used and power to detect association uncertain.
Stephens 1991[108]	55% (16/29) reported for people for completed study 22/41 (54%) reported in paper of 10 year follow-up among people who had been screened	Bilateral - Acoustical reasons; clarity, localisation, loudness.	Reported worse hearing ability as measured using SHHI and audiometry in both and the worse ear as predictors of binaural choice, but appropriateness of statistical analysis uncertain.
		Unilateral – convenience, acoustical, psychological, others	
Erdman 1981[41]	77% (23/30)	Bilateral – "I can hear better", "I can hear more easily".	

15.3.2 Economic evidence

15.3.2.1 Published literature

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

15.3.2.2 Original cost-effectiveness analysis

This analysis uses the same costs as used in the cost–utility analysis conducted for this guideline – please see appendix N for sources and further details. The committee agreed that the resources required for a hearing aid for the second ear (above those that would be required for a first hearing aid for 1 ear only) would be the cost of the hearing aid itself, a mould or thin tube and dome, and batteries. In addition, the committee cautiously assumed that people with 2 hearing aids would obtain 1 additional aftercare appointment each year for hearing aid repairs and maintenance compared with people with 1 hearing aid (for example, if people with 1 hearing aid accessed 1 aftercare appointment per year, people with 2 hearing aids might access 2 aftercare appointments per year). The committee agreed that this is likely to overestimate the differential demand for aftercare. It is perhaps more likely that people with 2 hearing aids would access aftercare services a similar number of times, but may require more inputs (such as repairs) during each appointment. However, the committee wished to be cautious in not risking underestimating costs, and so chose to assume that there would be an additional aftercare appointment each year, to represent the maximum possible difference in costs between 1 hearing aid and 2 hearing aids being fitted.

There will be no difference in costs for fitting or follow-up appointments, as an individual will have the same number of appointments whether they are having 1 or 2 hearing aids fitted. This analysis considers a period of 3 years, as that is expected to be the shortest length of time hearing aids would usually be kept before an individual's hearing is reassessed and they may receive new hearing aid(s). (See also the recommendations regarding follow-up in section 17.3.4. The committee has not recommended a particular frequency of reassessment, and this could be longer than 3 years.) The costs are shown in Table 91.

Table 91: Additional costs of supplying a second hearing aid for an individual's second ear

Equipment	Cost each	Cost per 3 years
Hearing aid, average cost	£70.96	£70.96
Cost of mould or thin tube and dome, average	£2.81	£2.81
Batteries, per year	£3.63	£10.88
Aftercare appointment	£29.81	£89.43
TOTAL		**£174.08**

It should be noted that the total 3-year cost of £174 is not intended to be a true reflection of the average difference in costs of fitting 1 or 2 hearing aids in a person with bilateral hearing loss, and so this should not be taken as a saving that would be expected if people were given only 1 rather than 2 hearing aids. This figure has been calculated as an upper limit of the potential difference, to ensure that the further calculations below are conservative, and tend towards underestimating rather than overestimating the cost effectiveness of the approach being studied. This difference can be compared against the difference in the NHS England non-mandatory tariffs for fitting 1 or 2 hearing aids. These were £294 compared with £388, a difference of £94, in 2011/12 when the tariff included the costs of 3 years of aftercare.[86] These tariffs have since been withdrawn. Local areas have their own tariffs, and in most cases these are lower than the former NHS England tariff for both 1 and 2 hearing aids. Whilst costs will differ depending on locally implemented delivery pathways, this

indicates that £174 is certainly an upper bound for the difference in costs, and higher than would reasonably be expected.

To calculate the threshold for the improvement in utility (quality of life) that would be necessary to make this expenditure cost effective at a cost-effectiveness threshold of £20,000 per QALY gained, we need to divide the total cost of £174.08 by £20,000.

This gives a utility increment of 0.0087 QALYs (or, alternatively, 3.2 quality-adjusted life days) over a period of 3 years, or **0.0029 QALYs per year**.

There are no published figures for the improvement in utility to be expected by adding a second hearing aid. However, there are figures for the improvement caused by the adoption of hearing aid(s) by people with hearing loss who previously did not have any hearing aids. As discussed in greater detail in appendix N, the committee has agreed that the most appropriate source for this measurement is the study by Barton 2004 using the HUI3 tool which gave this improvement in utility as 0.060 QALYs.[11]

0.0029 QALYs is 4.8% of 0.060 QALYs.

So if we compare the benefit gained by someone with hearing loss who previously had no hearing aids and adopts hearing aids (0.060 QALYs) with the benefit required by someone with hearing loss in both ears who currently has 1 hearing aid and is now adopting a second hearing aid (0.0029 QALYs) we find that the second person would need to benefit by at least 5% (a twentieth) as much from their second hearing aid as the first person benefits from their hearing aids for this to be cost effective at a cost-effectiveness threshold of £20,000 per QALY gained.

15.3.3 Evidence statements

Clinical

- There was insufficient evidence to determine if there was a clinically important benefit of using 2 hearing aids compared with 1 hearing aid for the outcomes of patient preference (very low quality evidence, 4 studies), usage of hearing aids, sound localisation and speech in noise detection (very low quality evidence, 5 studies).
- There was no evidence for any of the other outcomes of interest.

Economic

- No relevant economic evaluations were identified.

15.3.4 Recommendations and link to evidence

Recommendations	**26. Offer 2 hearing aids to adults with aidable hearing loss in both ears. Explain that wearing 2 hearing aids can help to make speech easier to understand when there is background noise, make it easier to tell where sounds are coming from, and improve sound quality.** **27. For adults with hearing loss in both ears who chose a single hearing aid, consider a second hearing aid at the follow-up appointment.**
Relative values of different outcomes	The following outcomes were identified as critical for this review: hearing-specific health-related quality of life, health-related quality of life, listening ability, outcomes reported by carers or 'communications partner' and patient preference. Important outcomes agreed were usage of hearing aids (including from data logging and self-reported), adverse effects (pain, infection), annoyance scale in patient

	reported outcome measures, sound localisation as measured by laboratory tests and speech in noise detection as measured by laboratory tests.
Quality of the clinical evidence	The quality of evidence for all outcomes reported was very low. This was mainly due to the following: • Risk of bias because none of the studies had described methods of randomisation and allocation concealment methods, and because of lack of blinding of assessors and no indication that outcome measures were validated. One study used alternation (quasi-randomised), whereas 2 other studies did not describe sequence generation method. Risk of detection bias from lack of blinding is high because the outcome was subjective. In addition 3 of these studies did not describe the protocols for fitting. • Imprecision due to small sample sizes. • Indirectness as the largest study randomised participants to 1 week phases of each fitting before asking patients to use the hearing aids as they liked for another 9 weeks, while another study only fitted patients alternately for 1 hour before trialling the other option. It was uncertain if the 1 week period is sufficient for patients to get used to the fitting. Evidence was available for patient preference and usage. Sound localisation and speech detection were also reported by 1 study. For the patient preference data, all studies asked patients which arrangement they preferred at the end of the trial. Two of these studies randomised patients to 3 groups, with 2 groups randomised to either the left ear or the right ear and 1 randomised to both ears. Therefore, the randomisation was 2:1 rather than 1:1. The direction of bias is uncertain. The third study randomised equal numbers of patients to bilateral and unilateral fitting before crossing these over, but all the participants in the study had chosen to be fitted with hearing aids unilaterally prior to randomisation. This indicates a potential bias favouring unilateral fitting, possibly due to a prior preference of participants or information received. The other study allocated people by alternation to 1 hour of bilateral and unilateral use each. For usage of hearing aids, although the 3 studies reported this outcome, data from 2 of these cannot be used because they reported the mean daily usage according to the preferred fitting by the participants rather than usage while being allocated to unilateral versus bilateral hearing aids. These results do not tell us whether someone will use hearing aids more when they are allocated 1 or 2 hearing aids. The information for usage, sound localisation and speech in noise detection was measured using a questionnaire at the end of each 10-week phase. It is uncertain if the questionnaire was validated and how the data were collected. It was impossible to blind outcome reporting, but unclear if the person collecting the data from the patient was a 'neutral' party or someone involved in delivery of the intervention. The potential benefits of speech in noise detection and sound localisation needed to be measured against the overall benefit from using the hearing aids, such as quality of life. However, there were no data for this. It was noted that the evidence was from very old studies conducted over 20 years ago when most hearing aids were likely to be either analogue or much less technologically advanced. This may have influenced the ability of the patients to use them and may have affected their preferences. In addition, as attitudes and beliefs change over time, this may also influence patient preference and this may impact the applicability of results derived from studies conducted many years ago. Due to the very low quality of the evidence and the uncertainty around it as well as the lack of evidence for many of the outcomes of interest, it was difficult to ascertain whether there was a clinically important benefit of fitting 2 hearing aids compared with 1 hearing aid.

Trade-off between clinical benefits and harms	Three studies reported that the preference for unilateral versus bilateral fitting of hearing aids was roughly divided equally, while another study suggested more people had a preference for bilateral hearing aid fitting. The only study that provided more information to suggest some benefits of unilateral fitting (in terms of usage, sound localisation and speech in noise detection) was also the study that had a higher preference for unilateral fitting (60%). Of patients with an initial preference for a unilateral hearing aid, 40% changed their mind after trying bilateral hearing aids. The committee noted that current practice, based on the NHS England commissioning framework,[86] is to prescribe and fit hearing aids bilaterally when there is a bilateral aidable hearing loss. The clinical experience of the group corroborates the potential benefit of bilateral fitting of hearing aids for restoring binaural hearing, although no evidence was identified to support this. There is, however, evidence that shows 2 ears are better than 1 and also laboratory evidence showing the benefit of 2 hearing aids. In the absence of good quality evidence with direct applicability, the committee decided to reinforce current practice in the recommendations, though also highlighting the importance of patient choice. The studies were all of a short duration and the group considered that these timings were not long enough for people to make an informed choice. Adequate time (with appropriate information) needs to be given to enable people to get used to wearing hearing aids, along with a follow-up appointment to provide any adjustments to the devices and support to enable continued usage. The committee agreed that bilaterally worn hearing aids have the potential to facilitate communication as sound quality may be better than with a unilaterally worn hearing aid. The impact on family and carers' ability to communicate with the person also needs to be considered. The committee also considered the balance of benefits and potential disadvantages of binaural stimulation. The benefits include improved: intelligibility of speech in background noise, sound localisation, and sound quality. It also has the potential to avoid deficits that may develop over time if only 1 hearing aid is fitted and the unaided ear is deprived of stimulation. The NHS England commissioning framework notes that "Fitting of bilateral hearing aids is beneficial as many modern hearing aids interact with each other to offer greater improvement in speech discrimination in everyday environments". On the other hand, potential disadvantages of bilateral fitting include additional cost (to the NHS), a perception from some that 2 devices may be too complex for some people to use, and, for a few, binaural interference (that is, reduced speech intelligibility compared with performance with a single device).
Trade-off between net clinical effects and costs	No published health economic evaluations were identified for this question. The committee noted a lack of clear clinical evidence, and so the effect on quality of life could not be quantified. However, the committee is aware of the basic scientific research that demonstrates the acoustic advantage of wearing 2 hearing aids and noted that the NHS commissioning framework recommends that providing 2 hearing aids should be standard practice. An original cost threshold analysis was therefore undertaken to consider the difference in costs between prescribing and fitting hearing aids unilaterally and bilaterally. The number of appointments and time taken to prescribe and fit hearing aids would not differ significantly between the process of fitting a single hearing aid and that for fitting 2 hearing aids bilaterally. There would however be increased costs for a second hearing aid (average £71), associated mould or thin tube and dome (£3) and batteries (£4 per year). For the purpose of this analysis the committee assumed that the hearing aid would be used for 3 years before being replaced, and that the user would seek 1 extra aftercare appointment for hearing aid maintenance (£30) each year. This gives a total additional cost of £174 over 3 years for providing a second hearing aid. When compared with the NICE cost-effectiveness threshold of £20,000 per QALY

	gained, this means that to be cost effective the addition of a hearing aid for the second ear would need to lead to an average increase in health-related quality of life of 0.0029 QALYs per year during the 3 years in which it is in use. This is equivalent to 4.8% of the benefit (0.06 QALYs per year) conferred by hearing aid use compared with no hearing aid use found by Barton 2004,[11] which was used as the basis of the calculation of quality of life gain in the original economic modelling for this guideline (appendix N). That is, if the benefit of adding the second hearing aid is 5% or more of the benefit found from using hearing aids compared with using none, then it is cost effective to provide 2 hearing aids. The committee was confident that the benefits of bilateral hearing would be considerably greater than this threshold, and hence bilateral hearing aids would be cost effective. The committee also noted that the original economic modelling for this guideline assumed that all people receiving treatment would have bilateral hearing loss and be provided with 2 hearing aids, and on this basis both early and delayed provision of hearing aids were found to be highly cost effective compared with no hearing aid use at a cost-effectiveness threshold of £20,000 per QALY gained. As a result the committee agreed to recommend that the current practice of offering 2 hearing aids to people with hearing loss in both ears should be continued.
Other considerations	In 1 study the population was made up of military personnel and the committee noted that some people would have concerns about any impact hearing loss might have on their employment and career opportunities and may base their choices on these factors. The committee noted that some people who initially opt to have a unilateral hearing aid would later be willing to undergo a trial of a second hearing aid in the other ear – either due to a change of mind or due to deteriorating hearing. The need for follow-up was also identified as one of the main findings that is important to people with hearing loss (see section 12.2.4). The recommendations highlight the importance of follow-up for continued use of hearing aids. People should be offered the opportunity to either add or reject a hearing aid after trying out the option they initially chose. The committee noted evidence from 1 study following up people 12 years after they first had hearing aids fitted, which found that agreeing to have 2 hearing aids fitted rather than only accepting 1 hearing aid was strongly associated with an increased chance that the person would still be using hearing aids 12 years later.[28] Although the NHS England commissioning framework recommends prescribing and fitting 2 hearing aids for bilateral hearing loss,[86] the committee highlighted anecdotal evidence indicating variation in practice geographically with some areas of the country routinely initially prescribing 1 hearing aid. The committee was concerned with this approach and emphasised that prescribing 2 hearing aids is cost effective compared with prescribing 1 hearing aid.

16 Hearing aid microphones and noise reduction algorithms

16.1 Introduction

The most common complaint of adults with hearing loss is difficulty understanding speech in the presence of background noise or competing speech. Because hearing aids cannot improve deficits in frequency, temporal and spatial resolution, an adult with hearing loss may continue to experience some difficulties, even when wearing hearing aids. The perception, and acceptance, of hearing aids is likely to be improved if they can be shown to improve listening to speech in the presence of background noise.

One hearing aid option that has been developed to distinguish speech from noise, and improve the speech-to-noise ratio (SNR), is the implementation of directional microphones. In contrast to omnidirectional microphones, which respond equally well to sounds arriving from all directions, a directional microphone is more sensitive to sounds from one direction (for example, speech coming from directly in front of the hearing aid user) and less sensitive to other directions (for example, background noise from the side or behind the hearing aid user). Directional microphones have the potential to benefit all hearing aid users. A disadvantage is that the signal of interest to the hearing aid user may come from a location where the microphone is least sensitive (for example, from behind). Modern hearing aids generally have microphones that can be enabled as omnidirectional or directional, usually involving the user selecting a different setting or programme on the hearing aid. Directional microphones have been shown to be efficacious in the research laboratory although their effectiveness in the real world is less clear.

Background noise can be reduced using adaptive (or digital) noise reduction. The aim of a hearing aid that has adaptive noise reduction is to provide less amplification to noise than to speech. This is achieved by identifying the frequencies (or time) where noise is particularly intense, relative to speech, and applying less amplification. Since the noise and the signal will be reduced in this frequency range, the speech-to-noise ratio remains unchanged, but there is the potential to improve listener comfort, reduce listening effort and achieve sustained performance throughout the day. Again, users often have the option of enabling or disabling the noise reduction setting on the hearing aid by selecting a different listening programme.

The benefits of directional microphones and adaptive noise reduction are based largely on theoretical advantages and studies of efficacy. The intention of this chapter is to review the evidence on the clinical and cost effectiveness of these hearing aid technologies and to develop recommendations for their use in adults with hearing loss.

16.2 Review question: What is the clinical and cost effectiveness of directional versus omnidirectional microphones?

For full details see review protocol in appendix C.

Table 92: PICO characteristics of review question

Population	Adults aged 18 and over with hearing loss who use hearing aids
Interventions	Hearing aids with directional microphones (usually amplifying sound that is coming from directly in front) - also known as dual microphones
Comparisons	Hearing aids with omnidirectional microphones (amplifying sound from all directions) Disabled directional (that is, omnidirectional)

Outcomes	**Critical:** • Speech recognition in noise • Ease of listening or listening effort (objective or self-reported) • Hearing-specific health-related QoL ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant **Important:** • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment and education ○ Health-related quality of life: - Health Utilities Index Mark 3 (HUI-3) - EQ-5D - SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) • Listening ability ○ Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities (SSQ) Hearing Scale ○ Glasgow Hearing Aid Benefit Profile (GHABP) disability subscale ○ Any questionnaire not specified above that is relevant • Safety for example lack of awareness of environmental noise as an adverse effect • Adherence
Study design	Systematic review of RCTs and RCTs

16.2.1 Clinical evidence

A search was conducted for systematic reviews and randomised controlled trials comparing the effectiveness of hearing aids with directional microphones versus hearing aids with omnidirectional or disabled microphones to improve listening for adults with hearing loss in the presence of background noise.

One study was included in the review;[103] and is summarised in Table 93 below. Evidence from this study is summarised in the clinical evidence summary below (Table 94). See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L.

The aim of the study was to determine the impact of hearing aids with directional microphones on self-perceived localisation disability and concurrent handicap among older individuals with impaired hearing.

Table 93: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Ruscetta 2007	Hearing aids with directional microphone	n=57	Adjusted mean total scores (and p-values) at 3 months post-fitting (end of	Gender proportions, average age, average duration of hearing

Study	Intervention and comparison	Population	Outcomes	Comments
	(DIM) Hearing aids with omnidirectional microphone (ODM)	60–75 year olds with moderate, symmetrical, bilateral sensorineural hearing loss	intervention period): Self-perceived level of ability to tell the direction of sounds (localisation disability) (n=19)[a] Self-perceived amount of withdrawal from activities of daily living (localisation handicap) (n=19)[a]	loss and duration of hearing loss range were given for each intervention group but no other baseline characteristics were provided and any differences between the groups were not investigated.

[a]*The study applied three intervention groups with hearing aids (n=57 in total; 19 in each group) and one control group with no hearing aids (n=57). Only 2 of the intervention groups were relevant to this review and are therefore presented.*

Table 94: Clinical evidence summary: Directional microphones compared with Omnidirectional microphones for hearing loss

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Omnidirectional microphones	Risk difference with Directional microphones (95% CI)
Self-perceived level of ability to tell the direction of sounds (localisation disability)	38 (1 study) 3 months	VERY LOW[a,b] due to risk of bias, imprecision		The mean self-perceived level of ability to tell the direction of sounds (localisation disability) in the control groups was 3.06	The mean self-perceived level of ability to tell the direction of sounds (localisation disability) in the intervention groups was 0.08 lower (67.97 lower to 67.81 higher)
Self-perceived amount of withdrawal from activities of daily living (localisation handicap)	38 (1 study) 3 months	VERY LOW[a,b] due to risk of bias, imprecision		The mean self-perceived amount of withdrawal from activities of daily living (localisation handicap) in the control groups was 3.92	The mean self-perceived amount of withdrawal from activities of daily living (localisation handicap) in the intervention groups was 0.05 higher (12.66 lower to 12.76 higher)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias or by 2 increments if the majority of the evidence was at very high risk of bias.
[b] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

16.2.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

16.2.3 Evidence statements

Clinical

Directional compared with omnidirectional microphones

- There was no clinically important difference in localisation disability and localisation handicap (very low quality evidence, 1 study).

Economic

- No relevant economic evaluations were identified.

16.2.4 Recommendations and link to evidence

Recommendations	**28. When prescribing and fitting hearing aids, explain the features on the hearing aid that can help the person to hear in background noise, such as directional microphone and noise reduction settings.** **29. Advise adults with hearing aids about choosing microphone and noise reduction settings that will meet their needs in different environments, and ensure that they know how to use them.**
Relative values of different outcomes	The guideline committee agreed that the following critical outcomes should be included in the review: speech recognition in noise, ease of listening, and hearing-specific health-related quality of life including the Hearing Handicap Inventory for the Elderly (HHIE). The committee agreed that the following important outcomes should be included in the review: outcomes reporting restricted participation or activity limitation and social interactions, employment and education, health-related quality of life including the Health Utilities Index Mark 3 (HUI-3), and other outcomes such as safety, adverse effects and adherence.
Quality of the clinical evidence	One study comparing hearing aids with directional microphones to hearing aids with omnidirectional microphones was included in this review. This study reported on 'localisation disability' defined as self-perceived level of ability to tell the direction of sounds, and on 'localisation handicap' defined as self-perceived amount of withdrawal from activities of daily living, at 3 months post-fitting. The committee considered the potential for hearing aids, particularly those with directional microphones to reduce localisation skills, relative to the unaided condition. There was a high risk of bias in the selection of participants, lack of blinding and imprecision. The participants' gender, average age, average duration of hearing loss and duration of hearing loss range are given. However comparability of these factors between groups has not been analysed and no other potential confounding factors have been explored. Therefore, the evidence for these outcomes was rated as very low. The committee noted that although the included paper was published in 2007, microphone technology has not improved in a significant way since then apart from some improvements in processors. Therefore, it was agreed that the evidence is still

	useful to consider.
Trade-off between clinical benefits and harms	Directional microphones have been shown to markedly improve the signal-to-noise ratio, compared with omnidirectional microphones, in many lab-based studies where the signal of interest is presented from directly in front of the listener and the noise is presented from other locations. The committee noted that there may be some occasions in real life when omnidirectional microphones may be more helpful such as being able to hear traffic approaching from different directions. No studies investigating signal-to-noise ratio in real life met the inclusion criteria. An important auditory ability is to localise sound. If hearing aids interfere with this ability this could result in a safety issue such as not being able to locate a warning sound. The evidence from the review is that hearing aids did not introduce localisation problems but there is a need for self-report to be verified empirically by directly measuring localisation abilities. The evidence from this review showed no difference between directional or omnidirectional microphones for the outcomes measuring ability to tell the direction of sounds, and activity limitation through withdrawal from activities of daily living, however the committee noted that the 1 study included in the review was very small and underpowered. Given the lack of evidence the committee was unable to recommend one type of microphone over another, but agreed it was important to highlight the benefits microphones can provide and the different settings for different situations and environments should be explained to people. The committee confirmed that all hearing aids provided through the NHS have both directional and omnidirectional microphones. Audiologists are able to activate the microphones when setting the hearing aid programmes for individuals' needs. Hearing aids have several programmes for different listening situations such as 'party' or 'quiet' and the microphone setting is an important factor. The hearing aid user can select different programmes once they have been activated by the audiologist. The audiologist also ensures that the user knows how and when to activate the settings. If the audiologist does not set up these microphone options when the hearing aid is first prescribed and fitted, a further face-to-face appointment will be required at a later date. The committee considered that some people may not be aware that there is capacity to change the microphone programmes available on their hearing aids or the different modes available in order to improve listening in different acoustic situations. Current good practice is to provide the person with information on the features available and to work with the person to select the appropriate programmes that meet individual needs. The committee also stressed that the follow-up appointment should include a review of the person's experience in using the microphone features and any changes required. The committee based its recommendations on its experience and knowledge.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The recommendations made for this review concern the content of advice given to hearing aid users in their fitting and follow-up appointments. These appointments are already necessary or recommended, and are discussed further in other chapters of this guideline. The nature of the advice given in these appointments will not give rise to any additional costs given that the appointments will be taking place and will be of fixed cost. The advice relates to the use of functions that can already be found on standard hearing aids prescribed in the NHS.

	Giving advice on how hearing aids can be used more effectively will increase the effectiveness of hearing aid use for no additional cost and so will be cost effective compared with not giving such advice, and may be cost saving if it reduces any need for additional subsequent appointments.
Other considerations	The committee stressed that directional microphones can be helpful for listening and speaking situations where filtering out sound around the person is needed.

16.3 Review question: What is the clinical and cost effectiveness of noise reduction algorithms?

For full details see review protocol in appendix C.

Table 95: PICO characteristics of review question

Population	Adults aged 18 and over with hearing loss who use hearing aids
Interventions	Digital or adaptive noise reduction algorithms
Comparisons	No noise reduction or noise reduction algorithm disabled
Outcomes	**Critical:** • Speech recognition in noise • Ease of listening or listening effort (objective or self-reported). *Note: These may be measured by self-report; behavioural measures of reduced processing load (for example, faster responses times when completing a listening task, or improved ability to multitask while listening; physiological measures such as lower skin conductance)* • Hearing-specific health-related quality of life ○ Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) ○ Quantified Denver Scale of Communication (QDS) ○ Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) ○ Device Orientated Subjective Outcome Scale ○ Any questionnaire not specified above that is relevant **Important:** • Any outcomes reporting: ○ Restricted participation or activity limitation ○ Social interactions, employment and education ○ Listening ability Abbreviated Profile of Hearing Aid Benefit (APHAB) ○ Speech, Spatial and Qualities (SSQ) Hearing Scale ○ Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale • Health-related quality of life ○ Health Utilities Index Mark 3 (HUI-3) ○ EQ-5D ○ SF-36 ○ Glasgow Benefit Inventory (GBI) ○ WHO Disability Assessment Schedule (WHODAS) ○ Self-Evaluation of Life Function (SELF) ○ Any questionnaire not specified above that is relevant • Safety (for example, lack of awareness of environmental noise as adverse effect) • Adherence
Study design	Systematic review of RCTs and RCTs

16.3.1 Clinical evidence

The aim of this study was to determine the impact of digital or adaptive noise reduction algorithms in a hearing aid without concomitant directional microphone use in both laboratory and field settings.

A search was conducted for randomised controlled trials that estimate the clinical effectiveness of noise reduction algorithms used to improve listening in the presence of background noise.

No studies were identified for inclusion in this review. See study selection flow chart in appendix E and the excluded studies list in appendix L.

16.3.2 Economic evidence

No relevant health economic studies were identified.

See also the health economic study selection flow chart in appendix F.

16.3.3 Evidence statements

Clinical

- No relevant clinical evidence was found.

Economic

- No relevant economic evaluations were identified.

16.3.4 Recommendations and link to evidence

Recommendations	**Please see the recommendations in section 16.2.4.**
Research recommendation	**What is the most suitable outcome measure to use when investigating the clinical and cost effectiveness of directional microphones and digital (adaptive) noise reduction?**
Relative values of different outcomes	The guideline committee considered the following outcomes to be critical for this review: ease of listening, reduced listening effort and hearing-specific health-related quality of life including the Hearing Handicap Inventory for the Elderly (HHIE). The following outcomes were considered important: speech recognition in noise, outcomes reporting restricted participation or activity limitation and social interactions, employment and education, health-related quality of life including the Health Utilities Index Mark 3 (HUI-3), and other outcomes such as safety, adverse effects and adherence.
Quality of the clinical evidence	No clinical evidence was identified.
Trade-off between clinical benefits and harms	A noise reduction mode is provided as standard on most hearing aids. A follow-up appointment may be required to adjust settings as individuals assess their needs in different environments. For example, a person living in a care home may require different settings to a person living in their own home. Having multiple settings is not appropriate for all people. Those who have physical or cognitive impairments may not be able to manage switching between settings. Hearing aid features should be set up based on individual need. As no evidence was found, the committee based its recommendations on its knowledge and experience of noise reduction features being underutilised in some cases. This is due to users not being aware of noise reduction functions available on

	their devices or not knowing how to use them. The committee noted that noise reduction algorithms are not helpful for all people. Some do not like the quality of the sound when noise reduction is turned on and therefore there is a trade-off between reducing overall sound level to improve listening comfort but losing other qualities of the sound. Since no evidence was identified for this clinical question, the committee agreed that further research is needed to assess the benefit of the noise reduction function and decided to make a research recommendation in this area.
Trade-off between net clinical effects and costs	No health economic evidence was identified for this question. The recommendations made regarding noise reduction algorithms can be found in the reviews regarding the use of microphones (section 16.2.4) and interventions to support the use of hearing aids (section 18.2.4). They concern the content of advice given to hearing aid users in their fitting and follow-up appointments. These appointments are already necessary or recommended, and are discussed further in other chapters of this guideline. The nature of the advice given in these appointments will not give rise to any additional costs given that the appointments will be taking place and will be of fixed cost. The advice relates to the use of functions that can already be found on standard hearing aids prescribed in the NHS. Giving advice on how hearing aids can be used more effectively will increase the effectiveness of hearing aid use for no additional cost and so will be cost effective compared with not giving such advice, and may be cost saving if it reduces any need for additional subsequent appointments.
Other considerations	The committee agreed that all hearing aids currently provided by the NHS have a noise reduction feature available. However, these need to be enabled by an audiologist. There are different modes of noise reduction available, which the audiologist will programme together with other features, for example directional or omnidirectional microphones. All hearing aid features should be set up with the individual and based on individual needs and preferences. The committee agreed that the option to review these settings following a trial period in the real world is important so that features can be adjusted, added or removed based on user experience .Functionality can be limited because the technology does not allow the user to be able to control or adjust modes themselves, and they need to seek help from audiology services.

17 Monitoring and follow-up

17.1 Introduction

Many people use hearing aids as part of the management of their hearing and communication needs. Hearing aids are usually fitted in a clinic setting by an audiologist who should also advise on the use and management of the device, as well as aspects of communication specific to the individual. Hearing aids should be programmed and functionality set to meet individual needs and capabilities.

Traditionally, after the hearing aid fitting there is a follow-up appointment. This follow-up enables: the individual to share their experience with the audiologist and for adjustments to be made, for the audiologist to provide further advice and support including onward referral to other agencies as required, for the audiologist to observe the correct fitting and handling of the device and for patient-reported outcome and experience measures to be obtained.

A follow-up appointment as part of the hearing aid fitting pathway is included within current recommended practice documents; for example, within the adult service model specification outlined within NHS England's 'Commissioning Services for People with Hearing Loss: A framework for clinical commissioning groups'.[86] Additional recommendations for good practice appear in the Welsh and Scottish quality standards for adult hearing rehabilitation.[90]

Despite this guidance, current provision of a follow-up appointment is variable across the UK with some services offering no follow-up appointment and no opportunity to re-access the service following the initial hearing aid fitting. Where a follow-up appointment is offered, these are sometimes face-to-face in clinic and sometimes over the telephone. It is also unclear as to the optimal timing for follow-up and if further long-term monitoring is of value.

The current guidance documents also indicate that people should be offered an appointment to reassess their hearing and communication needs 3 years following their previous assessment. However, this invitation for review currently varies depending on location and service provider and service users may be unaware that reassessment is an option. Exceptions may include groups of people who are considered suitable for reassessment for a specific reason, for example, people with dual sensory impairment or people with learning disabilities.

This chapter aims to explore the benefits of providing follow-up to those people with hearing aids and for the ongoing monitoring of people with identified hearing and communication needs who may or may not have hearing aids.

It was thought that most relevant papers would be likely to include both the 'when' and the 'how' aspects of follow-up and that the ensuing recommendations would reflect that. Therefore, this chapter includes 2 clinical questions for which a combined search strategy was used to identify relevant papers.

17.2 Review question 1: What is the most clinically and cost-effective method of delivery of monitoring and follow-up of people with hearing-related communication needs (including those with hearing aids)?

Table 96: PICO characteristics of review question 1

Population	Adults aged 18 and over presenting with hearing loss
Interventions and	Examples mode of delivery:

comparators	• Telephone • Email • face-to-face • questionnaire • online resources Compared with each other and to no follow-up or usual care
Outcomes	**Critical:** 1. Hearing-specific health-related quality of life • Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) • Quantified Denver Scale of Communication (QDS) • Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) • Device Orientated Subjective Outcome Scale • Any questionnaire not specified above that is relevant 2. Health-related quality of life • Health Utilities Index Mark 3 (HUI-3) • EQ-5D • SF-36 • Glasgow Benefit Inventory (GBI) • WHO Disability Assessment Schedule (WHODAS) • Self-Evaluation of Life Function (SELF) • HRQoL • Any questionnaire not specified above that is relevant 3. Listening ability • Abbreviated Profile of Hearing Aid Benefit (APHAB) • Speech, Spatial and Qualities (SSQ) Hearing Scale • Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale 4. Speech recognition in noise test 5. Usage of hearing aids (including data logging and self-report (if applicable) **Important:** 6. Social functioning or employment
Study design	RCT and systematic reviews of RCTs If not enough RCT evidence is found, cohort studies will be considered

17.3 Review question 2: When should people with hearing-related communication needs (including those with hearing aids) be monitored and followed up?

For full details see review protocols in appendix C.

Table 97: PICO characteristics of review question 2

Population	Adults aged 18 and over presenting with hearing loss
Interventions and	Short-term: less than 12 weeks

comparators	Medium term: 1 year Long-term: 3 years Compared with each other or to no follow-up if appropriate
Outcomes	**Critical:** 1. Hearing-specific health-related quality of life • Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) • Quantified Denver Scale of Communication (QDS) • Auditory Disability Preference – Visual Analog Scale (ADPI-VAS) • Device Orientated Subjective Outcome Scale • Any questionnaire not specified above that is relevant 2. Health-related quality of life • Health Utilities Index Mark 3 (HUI-3) • EQ-5D • SF-36 • Glasgow Benefit Inventory (GBI) • WHO Disability Assessment Schedule (WHODAS) • Self-Evaluation of Life Function (SELF) • HRQoL • Any questionnaire not specified above that is relevant 3. Listening ability • Abbreviated Profile of Hearing Aid Benefit (APHAB) • Speech, Spatial and Qualities of Hearing (SSQ) • Glasgow Hearing Aid Benefit Profile (GHABP) residual disability subscale 4. Speech recognition in noise test 5. Usage of hearing aids (including data logging and self-report (if applicable) **Important:** 6. Social functioning or employment
Study design	RCT and systematic reviews of RCTs

17.3.1 Clinical evidence

No clinical evidence was identified comparing different methods of follow-up and monitoring or different frequencies. See study selection flow chart in appendix E and the excluded studies list in appendix L.

17.3.2 Economic evidence

No relevant health economic studies were identified for either review question.

See also the health economic study selection flow chart in appendix F.

17.3.3 Evidence statements

Clinical

- No relevant clinical evidence was found.

Economic

- No relevant economic evaluations were identified.

17.3.4 Recommendations and link to evidence

Recommendations	**30. Offer adults with hearing aids a face-to-face follow-up audiology appointment 6 to 12 weeks after the hearing aids are fitted, with the option to attend this appointment by telephone or electronic communication if the person prefers.** **31. For adults with hearing loss who have chosen a management strategy other than hearing aids, such as assistive listening devices or communication strategies, offer a follow-up appointment when the effectiveness of the device or strategy can be evaluated.** **32. Tell adults with hearing loss who have chosen not to have a hearing aid or other device how to contact audiology services in the future.** **33. Consider having a system in place for recalling people with hearing devices for regular reassessment of hearing needs and devices.**
Research recommendation	**5. What is the clinical and cost effectiveness of monitoring and follow-up for adults with hearing loss post-intervention compared with usual care?**
Relative values of different outcomes	The following critical outcomes were included in this review: hearing-specific health-related quality of life including HHIE, QDS and Auditory Disability Preference – Visual Analog Scale (ADPI-VAS)., health-related quality of life including HUI-3, EQ-5D, Glasgow Benefit Inventory (GBI) and WHODAS., listening ability including APHAB, SSQ and GHABP, speech recognition in noise test, usage of hearing aids (including data logging and self-report if applicable). Outcomes reporting social functioning or employment were considered important outcomes.
Quality of the clinical evidence	No evidence was identified for inclusion in this review.
Trade-off between clinical benefits and harms	The committee made consensus recommendations based on its clinical knowledge and expertise. **Method of delivery of follow-up** Current recommended practice is to offer a follow-up appointment 6 to 12 weeks after fitting a hearing device and the committee considered it very important that people have this in order to assess how they are adapting to the hearing device and to resolve any difficulties or problems early. Not providing this service can result in people giving up using their hearing aids and may consequently have a negative impact on their quality of life over time as their ability to communicate and participate in everyday situations declines. The committee agreed that face-to-face follow-up appointments have traditionally been used, however either face-to-face or telephone appointments are currently permitted. The committee noted that for people who have been fitted with hearing aids a face-to-face appointment is preferable in order to check the fitting of the device and make any necessary adjustments (see section 18.2.4, interventions to support the use of hearing aids), and a telephone appointment would not be as

helpful. The committee further noted that ability to use the telephone is one of the issues that needs to be addressed by this appointment, precisely because many hearing aid users struggle with this, and so a substantial proportion of hearing aid users would be unable to use a telephone well at the time of the appointment.

The committee discussed the difficulties some people may have in attending audiology services in person for hearing assessments, fitting of hearing aids, demonstrating other listening devices and ongoing management. The committee acknowledged the inequalities in accessing audiology services for some populations, such as older people, those who live in residential care homes or those with learning disabilities. The committee noted a flexible approach in the delivery of hearing services is desirable to ensure such populations are not disadvantaged.

The committee discussed provision of follow-up appointments for people who opt to have other interventions such as assistive listening devices or other auditory support strategies rather than a hearing aid. However, it would not be possible to indicate a time frame when this should occur because this would be dependent on the intervention chosen and how long the user would need to use it for before a useful assessment could be made. However the committee agreed that a follow-up appointment should be discussed with the person and offered for a time when an evaluation could be made. This could be arranged over the phone or face-to-face at the clinic dependent on what was appropriate.

Some people may decline all interventions, in which case it was agreed by the committee that information on how to access audiology services again at a future point should be provided to the person in order that they can obtain further advice or reassessment when required.

Frequency of monitoring

The committee discussed the absence of any evidence on the frequency of monitoring. Currently there is no national automatic system to recall people for ongoing monitoring. Some local areas and some providers have their own systems that automatically recall people, most often every 3 years, but in some cases every 5 years. In other areas it is up to the individual to self-refer when they think they need their hearing reassessed or require assistance with their hearing device. Although the recommended practice provided by the NHS England model adult service specifications[85, 86] is that hearing needs should be reviewed 3 years after fitting a hearing device, and this fits in with the current funding model for some providers, the committee noted that there is variation in practice across the country. The committee is aware of a pilot study recalling people after 3 years that found that 100% needed minor interventions (such as repairs or advice) and 39% needed a major intervention (such as new hearing aids).[49] This study had no control group and did not compare with other recall frequencies, so it is not possible to determine the optimum recall frequency. This is however an important question.

The committee agreed that as no evidence was identified a research recommendation should be made to establish the clinical and cost effectiveness of monitoring and follow-up, and to understand how and when they might best be used in clinical practice. In the meantime, the committee was unable to recommend any particular frequency of monitoring. However, noting that automatic recall is already recommended by NHS England and is in place in some areas, and the risk that people not recalled may not receive any ongoing care after 12 weeks, the committee recommended that all providers consider implementing a recall system, with the frequency of recall being carefully considered at a local level. The committee agreed that this was particularly important for those who were unlikely to request a review such as those with mild cognitive impairment, dementia, learning difficulties and the elderly.

The committee agreed that it is important that all patients are aware of how to re-access audiology services when needed, and that health professional's update and maintain patient records to facilitate follow-up and ongoing monitoring of patients

	and to improve information sharing between health professionals. **Additional support** Some people have significant problems coming to terms with their hearing problems. These people may benefit from working alongside a hearing therapist or a psychologist to adjust to hearing loss, develop communication skills and manage the psychosocial challenges of hearing loss.
Trade-off between net clinical effects and costs	No health economic evaluations were identified specifically comparing methods of delivery of follow-up or different timings of follow-up. However, the committee noted that the economic evaluation identified for the review of interventions to support the use of hearing aids (section 18.2.2) addressed the cost effectiveness of implementing a single follow-up appointment after 6 months and suggested that this intervention was effective. The original economic modelling conducted for this guideline (see appendix N) assumed that a follow-up appointment would be included 6–12 weeks following hearing aid fitting, and the cost of that appointment (conducted by an audiologist) was included in the modelling, which found the whole pathway, including hearing assessment, hearing aid fitting and follow-up appointment, to be cost effective. As follow-up appointments are expected to increase the benefits gained by hearing aid use, by increasing the proportion of the time hearing aids are used successfully, such appointments are not just cost effective on their own, but are integral to making the whole process of hearing aid fitting and use cost effective, and so excluding this aspect of the pathway would damage the effectiveness and cost effectiveness of the pathway as a whole. A follow-up appointment 6–12 weeks after initial hearing aid fitting is current best practice, and is recommended in the NHS England commissioning framework.[86] This recommendation therefore requires no more activity than is already expected, however, the committee noted that at present not all providers are offering follow-up appointments. Therefore it is likely that an increase in planned early follow-up appointments will be required, which is expected to increase upfront costs. However, the committee noted that this would reduce the number of later unplanned follow-up audiology aftercare and GP appointments booked by the hearing aid users, which would lead to some savings. The committee also noted the clinical benefits of increasing the number of people able to use their hearing aids effectively, thereby avoiding a waste of money on hearing aids that are not used, or used suboptimally. The committee noted the qualitative evidence from the information, support and advice review (see chapter 12) about the importance of follow-up. The committee is aware that some providers currently favour telephone appointments. This is generally because in current practice they are typically briefer than in-person appointments, and because in some cases they are delegated to less highly trained (and therefore less expensive) staff members. The committee has made recommendations in the chapter on interventions to support the use of hearing aids (section 18.2.4) on the tasks that should be included in any follow-up appointment. These must be the same whatever the method of delivery. Telephone consultations are currently seen as quicker because they tend to be less thorough than in-person appointments, and so take less time. However, when the full list of tasks necessary to establish that a hearing aid is working properly are conducted, the method of communication does not affect the length of the appointment (indeed, for someone struggling to use a telephone due to their hearing difficulties, that method might well take longer than an appointment in person). Regarding who conducts the follow-up appointment, the committee was clear that this must be someone suitably trained with expertise in operating and explaining the working of hearing aids, though not necessarily an audiologist. Whichever method of communication is used to conduct a follow-up appointment, the staff conducting the

appointment should be equivalent.

The committee agreed that using more junior staff to speak to people on the telephone, and conducting only a brief check-up that does not cover all aspects of follow-up as recommended in this guideline are completely unacceptable. As a means of saying money they are likely to be counterproductive in the long run, as inadequate follow-up checks will increase the proportion of hearing aid users unable to use their hearing aids to maximum benefit, or to use them at all, therefore wasting the costs of the hearing aids themselves and the previous assessment and fitting appointments.

When appointments of the same length and thoroughness, using equivalent members of staff are compared, the means of communication does not affect the cost of the appointment, as this is dependent on the length of time the healthcare professional spends conducting the appointment. Face-to-face appointments have benefits over telephone consultations in that the clinician can physically modify the hearing aids and communication between the patient and clinician is easier. Therefore, there is no economic reason not to favour face-to-face appointments over telephone appointments. Some electronic communication methods, such as video links, offer many of the same benefits of face-to-face appointments, as both participants can see each other, although physical adjustment of the hearing aid settings is not possible.

The committee is therefore confident that conducting a face-to-face follow-up appointment 6–12 weeks after hearing aid fitting is either cost saving or cost effective at a cost-effectiveness threshold of £20,000 per QALY gained.

However, the committee noted that a proportion of patients do themselves express a preference for telephone communication. These may be experienced hearing aid users who are being fitted with hearing aids for a second or subsequent time, already understand most of the hearing aids' settings well and are able to hear effectively over the telephone. The committee noted stakeholder comments that face-to-face only strategies are thought to have higher non-attendance rates, which would be a matter for concern. Therefore the committee agreed that hearing aid users should be able to choose telephone or other methods of contact (if available) as their personal preference. However, the committee was clear that face-to-face is the preferred option and so should be offered to all patients as the first choice. A decision to have a telephone appointment should only be made by the hearing aid user not the provider. The hearing aid user must never be offered a telephone appointment as their only option.

Given that current practice varies across the country between face-to-face appointments, telephone appointments and no follow-up appointments at all, implementing this recommendation for all providers would be expected to increase total upfront costs. However, as noted there may be savings from a reduction in later additional audiology aftercare or GP appointments from people presenting with problems with using their hearing aids.

People who have chosen management strategies other than hearing aids would also be expected to benefit from a follow-up appointment, for similar reasons to hearing aid users. A short amount of time spent ensuring that an individual is following the optimum communication strategies, or can use their assistive listening device effectively, could lead to much greater success for the individual, and could reduce future unplanned appointments or other unnecessary use of resources due to problems accessing healthcare. Therefore the committee expects that a follow-up appointment for people in this group would also be cost effective or cost saving. However, given a lack of evidence or current standard practice, and the diversity of options in this category, the committee chose not to define a time period for the follow-up appointment, believing that this would be best chosen at the point that the management strategy is started.

Regarding the routine recall of people for periodic reassessment of their hearing, and consideration for new hearing aids, the committee noted that the original

	economic modelling conducted for this guideline used a base case of reassessment every 3 years (see appendix N). The whole pathway of hearing aid use, including regular reassessment, was found to be highly cost effective compared with not using hearing aids. Sensitivity analyses considered the difference made if this period was reduced to 2 years or extended to 10 years. This correspondingly increased and decreased the ICERs for the pathway, although all values were below £7,000 per QALY gained. However, given a lack of information, the modelling was not able to consider the differential effectiveness of hearing aids dependent on their age or the length of time since they were last checked. The model can therefore not be used to determine what the best frequency of reassessment would be, but it suggests that whatever frequency is appropriate on clinical grounds as optimising the effectiveness of hearing aid use is likely to be cost effective. The committee therefore recommended that providers should consider adopting a system of automatic recall to ensure that their patients receive some regular monitoring, but was not able to recommend a particular frequency. The committee also made a research recommendation, to gather further information that would be useful in updating these recommendations in future, and in particular in determining the most cost effective frequency of monitoring, and what that monitoring should include.
Other considerations	The committee is aware that there are emerging technologies such as self-fitting and remote fitting hearing aids and tele-audiology which are suitable for some individuals with non-complex hearing loss. However, no evidence to support making a recommendation on their use was found. The committee consider that it is important that GPs and other health professionals recognise the need for continuing audiological monitoring and care for individuals with hearing loss, whether or not they are using amplification, and refer back into local audiological services if indicated.

18 Interventions to support the use of hearing aids

18.1 Introduction

Many people choose to use hearing aids as part of the management of their hearing and communication difficulties. Hearing aids are the primary management option for hearing loss and have been shown to be effective in reducing the participation restrictions associated with hearing and communication needs, and improving listening abilities and health-related quality of life.

While the majority of people go on to use their hearing aids successfully, others stop using their hearing aids. Reported rates of non-use of hearing aids vary widely.[43] The reasons for non-use are reported as many and varied including: unrealistic expectations, unsatisfactory sound quality, poor hearing aid handling skills, discomfort, limited knowledge about and access to support, psychosocial factors, poor manual dexterity, low self-efficacy, limited support from family members, and the attitude of healthcare professionals.

Clinical practice across the UK is variable. Some services may include assessment of motivation, offer follow-up appointments, peer or volunteer support or self-management courses, or provide more personalised information. However, it is unclear which of these, or other interventions, contribute to continued and effective use of hearing aids. Other services provide no follow-up (or follow-up only if requested), no support and no signposting to other services.

This chapter aims to examine which interventions support the continued effective use of hearing aids and which interventions or approaches may reduce the non-use of hearing aids.

18.2 Review question: What is the clinical and cost effectiveness of interventions to support continuing use of hearing aids?

For full details see review protocol in appendix C.

Table 98: PICO characteristics of review question

Population	Adults, aged 18 and over, using at least one prescribed hearing aid

Interventions	• Patient education
	• Patient activation
	• Peer support
	• Self-management resources and tools for example:
	  ○ collaborative decision-making
	  ○ battery replacement services

Comparisons	To each other

Outcomes	**Critical outcomes**
	• Hearing aid use (measured as adherence or daily hours of use)
	• Adverse effects (inappropriate advice or clinical practice, or patient complaints)
	• Patient-reported outcomes including:
	  ○ quality of life,
	  ○ hearing handicap,
	  ○ hearing aid benefit and communication
	• Restricted participation/activity limitation
	• Hearing aid benefit and communication
	• Outcomes reported by carers or relatives

	Outcomes measured over the short (≤12 weeks), medium (>12 to <52 weeks) and long term (≥1 year).
Study design	Randomised control trials (RCT) Quasi-RCTs Systematic review of RCTs Cross-over studies where data are reported prior to cross-over

18.2.1 Clinical evidence

A recent Cochrane review[9] was identified that addresses our clinical question, and an expanded search was performed to fully cover our protocol and broaden the search, adding terms for aftercare, repairs, maintenance, batteries and peer support. These terms were not specifically excluded from the Cochrane search but were identified by the committee as important terms to include in our search strategy. No further studies were identified for inclusion from this expanded Cochrane search. A further 3 studies were identified [42, 129];[1] from searches on decision tools and were thought to fit better within this review, therefore 4 studies were included in the review; these are summarised in Table 99 below. Evidence from these studies is summarised in the clinical evidence summary tables below (Table 100 to Table 105).

The published review[9] was incorporated into our guideline in the following ways:

- Article selection and risk of bias assessment per study were directly adopted without further checking.
- GRADE assessments for risk of bias, imprecision and inconsistency per outcome were checked. If differences with the standard methodology used within this guideline were found, GRADE ratings and subgroup analyses were amended accordingly to ensure consistency across the reviews within this guideline.
- Data for all outcomes were incorporated into the summary of findings table, including short and medium term outcomes that were not fully assessed in the published review.[9]

See also the study selection flow chart in appendix E, forest plots in appendix K, study evidence tables in appendix H, GRADE tables in appendix J and excluded studies list in appendix L. All amendments made to the published review[9] are detailed in appendix R.

The Cochrane review aimed to identify whether any interventions can improve hearing aid use in adults. This systematic review included RCTs and quasi-randomised studies and reported on 37 studies involving 4,129 participants. The interventions included varied widely between studies and were categorised as:

- Self-management support (SMS) interventions, which aim to enable patients to optimally manage their own health, such as:
  - training and practice in skills and coping strategies for communication
  - psychosocial exercises addressing the impact of hearing loss
  - information on hearing aids and practice/problem-solving opportunities
  - self-help literature.
- Delivery system design (DSD) interventions that change the mode, format, timing or follow-up pattern of self-management support. This may include:
  - remote online fitting versus face-to-face fitting
  - telephone follow-up versus face-to-face follow-up
  - group versus individual training session
  - post-fitting adjustment versus no post-fitting adjustment.
- Combined self-management support and delivery system design interventions.

Table 99: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Aazh 2016[1]	Intervention (n=19): Motivational interviewing (MI) plus standard care. Comparison (n=17): Standard care. Significant other accompanied participant for first visit if they wanted to take part in the study	n=36 Adults fitted with hearing aids who reported using their hearing aids for 4 hours or less per day. Mean (SD) age: Intervention group 75 (8.8), control group 69 (13.6). 22 males, 15 females	Hearing aid use: daily hours of use by data logging Hearing-specific health-relate quality of life International Outcome Inventory for Hearing Aids (IOI-HA) International Outcome Inventory for Hearing Aids – Significant Other World Health Organization's Disability Assessment Schedule II Hospital Anxiety and Depression Scale)	RCT Intervention post-fitting GHABP handicap score at baseline higher in standard care group (46.6 versus 36.6%) HADS depression score lower at baseline in standard care group (1.8 versus 3.9 on 0-21 scale) 80% of MI group and 53% of standard care group had bilateral hearing aids Recruitment rate was 17% of those invited
Barker 2016[9]	Systematic review of RCTs and quasi-randomised studies including the following comparisons: Self-management support interventions versus alternative interventions that control for other elements delivery method/pattern. Delivery system design interventions versus alternative interventions that control for content. Combined self-management support/delivery system design interventions versus standard care/control.	Adults with hearing loss who use hearing aids (37 studies; n=4129) Age: most studies included only those >50 years. Mean age generally in the 60-70-year age range.	Primary outcomes: Hearing aid use Adherence Daily hours of hearing aid use Adverse effects Inappropriate advice/clinical practice Patient complaints (around physical and psychosocial management of the hearing aid, or about the intervention) Secondary outcomes: Quality of life Hearing handicap Hearing aid benefit Communication	Unclear if all participants of all included trials had adult-onset hearing loss Outpatient clinic setting

Study	Intervention and comparison	Population	Outcomes	Comments
	Decision support interventions versus standard care. Clinical information system interventions versus standard care.		All outcomes recorded for short- (≤12 weeks), medium- (>12-<52 weeks), and long-term (≥1 year) time points where available	
Ferguson 2016[42] UK	Intervention (n=32): Motivational engagement using Motivational Tools: the tools include the Line, Box and Circle. Comparison (n=36): standard care only	n=68 First-time adult hearing aid users, who had already opted to use HAs Mean age (SD) Intervention group: 71.85 (9.7) Control group: 70.31 (9.8) 34 males: 34 females	Hearing-specific health-related quality of life Glasgow Hearing Aid Benefit Profile (GHABP) Short Form Patient Activation Measure (PAM): Satisfaction with Amplification in Daily Life (SADL) Health-related quality of life Hospital Anxiety and Depression Scale (HADS) Other Measure of Audiologic Rehabilitation Self-efficacy for Hearing Aids (MARS-HA) Hearing Health Care Intervention Readiness (HHCIR) Adherence Hearing aid use	Quasi-RCT The outcome Hearing Health Care Intervention Readiness (HHCIR) was measured at assessment but not at follow-up Pre-fitting intervention
Zarenoe 2016[129] Sweden	Intervention (n=25): Hearing aid selection and fitting (including counselling, fine-tuning of amplification and functional evaluation), with a brief Motivational Interviewing Program at each stage using open questions, reflective listening, summaries and affirmations. Involves four processes: engaging, focusing, evoking and planning.	n=50 Adults with both tinnitus and sensorineural hearing loss Mean age (SD) Intervention group: 56.5 (8.3) Control group: 62.8 (10.8)	Hearing-specific health-relate quality of life International Outcome Inventory for Hearing Aids (IOI-HA)	RCT Intervention at time of fitting and post-fitting Patients were primarily presenting for management of their tinnitus The control group had greater hearing loss in the better ear when measured at follow-up

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=25): conventional hearing aid fitting as above, without MI. Number of visits in both groups was usually 3-5 and each session was a maximum of 60 minutes	31 males: 15 females		(mean PTA 26.9 versus 17.7 dB in MI group) The number of visits ranged between 3 and 5 and was on average lower in the MI group (3.3 versus 4.1 in the control group)

Table 100: Clinical evidence summary: self-management support (SMS) interventions versus control

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with self-management support interventions versus no intervention (95% CI)
Adherence	No studies identified				
Daily hours of hearing aid use	One study reported daily hours of hearing aid use but data could not be analysed				
Hearing aid use (>8 h/day)	40 (1 study) 8-10 weeks	VERY LOW [a,b] due to risk of bias, imprecision	RR 4.00 (0.49 to 32.72)	50 per 1000	150 more per 1000 (from 25 fewer to 1000 more)
Adverse effects	No studies identified				
Quality of life (WHODAS 2.0 scale, 0 to 100, 100 worst)	35 (1 study) 0–12 months	VERY LOW [a,b] due to risk of bias, imprecision	-	The mean WHODAS 2.0 score (scale 0-100) in the control group was 28.6 (SD: 19.3)	The mean WHODAS 2.0 score (scale 0-100) in the intervention group was 9.1 lower (21.33 lower to 3.13 higher)
Self-reported hearing handicap	87	LOW [a,b]	-	The mean self-reported hearing	The mean self-reported hearing

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with self-management support interventions versus no intervention (95% CI)
(HHIE scale, 0 to 100, 100 worst)	(2 studies) 0–12 months	due to risk of bias, imprecision		handicap in the control groups ranged from 39.0 to 58.6	handicap in the intervention groups was 12.80 lower (23.11 lower to 2.48 lower)
Communication (verbal subscale of the CPHI scale from 0 to 5, 5 best)	52 (1 study) 0–12 months	LOW [a,b] due to risk of bias, imprecision[d]	-	The mean reported use of verbal communication strategy in the control group was 2.89 (SD 0.87)	The mean reported use of verbal communication strategy in the intervention group was 0.72 higher (0.21 higher to 1.23 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c The minimal important difference on this scale is reported to be 18.7 for face-to-face administration and 36 for pencil and paper (Weinstein 1986). Both included studies used face-to-face administration.

d The minimal important difference for this subscale of the CPHI is 0.93 at the 0.05 level (Demorest 1988).

Table 101: Clinical evidence summary: delivery system design (DSD) interventions versus control

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Delivery system design interventions versus control (95% CI)
Adherence Number of people fitted with hearing aid/number of people who use the aids	686 (2 studies) 0–12 months	HIGH	RR 1.02 (0.99 to 1.05)	928 per 1000	19 more per 1000 (from 9 fewer to 46 more)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Delivery system design interventions versus control (95% CI)
Daily hours of hearing aid use Average self-reported or data-logged hours of use per day. Scale from: 0 to 12 hours	700 (4 studies) 0–12 months	HIGH	-	The mean daily hours of hearing aid use in the control groups ranged from 6.75 to 10.2	The mean daily hours of hearing aid use in the intervention groups was 0.06 lower (1.06 lower to 0.95 higher)
Adverse effects Number of outstanding complaints	98 (1 study) ≥1 year	LOW [a,b] due to risk of bias, imprecision	RR 0.75 (0.5 to 1.12)	571 per 1000	143 fewer per 1000 (from 285 fewer to 69 more)
Self-reported hearing handicap (HHIE scale, 0 to 100, 100 worst)	628 (2 studies) 0 to 12 months	HIGH	-	The mean self-reported hearing handicap in the control groups ranged from 15 to 24	The mean self-reported hearing handicap in the intervention groups was 0.7 lower (5.22 lower to 3.81 higher)
Hearing aid benefit (Outer EAR scale, 0 to 100, 100 best)	582 (1 study) Mean 6 months	HIGH	-	The mean hearing aid benefit in the control group was 67	The mean hearing aid benefit in the intervention group was 1.8 higher (3.1 lower to 6.7 higher)
Use of verbal communication strategy (verbal subscale of the CPHI scale, 0 to 5, 5 best)	588 (1 study) 0–12 months	MODERATE[d] due to indirectness	-	The mean use of verbal communication	The mean use of verbal communication strategy in the intervention group was 0.1 lower

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Delivery system design interventions versus control (95% CI)
				strategy in the control group was 67	(0.4 lower to 0.2 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c The minimal important difference on this scale is reported to be 18.7 for face-to face administration and 36 for pencil and paper (Weinstein 1986).
d Downgraded by 1 increment because the outcome did not cover all aspects of communication

Table 102: Clinical evidence summary: combined self-management support (SMS)/delivery system design (DSD) interventions versus control

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Combined SMS/DSD interventions (95% CI)
Adherence Number of people fitted with hearing aid/number of people using hearing aid	162 (1 study) 5-8 weeks	HIGH	RR 1.06 (1 to 1.12)	943 per 1000	57 more per 1000 (from 0 more to 113 more)
Daily hours of hearing aid use Self-reported or data-logged average hours of use per day. Long term Scale from: 0 to 12 hrs, high best.	69 (2 studies) ≥1 year	VERY LOW[a,b] due to imprecision, inconsistency	-	The mean daily hours of hearing aid use in the control groups ranged from 3.7 to 4.0	The mean daily hours of hearing aid use in the intervention groups was 0.04 higher (0.64 lower to 0.73 higher)
Daily hours of hearing aid use	534	HIGH		The mean daily hours of	The mean daily hours of hearing aid use in

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Combined SMS/DSD interventions (95% CI)
Self-reported or data-logged average hours of use per day. Short/medium term Scale from: 0 to 12 hrs, high best.	(9 studies) 0–12 months			hearing aid use in the control groups ranged from 4.0 to 11.62	the intervention groups was 0.19 higher (0.01 lower to 0.4 higher)
Quality of life Validated self-report measures. Scale from: 0 to 5, 5 best.	69 (2 studies) ≥1 year	MODERATE[b] due to imprecision		The mean quality of life in the control groups ranged from 3.6 to 4.1	The mean quality of life in the intervention groups was 0.32 higher (0.17 lower to 0.8 higher)
Quality of life - short/medium-term (High best)	530 (8 studies) 0–12 months	MODERATE[d] due to risk of bias		Unable to summarise as different scales used	The mean quality of life in the intervention groups was 0.02 standard deviations higher (0.15 lower to 0.19 higher)
Self-reported hearing handicap Validated self-report measures (scale 0-100, 0 best) Activate - symptoms	69 (2 studies) ≥1 year	MODERATE[b] due to imprecision		The mean self-reported hearing handicap in the control groups ranged from 14 to 18.2	The mean self-reported hearing handicap in the intervention groups was 0.11 lower (6.02 lower to 5.80 higher)
Self-reported hearing handicap Validated self-report measures (scale 0-63, 0 best) Activate - psychosocial	19 (1 study) ≥1 year	LOW[b,d] due to risk of bias, imprecision		The mean self-reported hearing handicap in the control group was 19.7	The mean self-reported hearing handicap in the intervention group was 8.30 lower (13.72 to 2.88 lower)
Self-reported hearing handicap	728 (15 studies)	LOW[a,d] due to risk of		Unable to summarise as different scales used,	The mean self-reported hearing in the intervention groups was

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Combined SMS/DSD interventions (95% CI)
Validated self-report measures (low best)	0–12 months	bias, inconsistency		and some change scores	0.26 standard deviations lower (0.48 to 0.04 lower)
Hearing aid benefit Validated self-report measures (IOI-HA item 4; scale from: 0 to 5, 0 best).	69 (2 studies) ≥1 year	MODERATE[b] due to imprecision		The mean hearing aid benefit in the control groups ranged from 4.1 to 4.2	The mean hearing aid benefit in the intervention groups was 0.3 higher (0.02 to 0.58 higher)
Hearing aid benefit - short/medium-term (high best)	361 (7 studies) 0–12 months	HIGH		Unable to summarise as different scales used	The mean hearing aid benefit in the intervention groups was 0.1 standard deviations higher (0.15 lower to 0.36 higher)
Use of verbal communication strategy Validated self-report measures (Verbal subscale of the CPHI; scale from: 0 to 5, 5 best).	34 (1 study) ≥1 years	LOW[b,f] due to imprecision, indirectness		The mean use of verbal communication strategy in the control group was 2.2	The mean use of verbal communication strategy in the intervention group was 0.3 higher (0.2 lower to 0.8 higher)
Use of verbal communication strategy - short/medium-term Verbal subscale of the CPHI; scale from: 0 to 5, 5 best.	223 (4 studies) 0–12 months	VERY LOW[b,d,f] due to risk of bias, imprecision, indirectness		The mean use of verbal communication strategy in the control group ranged from 2.0 to 3.22	The mean use of verbal communication strategy in the intervention group was 0.45 higher (0.15 higher to 0.74 higher)

a Downgraded by 1 or 2 increments because of heterogeneity
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Combined SMS/DSD interventions (95% CI)
c MID for this subscale of the IOI-HA is 0.32 for those with mild-moderate hearing loss and 0.28 for those with moderate to severe hearing loss d Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias e MID for this subscale of the IOI-HA is 0.39 for those with mild-moderate hearing loss and 0.32 for those with moderate to severe hearing loss f Downgraded 1 increment because of lack of a global measure of communication MID for this subscale of the CPHI in 0.93 at 0.05 level					

Table 103: Clinical evidence summary: motivational interviewing versus usual care (first time hearing aid users)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Motivational interviewing versus usual care (95% CI)
International Outcome Inventory for Hearing Aids Scale: 7-35 (high best)	46 (1 study) 3 months	VERY LOW[a,b] due to risk of bias, imprecision		The mean international outcome inventory for hearing aids in the control groups was 27.2	The mean international outcome inventory for hearing aids in the intervention groups was 3.1 higher (0.72 to 5.48 higher)
a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs c MID for the IOI-HA is 1.75 for those with mild-moderate hearing loss and 1.62 for those with moderate to severe hearing loss					

Table 104: Clinical evidence summary: motivational interviewing versus usual care (hearing aid users reporting ≤4 hours use per day)

Outcomes	No of	Quality of	Relative	Anticipated absolute effects

	Participants (studies) Follow-up	the evidence (GRADE)	effect (95% CI)	Risk with usual care	Risk difference with Motivational interviewing
Change in hearing aid use (hours/day)	36 (1 study) 1 month	LOW[a,b] due to risk of bias, imprecision		The mean change in hearing aid use in the control group was +2.8 hours/day	The mean change in hearing aid use in the intervention groups was 3.2 higher (1.03 to 5.37 higher)
International Outcome Inventory for Hearing Aids (change score) Scale: 7-35 (high best)	36 (1 study) 1 month	VERY LOW[a,b] due to risk of bias, imprecision		The mean change in IOI-HA in the control group was +7.5	The mean change in IOI-HA in the intervention groups was 0.8 higher (3.61 lower to 5.21 higher)
International Outcome Inventory for Hearing Aids – Significant Other (change score) Scale: 7-35 (high best)	36 (1 study) 1 month	LOW[a,b] due to risk of bias, imprecision		The mean change in IOI-HA-SO in the control group was +8	The mean change in IOI-HA-SO in the intervention groups was 2.9 higher (4.8 lower to 10.6 higher)
World Health Organization's Disability Assessment Schedule II (change score) Scale: 12-60 (low best)	36 (1 study) 1 month	LOW[b,c] due to risk of bias, imprecision		The mean change in WHO DASII in the control groups was −0.4	The mean change in WHO DASII in the intervention groups was 0.9 lower (3.08 lower to 1.28 higher)
Hospital Anxiety and Depression Scale - Anxiety score (change score) Scale: 0-21 (low best)	36 (1 study) 1 month	VERY LOW[a,b] due to risk of bias, imprecision		The mean change in HADS - anxiety score in the control groups was −0.9	The mean change in HADS - anxiety score in the intervention groups was 0.27 higher (1.16 lower to 1.7 higher)
Hospital Anxiety and Depression Scale - Depression score (change score) Scale: 0-21 (low best)	36 (1 study) 1 month	LOW[a,b] due to risk of bias, imprecision		The mean change in HADS - depression score in the control groups was −0.5	The mean change in HADS - depression score in the intervention groups was 0.1 lower (1.77 lower to 1.57 higher)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with usual care	Risk difference with Motivational interviewing

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c MID for the IOI-HA is 1.75 for those with mild-moderate hearing loss and 1.62 for those with moderate to severe hearing loss

Table 105: Clinical evidence summary: motivational engagement versus usual care

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Motivational engagement versus usual care (95% CI)
Hearing aid use (hours/day)	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean hearing aid use (hours/day) in the control groups was 8.73 hours	The mean hearing aid use (hours/day) in the intervention groups was 1.28 higher (1.54 lower to 4.1 higher)
Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids - Overall Scale from: 0 to 100 (high best)	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean measure of audiologic rehabilitation self-efficacy for hearing aids - overall in the control groups was 81.32	The mean measure of audiologic rehabilitation self-efficacy for hearing aids - overall in the intervention groups was 3.93 higher (2.93 lower to 10.79 higher)
Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids - Aided listening Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean measure of audiologic rehabilitation self-efficacy for hearing aids - aided listening in the control groups was 85.54	The mean measure of audiologic rehabilitation self-efficacy for hearing aids - aided listening in the intervention groups was 0.81 higher (7.05 lower to 8.67 higher)

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Motivational engagement versus usual care (95% CI)
Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids - Advanced handling Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean measure of audiologic rehabilitation self-efficacy for hearing aids - advanced handling in the control groups was 56.15	The mean measure of audiologic rehabilitation self-efficacy for hearing aids - advanced handling in the intervention groups was 10.44 higher (4.93 lower to 25.81 higher)
Glasgow Hearing Aid Benefit Profile - Overall Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean Glasgow hearing aid benefit profile - overall in the control groups was 80.49	The mean Glasgow hearing aid benefit profile - overall in the intervention groups was 1.94 lower (11.36 lower to 7.48 higher)
Glasgow Hearing Aid Benefit Profile - Benefit Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean Glasgow hearing aid benefit profile - benefit in the control groups was 68.26	The mean Glasgow hearing aid benefit profile - benefit in the intervention groups was 2.43 lower (14.11 lower to 9.25 higher)
Glasgow Hearing Aid Benefit Profile - Satisfaction Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean Glasgow hearing aid benefit profile - satisfaction in the control groups was 73.41	The mean Glasgow hearing aid benefit profile - satisfaction in the intervention groups was 4.92 higher (6 lower to 15.84 higher)
Glasgow Hearing Aid Benefit Profile - Residual disability Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias,		The mean Glasgow hearing aid benefit profile - residual disability in the control groups was	The mean Glasgow hearing aid benefit profile - residual disability in the intervention groups was

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Motivational engagement versus usual care (95% CI)
		imprecision		15.48	1.11 higher (6.34 lower to 8.56 higher)
Short form Patient Activation Measure Scale from: 0 to 100 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean short form patient activation measure in the control groups was 65.55	The mean short form patient activation measure in the intervention groups was 1.84 higher (6.36 lower to 10.04 higher)
Hospital Anxiety and Depression scale - Overall Scale from: 0 to 42 (high worst).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean hospital anxiety and depression scale - overall in the control groups was 5.81	The mean hospital anxiety and depression scale - overall in the intervention groups was 1.01 lower (2.72 lower to 0.7 higher)
Hospital Anxiety and Depression scale - Anxiety Scale from: 0 to 21 (high worst).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean hospital anxiety and depression scale - anxiety in the control groups was 5.41	The mean hospital anxiety and depression scale - anxiety in the intervention groups was 1.08 lower (2.95 lower to 0.79 higher)
Hospital Anxiety and Depression scale - Depression Scale from: 0 to 21 (high worst).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean hospital anxiety and depression scale - depression in the control groups was 6.38	The mean hospital anxiety and depression scale - depression in the intervention groups was 0.5 lower (2.4 lower to 1.4 higher)
Satisfaction with Amplification in Daily Life - Overall Scale from: 1 to 7 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias,		The mean satisfaction with amplification in daily life - overall in the control groups was	The mean satisfaction with amplification in daily life - overall in the intervention groups was

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Motivational engagement versus usual care (95% CI)
		imprecision		5.31	0.4 higher (0.01 to 0.79 higher)
Satisfaction with Amplification in Daily Life - Positive effect Scale from: 1 to 7 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean satisfaction with amplification in daily life - positive effect in the control groups was 5.03	The mean satisfaction with amplification in daily life - positive effect in the intervention groups was 0.3 higher (0.14 lower to 0.74 higher)
Satisfaction with Amplification in Daily Life - Negative features Scale from: 1 to 7 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean satisfaction with amplification in daily life - negative features in the control groups was 4.84	The mean satisfaction with amplification in daily life - negative features in the intervention groups was 0.72 higher (0.02 to 1.42 higher)
Satisfaction with Amplification in Daily Life - Personal image Scale from: 1 to 7 (high best).	53 (1 study) 1-7	VERY LOW[a,b] due to risk of bias, imprecision		The mean satisfaction with amplification in daily life - personal image in the control groups was 5.87	The mean satisfaction with amplification in daily life - personal image in the intervention groups was 0.43 higher (0.18 lower to 1.04 higher)
Satisfaction with Amplification in Daily Life - Service and cost Scale from: 1 to 7 (high best).	53 (1 study) 10 weeks	VERY LOW[a,b] due to risk of bias, imprecision		The mean satisfaction with amplification in daily life - service and cost in the control groups was 6.17	The mean satisfaction with amplification in daily life - service and cost in the intervention groups was 0.09 higher (0.33 lower to 0.51 higher)

a Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Motivational engagement versus usual care (95% CI)
b Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs					

18.2.2 Economic evidence

18.2.2.1 Published literature

One health economic study was identified with the relevant comparison and has been included in this review.[120] This is summarised in the health economic evidence profile below (Table 106) and the health economic evidence table in appendix I.

See also the health economic study selection flow chart in appendix F.

Table 106: Health economic evidence profile: before and after additional follow-up visit

Study	Applicability	Limitations	Other comments	Incremental cost[(c)]	Incremental effects	Cost effectiveness[(c)]	Uncertainty
Vuorialho 2006[120] (Finland)	Partially applicable [(a)]	Potentially serious limitations [(b)]	• Based on a single clinical study in Finnish public health service • Before-and-after study design, so no control group (n=98) • All patients were given 1 (monoaural) hearing aid and taught how to use and maintain it • All patients then also received a follow-up appointment after 6 months to check their ability to use the aid and its condition and to advise them further on how to use it • Usage of the hearing aids was measured	£51 per follow-up visit for each patient [Original fitting of a new hearing aid cost £621]	EQ-5D score: 0.00 [0.68 before and 0.68 after] Hearing aid use: Regular: +16% Occasional: −12% Non-users: −4% Handling skills (various): all improved Satisfaction: +9%	ICER (cost per QALY): N/A due to lack of effectiveness Hearing aid use: £310[(c)] per additional regular hearing aid user *Initial + additional appointments:* £867 per user	No sensitivity analysis was conducted.

Study	Applicability	Limitations	Other comments	Incremental cost[(c)]	Incremental effects	Cost effectiveness[(c)]	Uncertainty
			at 6 months (before additional advice) and 12 months: regular users (>2 hours per day); occasional users (at least once a week); non-users (seldom or never)			compared with £1,015 per user for initial advice only	

Abbreviations: ICER: incremental cost-effectiveness ratio; N/A: not applicable; QALY: quality-adjusted life years

(a) Study conducted in the Finnish public healthcare system – similar to the UK. Transportation costs were included, but these have been removed for our analysis. Results not given in terms of QALYs.

(b) Results are based on a single clinical trial. This was a before-and-after study so there is no independent control group. Sensitivity analysis was not undertaken.

(c) Converted from 2006 Euros. Transportation costs subtracted from published results for total costs.

18.2.2.2 Unit costs

See appendix P.

18.2.3 Evidence statements

Clinical

Self-management support (SMS) interventions versus control

- There was a clinically important benefit of SMS short term (8–10 weeks) for hearing aid use (>8 h/ day; very low quality evidence, 1 study).
- There was no clinically important difference in quality of life (World Health Organization's Disability Assessment Schedule II; very low quality evidence, 1 study), self-reported hearing handicap (HHIE scale; low quality evidence, 1 study) and for communication (verbal subscale of the CPHI; low quality evidence, 1 study).
- There was no evidence for adherence, adverse effects and hearing aid benefit.

Delivery system design (DSD) interventions versus control

- There was a clinically important benefit of DSD long term (≥12 months) for number of outstanding complaints (low quality evidence, 1 study).
- There was no clinically important difference in adherence (number of people fitted with hearing aid/number of people who use the aids; high quality evidence, 2 studies), daily hours of hearing aid use (high quality evidence, 4 studies), self-reported hearing handicap (HHIE scale; high quality evidence, 2 studies), hearing aid benefit (Outer Ear scale; high quality evidence, 1 study) and use of verbal communication strategy (verbal subscale of the CPHI scale; moderate quality evidence, 1 study).
- No evidence was identified for quality of life scales.

Combined self-management support (SMS)/delivery system design (DSD) interventions versus control

- There was a clinically important benefit of combined SMS/DSD for quality of life (moderate quality evidence, 2 studies) and for self-reported hearing handicap in the long term (≥12 months) (activate and psychosocial domains; low quality evidence, 1 study).
- There was no clinically important difference in adherence (high quality evidence, 1 study), long term daily hours of hearing aid use (very low quality evidence, 2 studies), short to medium term daily hours of use (high quality evidence, 9 studies), short to medium term quality of life (moderate quality evidence, 8 studies), self-reported hearing handicap for symptoms (moderate quality, 2 studies), Hearing aid benefit assessed by validated self-report measures (IOI-HA item 4; moderate quality, 2 studies), short/medium-term hearing aid benefit (high quality evidence, 7 studies) and short/medium-term use of verbal communication strategy (verbal subscale of the CPHI; very low quality evidence, 4 studies).
- No evidence was identified for adverse events.

Motivational interviewing versus usual care (first time hearing aid users)

- There was a clinically important benefit of motivational interviewing for measures of the International Outcome Inventory for Hearing Aids (very low quality evidence, 1 study).

Motivational interviewing versus usual care (hearing aid users reporting ≤4 hours use per day)

- There was a clinically important benefit of motivational interviewing for change in hearing aid use and for measures of International Outcome Inventory for Hearing Aids- Significant Other (low quality evidence, 1 study).
- There was no clinically important difference in quality of life as measured by the World Health Organization's Disability Assessment Schedule II score (low quality evidence, 1 study, Hospital Anxiety and Depression Scale - Anxiety score (very low quality evidence, 1 study) and Hospital Anxiety and Depression Scale – depression score (low quality evidence, 1 study).

Motivational engagement versus usual care

- There was a clinically important benefit of motivational engagement for hearing aid use and Measure of Audiologic Rehabilitation (Self-Efficacy for Hearing Aids - Advanced handling (very low quality evidence, 1 study).
- There was no clinically important difference in Measure of Audiologic Rehabilitation (Self-Efficacy for Hearing Aids – aided listening and overall), GHABP (benefit, satisfaction, residual disability and overall), Short Form Patient Activation Measure, Hospital Anxiety and Depression Scale (anxiety, depression and overall) and Satisfaction with Amplification in Daily Life (very low quality evidence, 1 study).

Economic

- One cost–consequences analysis found that adding a follow-up appointment to fitting a new hearing aid was more costly and more effective than no routine follow-up appointment after fitting a new hearing aid for adults with hearing loss but did not alter quality of life (£51 more per person, 16% increase in proportion of patients using their hearing aid regularly, 0 change in EQ-5D score). This analysis was assessed as partially applicable with potentially serious limitations.

18.2.4 Recommendations and link to evidence

Recommendations	**34. Consider using motivational interviewing or engagement strategies and goal setting when discussing hearing aids with adults for the first time, to encourage acceptance and use of hearing aids.** **35. Show the hearing aids when they are first offered and discuss their suitability with the person.** **36. At the follow-up audiology appointment for adults with hearing aids:** • **ask the person if they have any concerns or questions** • **address any difficulties with inserting, removing or maintaining their hearing aids** • **provide information on communication, social care or rehabilitation support services if needed** • **tell the person how to contact audiology services in the future for aftercare, including repairs and adjustments to accommodate changes in their hearing** • **ensure that the person's hearing aids and other devices meet their needs by checking:** i. **the comfort, sound quality and volume of hearing aids, including microphone and noise reduction settings, and fine-tuning them if**

	needed **ii. hearing aid cleaning, battery life and use with a telephone** **iii. use of assistive listening devices** **iv. hours the hearing aid has been used, if shown by automatic data-logging** • **review the goals identified in the personalised care plan and agree how to address any that have not been met (for information on the personalised care plan see recommendation 14).** • **update the personalised care plan and provide them with a copy.** **37. Give adults with hearing aids information about getting used to hearing aids, cleaning and caring for their hearing aids, and troubleshooting.**
Relative values of different outcomes	The following outcomes were identified as critical outcomes for this review: hearing aid use, adverse effects, hearing-specific health-related quality of life, health-related quality of life, restricted participation or activity limitation, hearing aid benefit and communication, outcomes reported by carers or relatives.
Quality of the clinical evidence	The evidence ranged from very low to high quality. Most of the studies had small numbers of participants and were at high risk of bias and this was one of the main reasons for downgrading the evidence. In particular, randomisation and allocation were unclear. Only a few studies adequately described these processes making it difficult to clearly assess the risk of selection bias. For the outcomes where clinical benefit was found, the quality of the evidence was as follows: • Self-management support (SMS) interventions; short term (8–10 weeks), very low quality evidence of clinical benefit to support hearing aid use for more than 8 hours a day. • Delivery system design (DSD) interventions; long term (≥12 months), low quality evidence of clinical benefit for adverse events (number of outstanding complaints). • Combined interventions (SMS and DSD), moderate quality evidence of clinical benefit for quality of life validated self-report measures in the long term (≥12 months).and low quality evidence of clinical benefit for self-reported hearing handicap in the long term (≥12 months), specifically for interventions targeting the 'activate –psychosocial' domain but not the 'activate – symptoms' domain • Motivational interviewing or motivational engagement, very low to low quality evidence of clinical benefit for increasing hearing aid use (1 month and 10 weeks) and low quality evidence of clinical benefit for motivational interviewing improving quality of life as experienced by the significant other (according to IOI-HA significant other) (1 month). Very low quality evidence of clinical benefit for motivational interviewing for quality of life (according to IOI-HA) in first time hearing aid users (3 months), but not in experienced users reporting ≤4h use per day (1 month). Very low quality evidence of clinical benefit of motivational engagement for improving hearing aid benefit assessed by MARS-HA advanced handling subscale (10 weeks).
Trade-off between clinical benefits and harms	Two types of interventions were considered in the systematic review: self-management support (SMS) interventions, which aim to enable patients to optimally manage their own health and delivery system design (DSD) interventions that change the mode, format, timing or follow-up pattern of self-management support. For self-management support alone, there was a clinical benefit for hearing aid use (>8 hours per day). The guideline committee noted that the clinical difference found was based on increased hearing aid use for those who received verbal pre-fitting counselling (during the fitting appointment) plus simulations representing the listening situations they identified as important to them compared with verbal pre-

	fitting counselling alone. All outcomes for self-management favoured the intervention, even if not reaching clinical importance. Hearing aid pre-fitting interventions included counselling or awareness training and demonstrations of listening situations. The committee agreed based on the evidence and its experience that providing information about hearing aids, how they work, what they offer, and demonstrating how to use them at the pre-fitting assessment would help improve adherence. The committee noted that hearing aid users may be reluctant or find it difficult to re-access services if their early listening experiences fall short of expectations. Therefore, providing sufficient information at the initial appointments will ensure realistic expectations as well as empower the individual to ask for support and also enable ongoing self-management. The committee noted the fewer number of outstanding complaints at 1 year follow-up and improved quality of life and self-reported hearing handicap for interventions targeting psychosocial elements of management in the long term. Methods of delivery of interventions described in the evidence included telephone follow-up post fitting of hearing aids. These were carried out at different time points including 4, 6, 9 and 12 weeks. The committee agreed usual practice would be to follow up at 6 to 12 weeks post-fitting and this might be carried out over the phone rather than in person, although it was noted that people with hearing loss find using a telephone difficult due to the narrow bandwidth and lack of visual cues. Follow-up earlier than 6 weeks was felt to be too soon but leaving this longer than 12 weeks could result in people with problems giving up rather than persisting with hearing aid use. It was felt that people would be reluctant to ask for follow-up if it were offered on a request basis only. Other interventions included pre-fitting sessions on how to use a hearing aid and allowing the person to use one at home before fitting a permanent device. Another study reported benefit from providing a post-fitting counselling session on hearing tactics and coping strategies. The committee agreed it is important to demonstrate how to use a hearing aid when first discussing the different management options. At the follow-up appointment an audiologist should check the hearing aid(s) are comfortable and fitted correctly and should make any adjustments or fine-tuning required. The audiologist should also ensure the person is able to insert the device and knows how to carry out basic maintenance and care, such as cleaning and replacing batteries. Further recommendations on follow-up for patients with hearing loss including those without hearing aids are included in section 17.3.4). The delivery of information varied between studies and included written information provided as booklets or a DVD to use at home. Some included interactive exercises on listening skills or in hearing aid management. The committee agreed that information formats should be tailored to the person's needs and individual learning styles. Motivational interviewing and engagement were found to be of benefit for increasing use of hearing aids, which the committee valued as a key outcome. Therefore, a recommendation was made to encourage the use of these strategies when first discussing the use of hearing aids with patients to assess their readiness and levels of motivation for having a hearing aid. The committee discussed the training requirements necessary for these strategies to be successfully implemented and agreed that training in motivational interviewing and engagement should be included in standard training for audiologists. Although no consistent benefit was seen for the quality of life or hearing benefit outcomes, it was noted that the length of follow-up in the studies may be too short for any benefits in these outcomes to be identified. No clinical harms were identified for any of the outcomes, but there was no clinical difference for the other outcomes for each type of intervention. Usual practice is to provide follow-up individually, and the practicalities of providing follow-up appointments to groups of patients was discussed. The committee agreed that organising appointments would be more difficult and parts of what is covered in

	follow-up appointments, such as fine-tuning hearing aids or discussing programming options, needs to be carried out face-to-face with the individual concerned. However other elements such as teaching basic maintenance and cleaning of devices, and information about support services available could be carried out in group situations. The committee discussed what should be included as part of a follow-up appointment. There is currently variation in practice in how comprehensive this is, but the committee noted that the model adult service specification within the Commissioning Services for People with Hearing Loss report gives recommendations on what should be included and the committee agreed that this is what is usually offered in areas delivering a good service to patients, and should form the minimum of what is provided. The committee noted that individual needs and learning styles differ and one size does not fit all people. Group follow-up may not be wanted by some or may not be appropriate, such as for people with cognitive or learning disabilities.
Trade-off between net clinical effects and costs	One health economic study was identified. This found an increase in hearing aid usage between 6 months and 12 months after initial fitting when hearing aid users were given a follow-up appointment at 6 months to help them with the use of their hearing aids (the proportion of people regularly using their hearing aid(s) increased from 61% to 78%). The study showed increases in the ability of hearing aid users to put in their own hearing aid (from 69% to 83%) and to use the hearing aid with telephones (27% to 68%), which supports the hypothesis that the follow-up appointment had led to the increased hearing aid usage. The study was a before-and-after design, so although improvement is shown with the intervention it cannot be proved whether this was due to the intervention or not. However, the committee discussed that it would be expected for hearing aid use to decline between 6 and 12 months, and so an increase strongly suggests effectiveness. No benefit was shown to quality of life as measured by EQ-5D, however this is not surprising given the limited ability of EQ-5D to detect changes in quality of life, and so it is not clear what benefit, if any, an increase in people using their hearing aids had on quality of life. However, the committee noted the increase in quality of life due to adoption of hearing aids found in other studies, which is discussed in more detail in the original economic modelling for this guideline (see appendix N). A programme including both initial fitting and follow-up cost £867 for each person subsequently regularly using their hearing aid, whereas a programme of only initial fitting and no follow-up cost £1,015 per regular user. Therefore the programme including follow-up had a greater impact per pound spent, although for the same number of people that programme would of course have a higher total cost. The committee noted that the 2016/17 NHS reference cost for a face-to-face audiology appointment is £52, whilst the NHS tariff cost for a hearing aid assessment and fitting in 2016 was £268 for 1 hearing aid, or £370 for a pair of hearing aids,[87] and that this tariff included the cost of 1 follow-up appointment [note, NHS England has withdrawn this tariff since the committee first discussed this question]. These costs are lower than those used in the published study. With a follow-up appointment costing £52, this would require a benefit to quality of life of only 0.0026 QALYs to be cost effective, which the committee thought highly plausible given the benefits to hearing shown by follow-up appointments. The clinical evidence and the committee's expert opinion did not support a follow-up intervention at 6 months as in that study, the committee instead preferred to keep the current UK practice of following up after 6–12 weeks, as discussed in the review of monitoring and follow-up (section 17.3.4). Motivational interviewing and engagement were found to be of benefit for increasing hearing aid use. This would therefore be expected to increase health-related quality of life as noted above. These methods can be carried out in a wide variety of ways, and therefore it is not possible to anticipate their possible cost. The committee therefore recommended that they be considered as additional tools, as

	they may be cost effective. The costs of adopting a particular motivational strategy, in particular initial training costs, will need to be considered locally before deciding to implement such a strategy. The other recommendations in this chapter relate to demonstrating hearing aids in the initial appointment and what should be included in a follow-up appointment. These appointments are already necessary or recommended, and are discussed further in other chapters of this guideline, particularly in section 17.3.4. The question of which issues should be covered in the follow-up appointment will influence costs insofar as it alters the average length of a follow-up appointment. It is likely that not all follow-up appointments currently conducted include all elements specified in this recommendation. As such the average follow-up appointment conducted in line with this recommendation is likely to be slightly longer in the case of face-to-face appointment, and significantly longer in the case of non-face-to-face appointments (which are currently cheaper, partly as a result of being typically shorter than face-to-face appointments). Hence the cost of delivering face-to-face appointments could rise modestly, and the cost of delivering non-face-to-face appointments would be expected to rise to similar to that of face-to-face appointments, if delivered at a similar high quality. The actions recommended will lead to hearing aids being used more often and more effectively, and so will increase the effectiveness of hearing aid use. There may also be cost savings from reducing the need for additional subsequent appointments. The cost effectiveness of providing follow-up appointments is addressed in section 17.3.4.
Other considerations	None.

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20 Acronyms and abbreviations

Acronym or abbreviation	Description
ADPI-VAS	Auditory Disability Preference – Visual Analog Scale
APHAB	Abbreviated Profile of Hearing Aid Benefit
AVM	Audiovestibular medicine
BAA	British Academy of Audiology
BSSHA	British Society of Hearing Aid Audiologists
CCA	Cost–consequences analysis
CEA	Cost-effectiveness analysis
CI	Confidence interval
COSI	Client Orientated Scale of Improvement
CPA	Cerebellopontine angle
CUA	Cost–utility analysis
DSD	Delivery system design
EAR	Effectiveness of Auditory Rehabilitation
ENT	Ear, nose and throat surgery or otorhinolaryngology
EQ-5D	EuroQol 5-dimension
GBI	Glasgow Benefit Inventory
GHABP	Glasgow Hearing Aid Benefit Profile
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HADS	Hospital Anxiety and Depression Scale
HCP	Healthcare professional
HHCIR	Hearing Health Care Intervention Readiness
HHIA	Hearing Handicap Inventory for Adults
HHIE	Hearing Handicap Inventory for the Elderly
HRQoL	Health-related quality of life
HUI-3	Health Utilities Index Mark 3
IAM	Internal auditory meatus
ICER	Incremental cost-effectiveness ratio
IOI-HA	International Outcome Inventory for Hearing Aids
IT	Intratympanic
IV	Intravenous
MARS-HA	Measure of Audiologic Rehabilitation Self-efficacy for Hearing Aids
NGC	National Guideline Centre
NICE	National Institute for Health and Care Excellence
PAM	Patient Activation Measure
PTA	Pure tone audiometry or pure tone average depending on context
QALY	Quality-adjusted life year
QDS	Quantified Denver Scale of Communication
RR	Risk ratio
SADL	Satisfaction with Amplification in Daily Life
SDS	Speech discrimination score
SELF	Self-Evaluation of Life Function

Acronym or abbreviation	Description
SF-12	12-Item Short Form Health Survey
SF-36	36-Item Short Form Health Survey
SMS	Self-management support
SSNHL	Sudden sensorineural hearing loss
SSQ	Speech, Spatial and Qualities of Hearing
VS	Vestibular schwannoma
WHODAS	WHO Disability Assessment Schedule
WRS	World recognition scores

21 Glossary

The NICE Glossary can be found at www.nice.org.uk/glossary.

21.1 Guideline-specific terms

Term	Definition
Assistive listening device	A device that transmits, processes or amplifies sound in order to support communication for the person with hearing loss. It does not usually refer to hearing aids.
Audiology	A healthcare science encompassing hearing, tinnitus and balance. Audiology services provide assessment, identification, intervention and rehabilitation services for children and adults with suspected or confirmed hearing, tinnitus and balance disorders.
Cochlear implant	A small electronic device that may improve hearing in people with severe to profound sensorineural hearing loss in both ears who do not get adequate benefit from the most powerful hearing aids.
Communication needs	Difficulty with hearing and communication including activity limitations and participation restrictions as a consequence of hearing difficulties. In addition, the term encompasses the psychological distress and reduction in quality of life that hearing difficulties can cause.
Communication partner	Someone who communicates with the person with hearing loss, for example a family member or spouse.
Conductive hearing loss	Hearing loss caused by a mechanical blockage, damage to, or abnormality in the structure that prevents sound vibrations from passing freely through the outer or middle ear. A conductive hearing loss can either be temporary or permanent.
dB HL	Sound levels are measured in dB (decibels). There are several scales of decibels and the one used for measuring hearing using a pure tone audiogram is dB HL (decibel hearing level). Where dB is used alone, as in reviewed papers referring to pure tone audiometric thresholds, it is understood to refer to dB HL.
Ear irrigation	The removal of earwax using an electronic ear irrigation machine. The machine pumps water into the ear canal at a controlled pressure, breaking down and flushing out earwax.
Ear syringing	A procedure where a metal syringe is used to pump water manually into the ear canal to try to move earwax and clear the ear.
Earwax softeners	Preparations used to soften earwax in the ear, for example oil, hydrogen peroxide and sodium bicarbonate. They are either used alone or prior to ear irrigation.
Hearing aid	An electronic device for amplifying sound and aiding perception, usually worn in or behind the ear of a person with hearing loss.
Hearing loss	Hearing loss, as defined by the World Health Organization (2008),[126] is a hearing threshold level greater than 25 dB HL averaged across 0.5, 1, 2, and 4 kHz . The British Society of Audiology (2011) describes the levels of hearing loss using a pure tone average of 0.25, 0.5, 1, 2, and 4 kHz as: • 20–40 dB HL: Mild hearing loss • 41–70 dB HL: Moderate hearing loss • 71–95 dB HL: Severe hearing loss • In excess of 95 dB HL: Profound hearing loss

Term	Definition
	A pure tone audiogram is a crude measure of hearing and there are conditions in which functional hearing is much worse that a PTA would suggest. Hearing loss can either be sensorineural, or conductive, or mixed (a combination of both types) or central. It can be congenital or acquired and of gradual or sudden onset. It can also be unilateral (affecting one ear) or bilateral (affecting both ears). A bilateral hearing loss can either be symmetrical (the hearing loss is about the same in both ears) or asymmetrical (hearing is different but present in both ears). Hearing loss can also be described by reference to the most affected frequencies for example, high frequency or low frequency. A flat hearing loss means that all hearing thresholds in one ear are about the same level.
Hyperacusis	Intolerance to everyday sounds that causes significant distress and affects a person's day-to-day activities.
Manual ear syringing	See ear syringing
Microsuction	A procedure where a small device is used to suck earwax out of the ear, under an operating microscope to give good vision.
Otalgia	Ear pain or ache.
Otorrhoea	Discharge from the ear.
Otoscopy	An examination of the ear that involves looking in the ear with an otoscope (or auroscope) which is a torch specially designed to examine the ear.
Pure tone audiometry	A test for the hearing of both ears. An audiometer is used to produce sounds at various volumes and pitches. The person listens through headphones and responds when they have heard them.
Pure tone average	A method of comparing levels of hearing that takes an average of the pure tone thresholds for a range of frequencies. Some studies use 3 frequencies and others up to 8.
Sensorineural hearing loss	Hearing loss caused by damage to the inner ear or nerve of hearing. More than 90% of hearing loss in adults is sensorineural and the leading cause of sensorineural hearing loss is the ageing process, although there are other less common causes
Threshold of hearing	This is the quietest sound that a person can hear and is measured over a number of frequencies in dB HL in a pure tone audiogram. Air conduction thresholds are measured using ear inserts or headphones with sound going down the ear canal. Bone conduction thresholds are measures that bypass the outer and middle ear and measure the function of the cochlea and nerve of hearing by transmitting sound through bone.
Tinnitus	A term for hearing sounds that come from inside the person’s body rather than from an outside source.
Tympanometry	A test for the condition of the middle ear and mobility of the eardrum using a machine that changes the pressure within the ear.
Vestibular schwannoma	Benign tumour of the cells that form the sheath around the vestibular nerve.

21.2 General terms

Term	Definition
Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
Allocation concealment	The process used to prevent advance knowledge of group assignment in an RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Applicability	How well the results of a study or NICE evidence review can answer a clinical question or be applied to the population being considered.
Arm (of a clinical study)	Subsection of individuals within a study who receive one particular intervention, for example placebo arm.
Association	Statistical relationship between 2 or more events, characteristics or other variables. The relationship may or may not be causal.
Base case analysis	In an economic evaluation, this is the main analysis based on the most plausible estimate of each input. In contrast, see Sensitivity analysis.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), with which subsequent results are compared.
Before-and-after study	A study that investigates the effects of an intervention by measuring particular characteristics of a population both before and after taking the intervention, and assessing any change that occurs.
Bias	Influences on a study that can make the results look better or worse than they really are. (Bias can even make it look as if a treatment works when it does not.) Bias can occur by chance, deliberately or as a result of systematic errors in the design and execution of a study. It can also occur at different stages in the research process, for example, during the collection, analysis, interpretation, publication or review of research data. For examples see selection bias, performance bias, information bias, confounding factor, and publication bias.
Blinding	A way to prevent researchers, doctors and patients in a clinical trial from knowing which study group each patient is in so they cannot influence the results. The best way to do this is by sorting patients into study groups randomly. The purpose of 'blinding' or 'masking' is to protect against bias. A single-blinded study is one in which patients do not know which study group they are in (for example whether they are taking the experimental drug or a placebo). A double-blinded study is one in which neither patients nor the researchers and doctors know which study group the patients are in. A triple blind study is one in which neither the patients, clinicians or the people carrying out the statistical analysis know which treatment patients received.
Carer (caregiver)	Someone who looks after family, partners or friends in need of help because they are ill, frail or have a disability.
Case–control study	A study to find out the cause(s) of a disease or condition. This is done by comparing a group of patients who have the disease or condition (cases) with a group of people who do not have it (controls) but who are otherwise as similar as possible (in characteristics thought to be unrelated to the causes of the disease or condition). This means the researcher can look for aspects of their lives that differ to see if they may cause the condition. For example, a group of people with lung cancer might be compared with a group of people the same age that do not have lung cancer. The researcher could compare how long both groups had been exposed to tobacco smoke. Such studies are retrospective because they look back in time from the outcome to the possible causes of a disease or condition.

Term	Definition
Clinical efficacy	The extent to which an intervention is active when studied under controlled research conditions.
Clinical effectiveness	How well a specific test or treatment works when used in the 'real world' (for example, when used by a doctor with a patient at home), rather than in a carefully controlled clinical trial. Trials that assess clinical effectiveness are sometimes called management trials. Clinical effectiveness is not the same as efficacy.
Clinician	A healthcare professional who provides patient care. For example, a doctor, nurse or physiotherapist.
Cochrane Review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
Cohort study	A study with 2 or more groups of people – cohorts – with similar characteristics. One group receives a treatment, is exposed to a risk factor or has a particular symptom and the other group does not. The study follows their progress over time and records what happens. See also observational study.
Comorbidity	A disease or condition that someone has in addition to the health problem being studied or treated.
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Confidence interval (CI)	There is always some uncertainty in research. This is because a small group of patients is studied to predict the effects of a treatment on the wider population. The confidence interval is a way of expressing how certain we are about the findings from a study, using statistics. It gives a range of results that is likely to include the 'true' value for the population. The CI is usually stated as '95% CI', which means that the range of values has a 95 in a 100 chance of including the 'true' value. For example, a study may state that "based on our sample findings, we are 95% certain that the 'true' population blood pressure is not higher than 150 and not lower than 110". In such a case the 95% CI would be 110 to 150. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment – often because a small group of patients has been studied. A narrow confidence interval indicates a more precise estimate (for example, if a large number of patients have been studied).
Confounding factor	Something that influences a study and can result in misleading findings if it is not understood or appropriately dealt with. For example, a study of heart disease may look at a group of people that exercises regularly and a group that does not exercise. If the ages of the people in the 2 groups are different, then any difference in heart disease rates between the 2 groups could be because of age rather than exercise. Therefore age is a confounding factor.
Control group	A group of people in a study who do not receive the treatment or test being studied. Instead, they may receive the standard treatment (sometimes called 'usual care') or a dummy treatment (placebo). The results for the control group are compared with those for a group receiving the treatment being tested. The aim is to check for any differences. Ideally, the people in the control group should be as similar as possible to those in the treatment group, to make it as easy as possible to detect any effects due to the treatment.
Cost-effectiveness analysis	Cost-effectiveness analysis is one of the tools used to carry out an economic evaluation. The benefits are expressed in non-monetary terms related to

Term	Definition
(CEA)	health, such as symptom-free days, heart attacks avoided, deaths avoided or life years gained (that is, the number of years by which life is extended as a result of the intervention).
Cost–utility analysis (CUA)	Cost–utility analysis is one of the tools used to carry out an economic evaluation. The benefits are assessed in terms of both quality and duration of life, and expressed as quality-adjusted life years (QALYs). See also utility.
Deterministic analysis	In economic evaluation, this is an analysis that uses a point estimate for each input. In contrast, see Probabilistic analysis
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.
Disutility	The loss of quality of life associated with having a disease or condition. See Utility
Dominance	A health economics term. When comparing tests or treatments, an option that is both less effective and costs more is said to be 'dominated' by the alternative.
Drop-out	A participant who withdraws from a trial before the end.
Economic evaluation	An economic evaluation is used to assess the cost effectiveness of healthcare interventions (that is, to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing). The aim of an economic evaluation is to maximise the level of benefits – health effects – relative to the resources available. It should be used to inform and support the decision-making process; it is not supposed to replace the judgement of healthcare professionals. There are several types of economic evaluation: cost–benefit analysis, cost–consequences analysis, cost-effectiveness analysis, cost-minimisation analysis and cost–utility analysis. They use similar methods to define and evaluate costs, but differ in the way they estimate the benefits of a particular drug, programme or intervention.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	A measure that shows the magnitude of the outcome in one group compared with that in a control group. For example, if the absolute risk reduction is shown to be 5% and it is the outcome of interest, the effect size is 5%. The effect size is usually tested, using statistics, to find out how likely it is that the effect is a result of the treatment and has not just happened by chance (that is, to see if it is statistically significant).
Effectiveness	How beneficial a test or treatment is under usual or everyday conditions, compared with doing nothing or opting for another type of care.
Efficacy	How beneficial a test, treatment or public health intervention is under ideal conditions (for example, in a laboratory), compared with doing nothing or opting for another type of care.
EQ-5D (EuroQol 5 dimensions)	A standardised instrument used to measure health-related quality of life. It provides a single index value for health status.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals or patients).
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.

Term	Definition
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore cost effective and should be preferred, other things remaining equal.
Follow-up	Observation over a period of time of an individual, group or initially defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health-related variables.
Generalisability	The extent to which the results of a study hold true for groups that did not participate in the research. See also external validity.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available to test for or treat a disease.
GRADE, GRADE profile	A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.
Harms	Adverse effects of an intervention.
Health economics	Study or analysis of the cost of using and distributing healthcare resources.
Health-related quality of life (HRQoL)	A measure of the effects of an illness to see how it affects someone's day-to-day life.
Heterogeneity or Lack of homogeneity	The term is used in meta-analyses and systematic reviews to describe when the results of a test or treatment (or estimates of its effect) differ significantly in different studies. Such differences may occur as a result of differences in the populations studied, the outcome measures used or because of different definitions of the variables involved. It is the opposite of homogeneity.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost	The extra cost linked to using one test or treatment rather than another. Or the additional cost of doing a test or providing a treatment more frequently.
Incremental cost-effectiveness ratio (ICER)	The difference in the mean costs in the population of interest divided by the differences in the mean outcomes in the population of interest for one treatment compared with another.
Indirectness	The available evidence is different to the review question being addressed, in terms of PICO (population, intervention, comparison and outcome).
Intervention	In medical terms this could be a drug treatment, surgical procedure, therapy such as psychological therapy, physiotherapy, hearing therapy or provision of a device such as a hearing aid, prosthetic limb, cardioverter. Examples of public health interventions could include action to help someone to be physically active or to eat a more healthy diet.
Licence	See 'Product licence'.
Life years gained	Mean average years of life gained per person as a result of the intervention compared with an alternative intervention.
Logistic regression or Logit model	In statistics, logistic regression is a type of analysis used for predicting the outcome of a binary dependent variable based on one or more predictor

Term	Definition
	variables. It can be used to estimate the log of the odds (known as the 'logit').
Loss to follow-up	A patient, or the proportion of patients, actively participating in a clinical trial at the beginning, but whom the researchers were unable to trace or contact by the point of follow-up in the trial
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them within a given time period (cycle).
Meta-analysis	A method often used in systematic reviews. Results from several studies of the same test or treatment are combined to estimate the overall effect of the treatment.
Multivariate model	A statistical model for analysis of the relationship between 2 or more predictor (independent) variables and the outcome (dependent) variable.
Negative predictive value (NPV)	In screening or diagnostic tests: A measure of the usefulness of a screening or diagnostic test. It is the proportion of those with a negative test result who do not have the disease, and can be interpreted as the probability that a negative test result is correct. It is calculated as follows: TN/(TN+FN)
Non-randomised intervention study	A quantitative study investigating the effectiveness of an intervention that does not use randomisation to allocate patients (or units) to treatment groups. Non-randomised studies include observational studies, where allocation to groups occurs through usual treatment decisions or people's preferences. Non-randomised studies can also be experimental, where the investigator has some degree of control over the allocation of treatments. Non-randomised intervention studies can use a number of different study designs, and include cohort studies, case–control studies, controlled before-and-after studies, interrupted-time-series studies and quasi-randomised controlled trials.
Observational study	Individuals or groups are observed or certain factors are measured. No attempt is made to affect the outcome. For example, an observational study of a disease or treatment would allow 'nature' or usual medical care to take its course. Changes or differences in one characteristic (for example, whether or not people received a specific treatment or intervention) are studied without intervening. There is a greater risk of selection bias than in experimental studies.
Odds ratio	Odds are a way to represent how likely it is that something will happen (the probability). An odds ratio compares the probability of something in one group with the probability of the same thing in another. An odds ratio of 1 between 2 groups would show that the probability of the event (for example a person developing a disease, or a treatment working) is the same for both. An odds ratio greater than 1 means the event is more likely in the first group. An odds ratio less than 1 means that the event is less likely in the first group. Sometimes probability can be compared across more than 2 groups – in this case, one of the groups is chosen as the 'reference category', and the odds ratio is calculated for each group compared with the reference category. For example, to compare the risk of dying from lung cancer for non-smokers, occasional smokers and regular smokers, non-smokers could be used as the reference category. Odds ratios would be worked out for occasional smokers compared with non-smokers and for regular smokers compared with non-smokers. See also confidence interval, risk ratio.
Outcome	The impact that a test, treatment, policy, programme or other intervention has on a person, group or population. Outcomes from interventions to improve the public's health could include changes in knowledge and

Term	Definition
	behaviour related to health, societal changes (for example, a reduction in crime rates) and a change in people's health and wellbeing or health status. In clinical terms, outcomes could include the number of patients who fully recover from an illness or the number of hospital admissions, and an improvement or deterioration in someone's health, functional ability, symptoms or situation. Researchers should decide what outcomes to measure before a study begins.
P value	The p value is a statistical measure that indicates whether or not an effect is statistically significant. For example, if a study comparing 2 treatments found that one seems more effective than the other, the p value is the probability of obtaining these results by chance. By convention, if the p value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance) it is considered that there probably is a real difference between treatments. If the p value is 0.001 or less (less than a 1% probability that the results occurred by chance), the result is seen as highly significant. If the p value shows that there is likely to be a difference between treatments, the confidence interval describes how big the difference in effect might be.
Placebo	A fake (or dummy) treatment given to participants in the control group of a clinical trial. It is indistinguishable from the actual treatment (which is given to participants in the experimental group). The aim is to determine what effect the experimental treatment has had – over and above any placebo effect caused because someone has received (or thinks they have received) care or attention.
Positive predictive value (PPV)	In screening or diagnostic tests: A measure of the usefulness of a screening or diagnostic test. It is the proportion of those with a positive test result who have the disease, and can be interpreted as the probability that a positive test result is correct. It is calculated as follows: TP/(TP+FP)
Power (statistical)	The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Pre-test probability	In diagnostic tests: The proportion of people with the target disorder in the population at risk at a specific time point or time interval. Prevalence may depend on how a disorder is diagnosed.
Prevalence	See Pre-test probability.
Primary care	Healthcare delivered outside hospitals. It includes a range of services provided by GPs, nurses, health visitors, midwives and other healthcare professionals and allied health professionals such as dentists, pharmacists and opticians.
Primary outcome	The outcome of greatest importance, usually the one in a study that the power calculation is based on.
Probabilistic analysis	In economic evaluation, this is an analysis that uses a probability distribution for each input. In contrast, see Deterministic analysis.
Product licence	An authorisation from the MHRA to market a medicinal product.
Prognosis	A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is associated with a high rate of undesirable outcomes.
Prospective study	A research study in which the health or other characteristic of participants is monitored (or 'followed up') for a period of time, with events recorded as they happen. This contrasts with retrospective studies.

Term	Definition
Publication bias	Publication bias occurs when researchers publish the results of studies showing that a treatment works well and do not publish those showing it did not have any effect. If this happens, analysis of the published results will not give an accurate idea of how well the treatment works. This type of bias can be assessed by a funnel plot.
Quality of life	See 'Health-related quality of life'.
Quality-adjusted life year (QALY)	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality of life score (on a scale of 0 to 1). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.
Randomisation	Assigning participants in a research study to different groups without taking any similarities or differences between them into account. For example, it could involve using a random numbers table or a computer-generated random sequence. It means that each individual (or each group in the case of cluster randomisation) has the same chance of receiving each intervention.
Randomised controlled trial (RCT)	A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or control group) receives an alternative treatment, a dummy treatment (placebo) or no treatment at all. The groups are followed up to see how effective the experimental treatment was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.
RCT	See 'Randomised controlled trial'.
Receiver operated characteristic (ROC) curve	A graphical method of assessing the accuracy of a diagnostic test. Sensitivity is plotted against 1 minus specificity. A perfect test will have a positive, vertical linear slope starting at the origin. A good test will be somewhere close to this ideal.
Reference standard	The test that is considered to be the best available method to establish the presence or absence of the outcome – this may not be the one that is routinely used in practice.
Reporting bias	See 'Publication bias'.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Retrospective study	A research study that focuses on the past and present. The study examines past exposure to suspected risk factors for the disease or condition. Unlike prospective studies, it does not cover events that occur after the study group is selected.
Review question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Risk ratio (RR)	The ratio of the risk of disease or death among those exposed to certain conditions compared with the risk for those who are not exposed to the same conditions (for example, the risk of people who smoke getting lung cancer compared with the risk for people who do not smoke). If both groups face the same level of risk, the risk ratio is 1. If the first group had a risk ratio of 2, subjects in that group would be twice as likely to have the event happen. A risk ratio of less than 1 means the outcome is less likely

Term	Definition
	in the first group. The risk ratio is sometimes referred to as relative risk.
Secondary outcome	An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.
Selection bias	Selection bias occurs if: a) The characteristics of the people selected for a study differ from the wider population from which they have been drawn, or b) There are differences between groups of participants in a study in terms of how likely they are to get better.
Sensitivity	How well a test detects the thing it is testing for. If a diagnostic test for a disease has high sensitivity, it is likely to pick up all cases of the disease in people who have it (that is, give a 'true positive' result). But if a test is too sensitive it will sometimes also give a positive result in people who do not have the disease (that is, give a 'false positive'). For example, if a test were developed to detect if a woman is 6 months pregnant, a very sensitive test would detect everyone who was 6 months pregnant, but would probably also include those who are 5 and 7 months pregnant. If the same test were more specific (sometimes referred to as having higher specificity), it would detect only those who are 6 months pregnant, and someone who was 5 months pregnant would get a negative result (a 'true negative'). But it would probably also miss some people who were 6 months pregnant (that is, give a 'false negative'). Breast screening is a 'real-life' example. The number of women who are recalled for a second breast screening test is relatively high because the test is very sensitive. If it were made more specific, people who do not have the disease would be less likely to be called back for a second test but more women who have the disease would be missed.
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalisability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): 2 or more parameters are varied at the same time and the overall effect on the results is evaluated. Threshold sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (for example, Monte Carlo simulation).
Significance (statistical)	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p<0.05$).
Specificity	The proportion of true negatives that are correctly identified as such. For example in diagnostic testing the specificity is the proportion of non-cases correctly diagnosed as non-cases. See related term 'Sensitivity'. In terms of literature searching a highly specific search is generally narrow and aimed at picking up the key papers in a field and avoiding a wide range of papers.

Term	Definition
Stakeholder	An organisation with an interest in a topic that NICE is developing a guideline or piece of public health guidance on. Organisations that register as stakeholders can comment on the draft scope and the draft guidance. Stakeholders may be: • manufacturers of drugs or equipment • national patient and carer organisations • NHS organisations • organisations representing healthcare professionals.
State transition model	See Markov model
Systematic review	A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. It may include a meta-analysis.
Time horizon	The time span over which costs and health outcomes are considered in a decision analysis or economic evaluation.
Transition probability	In a state transition model (Markov model), this is the probability of moving from one health state to another over a specific period of time.
Treatment allocation	Assigning a participant to a particular arm of a trial.
Univariate	Analysis which separately explores each variable in a data set.
Utility	In health economics, a 'utility' is the measure of the preference or value that an individual or society places upon a particular health state. It is generally a number between 0 (representing death) and 1 (perfect health). The most widely used measure of benefit in cost–utility analysis is the quality-adjusted life year, but other measures include disability-adjusted life years (DALYs) and healthy year equivalents (HYEs).