National Institute for Health and Care Excellence

Draft for consultation

Otitis media with effusion in under 12s

[J] Evidence reviews for hearing aids/devices for hearing loss associated with OME in children under 12 years

NICE guideline number tbc

Evidence reviews underpinning recommendations 1.4.1 to 1.4.4 and research recommendation in the NICE guideline

March 2023

Draft for consultation

This evidence review was developed by NICE

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/or their carer or guardian.

Local commissioners and/or 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.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive. All NICE guidance is subject to regular review and may be updated or withdrawn.

ISBN:

Contents

Hearing aids/devices for hearing loss associated with OME in children under 12 years

Review question

What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

Introduction

The aim of this review is to assess the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years.

Summary of the protocol

See Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	All children under 12 years with hearing loss due to confirmed otitis media with effusion
Intervention	• Air conduction hearing aid/device • Bone conduction hearing aid/device • Unspecified hearing aid/device
Comparison	• Head-to-head comparisons between the interventions • No hearing aid/device
Outcome	**Critical** • Hearing (measured by pure tone audiometry or speech recognition thresholds, in dB HL) • Quality of life (measured by OM8-30 questionnaire, Health Utilities Index Mark 3 (HUI3) questionnaire, Otitis Media-6 (OM-6) questionnaire, Quality of Life in Children's Ear Problems (OMQ-14) questionnaire, Evaluation of Children's Listening and Processing Skills (ECLiPS) questionnaire, Auditory Behaviour in Everyday Life (ABEL) questionnaire, Early Listening Function (ELF) questionnaire, Parents' Evaluation of Aural/Oral Performance of Children (PEACH) questionnaire, EuroQol 5 Dimensions (EQ-5D) questionnaire, Infant Toddler Quality of Life Questionnaire, or Child Heath Questionnaire) • Speech discrimination (measured by the McCormick Toy Test and the Manchester Picture Test) **Important** • Listening skills (for example, turning to sounds and voices, listening stories attentively, following instructions) • Receptive language skills (measured by Peabody-revised picture vocabulary test or the relevant domains of the Reynell Developmental Language Scales, Preschool Language Scale (PLS), or Sequenced Inventory of Communication Development (SICD)) • Psychosocial development (measured by the Social Skills Scale of the Social Skills Rating System or validated measures of self-esteem, confidence and peer and family relationships)

- Acceptability

For further details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and the methods document (supplementary document 1).

Declarations of interest were recorded according to NICE's conflicts of interest policy.

Effectiveness evidence

Included studies

A systematic review of the literature was conducted but no studies were identified which were applicable to this review question.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix J.

Summary of included studies

No studies were identified which were applicable to this review question (and so there are no evidence tables in Appendix D). No meta-analysis was conducted for this review (and so there are no forest plots in Appendix E).

Summary of the evidence

No studies were identified which were applicable to this review question (and so there are no GRADE tables in Appendix F).

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no economic studies were identified which were applicable to this review question.

Economic model

An economic model was undertaken which compared hearing aids, ventilation tubes and ventilation tubes with adjuvant adenoidectomy in children with hearing loss associated with OME. This model is discussed in Evidence review E.

The committee's discussion and interpretation of the evidence

The outcomes that matter most

Hearing loss or hearing difficulty is often associated with OME, and this could impact on the child's development. As the primary aim of hearing aids and devices is to improve hearing, hearing was prioritised as a critical outcome. Quality of life was also prioritised as a critical outcome as this is a global measure that takes into account both beneficial and adverse effects of the interventions. Difficulty with speech discrimination is common when hearing is impaired and therefore may be affected by hearing aids. Therefore, speech discrimination was also prioritised as a critical outcome.

Hearing loss can also lead to impairment of listening skills (for example, turning to sounds and voices, listening to stories attentively, following instructions) and receptive language skills, which can impact children's development and education. Similarly, psychosocial development may be affected if they have difficulty communicating with others. Due to the importance of these outcomes for children's development and the likelihood of them being affected by hearing aids, these were selected as important outcomes. Although hearing aids and devices may improve hearing, speech, language, and behavioural development in children with OME, children may not tolerate such devices or may not want to wear such devices. The overall ability and willingness of children to use such devices is important and this may depend on the type of hearing aid or device used. Therefore, acceptability was also selected as an important outcome.

The quality of the evidence

No studies were identified which were applicable to this review question.

Benefits and harms

There was no available evidence which was applicable to this review question on the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years. Therefore, the committee made recommendations based on current practice and their knowledge and expert opinion.

The committee acknowledged that there is high prevalence of OME in children, and the main aim of the management of hearing loss associated with OME is to minimise the negative impacts on children's learning, development and quality of life. The committee discussed that children with hearing loss associated with OME may hear many sounds around them, but they may be muffled and unclear, which may have impact on early speech and language development. In the committee's expert knowledge and experience, air conduction hearing aids and bone conduction devices may improve development in terms of hearing, wellbeing, behaviour, speech and language, and these devices may be effective for both new onset and chronic OME. Therefore, the committee agreed that these devices should be considered in children with OME-related hearing loss.

The committee discussed the indications for bone conduction devices and air conduction hearing aids. The committee were aware that air conduction hearing aids tend to offer better noise reduction, signal processing and connectivity features than current models of bone conduction hearing aids. These features may provide improved speech clarity and overall sound quality. However, when hearing level changes or fluctuates, air conduction hearing aids may need to be adjusted which often would require an additional appointment which could impact families and require additional resources; however, bone conduction devices do not require this adjustment for changes to hearing related to OME. In addition, in children with history of recurrent or persistent otorrhoea, air conduction hearing aids may not be suitable because otorrhoea can damage or occlude air conduction hearing aids, rendering them ineffective, or hearing aids might exacerbate otorrhoea. Similarly, air conduction

hearing aids may not be suitable for children with anatomical issues such as narrow ear canals, due to difficulty in inserting the hearing aid or increased likelihood of wax occlusion. Moreover, the committee acknowledged that, in their experience and knowledge, compared with bone conduction devices, air conduction hearing aids and their components may have a greater risk of choking, particularly in children with learning disabilities, because of smaller parts on air conduction hearing aids, which are easier to take apart. However, the committee were aware that bone conduction devices tend to have an obvious headband and are, therefore, less discrete than air conduction hearing aids, which may not be acceptable to some children or their families. Therefore, in general air conduction hearing aids may be considered more suitable when hearing loss is stable and such device is preferred or tolerated, and bone conduction hearing aids may be considered more suitable when hearing levels are known to fluctuate or there are contraindications to air conduction hearing aids as outlined above. The committee agreed that it can be difficult to decide what types of hearing aids or devices are more appropriate for individual children, so it was important to make recommendations about the indications and contraindications for the two different types to help aid decision making.

The committee recognised the risk of button batteries in hearing aids and hearing devices. Young children, and children with learning difficulties, may put things such as button batteries into their mouths; if ingested, button batteries pose a significant risk of harm to children, including tissue necrosis, perforation, haemorrhage, or death. Although the safety of hearing aids was outside the scope of this review and is not specific to children with OME, the committee agreed it was important to raise awareness of the risk of button batteries in hearing aids and hearing devices as it is an important safety issue that may be of particular concern for the population of this guideline due to their young age and the higher prevalence of OME among people with learning difficulties. Further, in the committee's experience, parents are not always alerted to the risk of button batteries. Therefore, the committee agreed to include a cross-reference to the NHS national patient safety alert on risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices (NHS England 2019).

The committee, based on their knowledge and experience, acknowledged that the use of air conduction and bone conduction hearing aids/devices is a common practice for managing OME-related hearing loss. As the primary aim of providing interventions for OME is to minimise negative impacts of hearing loss on the child's development and quality of life, interventions need to be effective in supporting hearing. In addition, interventions should be suitable and acceptable for children and their carers so that there is good uptake and cost-effectiveness. However, there is no available evidence to inform the clinical and cost-effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years. Therefore, the committee made a research recommendation about it (see Appendix K).

Cost effectiveness and resource use

These guideline recommendations have the potential both to increase costs and produce savings, but these are unlikely to be substantial and the extent of any increase in cost or saving will depend on the implementation of the guidance as they are mostly "consider" recommendations.

Compared to existing guidance, these recommendations make the provision of hearing aids for new or short-term hearing loss more permissive, and this could increase costs. However, as the guideline gives more scope to provide hearing aids as an alternative to ventilation tubes, this may reduce inpatient stays and costs associated with surgery. Furthermore, especially for children with learning disabilities, earlier intervention may have a positive impact on development and behaviour which then has the potential to reduce "downstream" costs. An economic model developed for this guideline suggested that hearing aids had comparable cost-effectiveness to surgical alternatives in children under 12 years with hearing

loss associated with OME. In the base case probabilistic analysis, the incremental cost-effectiveness ratio (ICER) for hearing aids was £20,475 relative to no intervention. Hearing aids had the highest net monetary benefit in that analysis of the interventions and a 21% probability of being the most cost-effective option (no intervention 10%; ventilation tubes 27%, ventilation tubes with adjuvant adenoidectomy 42%). Sensitivity analysis also indicated that the model conclusions were sensitive to many model inputs and considerable uncertainty remains with respect to the relative cost-effectiveness of hearing aids and surgical alternatives for hearing loss associated with OME.

The cost of a bone conduction device is considerably higher than for an air conduction device, but the committee noted that this would be offset to some extent by non-device costs which are higher for air conduction hearing aids. The number of children with narrow ear canals is small and therefore any increased use of bone conduction devices in this group is unlikely to lead to a significant increase in costs.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.4.1, 1.4.2, 1.4.3, and 1.4.4 and the research recommendation on the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years.

References – included studies

Other

NHS England 2019

National Health Service England (2019). Risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices. Available at: https://www.england.nhs.uk/wp-content/uploads/2020/02/NatPSA_hearing_aid_batteries_December_2019_FINAL.pdf [Accessed 10/08/2022]

Appendices

Appendix A Review protocols

Review protocol for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

Table 2: Review protocol

Field	Content
PROSPERO registration number	CRD42022333975
Review title	The effectiveness of air conduction and bone conduction hearing aids/devices in otitis media with effusion
Review question	What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?
Objective	To determine the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years.
Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • Epistemonikos • International Health Technology Assessment (INAHTA) database Searches will be restricted by: • OECD geographic study filter • Date limitations: 1990 • English language • Human studies

Field	Content
	The full search strategies for MEDLINE database will be published in the final review. For each search, the principal database search strategy is quality assured by a second information scientist using an adaptation of the PRESS 2015 Guideline Evidence-Based Checklist.
Condition or domain being studied	Otitis media with effusion
Population	All children under 12 years with hearing loss due to confirmed otitis media with effusion
Intervention/Exposure/Test	• Air conduction hearing aid/device • Bone conduction hearing aid/device • Hearing aid/device (unspecified)
Comparator/Reference standard/Confounding factors	• Head-to-head comparisons of interventions • No hearing aid/device
Types of study to be included	Include published full-text papers: • Systematic reviews of RCTs • RCTs • If insufficient RCTs*: comparative prospective cohort studies with at least 40 participants per arm • If insufficient comparative prospective cohort studies: comparative retrospective cohort studies with at least 40 participants per arm *Non-randomised studies will be considered for inclusion if insufficient RCT evidence is available for guideline decision making. Sufficiency will be judged taking into account factors including number/quality/sample size of RCTs, outcomes reported and availability of data from subgroups of interest. Non-randomised studies will only be included if they adjust for the following covariates in their analysis when there are differences between groups at baseline: Age Non-randomised studies will be downgraded for risk of bias if they do not adequately adjust for the following covariates, but will not be excluded for this reason: • Additional sensory or learning needs

Field	Content
	• Time since diagnosis • Severity of hearing loss at diagnosis
Other exclusion criteria	• Country limitations: limit studies to OECD high-income countries • Date limitations: 1990 as there has been significant change in practice and technology since then. • Language limitations: studies published not in English-language • Conference abstracts will not be considered
Context	This guidance will fully update the following NICE guideline: Otitis media with effusion in under 12s: surgery (2008; CG60)
Primary outcomes (critical outcomes)	• Hearing (measured by pure tone audiometry or speech recognition thresholds, in dB HL) • Quality of life (measured by OM8-30 questionnaire, Health Utilities Index Mark 3 (HUI3) questionnaire, Otitis Media-6 (OM-6) questionnaire, Quality of Life in Children's Ear Problems (OMQ-14) questionnaire, Evaluation of Children's Listening and Processing Skills (ECLiPS) questionnaire, Auditory Behaviour in Everyday Life (ABEL) questionnaire, Early Listening Function (ELF) questionnaire, Parents' Evaluation of Aural/Oral Performance of Children (PEACH) questionnaire, EuroQol 5 Dimensions (EQ-5D) questionnaire, Infant Toddler Quality of Life Questionnaire, or Child Heath Questionnaire) • Speech discrimination (measured by the McCormick Toy Test and the Manchester Picture Test)
Secondary outcomes (important outcomes)	• Listening skills (for example, turning to sounds and voices, listening stories attentively, following instructions) • Receptive language skills (measured by Peabody-revised picture vocabulary test or the relevant domains of the Reynell Developmental Language Scales, Preschool Language Scale (PLS), or Sequenced Inventory of Communication Development (SICD)) • Psychosocial development (measured by the Social Skills Scale of the Social Skills Rating System or validated measures of self-esteem, confidence and peer and family relationships) • Acceptability

Field	Content
Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI and de-duplicated. Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. Dual sifting will be performed on at least 10% of records; 90% agreement is required. Disagreements will be resolved via discussion between the two reviewers, and consultation with senior staff if necessary. Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion. A standardised form will be used to extract data from studies. The following data will be extracted: study details (reference, country where study was carried out, type and dates), participant characteristics, inclusion and exclusion criteria, details of the interventions if relevant, setting and follow-up, relevant outcome data and source of funding. One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer
Risk of bias (quality) assessment	Quality assessment of individual studies will be performed using the following checklists: • ROBIS tool for systematic reviews • Cochrane RoB tool v.2 for RCTs and quasi-RCTs • Cochrane ROBINS-I tool for non-randomised (clinical) controlled trials and cohort studies The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
Strategy for data synthesis	Quantitative findings will be formally summarised in the review. Where possible, meta-analyses will be conducted using Cochrane Review Manager software. A fixed effect meta-analysis will be conducted and data will be presented as risk ratios or odds ratios for dichotomous outcomes, and mean differences or standardised mean differences for continuous outcomes. Heterogeneity in the effect estimates of the individual studies will be assessed using the I2 statistic. Alongside visual inspection of the point estimates and confidence intervals, I2 values of greater than 50% and 80% will be considered as significant and very significant heterogeneity, respectively. Heterogeneity will be explored as appropriate using sensitivity analyses and pre-specified subgroup analyses.

Field	Content
	If heterogeneity cannot be explained through subgroup analysis then a random effects model will be used for meta-analysis, or the data will not be pooled if the random effects model does not adequately address heterogeneity. The confidence in the findings across all available evidence will be evaluated for each outcome 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/ **Minimally important differences (MIDs):** • Validated scales: Published MIDs where available; if not GRADE default MIDs • All other outcomes: GRADE default MIDs
Analysis of sub-groups	Evidence will be stratified by: **Craniofacial anomalies** • Children with Down's syndrome • Children with cleft palate • Children with other craniofacial anomalies • Children without craniofacial anomalies **Mucociliary condition such as cystic fibrosis** Evidence will be subgrouped by the following only in the event that there is significant heterogeneity in outcomes: **Type of OME** • Fluctuating OME • Persistent OME **Episode of OME** • First episode

Field	Content	
	• Recurrent episode **Previous intervention** • Previous grommet insertion • No previous grommet insertion **Age** • Children <2 years vs ≥2 years • Children <4 years vs ≥4 years • Children <6 years vs ≥6 years Where evidence is stratified or subgrouped the committee will consider on a case by case basis if separate recommendations should be made for distinct groups. Separate recommendations may be made where there is evidence of a differential effect of interventions in distinct groups. If there is a lack of evidence in one group, the committee will consider, based on their experience, whether it is reasonable to extrapolate and assume the interventions will have similar effects in that group compared with others.	
Type and method of review	☒	Intervention
	☐	Diagnostic
	☐	Prognostic
	☐	Qualitative
	☐	Epidemiologic
	☐	Service Delivery
	☐	Other (please specify)
Language	English	
Country	England	
Anticipated or actual start date	22/03/2022	

Field	Content		
Anticipated completion date	14/12/2022		
Stage of review at time of this submission	Review stage	Started	Completed
	Preliminary searches	☐	☑
	Piloting of the study selection process	☐	☑
	Formal screening of search results against eligibility criteria	☐	☑
	Data extraction	☐	☑
	Risk of bias (quality) assessment	☐	☑
	Data analysis	☐	☑
Named contact	Named contact: National Guideline Alliance Named contact e-mail: otitis@nice.org.uk Organisational affiliation of the review: National Institute for Health and Care Excellence (NICE) and National Guideline Alliance		
Review team members	National Guideline Alliance		
Funding sources/sponsor	This systematic review is being completed by the National Guideline Alliance which receives funding from NICE		
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.		

Field	Content	
Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10149.	
Other registration details	None	
Reference/URL for published protocol	https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022333975	
Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
Keywords	Otitis media with effusion, hearing aids, hearing devices, hearing, quality of life	
Details of existing review of same topic by same authors	None	
Current review status	☐	Ongoing
	☒	Completed but not published
	☐	Completed and published
	☐	Completed, published and being updated
	☐	Discontinued
Additional information	None	
Details of final publication	www.nice.org.uk	

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; GRADE: Grading of Recommendations Assessment, Development and Evaluation; MEDLINE: Medical Literature Analysis and Retrieval System Online; MID: minimally important difference; NICE: National Institute for Health and Care Excellence; PRESS: Peer Review of Electronic Search Strategies; RCT: randomised controlled trial; RoB: risk of bias; ROBINS-I: risk of bias in non-randomised studies – of interventions; ROBIS: risk of bias in systematic reviews; SD: standard deviation

Appendix B Literature search strategies

Literature search strategies for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

Clinical search

Database: MEDLINE – OVID interface

Date last searched: 09/11/2022

#	Searches
1	otitis media with effusion/
2	(glue ear or ((middle ear or otitis media) adj2 effusion*) or ome or ((secretory or serous) adj2 otitis media)).ti,ab.
3	1 or 2
4	Hearing Aids/ or Bone-Anchored Prosthesis/ or Bone Conduction/ or Cochlear Implants/ or Osseointegration/
5	((auditor* or cochlea* or hear* or listen* or sound*) adj3 (amplif* or aid* or device* or earphone* or ear phone* or headphone* or head phone* or headset* or implant* or instrument* or kit? or prosthe* or set? or system* or unit*)).ti,ab,kf.
6	(air conduct* or bone anchor* or bone conduct* or osseoanchor* or osseo anchor* or osseointegrat* or osseo integrat* or osseous integrat* or osteoconduct* or osteo conduct* or BAHA?).ti,ab.
7	or/4-6
8	3 and 7
9	limit 8 to english language
10	limit 9 to yr="1990 -Current"
11	(animals not humans).sh. or exp animals, laboratory/ or exp animal experimentation/ or exp models, animal/ or exp rodentia/ or (rat or rats or mouse or mice).ti.
12	10 not 11

Database: Embase – OVID interface

Date last searched: 09/11/2022

#	Searches
1	exp secretory otitis media/
2	(glue ear or ((middle ear or otitis media) adj2 effusion*) or ome or ((secretory or serous) adj2 otitis media)).ti,ab.
3	1 or 2
4	hearing aid/ or exp air conduction hearing aid/ or assistive listening device/ or bone conduction hearing aid/ or cochlea prosthesis/ or wireless air conduction hearing aid/ or air conduction/ or bone conduction/ or osseointegration/ or osseointegrated implant/
5	((auditor* or cochlea* or hear* or listen* or sound*) adj3 (amplif* or aid* or device* or earphone* or ear phone* or headphone* or head phone* or headset* or implant* or instrument* or kit? or prosthe* or set? or system* or unit*)).ti,ab,kf.
6	(air conduct* or bone anchor* or bone conduct* or osseoanchor* or osseo anchor* or osseointegrat* or osseo integrat* or osseous integrat* or osteoconduct* or osteo conduct* or BAHA?).ti,ab.
7	or/4-6
8	3 and 7
9	limit 8 to english language
10	limit 9 to yr="1990 -Current"
11	(animal/ not human/) or nonhuman/ or exp animal experiment/ or exp experimental animal/ or animal model/ or exp rodent/ or (rat or rats or mouse or mice).ti.
12	10 not 11
13	limit 12 to (conference abstract or conference paper or conference review or conference proceeding)
14	12 not 13

Database: Cochrane Database of Systematic Reviews (CDSR); Cochrane Central Register of Controlled Trials (CENTRAL) – Wiley interface

Date last searched: 09/11/2022

ID	Search
#1	MeSH descriptor: [Otitis Media with Effusion] this term only
#2	(("glue ear" or (("middle ear" or "otitis media") near/2 effusion*) or ome or ((secretory or serious) near/2 "otitis media"))):ti,ab,kw
#3	#1 or #2
#4	(hearing aids or bone-anchored prosthesis or bone conduction or cochlear implants or osseointegration):kw

ID	Search
#5	((auditor* or cochlea* or hear* or listen* or sound*) near/3 (amplif* or aid* or device* or earphone* or "ear phone*" or headphone* or "head phone*" or headset* or implant* or instrument* or kit? or prosthe* or set? or system* or unit*)):ti,ab
#6	("air conduct*" or "bone anchor*" or "bone conduct*" or osseoanchor* or "osseo anchor*" or osseointegrat* or "osseo integrat*" or "osseous integrat*" or osteoconduct* or "osteo conduct*" or BAHA?):ti,ab
#7	{or #4-#6}
#8	#3 and #7
#9	"conference":pt or (clinicaltrials or trialsearch):so
#10	#8 not #9 with Cochrane Library publication date Between Jan 1990 and Nov 2022

Database: Epistemonikos

Date last searched: 09/11/2022

#	Searches
1	(title:(("glue ear" OR (("middle ear" OR "otitis media") AND effusion*) OR ome OR ((secretory OR serous) AND "otitis media"))) OR abstract:(("glue ear" OR (("middle ear" OR "otitis media") AND effusion*) OR ome OR ((secretory OR serous) AND "otitis media")))
2	(title:((amplif* OR aid* OR device* OR earphone* OR "ear phone" OR "ear phones" OR headphone* OR "head phone" OR "head phones" OR headset* OR implant* OR instrument* OR kit OR kits OR prosthe* OR set OR sets OR system* OR unit*)) OR abstract:((amplif* OR aid* OR device* OR earphone* OR "ear phone" OR "ear phones" OR headphone* OR "head phone" OR "head phones" OR headset* OR implant* OR instrument* OR kit OR kits OR prosthe* OR set OR sets OR system* OR unit*))) OR (title:(("air conduct" OR "air conducting" OR "air conduction" OR "bone anchor" OR "bone anchored" OR "bone anchoring" OR "bone anchors" OR "bone conduct" "bone conducting" OR "bone conduction" OR osseoanchor* OR osseointegrat* OR "osseous integrated" "osseous integration" OR osteoconduct* OR "osteo conduct" OR "osteo conducting" OR "osteo conduction" OR BAHA*)) OR abstract:(("air conduct" OR "air conducting" OR "air conduction" OR "bone anchor" OR "bone anchored" OR "bone anchoring" OR "bone anchors" OR "bone conduct" "bone conducting" OR "bone conduction" OR osseoanchor* OR osseointegrat* OR "osseous integrated" "osseous integration" OR osteoconduct* OR "osteo conduct" OR "osteo conducting" OR "osteo conduction" OR BAHA*)))
3	1 AND 2
4	[Filters: min_year=1990, max_year=2022]

Database: International Network of Agencies for Health Technology Assessment (INAHTA)

Date last searched: 09/11/2022

#	Searches
1	"Otitis Media with Effusion"[mhe]
2	((“glue ear” or ((“middle ear” or “otitis media”) and effusion*) or ome or ((secretory or serous) and “otitis media”))
3	1 OR 2
4	(amplif* OR aid* OR device* OR earphone* OR "ear phone" OR "ear phones" OR headphone* OR "head phone" OR "head phones" OR headset* OR implant* OR instrument* OR kit OR kits OR prosthe* OR set OR sets OR system* OR unit*)) OR ("air conduct" OR "air conducting" OR "air conduction" OR "bone anchor" OR "bone anchored" OR "bone anchoring" OR "bone anchors" OR "bone conduct" "bone conducting" OR "bone conduction" OR osseoanchor* OR osseointegrat* OR "osseous integrated" "osseous integration" OR osteoconduct* OR "osteo conduct" OR "osteo conducting" OR "osteo conduction" OR BAHA*)))
5	3 AND 4 FROM 1900 TO 2022 AND (English)[Language]

Economic literature search strategy

A global, population-based search was undertaken to find economic evidence covering all parts of the guideline.

Database: MEDLINE – OVID interface

Date last searched: 09/11/2022

#	Searches
1	otitis media with effusion/
2	(glue ear or ((middle ear or otitis media) adj2 effusion*) or ome or ((secretory or serous) adj2 otitis media)).ti,ab.
3	1 or 2
4	Economics/
5	Value of life/
6	exp "Costs and Cost Analysis"/
7	exp Economics, Hospital/
8	exp Economics, Medical/
9	Economics, Nursing/

#	Searches
10	Economics, Pharmaceutical/
11	exp "Fees and Charges"/
12	exp Budgets/
13	budget*.ti,ab.
14	cost*.ti.
15	(economic* or pharmaco?economic*).ti.
16	(price* or pricing*).ti,ab.
17	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
18	(financ* or fee or fees).ti,ab.
19	(value adj2 (money or monetary)).ti,ab.
20	or/4-19
21	exp models, economic/
22	*Models, Theoretical/
23	*Models, Organizational/
24	markov chains/
25	monte carlo method/
26	exp Decision Theory/
27	(markov* or monte carlo).ti,ab.
28	econom* model*.ti,ab.
29	(decision* adj2 (tree* or analy* or model*)).ti,ab.
30	or/21-29
31	20 or 30
32	3 and 31
33	(animals/ not humans/) or exp animals, laboratory/ or exp animal experimentation/ or exp models, animal/ or exp rodentia/ or (rat or rats or mouse or mice).ti.
34	32 not 33
35	limit 34 to english language
36	limit 35 to yr="2000 -Current"

1 **Database: Embase – OVID interface**

2 Date last searched: 09/11/2022

#	Searches
1	exp secretory otitis media/
2	(glue ear or ((middle ear or otitis media) adj2 effusion*) or ome or ((secretory or serous) adj2 otitis media)).ti,ab.
3	1 or 2
4	health economics/
5	exp economic evaluation/
6	exp health care cost/
7	exp fee/
8	budget/
9	funding/
10	budget*.ti,ab.
11	cost*.ti.
12	(economic* or pharmaco?economic*).ti.
13	(price* or pricing*).ti,ab.
14	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
15	(financ* or fee or fees).ti,ab.
16	(value adj2 (money or monetary)).ti,ab.
17	or/4-16
18	statistical model/
19	exp economic aspect/
20	18 and 19
21	*theoretical model/
22	*nonbiological model/
23	stochastic model/
24	decision theory/
25	decision tree/
26	monte carlo method/
27	(markov* or monte carlo).ti,ab.
28	econom* model*.ti,ab.
29	(decision* adj2 (tree* or analy* or model*)).ti,ab.
30	or/20-29
31	17 or 30
32	3 and 31
33	(animal/ not human/) or nonhuman/ or exp animal experiment/ or exp experimental animal/ or animal model/ or exp rodent/ or (rat or rats or mouse or mice).ti.
34	32 not 33

#	Searches
35	limit 34 to english language
36	limit 35 to yr="2000 -Current"

Database: Cochrane Central Register of Controlled Trials (CENTRAL) – Wiley interface

Date last searched: 09/11/2022

ID	Search
#1	MeSH descriptor: [Otitis Media with Effusion] this term only
#2	(("glue ear" or (("middle ear" or "otitis media") near/2 effusion*) or ome or ((secretory or serious) near/2 "otitis media"))):ti,ab,kw
#3	#1 or #2
#4	MeSH descriptor: [Economics] this term only
#5	MeSH descriptor: [Value of Life] this term only
#6	MeSH descriptor: [Costs and Cost Analysis] explode all trees
#7	MeSH descriptor: [Economics, Hospital] explode all trees
#8	MeSH descriptor: [Economics, Medical] explode all trees
#9	MeSH descriptor: [Economics, Nursing] this term only
#10	MeSH descriptor: [Economics, Pharmaceutical] this term only
#11	MeSH descriptor: [Fees and Charges] explode all trees
#12	MeSH descriptor: [Budgets] explode all trees
#13	budget*:ti,ab
#14	cost*:ti
#15	(economic* or pharmaco?economic*):ti
#16	(price* or pricing*):ti,ab
#17	(cost* near/2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)):ab
#18	(financ* or fee or fees):ti,ab
#19	(value near/2 (money or monetary)):ti,ab
#20	{or #4-#19}
#21	MeSH descriptor: [Models, Economic] explode all trees
#22	MeSH descriptor: [Models, Theoretical] this term only
#23	MeSH descriptor: [Models, Organizational] this term only
#24	MeSH descriptor: [Markov Chains] this term only
#25	MeSH descriptor: [Monte Carlo Method] this term only
#26	MeSH descriptor: [Decision Theory] explode all trees
#27	(markov* or "monte carlo"):ti,ab
#28	(econom* next model*):ti,ab
#29	(decision* near/2 (tree* or analy* or model*)):ti,ab
#30	{or #21-#29}
#31	#20 or #30
#32	#3 and #31 with Cochrane Library publication date Between Jan 2000 and Apr 2022

Database: International Network of Agencies for Health Technology Assessment (INAHTA)

Date last searched: 09/11/2022

#	Searches
1	((("Otitis Media with Effusion"[mhe]) OR ((("glue ear" or (("middle ear" or "otitis media") and effusion*) or ome or ((secretory or serous) and "otitis media")))
2	1 and FROM 2000 TO 2022 AND (English)[Language]

Database: NHS Economic Evaluation Database (NHS EED) – CRD interface

Date last searched: 09/11/2022

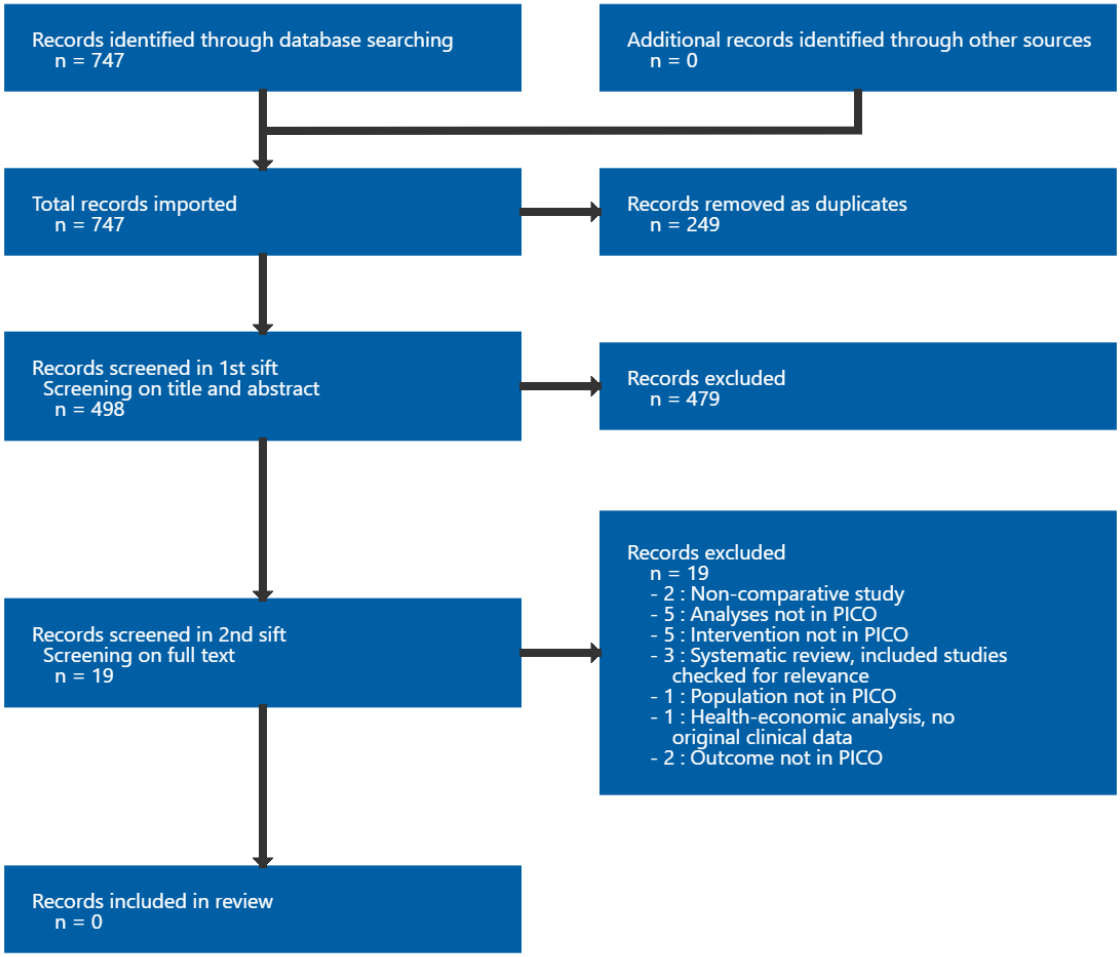
Line	Search for
1	MeSH DESCRIPTOR Otitis Media with Effusion EXPLODE ALL TREES
2	((glue ear or ((middle ear or otitis media) and effusion*) or ome or ((secretory or serous) and otitis media))) IN NHS EED
3	#1 OR #2

Appendix C Effectiveness evidence study selection

Study selection for: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

Clinical search

Figure 1: Study selection flow chart



Appendix D Evidence tables

Evidence tables for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

No evidence was identified which was applicable to this review question.

Appendix E Forest plots

Forest plots for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

No meta-analysis was conducted for this review question and so there are no forest plots.

Appendix F GRADE tables

GRADE tables for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

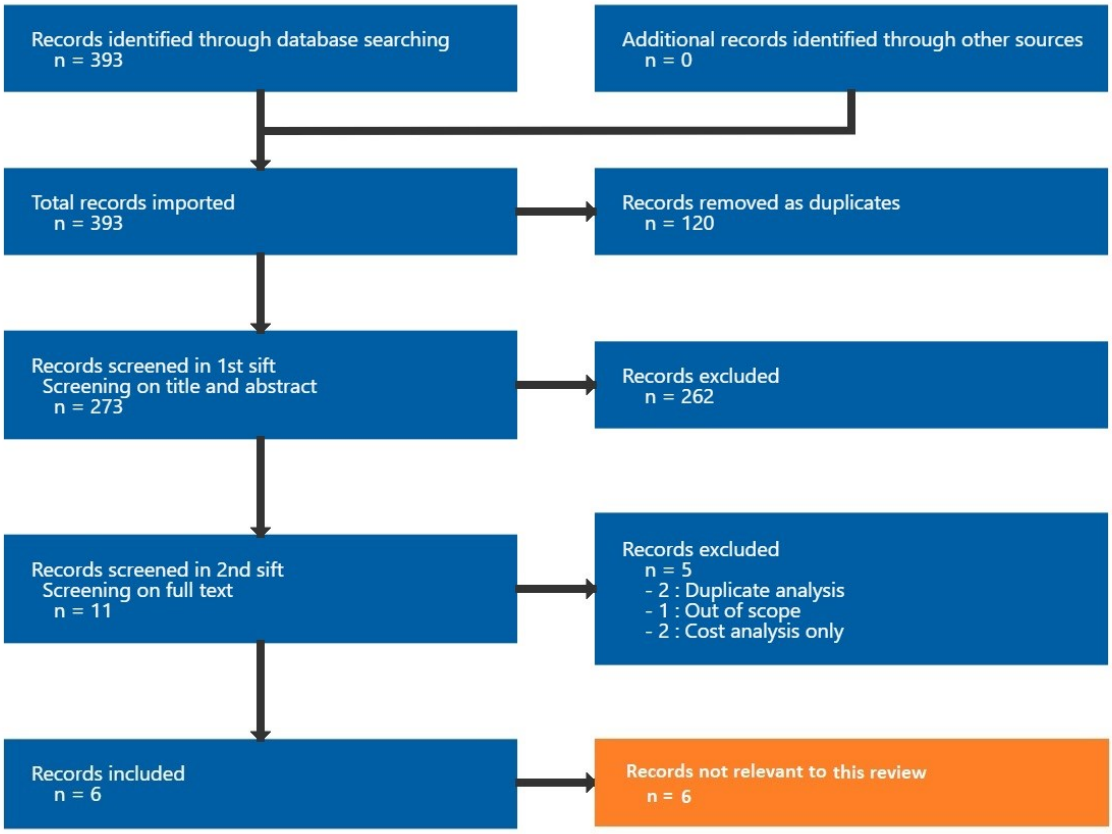
No evidence was identified which was applicable to this review question.

Appendix G Economic evidence study selection

Study selection for: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

A global economic literature search was undertaken for otitis media with effusion in under 12s. This covered all 14 review questions in this guideline. As shown in Figure 2 below, no economic studies were identified which were applicable to this review question.

Figure 2: Economic study selection flow chart



Appendix H Economic evidence tables

Economic evidence tables for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

No evidence was identified which was applicable to this review question.

Appendix I Economic model

Economic model for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

An economic model was undertaken which compared hearing aids, ventilation tubes and ventilation tubes with adjuvant adenoidectomy in children with hearing loss associated with OME. This model is discussed in Evidence review E.

Appendix J Excluded studies

Excluded studies for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

Excluded effectiveness studies

Table 3: Excluded studies and reasons for their exclusion

Study	Code [Reason]
Arick, Daniel S and Silman, Shlomo (2005) Nonsurgical home treatment of middle ear effusion and associated hearing loss in children. Part I: clinical trial. Ear, nose, & throat journal 84(9): 567-passim	- Intervention not in PICO *Modified Politzer device/air into nostrils*
Arman, S.; Amlani, A.; Doshi, J. (2020) Glue ear management & deprivation-A retrospective study of 89 patients. Clinical Otolaryngology 45(4): 616-618	- Analyses not in PICO *N5/73 had hearing aids; all comparative analyses examined effect of deprivation*
Banigo, A, Hunt, A, Rourke, T et al. (2016) Does the EarPopper(R) device improve hearing outcomes in children with persistent otitis media with effusion? A randomised single-blinded controlled trial. Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery 41(1): 59-65	- Intervention not in PICO *Modified Politzer/Ear popper device/air into nostrils*
Cambridgeshire Community Services NHS, Trust (2020) Exploring Interventions for Glue Ear During Covid-19. clinicaltrials.gov	- Non-comparative study
Gani, Bilal; Kinshuck, A J; Sharma, R (2012) A review of hearing loss in cleft palate patients. International journal of otolaryngology 2012: 548698	- Analyses not in PICO
Hall, A, Wills, A K, Mahmoud, O et al. (2017) Centre-level variation in outcomes and treatment for otitis media with effusion and hearing loss and the association of hearing loss with developmental outcomes at ages 5 and 7 years in children with non-syndromic unilateral cleft lip and palate: The Cleft Care UK study. Part 2. Orthodontics & craniofacial research 20suppl2: 8-18	- Analyses not in PICO
Holland Brown, Tamsin, Salorio-Corbetto, Marina, Gray, Roger et al. (2019) Using a Bone-Conduction Headset to Improve Speech Discrimination in Children With Otitis Media With Effusion. Trends in hearing 23: 2331216519858303	- Analyses not in PICO *N=19, all received same intervention [bone-conduction headset]. Analyses examined different conditions within each participant.*

Study	Code [Reason]
Homøe, P, Heidemann, CH, Damoiseaux, RA et al. (2020) Panel 5: Impact of otitis media on quality of life and development. International journal of pediatric otorhinolaryngology 130suppl1: 109837	- Systematic review, included studies checked for relevance
Maheshwar, A A, Milling, M A P, Kumar, M et al. (2002) Use of hearing aids in the management of children with cleft palate. International journal of pediatric otorhinolaryngology 66(1): 55-62	- Outcome not in PICO *Potentially relevant outcomes not clearly defined or reported; non-randomised study with n=17/70 receiving hearing aids only, 12/70 ventilation tubes only, 14/70 hearing aids + ventilation tubes and 27/70 no treatment; unclear inclusion criteria in terms of hearing and OME status "Between 1984 and 1998, 135 children with cleft lip, cleft palate or a combination of both were operated in the Gwent area, and were followed up in this clinic. We have carried out a retrospective study of the otological management of these children. Children with cleft lips only, sub mucosal cleft palates, patients who have moved to other areas, are deceased and those patients who defaulted were excluded from the study." (p. 56)*
Mohiuddin, Syed, Payne, Katherine, Fenwick, Elisabeth et al. (2015) A model-based cost-effectiveness analysis of a grommets-led care pathway for children with cleft palate affected by otitis media with effusion. The European journal of health economics : HEPAC : health economics in prevention and care 16(6): 573-87	- Health-economic analysis, no original clinical data
NHS Centre for Reviews and, Dissemination (1992) The treatment of persistent glue ear in children.	- Intervention not in PICO *Surgical interventions*
Parrella, A, Hiller, J et al. (2005) EarPopper (TM) for the treatment of otitis media with effusion in children.	- Intervention not in PICO *Modified Politzer/Ear popper device/air into nostrils*
Qureishi, A, Garas, G, Mallick, A et al. (2014) The psychosocial impact of hearing aids in children with otitis media with effusion. The Journal of laryngology and otology 128(11): 972-5	- Outcome not in PICO *Questionnaire regarding the parents of children who have either received grommets or hearing aids about their perception of hearing aids, thus the parents of the children with grommets have not had any actual experience of hearing aids; non-randomised study.*
Ramakrishnan, Y; Davison, T; Johnson, I J M (2006) How we do it: Softband--management of glue ear. Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery 31(3): 224-7	- Non-comparative study
Ramakrishnan, Y, Marley, S, Leese, D et al. (2011) Bone-anchored hearing aids in children and young adults: the Freeman Hospital	- Analyses not in PICO *Population received either bone-anchored hearing aids (mean age 16.1 years) or softband*

Study	Code [Reason]
experience. The Journal of laryngology and otology 125(2): 153-7	*(mean age 8.4); analyses either descriptive or focused on syndrome/non-syndrome comparison*
Sait, Salam; Alamoudi, Sarah; Zawawi, Faisal (2022) Management outcomes of otitis media with effusion in children with down syndrome: A systematic review. International journal of pediatric otorhinolaryngology 156: 111092	- Systematic review, included studies checked for relevance
Schilder, A.G.M., Marom, T., Bhutta, M.F. et al. (2017) Panel 7: Otitis Media: Treatment and Complications. Otolaryngology - Head and Neck Surgery (United States) 156(4suppl): 88-s105	- Systematic review, included studies checked for relevance
Shohet, J.A.; Gende, D.M.; Tanita, C.S. (2018) Totally implantable active middle ear implant: Hearing and safety results in a large series. Laryngoscope 128(12): 2872-2878	- Population not in PICO *Adults*
Silman, Shlomo; Arick, Daniel S; Emmer, Michele B (2005) Nonsurgical home treatment of middle ear effusion and associated hearing loss in children. Part II: Validation study. Ear, nose, & throat journal 84(10): 646-passim	- Intervention not in PICO *Modified Politzer device/air into nostrils*

1

2 **Excluded economic studies**

3 No economic evidence was identified for this review.

4

5

Appendix K Research recommendations – full details

Research recommendations for review question: What is the effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

K.1.1 Research recommendation

What is the clinical and cost-effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

K.1.2 Why this is important

There is high prevalence of OME in children under 12. The use of air conduction and bone conduction hearing aids/devices is a common practice for managing hearing loss associated with OME. The aim of providing interventions for OME is to minimise impacts on children's development and quality of life. Interventions therefore need to be effective in supporting hearing, suitable and acceptable for children and their carers so that there is good uptake, and have cost-effective outcomes. However, there is no available evidence to inform the clinical and cost-effectiveness of air conduction and bone conduction hearing aids/devices.

K.1.3 Rationale for research recommendation

Table 4: Research recommendation rationale

Importance to 'patients' or the population	There is a high prevalence of OME in children under 12. Hearing aids and devices are commonly used interventions. New evidence could improve knowledge of how effective hearing aids/devices are for managing hearing loss which could enable more effective and individualised care in the context of other management options.
Relevance to NICE guidance	The lack of evidence regarding this topic currently restricts the scope of NICE recommendations in this area and new research will be important for future updates.
Relevance to the NHS	Hearing loss in childhood can have a long-term negative impact on health and wellbeing as a result of language delay. Difficultly understanding adults and peers often adversely impacts behaviour, resulting in increased risk of mental health disorders. New evidence regarding clinical effectiveness of hearing aids/devices could improve quality of NHS services by improving understanding of the benefits and drawbacks of hearing aids/devices, which would help improve advice clinicians offer to parents/carers in helping them choose the best management option for their child. Improved understanding of the cost effectiveness of hearing aids/devices could lead to a financial benefit to the NHS. New technologies are increasing the potential scope of benefit and accessibility to amplification for children with OME.
National priorities	OME has a high rate of occurrence in children with Down's syndrome due to smaller craniofacial features. Providing the right care for children with a learning disability is stated as the NHS long-term plan to improve care for patients. Further knowledge of hearing aid/device effectiveness would help improve hearing loss management for children with Down's syndrome who have a higher likelihood to be offered hearing

	aids/devices due to difficulties in fitting grommets owing to smaller auditory structures. Core20PLUS5 (An approach to reducing health inequalities for children and young people) identified 20% of the national population as the most deprived population, and this group tends to struggle with adherence to hearing aid/device requirements. Children with learning difficulties also identified in the Core2050PLUS5 approach.
Current evidence base	There is a research gap, and no evidence was found for the review question in the current guideline update search.
Equality considerations	In line with the Equalities Act (2010) it is vital that young children under 12 with hearing loss have the best possible access to the spoken word to enable them to access education, succeed in their learning and promote positive mental health and wellbeing. Children with low socio-economic status/children without robust support network may struggle with ongoing adherence requirements of hearing aids. Hearing aids is the more common intervention for children with cranio-facial abnormalities due to difficulties inherent in insertion of grommets so comparative research of air conduction versus bone conduction hearing aids/devices would be relevant in ensuring this group has access to the most effective technology.

1 *NHS: National Health Service; NICE: National Institute for Health and Care Excellence; OME: otitis media with*
2 *effusion*

K.1.43 Modified PICO table

4 **Table 5: Research recommendation modified PICO table**

Population	All children under 12 years with hearing loss due to confirmed OME. Stratified sampling to ensure equal numbers across age groups and a sample that represents diversity across deprivation/affluence, urban/rural, ethnic minorities and additional needs. Study by deprivation (health economic status) and age band (pre-school and school age)
Intervention	• Air conduction hearing aids • Bone conduction hearing aids • Bone conduction hearing devices
Comparator	• Head-to-head comparisons of interventions • No hearing aid/device
Outcome	• Measured hearing thresholds • Quality of Life – OM8-30 questionnaire, EQ-5D, and HUI3 • Speech discrimination • Cost • Acceptability and attitudes to intervention • Uptake/usage continuation • Listening skills • Receptive language skills • Psychological development
Study design	• RCTs • Adjusted cohort studies* with at least 40 participants per arm • Economic evaluation • It would be advantageous to coordinate study design with that for other interventions – see research recommendations for ventilation tubes (see evidence review E).

	*Cohort studies should adjust for the following covariates in their analysis when there are differences between groups at baseline: age, additional sensory or learning needs, time since diagnosis, and severity of hearing loss at diagnosis
Timeframe	Two years from randomisation.
Additional information	It is important that participants in the trial adequately reflect the early years population. OME affects about 80% of children under the age of four. Incidence increases after birth reaching a peak at around 2 years. Issues related to compliance with hearing aids and early language development varies across this age range and it is vitally important to determine the benefits for very young children in addition to the school age population of children with OME. For children under 18 months, it will be difficult to collate information related to speech discrimination and listening skills and as such it is recommended that this should be considered as the lower age limit for these outcomes.

1 *EQ: EuroQoL; HUI: Health Utilities Index; NICE: National Institute for Health and Care Excellence; OM: otitis*
2 *media; OME: otitis media with effusion; RCT: randomised controlled trial*

3