

Otitis media with effusion in under 12s

[M] Evidence reviews for follow-up strategy after surgical treatment for OME-related hearing loss

NICE guideline number tbc

*Evidence reviews underpinning recommendations 1.6.11 to 1.6.14 and research recommendation in the NICE guideline
March 2023*

Draft for consultation

This evidence review was developed by NICE

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1 **Follow-up strategy after surgical treatment** 2 **for OME-related hearing loss**

3 **Review question**

4 What should the follow-up strategy be after surgical treatment for OME-related hearing loss
5 in children under 12 years?

6 **Introduction**

7 The aim of this review is to investigate follow-up strategies after surgical treatment for OME-
8 related hearing loss in children under 12 years.

9 At the time of development, the term ventilation tube (VT) was used to refer to tubes inserted
10 during surgery for OME. However, the committee agreed that the term grommet should be
11 used as this is likely to be the term that is more familiar to readers of the guideline and would
12 avoid confusion with tubes used to assist with breathing. Therefore, both terms appear in this
13 evidence review.

14 **Summary of the protocol**

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

1 Table 1: Summary of the protocol (PICO table)

Population	All children under 12 years who have had surgery for OME-related hearing loss.
Intervention	<ul style="list-style-type: none"> • Follow-up of duration A • Follow-up of frequency A • Personnel/professional group carrying out the follow-up A • Content of follow-up A
Comparison	<ul style="list-style-type: none"> • Follow-up of duration B • Follow-up of frequency B • Personnel/professional group carrying out the follow-up B • Content of follow-up B <p>Any comparisons (within the categories of duration, frequency, personnel/professional group and content) reported in the evidence will be included.</p>
Outcome	<p>Critical</p> <ul style="list-style-type: none"> • Hearing (measured by pure tone audiometry or speech recognition thresholds, in dB HL) • Additional intervention (e.g., repeat ventilation tube insertion, antibiotics) • Parent/carer and/or child satisfaction <p>Important</p> <ul style="list-style-type: none"> • Persistent otorrhoea (ear discharge) (either clinically confirmed or parent-reported) • Perforation of the tympanic membrane • 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 Health Questionnaire)

2 ABEL: Auditory Behaviour in Everyday Life; dB HL: decibel hearing levels; ECLiPS: Evaluation of Children's
3 Listening and Processing Skills; ELF: Early Listening Functioning; EQ: EuroQoL; HUI: Health Utilities Index;
4 PEACH: Parents' Evaluation of Aural/Oral Performance of Children; OM: otitis media; OME: otitis media with
5 effusion; OMQ: Otitis Media Quality of Life

6 For further details see the review protocol in appendix A.

7 Methods and process

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

12 Declarations of interest were recorded according to [NICE's conflicts of interest policy](#).

13 Effectiveness evidence**14 Included studies**

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

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

2 Excluded studies

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

5 Summary of included studies

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

9 Summary of the evidence

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

12 Economic evidence

13 Included studies

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

16 Economic model

17 No economic modelling was undertaken for this review because the committee agreed that
18 other topics were higher priorities for economic evaluation especially as it was anticipated
19 that there would be little if any effective evidence on which to underpin an analysis.

20 The committee's discussion and interpretation of the evidence

21 The outcomes that matter most

22 Hearing loss or hearing difficulty is often associated with OME, and this could impact on the
23 child's language and behavioural development. Effective follow-up strategy after surgical
24 treatment for OME-related hearing loss may improve hearing and may reduce the need for
25 additional intervention (for example, repeat ventilation tube insertion and antibiotics) by
26 identifying potential issues earlier. Therefore, hearing and additional intervention were
27 prioritised as critical outcomes. The committee agreed that parent, carer and child
28 satisfaction is an important dimension of quality of care and may be impacted by different
29 follow-up strategies; therefore, it was also prioritised as a critical outcome.

30 Otorrhoea is a common complication after surgery, which may both recur and lead to poor
31 quality of life in children with OME. The committee agreed that this may be impacted by
32 differences in follow-up as it may be identified and treated earlier if children are followed up
33 more regularly. Therefore, persistent otorrhoea was selected as an important outcome.
34 Similarly, perforation of the tympanic membrane was also selected as an important outcome
35 because differences in follow-up may lead to differences in the identification and treatment of
36 factors that may cause perforation, such as infection. In addition, quality of life was selected
37 as an important outcome as this is a global measure that takes into account both beneficial
38 and adverse effects of the interventions.

1 The quality of the evidence

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

3 Benefits and harms

4 There was no available evidence on the effectiveness of the follow-up strategy after surgical
5 treatment for OME-related hearing loss in children under 12 years. Therefore, the committee
6 made recommendations based on current practice and their knowledge and experience.

7 The committee acknowledged that it is important for medico-legal reasons to detect
8 complications of surgery as soon as possible, particularly hearing loss, to provide necessary
9 treatment and avoid its harmful impacts. The committee, based on their knowledge and
10 experience, were aware that post-operative hearing tests tend to be performed 6 weeks after
11 surgery, which should allow sufficient time for post-operative bleeding to resolve. This may
12 also give the opportunity to check if grommets have fallen out early which could happen, for
13 example, if the hole made for the grommet was too large. Despite the lack of evidence, the
14 committee made a strong recommendation that a post-operative hearing test should be
15 carried out 6 weeks after surgery, as this is in line with current practice and there could be
16 serious developmental consequences for the child if there is unidentified ongoing hearing
17 loss, such as profound speech, language, and developmental delay.

18 The committee were aware that children may still experience hearing loss after grommet
19 interventions, and one committee member was aware of a local audit that showed about 10%
20 of children may need further grommet surgery. In the committee's experience, hearing loss is
21 not always identified by parents and schoolteachers. If hearing loss is not noticed, the
22 consequences for the child can be serious, as discussed above. In the committee's
23 experience, grommets tend to fall out between 6 months and 18 months after surgery, with
24 most grommets falling out about 6 months after surgery. However, children, parents or
25 teachers may not necessarily know when grommets fall out. Therefore, children may be at
26 risk of further hearing loss from about 6 months after surgery as hearing loss can return
27 when grommets fall out. As a result, the committee agreed it may be important to have a
28 routine 1-year follow-up with a hearing test (for example, audiogram) to pick up children with
29 hearing loss that may not be obvious to the parents or teacher. It may also give the
30 opportunity to identify other potential complications after grommet surgery, such as
31 perforation of the tympanic membrane. The committee, based on their knowledge and
32 experience, acknowledged that there is variation in practice and, were aware that a routine 1-
33 year follow up plan may lead to a radical change in practice. It would lead to an increase in
34 resources in places that currently discharge children from follow-up once it has been
35 established that their hearing is normal (for example, 6 weeks post-surgery) but a decrease
36 in resources for places that currently have a 3 to 6 month, or more regular, follow-up. The
37 committee discussed that, given the lack of evidence and potentially large change to
38 practice, a strong recommendation in support of routine 1-year follow-up could not be made.
39 However, the committee agreed that having a routine 1-year follow-up for every child after
40 grommet surgery would be important for reducing the risk of inequality that may otherwise
41 occur if relying on families to identify and raise concerns. Some populations, for example
42 parents with their own communication difficulties, may be less likely to identify concerns or
43 find it more difficult to raise any concerns they do identify which could disadvantage some
44 children if a standard follow-up process is not followed. Therefore, the committee agreed that
45 a routine 1-year follow-up with a hearing test should be considered.

46 The committee discussed that some children could be at increased risk of having
47 unrecognised OME with hearing loss. For example, cognitive or communication difficulties
48 may inhibit their ability to recognise or communicate that they have hearing loss, so they may
49 need more frequent follow-up or targeted follow-up plans. Therefore, the committee agreed
50 that after surgery an individualised follow-up plan should be considered in these children as it
51 is good clinical practice.

1 The committee discussed that parents should have the opportunity to contact audiology
2 services to discuss the need for further hearing assessment for their child when they are
3 concerned about recurrence of hearing loss after surgery. The committee felt that it may
4 reduce delays in identifying recurrent hearing loss and therefore, appropriate interventions to
5 address this and avoid adverse effects on the child's development and wellbeing as people
6 will not have to go through GP referral. However, the committee were aware that there is
7 variation in practice, and audiology services may or may not accept direct referrals
8 depending on when reassessment is needed. They discussed that it is fairly common in
9 practice that audiology services may only accept direct referrals for reassessment within one
10 year after discharge, but reassessment may be carried out by GP if it is after one year. The
11 committee agreed that the recommendation will give the flexibility for audiology services to
12 accept direct referrals or to refer the child back to the GP if this is necessary.

13 The committee acknowledged that it is important to understand the follow-up strategy
14 required for children who undergo grommet insertion as this may have a significant impact on
15 patient experience, NHS resources, and health outcomes, including hearing and quality of
16 life. The committee also acknowledged that understanding the appropriate follow-up strategy
17 for children with cognitive or communication difficulties is important as they may need
18 targeted follow-up plans. However, there was no available evidence on the follow-up strategy
19 after surgical treatment for OME-related hearing loss in children under 12 years. Therefore,
20 the committee agreed that research is needed to inform appropriate follow-up strategy and
21 made a research recommendation on the follow-up strategy after surgical treatment for
22 OME-related hearing loss in children under 12 years (see Appendix K).

23 **Cost effectiveness and resource use**

24 This review question was not prioritised for economic analysis and therefore the committee
25 made a qualitative assessment of the likely cost-effectiveness of their recommendations. The
26 committee considered that it would be cost-effective to offer post-operative hearing tests at 6
27 weeks after surgery as they reasoned that unidentified ongoing hearing loss could result in
28 serious developmental harms, which would impact negatively on quality of life and be costly
29 to address. They noted that this was current practice and therefore their recommendation
30 would not have any cost impact to the NHS.

31 The committee agreed it was difficult to determine the most cost-effective time for
32 subsequent follow-up and they also noted there was considerable variation in practice. They
33 did not recommend regular 3-6 month follow up, as occurs in some places, as they were
34 unconvinced that such a resource intensive approach would be commensurate with any
35 benefits obtained. However, the committee did make a weak recommendation for routine 1-
36 year follow-up which would represent a change in practice and increase in resources for
37 those areas where children are discharged once it is established that hearing is normal. The
38 committee reasoned that some families may not identify and raise concerns in the absence
39 of any such follow-up. However, the committee recognised there was not clinical or cost-
40 effectiveness evidence to support this approach and this was reflected in the strength of the
41 recommendation. The committee also recommended that a more regular and individualised
42 follow-up plan could be considered for children with an increased risk of unrecognised OME
43 with hearing loss. They reasoned that this was a relatively small population and so would not
44 have a significant resource impact and that it would help mitigate adverse impacts on health-
45 related quality of life.

46 The committee also made a recommendation to advise parents to seek reassessment of
47 their child by audiology services if they have concerns about recurrence of hearing loss after
48 surgery. Ideally, the committee believed that this should be possible from self-referral but
49 recognised that direct referrals were not always possible. Again, the committee considered
50 that this would only apply to a subset of the population having surgery and therefore they did
51 not anticipate a large resource impact to the NHS whilst facilitating early identification of
52 hearing loss.

1 Recommendations supported by this evidence review

2 This evidence review supports recommendations 1.6.11, 1.6.12, 1.6.13 and 1.6.14 and the
3 research recommendation on the follow-up strategy after surgical treatment for OME-related
4 hearing loss in children under 12 years.

5 References – included studies

6 Effectiveness

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

8

1 Appendices

2 Appendix A Review protocols

3 Review protocol for review question: What should the follow-up strategy be after surgical treatment for OME-related hearing loss in children under 12 years?

5 Table 2: Review protocol

Field	Content
PROSPERO registration number	CRD42022349578
Review title	Follow-up strategy after surgical treatment for OME-related hearing loss
Review question	What should the follow-up strategy be after surgical treatment for OME-related hearing loss in children under 12 years?
Objective	To determine the effectiveness and acceptability of different follow-up strategies after surgery for hearing loss associated with OME in children under 12 years.
Searches	<p>The following databases will be searched:</p> <ul style="list-style-type: none">• Cochrane Central Register of Controlled Trials (CENTRAL)• Cochrane Database of Systematic Reviews (CDSR)• Embase• MEDLINE• Epistemonikos• International Health Technology Assessment (INAHTA) database <p>Searches will be restricted by:</p> <ul style="list-style-type: none">• OECD geographic study filter• Date limitations: 2000• English language• Human studies

Field	Content
	<p>Other searches:</p> <ul style="list-style-type: none"> • Inclusion lists of systematic reviews <p>With the agreement of the guideline committee the searches will be re-run between 6-8 weeks before final submission of the review and further studies retrieved for inclusion.</p> <p>The full search strategies for MEDLINE database will be published in the final review</p>
Condition or domain being studied	Hearing loss associated with otitis media with effusion
Population	Inclusion: All children under 12 years who have had surgery for OME-related hearing loss.
Intervention/Exposure/Test	<ul style="list-style-type: none"> • Follow-up of duration A • Follow-up of frequency A • Personnel/professional group carrying out the follow-up A • Content of follow-up A
Comparator/Reference standard/Confounding factors	<ul style="list-style-type: none"> • Follow-up of duration B • Follow-up of frequency B • Personnel/professional group carrying out the follow-up B • Content of follow-up B <p>Any comparisons (within the categories of duration, frequency, personnel/professional group and content) reported in the evidence will be included.</p>
Types of study to be included	<p>Include published full-text papers:</p> <ul style="list-style-type: none"> • 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

Field	Content
	<p>*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.</p> <p>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:</p> <ul style="list-style-type: none"> • Age • Craniofacial anomalies • Socioeconomic status • Additional sensory or learning needs
Other exclusion criteria	<p>Country limitations: limit studies to OECD high-income countries</p> <p>Date limitations: 2000 as the 2008 OME guideline has changed practice. However, the committee wanted to capture research leading up to the 2008 guideline also, and not just research conducted afterwards.</p> <p>Language limitations: studies published not in English-language</p> <p>Conference abstracts will not be considered.</p>
Context	This guidance will fully update the following NICE guideline: Otitis media with effusion in under 12s: surgery (2008; CG60)
Primary outcomes (critical outcomes)	<ul style="list-style-type: none"> • Hearing (measured by pure tone audiometry or speech recognition thresholds, in dB HL) • Additional intervention (e.g., repeat ventilation tube insertion, antibiotics) • Parent/carer and/or child satisfaction
Secondary outcomes (important outcomes)	<ul style="list-style-type: none"> • Persistent otorrhoea (ear discharge) (either clinically confirmed or parent-reported) • Perforation of the tympanic membrane

Field	Content
	<ul style="list-style-type: none"> • 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 Health Questionnaire)
Data extraction (selection and coding)	<p>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, if capacity allows it; 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.</p> <p>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.</p>
Risk of bias (quality) assessment	<p>Quality assessment of individual studies will be performed using the following checklists:</p> <ul style="list-style-type: none"> • 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 <p>The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.</p>

Field	Content
Strategy for data synthesis	<p>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. 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.</p> <p>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/</p> <p>Minimally important differences (MIDs):</p> <ul style="list-style-type: none"> Validated scales: Published MIDs where available; if not 0.8 and 1.25 for dichotomous outcomes and 0.5 SD of the control group at baseline for continuous outcomes All other outcomes: 0.8 and 1.25 for dichotomous outcomes and 0.5 SD of the control group at baseline for continuous outcomes
Analysis of sub-groups	<p>Evidence will be stratified by:</p> <p>Craniofacial anomalies</p> <ul style="list-style-type: none"> Children with Down's syndrome Children with cleft palate Children with other craniofacial anomalies Children without craniofacial anomalies

Field	Content														
	<p>Mucociliary condition such as cystic fibrosis</p> <p>Evidence will be subgrouped by the following only in the event that there is significant heterogeneity in outcomes:</p> <ul style="list-style-type: none"> • Previous episode of otorrhoea • Previous episode of acute otitis media • Age <ul style="list-style-type: none"> ○ Children <2 years vs ≥2 years ○ Children <4 years vs ≥4 years ○ Children <6 years vs ≥6 years <p>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.</p>														
Type and method of review	<table border="1"> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>Intervention</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Diagnostic</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Prognostic</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Qualitative</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Epidemiologic</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Service Delivery</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Other (please specify)</td> </tr> </tbody> </table>	<input checked="" type="checkbox"/>	Intervention	<input type="checkbox"/>	Diagnostic	<input type="checkbox"/>	Prognostic	<input type="checkbox"/>	Qualitative	<input type="checkbox"/>	Epidemiologic	<input type="checkbox"/>	Service Delivery	<input type="checkbox"/>	Other (please specify)
<input checked="" type="checkbox"/>	Intervention														
<input type="checkbox"/>	Diagnostic														
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<input type="checkbox"/>	Qualitative														
<input type="checkbox"/>	Epidemiologic														
<input type="checkbox"/>	Service Delivery														
<input type="checkbox"/>	Other (please specify)														
Language	English														
Country	England														
Anticipated or actual start date	26/07/2022														

Field	Content		
Anticipated completion date	28/09/2023		
Stage of review at time of this submission	Review stage	Started	Completed
	Preliminary searches	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Piloting of the study selection process	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Formal screening of search results against eligibility criteria	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Data extraction	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Risk of bias (quality) assessment	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Data analysis	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Named contact	<p>Named contact: National Guideline Alliance</p> <p>Named contact e-mail: otitis@nice.org.uk</p> <p>Organisational affiliation of the review: National Institute for Health and Care Excellence (NICE) and National Guideline Alliance</p>		
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	<p>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.</p>		

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-ng10193
Other registration details	None
Reference/URL for published protocol	https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022349578
Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: <ul style="list-style-type: none"> • 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, surgery, ventilation tubes, grommets, hearing loss, follow-up
Details of existing review of same topic by same authors	None
Current review status	<input type="checkbox"/> Ongoing <input checked="" type="checkbox"/> Completed but not published <input type="checkbox"/> Completed and published <input type="checkbox"/> Completed, published and being updated <input type="checkbox"/> Discontinued
Additional information	None
Details of final publication	www.nice.org.uk

- 1 ABEL: Auditory Behaviour in Everyday Life; CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; dB HL: decibel hearing levels; ECLiPS: Evaluation of Children's Listening and Processing Skills; ELF: Early Listening Functioning; EPPI: Evidence for Policy and Practice Information; EQ: EuroQoL; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HUI: Health Utilities Index; INAHTA: International Health Technology Assessment database; MEDLINE: Medical Literature Analysis and Retrieval System Online; MID: minimally important difference; NICE: National Institute for Health and Care Excellence; OECD: Organisation for Economic Co-operation and Development; OM: otitis media; OME: otitis media with effusion; OMQ: Otitis Media Quality of Life; PEACH:

- 1 *Parents' Evaluation of Aural/Oral Performance of Children; RCT: randomised controlled trial; RoB: risk of bias; ROBINS-I: risk of bias in non-randomised studies – of*
- 2 *interventions; ROBIS: risk of bias in systematic reviews; SD: standard deviation*

1 Appendix B Literature search strategies

2 Literature search strategies for review question: What should the follow-up 3 strategy be after surgical treatment for OME-related hearing loss in children 4 under 12 years?

5 Clinical search

6 Database: MEDLINE – OVID interface

7 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	exp Aftercare/ or "Continuity of Patient Care"/ or Disease Management/ or Follow-Up Studies/ or Long-Term Care/ or Monitoring, Physiologic/ or Patient Discharge/ or Population Surveillance/ or Postoperative Care/ or Postoperative Period/
5	(aftercare or check up* or checkup* or convales* or follow up* or followup* or postadenoidectomy* or postadenotonsillectomy* or postimplant* or postmyringoplast* or postmyringotomy* or postoperat* or postsurg* or posttonsillectomy* or posttubulat* or posttympanoplast* or posttympanostomy* or postventilat* or recover* or recuperat* or surveillance or ((periodic* or regular*) adj2 (check* or exam* or monitor*)) or ((after* or check* or continu* or evaluat* or follow* or monitor* or post or rehab* or review*) adj3 (care or discharg* or adenoidectomy* or adenotonsillectomy* or excis* or grommet* or implant* or myringoplast* or myringostomy* or myringotomy* or operat* or stapes or surg* or tonsillectomy* or treatment* or tube* or tubulat* or tympanoplast* or tympanostomy* or ventilat*)))).ti,ab,kw.
6	4 or 5
7	3 and 6
8	letter/ or editorial/ or news/ or exp historical article/ or Anecdotes as Topic/ or comment/ or case report/ or (letter or comment*).ti.
9	randomized controlled trial/ or random*.ti,ab.
10	8 not 9
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 or 11
13	7 not 12
14	limit 13 to (english language and yr="2000 -Current")
15	meta-analysis/ or meta-analysis as topic/ or "systematic review"/
16	(meta analy* or metanaly* or metaanaly* or ((evidence or systematic*) adj2 (overview* or review*))).ti,ab.
17	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
18	(search strategy or search criteria or systematic search or study selection or data extraction or (search* adj4 literature)).ab.
19	(MEDLINE or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
20	cochrane.jw.
21	or/15-20
22	14 and 21
23	(controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt.
24	drug therapy.fs.
25	(groups or placebo or randomi#ed or randomly or trial).ab.
26	Clinical Trials as Topic/
27	trial.ti.
28	or/23-27
29	14 and 28
30	Observational Studies as Topic/
31	Observational Study/
32	Epidemiologic Studies/
33	exp Case-Control Studies/
34	exp Cohort Studies/
35	Cross-Sectional Studies/
36	Controlled Before-After Studies/
37	Historically Controlled Study/
38	Interrupted Time Series Analysis/
39	Comparative Study.pt.
40	case control\$.tw.
41	case series.tw.
42	(cohort adj (study or studies)).tw.

#	Searches
43	cohort analy\$.tw.
44	(follow up adj (study or studies)).tw.
45	(observational adj (study or studies)).tw.
46	longitudinal.tw.
47	prospective.tw.
48	retrospective.tw.
49	cross sectional.tw.
50	or/30-49
51	14 and 50
52	22 or 29 or 51

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	exp aftercare/ or clinical monitoring/ or convalescence/ or hospital discharge/ or long term care/ or patient monitoring/ or periodic medical examination/ or population surveillance/ or postoperative care/ or postoperative period/
5	(aftercare or check up* or checkup* or convales* or follow up* or followup* or postadenoidectomy* or postadenotonsillectomy* or postimplant* or postmyringoplast* or postmyringostomy* or postmyringotomy* or postoperat* or postsurg* or posttonsillectomy* or posttubulat* or posttympanoplast* or posttympanostomy* or postventilat* or recover* or recuperat* or surveillance or ((periodic* or regular*) adj2 (check* or exam* or monitor*)) or ((after* or check* or continu* or evaluat* or follow* or monitor* or post or rehab* or review*) adj3 (care or discharg* or adenoidectomy* or adenotonsillectomy* or excis* or grommet* or implant* or myringoplast* or myringostomy* or myringotomy* or operat* or stapes or surg* or tonsillectomy* or treatment* or tube* or tubulat* or tympanoplast* or tympanostomy* or ventilat*)))).ti,ab,kw.
6	4 or 5
7	3 and 6
8	letter.pt. or letter/ or note.pt. or editorial.pt. or case report/ or case study/ or (letter or comment*).ti.
9	randomized controlled trial/ or random*.ti,ab.
10	8 not 9
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 or 11
13	7 not 12
14	limit 13 to (english language and yr="2000 -Current")
15	limit 14 to (conference abstract or conference paper or conference review or conference proceeding)
16	14 not 15
17	systematic review/ or meta-analysis/
18	(meta analy* or metanaly* or metaanaly* or ((evidence or systematic*) adj2 (overview* or review*))).ti,ab.
19	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
20	(search strategy or search criteria or systematic search or study selection or data extraction or (search* adj4 literature)).ab.
21	(MEDLINE or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
22	cochrane.jw.
23	or/17-22
24	16 and 23
25	(random* or factorial* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or assign* or allocat* or volunteer* or placebo*).ti,ab.
26	crossover procedure/ or single blind procedure/ or randomized controlled trial/ or double blind procedure/
27	25 or 26
28	16 and 27
29	Clinical study/
30	Case control study/
31	Family study/
32	Longitudinal study/
33	Retrospective study/
34	comparative study/
35	Prospective study/
36	Randomized controlled trials/
37	35 not 36
38	Cohort analysis/
39	cohort analy\$.tw.
40	(Cohort adj (study or studies)).tw.
41	(Case control\$ adj (study or studies)).tw.
42	(follow up adj (study or studies)).tw.

#	Searches
43	(observational adj (study or studies)).tw.
44	(epidemiologic\$ adj (study or studies)).tw.
45	(cross sectional adj (study or studies)).tw.
46	case series.tw.
47	prospective.tw.
48	retrospective.tw.
49	or/29-34,37-48
50	16 and 49
51	or/24,28,50

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

- 3 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 serous) near/2 "otitis media"):ti,ab
#3	#1 or #2
#4	MeSH descriptor: [Aftercare] explode all trees
#5	MeSH descriptor: [Continuity of Patient Care] this term only
#6	MeSH descriptor: [Disease Management] this term only
#7	MeSH descriptor: [Follow-Up Studies] this term only
#8	MeSH descriptor: [Long-Term Care] this term only
#9	MeSH descriptor: [Monitoring, Physiologic] this term only
#10	MeSH descriptor: [Patient Discharge] this term only
#11	MeSH descriptor: [Population Surveillance] this term only
#12	MeSH descriptor: [Postoperative Care] this term only
#13	MeSH descriptor: [Postoperative Period] this term only
#14	(aftercare or "check up" or checkup* or convales* or "follow up" or followup* or postadenoidectomy* or postadenotonsillectomy* or postimplant* or postmyringoplast* or postmyringotomy* or postoperat* or postsurg* or posttonsillectomy* or posttubulat* or posttympanoplast* or posttympanostomy* or postventilat* or recover* or recuperat* or surveillance or ((periodic* or regular*) near/2 (check* or exam* or monitor*)) or ((after* or check* or continu* or evaluat* or follow* or monitor* or post or rehab* or review*) near/3 (care or discharg* or adenoidectomy* or adenotonsillectomy* or excis* or grommet* or implant* or myringoplast* or myringotomy* or myringotom* or operat* or stapes or surg* or tonsillectomy* or treatment* or tube* or tubulat* or tympanoplast* or tympanostomy* or ventilat*))):ti,ab,kw
#15	{or #4-#14}
#16	#3 and #15
#17	"conference":pt or (clinicaltrials or trialsearch):so
#18	#16 not #17 with Cochrane Library publication date Between Jan 2000 and Nov 2022

- 4 Database: Epistemonikos

- 5 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:(("aftercare or "check up" or "check ups" or checkup* or convales* or "follow up" or "follow ups" or followup* or postadenoidectomy* or postadenotonsillectomy* or postimplant* or postmyringoplast* or postmyringotomy* or postmyringotom* or postoperat* or postsurg* or posttonsillectomy* or posttubulat* or posttympanoplast* or posttympanostomy* or postventilat* or recover* or recuperat* or surveillance) OR abstract:(("aftercare or "check up" or "check ups" or checkup* or convales* or "follow up" or "follow ups" or followup or postadenoidectomy* or postadenotonsillectomy* or postimplant* or postmyringoplast* or postmyringotomy* or postmyringotom* or postoperat* or postsurg* or posttonsillectomy* or posttubulat* or posttympanoplast* or posttympanostomy* or postventilat* or recover* or recuperat* or surveillance)))
3	(title:(("periodic or regular") AND (check* or exam* or monitor*)) OR abstract:(("periodic or regular") AND (check* or exam* or monitor*)))
4	(title:(("after* or check* or continu* or evaluat* or follow* or monitor* or post or rehab* or review*) AND (care or discharg* or adenoidectomy* or adenotonsillectomy* or excis* or grommet* or implant* or myringoplast* or myringotomy* or myringotom* or operat* or stapes or surg* or tonsillectomy* or treatment* or tube* or tubulat* or tympanoplast* or tympanostomy* or ventilat*)) OR abstract:(("after* or check* or continu* or evaluat* or follow* or monitor* or post or rehab* or review*) AND (care or discharg* or adenoidectomy* or adenotonsillectomy* or excis* or grommet* or implant* or myringoplast* or myringotomy* or myringotom* or operat* or stapes or surg* or tonsillectomy* or treatment* or tube* or tubulat* or tympanoplast* or tympanostomy* or ventilat*)))
5	2 OR 3 OR 4
6	1 AND 5
7	[Filters: min_year=2000, max_year=2022]

1 Database: International Network of Agencies for Health Technology Assessment 2 (INAHTA)

3 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
5	3 AND 4 FROM 2000 TO 2022 AND (English)[Language]

4

5 Economic literature search strategy

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

8 Database: MEDLINE – OVID interface

9 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/
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"

10 Database: Embase – OVID interface

11 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/

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

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

2 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}

ID	Search
#31	#20 or #30
#32	#3 and #31 with Cochrane Library publication date Between Jan 2000 and Apr 2022

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

3 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]

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

5 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

6

7

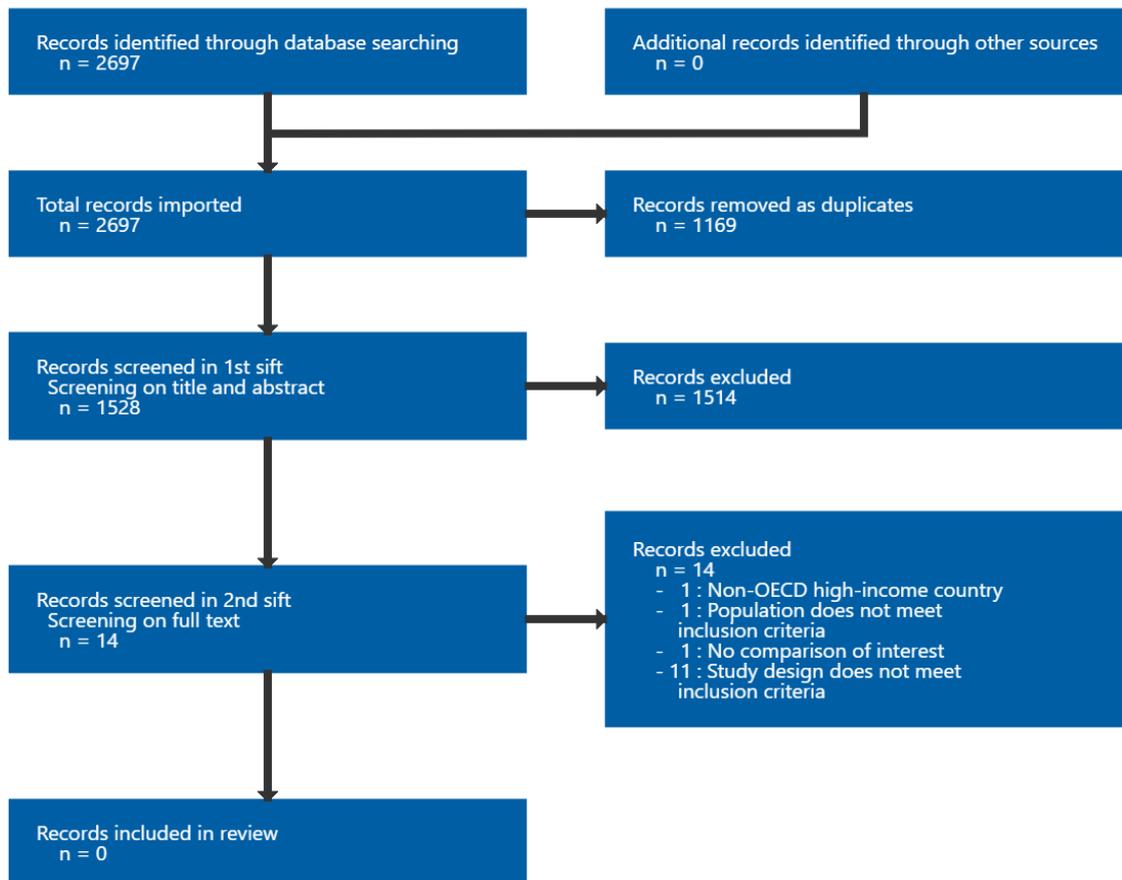
8

1 Appendix C Effectiveness evidence study selection

2 Study selection for: What should the follow-up strategy be after surgical 3 treatment for OME-related hearing loss in children under 12 years?

4 Clinical search

Figure 1: Study selection flow chart



5

6

1 **Appendix D Evidence tables**

2 **Evidence tables for review question: What should the follow-up strategy be after surgical treatment for OME-related hearing** 3 **loss in children under 12 years?**

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

5

6

1 **Appendix E Forest plots**

2 **Forest plots for review question: What should the follow-up strategy be after surgical treatment for OME-related hearing loss** 3 **in children under 12 years?**

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

5

1 **Appendix F GRADE tables**

2 **GRADE tables for review question: What should the follow-up strategy be after surgical treatment for OME-related hearing** 3 **loss in children under 12 years?**

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

5

6

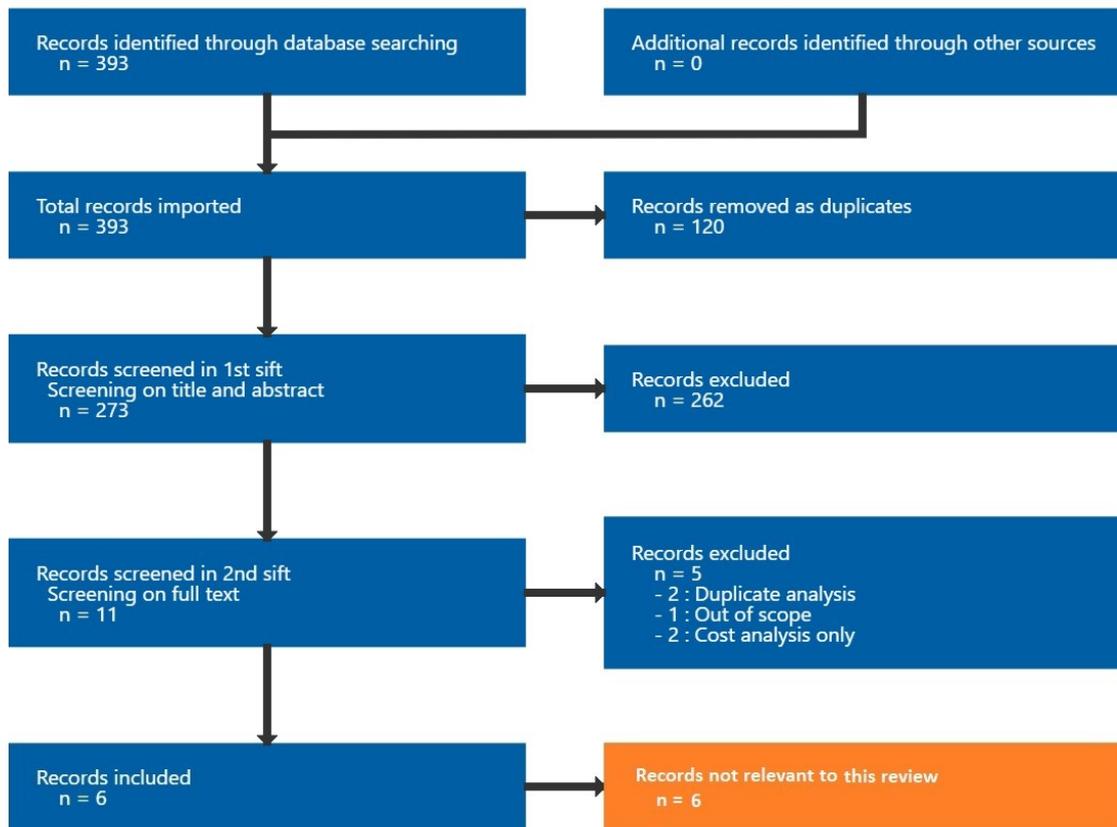
7

1 Appendix G Economic evidence study selection

2 Study selection for: What should the follow-up strategy be after surgical 3 treatment for OME-related hearing loss in children under 12 years?

4 A global search was undertaken to cover all the review questions considered in this
5 guideline, but no economic evidence was identified which was applicable to this review
6 question (see Figure 2).

Figure 2: Study selection flow chart



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8
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10
11

1 **Appendix H Economic evidence tables**

2 **Economic evidence tables for review question: What should the follow-up** 3 **strategy be after surgical treatment for OME-related hearing loss in children** 4 **under 12 years?**

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

6

1 **Appendix I Economic model**

2 **Economic model for review question: What should the follow-up strategy be**
3 **after surgical treatment for OME-related hearing loss in children under 12**
4 **years?**

5 No economic analysis was conducted for this review question.

6

7

1 Appendix J Excluded studies

2 Excluded studies for review question: What should the follow-up strategy be 3 after surgical treatment for OME-related hearing loss in children under 12 4 years?

5 Excluded effectiveness studies

6 Table 3: Excluded studies and reasons for their exclusion

Study	Code [Reason]
Adkins, A P and Friedman, Ellen M (2005) Surgical indications and outcomes of tympanostomy tube removal. International journal of pediatric otorhinolaryngology 69(8): 1047-51	- Study design does not meet inclusion criteria <i>The study investigates the factors affecting perforation healing after tympanostomy tube removal, and unclear whether participants had OME</i>
Charlett, Simon D and Knight, Lindsay C (2009) Pediatric myringoplasty: does previous adenoidectomy improve the likelihood of perforation closure?. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology 30(7): 939-42	- Study design does not meet inclusion criteria <i>The study investigates the effect of previous adenoidectomy on perforation closure after myringoplasty, and unclear whether participants had OME</i>
Conrad, David E, Levi, Jessica R, Theroux, Zachary A et al. (2014) Risk factors associated with postoperative tympanostomy tube obstruction. JAMA otolaryngology-- head & neck surgery 140(8): 727-30	- Study design does not meet inclusion criteria <i>The study investigates the factors associated with tube obstruction, and unclear whether participants had OME</i>
Hanes, Lauren A, Murphy, Amanda, Hatchette, Jill E et al. (2015) Chronic Otitis Media with Effusion Is Associated with Increased Risk of Secondary Speech Surgery. Plastic and reconstructive surgery 136(2): 343-349	- Study design does not meet inclusion criteria <i>Case-control study that investigates the association between otitis media with effusion requiring myringotomy tubes and the need for secondary speech surgery</i>
Hu, Shirley; Patel, Neha A; Shinhar, Shai (2015) Follow-up audiometry after bilateral myringotomy and tympanostomy tube insertion. International journal of pediatric otorhinolaryngology 79(12): 2068-71	- No comparison of interest <i>The study compared preoperative sound field threshold with postoperative sound field threshold, and preoperative air-bone gap with postoperative air-bone gap</i>
Kao, Richard; Kirse, Daniel J; Evans, Adele K (2014) Compliance with recommendations for tympanostomy tube follow-up: patient characteristics. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery 151(3): 489-95	- Study design does not meet inclusion criteria <i>The study investigates the association between follow-up behaviours and graduation (receiving discharge from care with "follow-up pro re nata" status), and unclear whether participants had OME</i>
Mughal, Zahir, Thirunavukarasu, Vijay, Darr, Adnan et al. (2016) Follow-up care after grommet insertion in children: Review article. International journal of pediatric otorhinolaryngology 88: 25-9	- Study design does not meet inclusion criteria <i>Narrative review</i>

Study	Code [Reason]
Nomura, Y., Oshima, H., Nomura, K. et al. (2022) Outcome of the 'waiting until spontaneous extrusion' strategy for long-term tympanostomy tube placement in children with cleft palate. Acta Oto-Laryngologica 142(34): 248-253	- Study design does not meet inclusion criteria <i>The study investigates the outcomes of the waiting until spontaneous extrusion strategy for long-term tympanostomy tube placement in children with cleft palate</i>
Parlea, E; Georgescu, M; Calarasu, R (2012) Tympanometry as a predictor factor in the evolution of otitis media with effusion. Journal of medicine and life 5(4): 452-4	- Non-OECD high-income country <i>Romania</i>
Payten, C.L., Eakin, J., Smith, T. et al. (2020) Outcomes of a multidisciplinary Ear, Nose and Throat Allied Health Primary Contact outpatient assessment service. Clinical Otolaryngology 45(6): 904-913	- Study design does not meet inclusion criteria <i>The study investigates the service impact of allied health primary contact clinics on wait-times and access to treatment, and comparison not of interest</i>
Powell, J, Powell, S, Lennon, M et al. (2015) Paediatric ventilation tube insertion: our experience of seventy-five children in audiology-led follow-up. Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery 40(4): 385-9	- Study design does not meet inclusion criteria <i>Non-comparative study</i>
Stephens, M B (2001) Does delaying placement of tympanostomy tubes have an adverse effect on developmental outcomes in children with persistent middle ear effusions?. The Journal of family practice 50(8): 651	- Study design does not meet inclusion criteria <i>The study investigates the association between delaying placement of tympanostomy tubes and developmental outcomes, and comparison not of interest</i>
Uppal, Sandeep, Lee, Carline, Mielcarek, Mateusz et al. (2004) A comparison of patient satisfaction with conventional and nurse led outpatient follow-up after grommet insertion. Auris, nasus, larynx 31(1): 23-8	- Study design does not meet inclusion criteria <i>Cross-sectional survey and audit of practice, and unclear whether participants had OME</i>
Wallace, H C and Newbegin, C J R (2004) Does ENT outpatient review at 1-week post ventilation tube insertion improve outcome at 1 month in paediatric patients?. Clinical otolaryngology and allied sciences 29(6): 595-7	- Population does not meet inclusion criteria <i>Only about 18% of participants had OME and results not presented separately for them</i>

1 OECD: Organisation for Economic Co-operation and Development; OME: otitis media with effusion

2 Excluded economic studies

3 No economic evidence was identified for this review.

4

1 Appendix K Research recommendations – full details

2 Research recommendations for review question: What should the follow-up 3 strategy be after surgical treatment for OME-related hearing loss in children 4 under 12 years?

K.1.15 Research recommendation

6 What should the follow-up strategy be after surgical treatment for OME-related hearing loss
 7 in children under 12 years?

K.1.28 Why this is important

9 It is important to understand the follow up required for patients who undergo ventilation tube
 10 insertion as this can have a significant impact on patient experience and NHS resources.
 11 However, there was no available evidence on the follow-up strategy after surgical treatment
 12 for OME-related hearing loss in children under 12 years, and research is needed to inform
 13 appropriate follow-up strategy.

K.1.34 Rationale for research recommendation

15 **Table 4: Research recommendation rationale**

Importance to ‘patients’ or the population	It is important to understand the follow up required for patients who undergo ventilation tube insertion as this can have a significant impact on patient care, patient experience and NHS resources.
Relevance to NICE guidance	The research is essential to inform future updates of key recommendations regarding appropriate follow up after ventilation tube insertion in this guidance.
Relevance to the NHS	There would be an advantage in ensuring patients get the right kind of follow up at the right time, and a financial advantage in reducing unnecessary follow up as well as improving patient and staff experience.
National priorities	There would be a benefit in ensuring patients get appropriate follow up and care. There would also be a benefit of reducing unnecessary follow up in line with the NHS Long Term Plan.
Current evidence base	No available evidence on the follow-up strategy after surgical treatment for OME-related hearing loss in children under 12 years.
Equality considerations	Children with cognitive and communication difficulties may need targeted follow-up plans. Understanding the appropriate follow-up strategy for these children may contribute to the reduction of health care inequalities at both national and system level.

16 *NHS: National Health Service; NICE: National Institute for Health and Care Excellence*

K.1.47 Modified PICO table

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

Population	All children under 12 years who have had surgery for OME-related hearing loss
Intervention	• Follow-up of duration A

	<ul style="list-style-type: none"> • Follow-up of frequency A • Personal/professional group carrying out the follow-up A • Content of follow-up A
Comparator	<ul style="list-style-type: none"> • Follow-up of duration B • Follow-up of frequency B • Personal/professional group carrying out the follow-up B • Content of follow-up B
Outcome	<ul style="list-style-type: none"> • Hearing (measured by pure tone audiometry or speech recognition thresholds, in dB HL) • Additional intervention (e.g., repeat ventilation tube insertion, antibiotics) • Parent/carer and/or child satisfaction • Persistent otorrhoea (ear discharge) (either clinically confirmed or parent-reported) • Perforation of the tympanic membrane • 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 Health Questionnaire)
Study design	<ul style="list-style-type: none"> • Randomised controlled trial • Adjusted cohort studies* with at least 40 participants per arm <p>*Cohort studies should adjust for the following covariates in their analysis when there are differences between groups at baseline: age, craniofacial anomalies, socioeconomic status, and additional sensory or learning needs</p>
Timeframe	2 years
Additional information	N/A

1 ABEL: Auditory Behaviour in Everyday Life; dB HL: decibel hearing levels; ECLiPS: Evaluation of Children's
2 Listening and Processing Skills; ELF: Early Listening Functioning; EQ: EuroQoL; HUI: Health Utilities Index; N/A:
3 not applicable; PEACH: Parents' Evaluation of Aural/Oral Performance of Children; OM: otitis media; OME: otitis
4 media with effusion; OMQ: Otitis Media Quality of Life
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