

Otitis media with effusion in under 12s

[F] Evidence reviews for adenoidectomy for children with otitis media with effusion (OME)

NICE guideline number tbc

Evidence reviews underpinning recommendations 1.6.3 and 1.6.4 in the NICE guideline

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Draft for consultation

This evidence review was developed by NICE

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1 Adenoidectomy for children with otitis 2 media with effusion (OME)

3 Review question

4 What is the effectiveness of adenoidectomy (with or without ventilation tubes) for managing
5 OME with associated hearing loss in children under 12 years?

6 Introduction

7 The aim of this review is to assess the effectiveness of adenoidectomy (with or without
8 ventilation tubes) in managing OME with associated hearing loss in children under 12 years.

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

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

Population	Inclusion: Children aged 6 months to 12 years with unilateral or bilateral otitis media with effusion (OME). <ul style="list-style-type: none">• If a study includes children aged younger than 6 months and older than 12 years, we will only include the study if the majority of children fit our inclusion criteria or only if the trialists present outcome data by age group.• Include all children regardless of any comorbidity such as Down syndrome or cleft palate• Include studies where children have had OME for at least three months Clinical diagnosis of OME will be confirmed by otoscopy and/or tympanometry
Intervention	Adenoidectomy (either alone or in combination with grommets)
Comparison	<ul style="list-style-type: none">• Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting;• Adenoidectomy (with or without myringotomy) versus non-surgical treatment;• Adenoidectomy and bilateral grommets versus bilateral grommets only;• Adenoidectomy and unilateral grommet versus unilateral grommet only.• Adenoidectomy and grommets vs no treatment/watchful waiting• Adenoidectomy and grommets vs non-surgical treatment. If study participants have received other treatments in addition to the main intervention, for example intranasal steroids, oral steroids, antibiotics, mucolytics or decongestants, we will include these studies if both arms of the study received identical treatment.

Outcome

We will analyse the following outcomes in the review, but we will not use them as a basis for including or excluding studies. We will assess all outcomes in the very short term (< 6 weeks for postoperative adverse events), short term (<= 3 months), medium term (> 3 months to <= 1 year) and long term (> 1 year).

Critical

- Hearing
 - proportion of children whose hearing has returned to normal;
 - mean final hearing threshold (determined for the child or ear, depending on the unit of analysis);
 - change in hearing threshold from baseline (determined for the child or ear, depending on the unit of analysis).
- Disease-specific quality of life measured using a validated instrument, for example:
 - OM8-30;
 - Otitis Media-6.
- Adverse events: Serious haemorrhage and its consequences.

Important

- Presence/persistence of OME
- Adverse events - measured by the number of participants affected.
 - Tympanic membrane changes, such as:
 - atrophy;
 - atelectasis or retraction;
 - myringosclerosis;
 - tympanosclerosis.
 - Patient-related:
 - recurring haemorrhage;
 - transient postoperative velopharyngeal insufficiency;
 - pain
 - infection;
 - lip/tooth/tongue injury;
 - velopharyngeal reflux/nasal escape
 - other surgical complications
- Receptive language skills, measured using a validated scale, for example:
 - Peabody Picture Vocabulary Test – Revised;
 - Reynell Developmental Language Scales (relevant domains);
 - Preschool Language Scale (PLS) (relevant domains);
 - Sequenced Inventory of Communication (SCID) (relevant domains).
- Speech development, or expressive language skills, measured using a validated scale, for example:
 - Schlichting test;
 - Lexi list;
 - Reynell Developmental Language Scales (relevant domains);
 - PLS (relevant domains);
 - SCID (relevant domains).
- Cognitive development, measured using a validated scale, for example:
 - Griffiths Mental Development Scales;
 - McCarthy General Cognitive Index;
 - Bayley Scales of Infant and Toddler Development.
- Psychosocial outcomes, measured using a validated scale, for example:
 - Social Skills Scale of the Social Skills Rating System;
 - Child behaviour Checklist;
 - Strengths and Difficulties Questionnaire;

- Pediatric Symptom Checklist.
- Listening skills, for example, listening to stories and instructions effectively. Given that there are few validated scales to assess listening skills in children with OME, we will include any methods used by trialists.
- Generic health-related quality of life assessed using a validated instrument, for example:
 - EQ-5D;
 - TNO AZL Children's QoL (TACQOL);
 - TNO AZL Pre-school children QoL (TAPQOL);
 - TNO AZL Infant Quality of Life (TAIQOL);
 - Infant Toddler Quality of Life Questionnaire (ITQOL);
 - Child Health Questionnaire (CHQ).
- Parental stress, measured using a validated scale, for example:
 - Parenting Stress Index.
- Vestibular function
 - balance;
 - coordination.
- Number of doctor-diagnosed AOM episodes within a specified time frame

- 1 AOM: acute otitis media; CHQ: Child Health Questionnaire; EQ: EuroQol; ITQOL: Infant Toddler Quality of Life;
 2 OM: otitis media; OME: otitis media with effusion; PLS: Preschool Language Scale; QoL: quality of life; SCID:
 3 Sequenced Inventory of Communication; TACQOL: TNO AZL Children's Quality of Life Questionnaire; TAIQOL:
 4 TNO AZL Infant Quality of Life; TAPQOL: TNO AZL Pre-school children's Quality of Life questionnaire; TNO AZL:
 5 Netherlands Organisation for Applied Scientific Research Academic Medical Centre

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

7 Methods and process

8 During the development of this guideline, a registered Cochrane protocol was identified
 9 which matched the committee's intended PICOs.

10 The Cochrane review team completed a review investigating the effectiveness of
 11 adenoidectomy for OME in children (MacKeith 2023b) during guideline development and
 12 presented their results to the committee, who used them to make recommendations.
 13 Cochrane's methods are closely aligned to standard NICE methods, minor deviations
 14 (defining primary and secondary outcomes as opposed to critical and important, assessing
 15 the risk of bias in primary studies using version 1 (as opposed to version 2) of the Cochrane
 16 Risk of Bias tool, how clinically important differences are determined, and including countries
 17 from a broader range of income categories than the majority of the other reviews in the
 18 guideline) relevant to the topic area were highlighted to the committee and taken into account
 19 in discussions of the evidence. Full details of the Cochrane review, including methods, are
 20 available in the review of adenoidectomy for children with OME, see MacKeith 2023b at
 21 <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

22 We thank the Cochrane ENT Group for their assistance in providing the literature searches
 23 and data for review questions relating to Otitis media with effusion in under 12s.

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

25 Effectiveness evidence

26 Included studies

27 A Cochrane review (MacKeith 2023b) including 8 randomised controlled trials (Dempster
 28 1993; Fiellau-Nikolajsen 1982; Gates 1989; Haggard 2012; Hao 2019; Jabeen 2019; Maw
 29 1993; Sagnelli 1990) is considered in this report. This review was used for making

1 recommendations by the committee, as it was considered sufficiently relevant, high quality
2 and up to date.

3 Two studies included children aged up to 4 years (Fiellau-Nikolajsen 1982; Gates 1989), and
4 6 studies included children aged over 4 years (Dempster 1993; Haggard 2012; Hao 2019;
5 Jabeen 2019; Maw 1993; Sagnelli 1990). All studies did not report data on whether
6 participants had allergy, previous adenoidectomy, previous grommets, or Down's syndrome
7 (Dempster 1993; Fiellau-Nikolajsen 1982; Gates 1989; Haggard 2012; Hao 2019; Jabeen
8 2019; Maw 1993; Sagnelli 1990).

9 The Cochrane review is summarised in Table 2.

10 See the Cochrane review for the literature search strategies) and study selection flow charts,
11 at MacKeith 2023b at [https://www.nice.org.uk/guidance/indevelopment/gid-](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents)
12 [ng10193/documents](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents).

13 Excluded studies

14 See the lists of excluded studies in the Cochrane review with reasons for their exclusions, at
15 MacKeith 2023b at [https://www.nice.org.uk/guidance/indevelopment/gid-](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents)
16 [ng10193/documents](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents).

17 Summary of included studies

18 Summaries of the studies that were included in this review are presented in Table 2.

19 **Table 2: Summary of included studies.**

Study	Population	Comparison	Outcomes
MacKeith 2023b Systematic review UK	Children aged 2.2 years to 7.7 years with unilateral or bilateral otitis media with effusion for a duration of at least three months. Number of studies: 8 Number of participants: 1529	Adenoidectomy (with or without myringotomy) vs no treatment/watchful waiting 3 trials, N=366 children with OME (Fiellau-Nikolajsen 1982; Gates 1989; Sagnelli 1990) Adenoidectomy and bilateral grommet vs bilateral grommet only 4 trials, N=560 children with OME (Gates 1989; Haggard 2012; Hao 2019; Jabeen 2019) Adenoidectomy and unilateral grommet vs unilateral grommet only 2 trials, N=189 children with OME (Dempster 1993; Maw 1993) Adenoidectomy and grommet vs no treatment/watchful waiting	Primary: <ul style="list-style-type: none"> Hearing as <ol style="list-style-type: none"> return to normal; mean threshold; and change from baseline Adverse events: serious haemorrhage Secondary: <ul style="list-style-type: none"> Presence/Persistence of OME Adverse events: Tympanic membrane changes (tympanosclerosis) Number of doctor-diagnosed AOM episodes

Study	Population	Comparison	Outcomes
		2 trials, N=527 children with OME (Gates 1989; Haggard 2012)	

1 AOM: acute otitis media; OME: otitis media with effusion;

2 See the Cochrane review for characteristics of studies tables and forest plots, MacKeith

3 2023b at <https://www.nice.org.uk/guidance/indevelopment/qid-ng10193/documents>.

4 Summary of the evidence

5 The Cochrane review of adenoidectomy for children with OME investigated 4 comparisons,
6 with the following findings:

- 7
- 8 • Comparison 1: Adenoidectomy (with or without myringotomy) versus no
9 treatment/watchful waiting
10 Adenoidectomy (with or without myringotomy) had an important benefit in terms of
11 reducing time with effusion in the long-term compared with no treatment/watchful
12 waiting, but the certainty of the evidence was very low. The comparison showed no
13 evidence of important differences for hearing returned to normal in the short-term and
14 medium-term, haemorrhage, presence/persistence of OME in the short-term,
15 medium-term and long-term, and number of doctor-diagnosed AOM episodes in the
16 medium-term. The certainty of the evidence was low to very low for these outcomes.
17 No evidence was available for any of the other outcomes specified in the protocol.
 - 18 • Comparison 2: Adenoidectomy and bilateral grommet versus bilateral grommet only
19 Adenoidectomy and bilateral grommet had an important benefit in terms of reducing
20 presence/persistence of OME in the short-term compared with bilateral grommet only;
21 however, the certainty of the evidence was very low. There was no evidence of
22 important differences for the other outcomes identified: hearing threshold in the short-
23 term, medium-term and long-term, haemorrhage, presence/persistence of OME in the
24 medium-term and long-term, and time with effusion in the long-term. The certainty of
25 the evidence for these outcomes was very low. No evidence was available for any of
26 the other outcomes specified in the protocol.
 - 27 • Comparison 3: Adenoidectomy and unilateral grommet versus unilateral grommet
28 only
29 Adenoidectomy and unilateral grommet had an important benefit in terms of reducing
30 presence/persistence of OME in the short-term and medium-term compared with
31 unilateral grommet only. There was no evidence of important differences for hearing
32 returned to normal and hearing threshold (change from baseline) in the medium-term,
33 presence/persistence of OME in the long-term, and tympanosclerosis. The certainty
34 of the evidence for all outcomes identified was very low. There was no evidence
35 available for this comparison for any of the other outcomes specified in the protocol.
 - 36 • Comparison 4: Adenoidectomy and grommet versus no treatment/watchful waiting
37 Adenoidectomy and grommet had an important benefit in terms of improvement in
38 hearing threshold in the short-term and reducing time with effusion in the long-term
39 compared with no treatment/watchful waiting. This comparison showed no evidence
40 of important differences for hearing threshold in the medium-term and long-term, and
41 presence/persistence of OME in the long-term. The certainty of the evidence for all
42 outcomes identified was very low, and no evidence was available for any of the other
43 outcomes specified in the protocol.

43 There were two comparisons in the Cochrane review protocol that were not reported on by
44 any studies: adenoidectomy (with or without myringotomy) versus non-surgical treatment,
45 and adenoidectomy and grommets versus non-surgical treatment.

- 1 See the Cochrane review for summary of findings tables and full results, including all primary
- 2 and secondary outcomes and sub-group analyses, MacKeith 2023b at
- 3 <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

4 **Economic evidence**

5 **Included studies**

- 6 A global health economic search was undertaken to cover all the review questions
- 7 considered in this guideline, but no economic studies were identified which were applicable
- 8 to this review question.

9 **Excluded studies**

- 10 Economic studies not included in this review are listed, and reasons for their exclusion are
- 11 provided in appendix J.

12 **Economic model**

- 13 An economic model was undertaken which compared hearing aids, grommets and grommets
- 14 with adjuvant adenoidectomy in children with hearing loss associated with OME. This model
- 15 is discussed in Evidence review E.

16 **The committee's discussion and interpretation of the evidence**

17 **The outcomes that matter most**

- 18 The primary outcomes were hearing, disease-specific quality of life, and serious
- 19 haemorrhage and its consequences. The committee agreed these outcomes were critical:
- 20 hearing loss is often associated with OME, and this could impact on the child's development
- 21 and measuring hearing would be a direct measure of any differential effectiveness
- 22 associated with adenoidectomy. Disease-specific quality of life is a global measure of
- 23 wellbeing that takes into account both beneficial and adverse effects of the interventions.
- 24 Adenoidectomy may have adverse events associated with it, the most likely being serious
- 25 haemorrhage and its consequences.

- 26 All other outcomes listed in the protocol (presence or persistence of OME, adverse events
- 27 (other than serious haemorrhage and its consequences), receptive language skills, speech
- 28 development or expressive language skills, cognitive development, psychosocial outcomes,
- 29 listening skills, generic health-related quality of life, parental stress, vestibular function and
- 30 number of doctor-diagnosed acute otitis media (AOM) episodes were agreed to be important
- 31 outcomes by the committee. Presence or persistence of OME after adenoidectomy can
- 32 directly indicate the effectiveness of the intervention, and adverse events other than serious
- 33 haemorrhage and its consequences (including tympanic membrane changes such as
- 34 atrophy; and patient-related complications such as recurring haemorrhage), that may be
- 35 relatively common with adenoidectomy, are important to measure because they capture risks
- 36 associated with the intervention. OME can be associated with impairment of receptive and
- 37 expressive language skills, cognitive development, psychological outcomes, listening skills,
- 38 and vestibular function, which could impact on the child's development and quality of life.
- 39 Therefore, the committee agreed these were important outcomes. The committee agreed
- 40 that generic health-related quality of life was important because this would measure the well-
- 41 being of the child more generally than disease-specific scales. The parents of children who
- 42 have OME may have high level of stress, and thus parental stress was an important outcome
- 43 to see if adenoidectomy can help reduce this stress. Number of doctor-diagnosed AOM
- 44 episodes was also an important outcome because adenoidectomy may have a protective
- 45 role for recurrent AOM.

1 The quality of the evidence

2 The quality of the evidence was assessed using GRADE methodology. Apart from presence
3 or persistence of OME up to 3 and 12 months for the comparison between adenoidectomy
4 and no treatment or watchful waiting, which was low quality, the evidence for all outcomes
5 identified in this review was very low quality, because of high or moderate risk of bias
6 assessed using version 1 of the Cochrane risk of bias tool, and serious or very serious
7 imprecision. Publication bias was also strongly suspected for some outcomes due to
8 retrospective registration of trials.

9 Benefits and harms

10 The committee discussed that hearing is the most important outcome in children with OME in
11 terms of measuring the effectiveness of interventions. There was very limited and very low-
12 quality evidence that adenoidectomy and grommet had an important benefit in terms of
13 hearing threshold, when measured in the short term, compared with no treatment or watchful
14 waiting, but there was no evidence of important differences when this outcome was
15 measured in the medium or long term, or in hearing outcomes for the remaining comparisons
16 (adenoidectomy without grommet compared with no treatment or watchful waiting,
17 adenoidectomy and bilateral grommet compared with bilateral grommet only, or
18 adenoidectomy and unilateral grommet compared with unilateral grommet only). Therefore,
19 the committee agreed that there was no evidence that adenoidectomy itself resulted in
20 clinically important benefits in hearing outcomes. However, there was very low-quality
21 evidence that adenoidectomy with unilateral or bilateral grommet reduced presence or
22 persistence of OME compared with unilateral or bilateral grommet alone, although there was
23 some variation in whether an important benefit was found for persistence of OME depending
24 on the length of follow-up. There was very low-quality evidence that adenoidectomy and
25 grommet also reduced time with effusion compared with no treatment or watchful waiting.
26 The committee discussed that if adenoidectomy improves the OME, in their experience it
27 may also have beneficial effects on hearing. They also acknowledged that there was no
28 evidence of important differences in rates of haemorrhage or tympanosclerosis for any of the
29 comparisons and that surgical approaches to adenoidectomy are safer now than when some
30 of the studies were conducted, as there is a lower risk of significant bleeding with ablation,
31 which is now commonly used, compared with curettage. Therefore, if someone is already
32 having general anaesthesia for grommet, the added risk of doing adenoidectomy too is likely
33 to be very small. Therefore, on balance, the committee agreed that the potential of improving
34 OME, and in turn hearing, outweighed any risk associated with performing adenoidectomy in
35 children underdoing grommet surgery. However, the committee were aware that
36 adenoidectomy is likely to lead to velopharyngeal insufficiency or nasal regurgitation in
37 children with an abnormality with the palate so they agreed that adenoidectomy would not be
38 appropriate for this group. The committee also discussed whether adenoidectomy should
39 only be considered if there are nasal symptoms or nasal obstruction, or if a stronger
40 recommendation should be made in support of adenoidectomy for children with nasal
41 obstruction. However, they were aware that adenoids can act as a reservoir for bacteria, and
42 thus the presence of adenoids at all may be a risk factor for OME, which may be reduced by
43 removing the adenoids, regardless of the size of adenoids and the presence of nasal
44 symptoms or nasal obstruction. Therefore, they agreed that adjuvant adenoidectomy should
45 be considered in children undergoing grommet surgery.

46 The committee were aware of potential risks of adenoidectomy, such as haemorrhage and
47 velopharyngeal insufficiency. Although the risks of these occurring are small in children
48 without anomalies with the palate, in their experience they are not routinely discussed with
49 the child and their family or carers, and it is important that they are aware of the benefits and
50 risks and are supported to make shared decisions around adenoidectomy. Therefore, the
51 committee recommended that the benefits and risks of adenoidectomy should be discussed
52 with the family.

1 Cost effectiveness and resource use

2 The committee considered an original economic evaluation undertaken for the guideline to
3 compliment the clinical evidence review. A fully incremental analysis, in line with the NICE
4 reference case, compared no intervention, hearing aids, grommet insertion alone and
5 grommet insertion with adjuvant adenoidectomy. It found that grommet insertion with
6 adjuvant adenoidectomy was generally more cost-effective than no intervention, although it's
7 cost-effectiveness relative to grommet insertion alone or hearing aids was less clear cut. In
8 many of the scenarios presented adjuvant adenoidectomy had the highest probability of
9 being cost-effective but this was very dependent on assumptions made with respect to the
10 natural history of OME and relative treatment effect. Given the limitations of the analysis and
11 inherent uncertainty in the model inputs, the committee concluded that there was not a single
12 intervention that was clearly the most cost-effective but considered there was sufficient
13 evidence to support a recommendation to consider adjuvant adenoidectomy. Whilst this is a
14 change from previous NICE guidance the committee, based on their own experience, did not
15 think it would dramatically change current NHS practice especially as the strength of the
16 recommendation, they made was weak. They reasoned that their recommendation was
17 unlikely to have a significant resource impact. They also noted that the evidence that
18 grommet insertion with adjuvant adenoidectomy may lead to reduced presence or
19 persistence of OME and reduced time with effusion and the natural history of OME with
20 hearing loss could lead to wider societal benefits and savings than the NHS perspective
21 considered in the analysis.

22 Recommendations supported by this evidence review

23 This evidence review supports recommendations 1.6.3 and 1.6.4.

24

1 **References – included studies**

2 **Effectiveness**

3 **MacKeith 2023b**

4 MacKeith S, Mulvaney CA, Galbraith K, Webster KE, Paing A, Connolly R, Marom T, Daniel
5 M, Venekamp RP, Schilder AGM. Adenoidectomy for otitis media with effusion (OME) in
6 children. Cochrane Database of Systematic Reviews 2023. Art. No.: CD015252. DOI:
7 10.1002/14651858.CD015252.pub2

1 Appendices

2 Appendix A Review protocols

- 3 **Review protocol for review question: What is the effectiveness of adenoidectomy (with or without ventilation tubes) for**
- 4 **managing OME with associated hearing loss in children under 12 years?**
- 5 See the Cochrane review protocol, MacKeith 2023b at <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

Appendix B Literature search strategies

Literature search strategies for review question: What is the effectiveness of adenoidectomy (with or without ventilation tubes) for managing OME with associated hearing loss in children under 12 years?

Clinical search

See Appendix 1 and Appendix 2 of the Cochrane review, MacKeith 2023b at <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

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/
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"

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

#	Searches
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
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

ID	Search
#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 adenoidectomy (with or without ventilation tubes) for managing OME with associated hearing loss in children under 12 years?

Clinical search

See Results of the search – figure 1 from the Cochrane review, MacKeith 2023b at <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

1 **Appendix D Characteristics of studies tables**

2 **Characteristics of studies tables for review question: What is the effectiveness of adenoidectomy (with or without ventilation** 3 **tubes) for managing OME with associated hearing loss in children under 12 years?**

4 See the Characteristics of included studies tables from the Cochrane review, MacKeith 2023b at
5 <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

6

1 **Appendix E Data and analyses tables**

2 **Data and analyses tables for review question: What is the effectiveness of adenoidectomy (with or without ventilation tubes)** 3 **for managing OME with associated hearing loss in children under 12 years?**

4 See the Data and analyses tables from the Cochrane review, MacKeith 2023b at [https://www.nice.org.uk/guidance/indevelopment/gid-](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents)
5 [ng10193/documents](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents).

6

1 **Appendix F Summary of findings tables**

2 **Summary of findings tables for review question: What is the effectiveness of adenoidectomy (with or without ventilation** 3 **tubes) for managing OME with associated hearing loss in children under 12 years?**

4 See the Summary of findings tables from the Cochrane review, MacKeith 2023b at [https://www.nice.org.uk/guidance/indevelopment/gid-](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents)
5 [ng10193/documents](https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents).

6

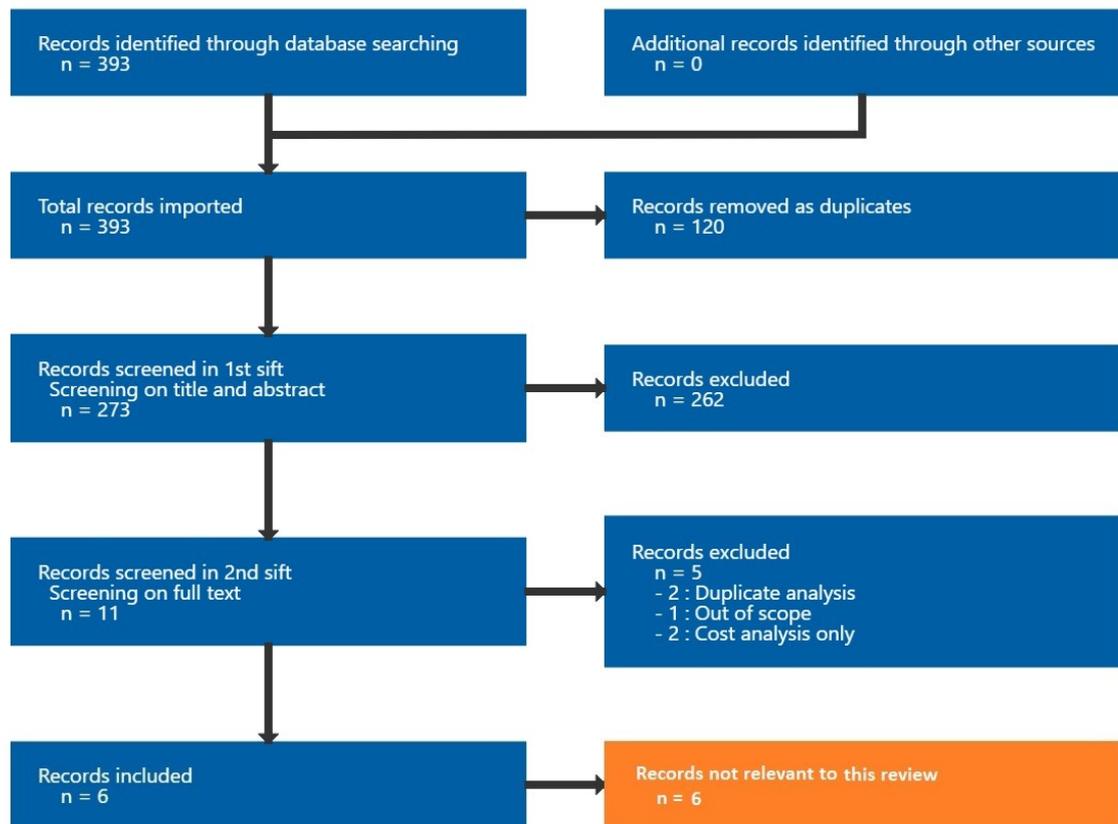
7

1 Appendix G Economic evidence study selection

2 Study selection for: What is the effectiveness of adenoidectomy (with or 3 without ventilation tubes) for managing OME with associated hearing loss in 4 children under 12 years?

5 A global economic literature search was undertaken for otitis media with effusion in under
6 12s. This covered all 14 review questions in this guideline. As shown in Figure 1 below, no
7 economic studies were identified which were applicable to this review question.

Figure 1: Study selection flow chart



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1 **Appendix H Economic evidence tables**

2 **Economic evidence tables for review question: What is the effectiveness of**
3 **adenoidectomy (with or without ventilation tubes) for managing OME with**
4 **associated hearing loss in children 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 is the effectiveness of**
3 **adenoidectomy (with or without ventilation tubes) for managing OME with**
4 **associated hearing loss in children under 12 years?**

5 An economic model relevant to this review question is reported in Evidence review E.

6

7

1 **Appendix J Excluded studies**

2 **Excluded studies for review question: What is the effectiveness of**
3 **adenoidectomy (with or without ventilation tubes) for managing OME with**
4 **associated hearing loss in children under 12 years?**

5 **Excluded effectiveness studies**

6 See the Characteristics of excluded studies table from the Cochrane review, MacKeith 2023b
7 at <https://www.nice.org.uk/guidance/indevelopment/gid-ng10193/documents>.

8 **Excluded economic studies**

9 No economic evidence was identified for this review.

10

1 **Appendix K Research recommendations – full details**

- 2 **Research recommendations for review question: What is the effectiveness of**
- 3 **adenoidectomy (with or without ventilation tubes) for managing OME with**
- 4 **associated hearing loss in children under 12 years?**
- 5 No research recommendations were made for this review question.