National Institute for Health and Care Excellence

Final

Otitis media with effusion in under 12s

[I] Evidence reviews for auto-inflation for children with otitis media with effusion (OME)

NICE guideline NG233

Evidence reviews underpinning recommendation 1.5.1 in the NICE guideline

August 2023

Final

This evidence review was developed by NICE

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Auto-inflation for children with otitis media with effusion (OME)

Review question

What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

Introduction

The aim of this review is to assess the effectiveness of auto-inflation in managing OME with associated hearing loss in children under 12 years.

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

Summary of the protocol

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

Table 1: Summary of the protocol (PICO table)

Population	**Inclusion:** Children aged 6 months to 12 years with unilateral or bilateral otitis media with effusion (OME). • 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 Clinical diagnosis of OME will be confirmed by oto(micro)scopy and/or tympanometry
Intervention	Auto-inflation by any method

Comparison	• Auto-inflation versus watchful waiting • Auto-inflation versus non-surgical (medical only) treatment • Auto-inflation versus grommet If trial participants have received other treatments, for example, intranasal steroids, oral steroids, antibiotics, mucolytics, or decongestants, the Cochrane group will include these trials if both arms of the study received identical treatments.

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: Pain and distress caused by the procedure.
	
	Important
	• Presence/persistence of OME
	• Adverse events - measured by the number of participants affected.
	  ○ eardrum perforation
	  ○ middle ear infection
	  ○ otalgia
	  ○ Acute otitis media (AOM)
	• Compliance
	• 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 Heath 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

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

For further details see the review protocol in appendix A.

Methods and process

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

The Cochrane review team completed a review investigating the effectiveness of auto-inflation for OME in children (Webster 2023) during guideline development and presented their results to the committee, who used them to make recommendations. Cochrane's methods are closely aligned to standard NICE methods, minor deviations (defining primary and secondary outcomes as opposed to critical and important, assessing the risk of bias in primary studies using version 1 (as opposed to version 2) of the Cochrane Risk of Bias tool, how clinically important differences are determined, and including countries from a broader range of income categories than the majority of the other reviews in the guideline) relevant to the topic area were highlighted to the committee and taken into account in discussions of the evidence. Full details of the Cochrane review, including methods, are available in the review of auto-inflation for children with OME, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

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

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

Effectiveness evidence

Included studies

A Cochrane review (Webster 2023) including 12 randomised controlled trials (Arick 2005; Banigo 2016; Bidarian-Moniri 2014; Blanshard 1993; Brooker 1992; Chan 1989; Ercan 2005; Heaf 1991; Scadding 2014; Stangerup 1992; Williamson 2015a; Williamson 2015b) is considered in this report. This review was used for making recommendations by the committee, as it was considered sufficiently relevant, high quality and up to date.

Two studies included children with air-conduction thresholds of 20 dBHL and over (Arick 2005; Bidarian-Moniri 2014), 2 studies included children with air-conduction thresholds of 25 dBHL and over (Banigo 2016; Heaf 1991), and 8 studies did not report data on levels of hearing loss (Blanshard 1993; Brooker 1992; Chan 1989; Ercan 2005; Scadding 2014; Stangerup 1992; Williamson 2015a; Williamson 2015b).

Seven studies included children aged up to 6 years (Banigo 2016; Bidarian-Moniri 2014; Blanshard 1993; Brooker 1992; Scadding 2014; Stangerup 1992; Williamson 2015a), 1 study included children aged 3 to 18 years (Chan 1989), 1 study included children aged 4 to 11 years (Williamson 2015b), 1 study included children aged over 6 years (Ercan 2005), and 2 studies did not report ages of participants (Arick 2005; Heaf 1991).

Eleven studies used auto-inflation devices (Arick 2005; Banigo 2016; Bidarian-Moniri 2014; Blanshard 1993; Brooker 1992; Chan 1989; Ercan 2005; Scadding 2014; Stangerup 1992; Williamson 2015a; Williamson 2015b), but in 1 study children were asked to blow their nose without using auto-inflation devices (Heaf 1991).

The Cochrane review is summarised in Table 2.

See the Cochrane review for the literature search strategies and study selection flow charts, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Excluded studies

See the lists of excluded studies in the Cochrane review with reasons for their exclusions, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Summary of included studies

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

Table 2: Summary of included studies.

Study	Population	Comparison	Outcomes
Webster 2023 Systematic review UK	Children aged 2 years to 12 years with unilateral or bilateral otitis media with effusion for a duration of at least one month. Number of studies: 12 Number of participants: 1117	**Auto-inflation versus watchful waiting (no treatment)** 12 trials (Arick 2005; Banigo 2016; Bidarian-Moniri 2014; Blanshard 1993; Brooker 1992; Chan 1989; Ercan 2005; Heaf 1991; Scadding 2014; Stangerup 1992; Williamson 2015a; Williamson 2015b)	Primary: • Hearing as (i) return to normal (ii) mean threshold • Disease-specific quality of life Secondary: • Presence/Persistence of OME • Adverse events: Otalgia • Number of doctor-diagnosed AOM episodes

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

See the Cochrane review for characteristics of studies tables and forest plots, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Summary of the evidence

The Cochrane review of auto-inflation for children with OME investigated 1 comparison, with the following findings:

- Auto-inflation versus watchful waiting (no treatment): hearing
  Auto-inflation had an important benefit in terms of hearing returned to normal in the very short-term (<6 weeks) compared with watchful waiting, but the certainty of the evidence was very low. In terms of hearing returned to normal in the short-term (>6 weeks to ≤3 months), one study (Arick 2005) showed that auto-inflation had an important benefit, but one study (Heaf 1991) did not. The inconsistency in the

effectiveness of intervention between these two studies may be due to the use of different auto-inflation methods. Auto-inflation improved hearing threshold (at 1 kHz and 4 kHz frequencies) in the short-term compared with watchful waiting (no treatment). There was no evidence of important differences between auto-inflation and watchful waiting for hearing returned to normal in the long-term (>12 months), hearing threshold (at 0.5 kHz and 2 kHz frequencies) in the short-term and hearing threshold in the very short-term. The certainty of the evidence was low to very low for these outcomes.

- Auto-inflation versus watchful waiting (no treatment): disease specific quality of life, presence/persistence of OME, otalgia, and number of doctor-diagnosed AOM Auto-inflation had an important benefit in terms of disease specific quality of life in the short-term compared with watchful waiting. There was no evidence of important differences between auto-inflation and watchful waiting for presence/persistence of OME in the very short-term and short-term, otalgia, and number of doctor-diagnosed AOM episodes in the short-term. The certainty of the evidence was low to very low for these outcomes, and no evidence was available for any of the other outcomes specified in the protocol.

There were two comparisons in the Cochrane review protocol that were not reported on by any studies: auto-inflation versus non-surgical (medical only) treatment, and auto-inflation versus grommet.

See the Cochrane review) for summary of findings tables and full results, including all primary and secondary outcomes and sub-group analyses, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Economic evidence

Included studies

A global health economic search was undertaken, independently of the Cochrane review, to cover all the review questions considered in this guideline. One economic study was identified which was relevant to this question (Williamson 2015).

Excluded studies

Economic studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of included economic evidence

See Table 3 for the economic evidence profile of the included study.

Table 3: Economic evidence profile of a systematic review of economic evaluations for auto-inflation for managing OME with associated hearing loss in children under 12 years

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effect	Cost effectivenss	
Williamson 2015 Nasal balloon auto inflatio	Minor limitations[1]	Partially applicable[2]	Economic evaluation alongside a randomised controlled trial	£14	0.003 QALYs 5	£8,463 per QALY gained	Probabilistic sensitivity analysis suggested there was a 50.1% chance that

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effect	Cost effectiveness	
n plus standard care versus standard care							nasal auto inflation was cost-effective as a cost-effectiveness threshold of £20,000 per QALY

QALYS =Quality adjusted life years
[1] A 3 month time horizon for outcomes may not have captured all the benefits of the intervention
[2] NICE reference case was not followed for the elicitation of QALY values

Economic model

No economic modelling was undertaken for this review because the committee agreed that other topics were higher priorities for economic evaluation as the intervention under review was considered low cost.

Unit costs

Resource	Unit costs	Source
Auto inflation device	£6.69	NHS Drugs Tariff December 2022

The committee's discussion and interpretation of the evidence

The outcomes that matter most

The primary outcomes were hearing, disease-specific quality of life, and pain and distress associated with the procedure. The committee agreed these outcomes were critical: hearing loss is often associated with OME, and this could impact on the child's development and measuring hearing would be a direct measure of any differential effectiveness associated with auto-inflation; disease-specific quality of life is a global measure of wellbeing that takes into account both beneficial and adverse effects of the interventions; and auto-inflation may have adverse events associated with it, the most likely being pain and distress caused by procedure.

All other outcomes listed in the protocol (presence or persistence of OME, adverse events (other than pain and distress), compliance, receptive language skills, speech development or expressive language skills, cognitive development, psychosocial outcomes, listening skills, generic health-related quality of life, parental stress, vestibular function and number of doctor-diagnosed acute otitis media (AOM) episodes were agreed to be important outcomes by the committee. Presence or persistence of OME after auto-inflation can directly indicate the effectiveness of the intervention, and adverse events other than pain and distress (including ear drum perforation, middle ear infection, otalgia, and acute otitis media), that may be relatively common with auto-inflation, are important to measure because they capture risks associated with the intervention. The committee were aware that some children may not engage or may not be able to use auto-inflation device; therefore, compliance with auto-inflation was selected as important outcome as it can influence the effectiveness of the intervention. OME can be associated with impairment of receptive and expressive language skills, cognitive development, psychological outcomes, listening skills, and vestibular function, which could impact on the child's development and quality of life. Therefore, these

were selected as important outcomes. The committee agreed that generic health-related quality of life was important because this would measure the well-being of the child more generally than disease-specific scales. The parents of children who have OME may have high level of stress, and thus parental stress was selected as an important outcome to see if auto-inflation can help reduce this stress. Number of doctor-diagnosed AOM episodes was also selected as an important outcome because auto-inflation may have a protective role for recurrent AOM.

The quality of the evidence

The quality of the evidence was assessed using GRADE methodology, and the evidence for all outcomes identified in this review was low to very low quality because of high or moderate risk of bias assessed using version 1 of the Cochrane RoB tool, serious or very serious heterogeneity and imprecision, and the inclusion of indirect interventions (such as nose-blowing and facemasks rather than use of an auto-inflation device).

Benefits and harms

The evidence showed that auto-inflation improved hearing in the very short-term (<6 weeks) and short-term (>6 weeks to ≤3 months) when reported as a proportion of children whose hearing has returned to normal and change in hearing threshold from baseline, respectively, compared with no treatment. However, there was no evidence of important differences in the proportion of children whose hearing has returned to normal in the long term (>12 months) as a result of auto-inflation, and there was inconsistency between studies regarding whether there was an important difference in the proportion of children whose hearing returned to normal in the short term (>6 weeks to ≤3 months), with one study showing higher rates of hearing returned to normal and one study showing no evidence of an important difference. The evidence showed that auto-inflation improved disease-specific quality of life (short term). There was no evidence of important differences in the following outcomes between the auto-inflation and no treatment groups: rates of persistence of OME (very short term and short term), episodes of acute otitis media (short term) and adverse events (otalgia). However, the quality of evidence was low to very low. Therefore, the committee made a recommendation based on the best available evidence, current practice and their knowledge and experience. The committee acknowledged that hearing is the most important outcome in children with OME, and that auto-inflation may improve hearing in the very-short term and short-term. The committee agreed the critical period to consider for hearing outcomes is in the short-term, because a negative impact on hearing levels even for short periods of time can significantly impact a child's development, and it is therefore important to negate these as soon as possible rather than waiting for spontaneous resolution. Therefore, the committee agreed that auto-inflation may have important benefits for children in the short term, and consequently may reduce the requirement of further active interventions. However, the committee were aware that some children, especially very young children, may not engage with or may not be able to use the device. They also acknowledged that children should use auto-inflation devices three times a day, and those attending preschool or school may not have the opportunity to do so. Therefore, they agreed that auto-inflation should be considered in children who can engage with the intervention. The committee noted that this recommendation would be in line with current practice.

Cost effectiveness and resource use

The committee were aware of one study (Williamson 2015) which reported an incremental cost-effectiveness ratio of £8,463 per QALY which would be considered cost-effective at a cost-effectiveness threshold of £20,000 per QALY. The committee noted that there was considerable uncertainty around this result with a probabilistic sensitivity analysis reporting that auto-inflation had a 50.1% probability of being cost-effective at a cost-effectiveness threshold of £20,000 per QALY. Although, the additional costs of the intervention including

training were small at £14, they were statistically significant. The QALY gain reported for auto-inflation did not reach statistical significance although the committee noted that the QALY gain was in the same direction as the trial's primary outcome, namely tympanometric resolution of type B effusions. Therefore, the committee concluded there was weak economic evidence to support the use of auto-inflation and they recommended that it could be considered in children who are able to engage with the treatment. The committee did not believe this recommendation would have a significant resource impact as it already reflects practice in some areas and is not an expensive intervention.

Recommendations supported by this evidence review

This evidence review supports recommendation 1.5.1.

References – included studies

Effectiveness

Webster 2023

Webster KE, Mulvaney CA, Galbraith K, Rana M, Marom T, Daniel M, Venekamp RP, Schilder AGM, MacKeith S. Autoinflation for otitis media with effusion (OME) in children. Cochrane Database of Systematic Reviews 2023, Issue 9. Art. No.: CD015253. DOI: 10.1002/14651858.CD015253.pub2
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015253.pub2/full

Williamson 2018

Williamson I, Vennik J, Harnden A, Voysey M, Perera R, Breen M, et al. An open randomised study of autoinflation in 4- to 11-year-old school children with otitis media with effusion in primary care.Health Technol Assess 2015;19(72)

Appendices

Appendix A Review protocols

Review protocol for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

See the Cochrane review protocol, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.

Appendix B Literature search strategies

Literature search strategies for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

Clinical search

See Appendix 1 and Appendix 2 of the Cochrane review, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

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 auto-inflation 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, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Appendix D Characteristics of studies tables

Characteristics of studies tables for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

See the Characteristics of included studies tables from the Cochrane review, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Appendix E Data and analyses tables

Data and analyses tables for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

See the Data and analyses tables from the Cochrane review, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Appendix F Summary of findings tables

Summary of findings tables for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

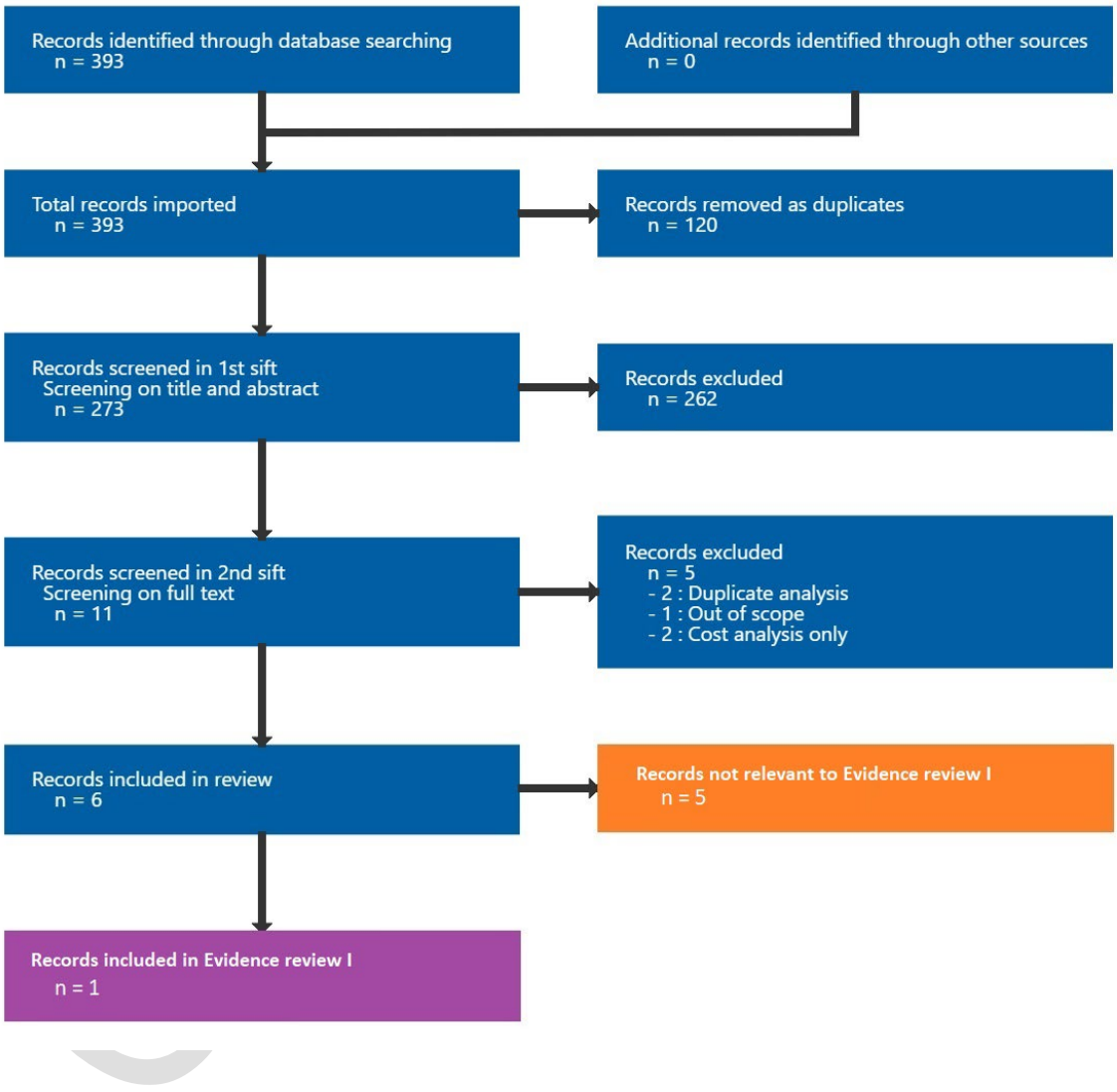
See the Summary of findings tables from the Cochrane review, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Appendix G Economic evidence study selection

Study selection for: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

A global search was undertaken to cover all the review questions considered in this guideline, and 1 study was identified which was applicable to this review question (see Figure 1).

Figure 1: Study selection flow chart



Appendix H Economic evidence tables

Economic evidence tables for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

Table 4: Economic evidence tables for auto-inflation for managing OME with associated hearing loss in children under 12 years

Study country and type	Intervention and comparator	Study population, design and data sources	Costs and outcomes (descriptions and values)	Results	Comments
Author and year: Williamson 2015 **Country:** UK **Type of economic analysis:** Cost utility analysis **Source of funding:** Heath Technology Assessment programme of the National Institute for Health Research	**Intervention:** 160 children in a primary care setting randomised to nasal balloon auto inflation (Otovent) plus standard care three times a day for 1-3 months for the treatment of OME **Comparator:** 160 children in a primary care setting randomised to standard care	**Population characteristics:** School children aged 4-11 years with a history of OME in the previous 3 months and a type B tympanogram indicating a diagnosis of middle ear effusion **Modelling approach/alongside an RCT:** Economic evaluation alongside an RCT **Source of baseline data:** Standard care arm in RCT **Source of effectiveness data:** Intervention arm in RCT **Source of cost data:**	**Mean cost per participant:** *Auto inflation:* £31.94 (95% CI: £24.20 to £39.90) *Standard care*: £17.61 (95% CI: £10.50 to £24.90) *Difference:* £14.33 (95% CI: £3.50 to £25.20) **Primary measure of outcome**: QALYs Quality of life was estimated using self-completed HUI3 questionnaires **Mean QALY per participant:** *Auto inflation:* 0.200 QALYs (95% CI: 0.192 to 0.208)	**ICERs:** £8,463 per QALY (95% CI: -£104,894 to £121,820) **Probability of being cost effective:** 50.1% at a cost-effectiveness threshold of £20,000 per QALY	**Perspective:** NHS and a Personal Social Services perspective **Currency:** GBP **Cost year:** Nor explicitly stated but costs sourced from 2012-2014 data **Time horizon:** 3 months **Discounting:** N/A **Applicability:** Directly applicable **Limitations:** Minor limitations **Other comments:** Time horizon may have been too short to capture differences in outcomes

Study country and type	Intervention and comparator	Study population, design and data sources	Costs and outcomes (descriptions and values)	Results	Comments
		Resource use data was collected as part of the trial by searching electronic records **Source of unit cost data:** BNF September 2012, PSSRU 2011-12; NHS Reference Costs 2013; Primary Care Foundation 2013; Company supplying Otovent to NHS	*Standard care*: 0.197 QALYs (95% CI: 0.191 to 0.209) *Difference:* 0..003 QALYs (95% CI: -0.010 to 0.020)		

BNF = British National Formulary; CI = Confidence interval; GBP = Great British Pound; HUI = Health Utilities Index; ICER = Incremental cost-effectiveness ratio; OME = Otitis media with effusion; PSSRU = Personal and Social Services Research Unit; QALYs = Quality adjusted life years; RCT = Randomised control trial;

Appendix I Economic model

Economic model for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

No economic analysis was conducted for this review question.

Appendix J Excluded studies

Excluded studies for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

Excluded effectiveness studies

See the Characteristics of excluded studies table from the Cochrane review, Webster 2023 at https://doi.org/10.1002/14651858.CD015253.pub2.

Excluded economic studies

No economic evidence was excluded that related to this review.

Appendix K Research recommendations – full details

Research recommendations for review question: What is the effectiveness of auto-inflation for managing OME with associated hearing loss in children under 12 years?

No research recommendations were made for this review question.