

Otitis media with effusion in under 12s: surgery

Consultation on draft scope Stakeholder comments table

08/09/21 to 11/10/21

Stakeholder	Chapter Name	Section Header	Section Number	Comments	Developer's response
British Association of Paediatricians in Audiology	key-issues-and-draft-questions	4.3 Natural history of OME (to help identify when intervention and follow-up is needed)	4.3	Fluctuating OME can cause significant problems for day to day management, advice to carer sand teachers and in decision to treat and what treatment options to use. Could fluctuating OME be considered separately?	Thank you for your comment. We agree about the importance of considering fluctuating OME and its implications. Our aim is to capture fluctuating OME in the review questions, particularly those on natural history and do not think a separate review question is needed.
British Association of Paediatricians in Audiology	key-issues-and-draft-questions	4.4 Interventions for children with OME	4.4	Some children may have a combination of treatments and maybe this should be highlighted. Watch and wait, amplification, surgery, moving between each over months/years. Children can move between services and not receive a joined up approach, Particularly important for high risk groups or where there is fluctuating OME with hearing loss	Thank you for your comment. The committee will consider combinations of treatments at the review protocol development stage. We recognise the importance of services being joined up and will consider this during the development of the guideline.
British Association of Paediatricians in Audiology	key-issues-and-draft-questions	4.5 Care during and after surgery	4.5	As well as care around surgery, should there be a section on care and follow up for the other treatment options?	Thank you for your comment. The review questions on natural history of OME are aiming to inform recommendations on follow-up. The specific review question on follow-up strategy after surgery was considered important due to the variation in current practice.
British Association of Paediatricians in Audiology	Why-the-guideline-is-needed	1	1	For children with Downs, cleft or other higher risk groups, will there be a specific section looking at the assessment and appropriate treatment options, such as preference for amplification, surgery in tertiary centres etc? Listed potential management starts with surgical	Thank you for your comment. Regarding your first point: Children with Down syndrome, children with cleft palate and other high risk groups are included within the population of this guideline update, however, we are not planning to conduct a separate evidence reviews on these.

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				treatment, perhaps implying this is the favoured option? Surgery has been removed from the guideline title so that other options can be considered. Could equal weight be given to hearing support and amplification?	Instead, we will be looking at evidence for various subgroups of children, for example those mentioned, details of which will be determined by the committee at protocol development stage. It should be noted that the current CG60 guideline specifically mentions children with Down syndrome and children cleft palate but excludes "children with other syndromal disorders, such as craniofacial dysmorphism or polysaccharide storage disease, and children with multiple complex needs". The scope for the update guideline proposes to do no such exclusions and therefore the guideline is more inclusive. Regarding your second point: The order of the options does not imply order of importance. However, we agree with your suggestion and have revised the text you are referring to by explicitly adding hearing support to the list of potential management options.
British Association of Teachers of the Deaf (BATOD)	General	General	General	BATOD feel this guideline is much needed. This is an excellent and important action to take.	Thank you for your comment.
British Association of	General	General	General	BATOD feel the right questions are being asked.	Thank you for your comment.

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Teachers of the Deaf (BATOD)					
British Association of Teachers of the Deaf (BATOD)	General	General	General	BATOD is pleased this draft guideline is coinciding with the availability of an app - HearGlue Ear which is CE marked as a medical device, and we understand commended by NICE. Some Teachers of the Deaf have been involved with a pilot study, contributing specialist Teacher of the Deaf advice in the information made available for families of children with glue ear.	Thank you for your comment and flagging the app.
Cochrane ENT	General	General	General	We agree with the proposed scope. Cochrane ENT formally scoped the topic otitis media with effusion in 2020 in order to prioritise a suite of up-to-date Cochrane reviews on the main management interventions: ventilation tubes, adenoidectomy and ventilation tubes, autoinflation, antibiotics and topical steroids (https://ent.cochrane.org/otitis-media-effusion-omeglue-ear). The planned scope appears to be broadly in line with our planned PICOs. In our Cochrane reviews we are expecting few validated measures for the outcomes listening	Thank you for your comment, we are pleased that Cochrane is updating these reviews.

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				skills, receptive language skills and speech development, and psychosocial development.	
Homerton Hospital NHS Foundation Trust	General	General	General	<p>Thank you for considering our evidence based comments regarding management of Otitis media with effusion in under 12 years. Our clinicians would like the below to be considered but I have no means of adding this onto Nice before the deadline:-</p> <p>My suggestion is that for children who require surgery for otitis media with effusion that they undergo both grommets AND primary adenoidectomy. Previous guidance from 10 years ago suggested adenoidectomy only if the glue ear (and hearing loss and all the sequelae of this were to recur). Hower the risk of recurrence will reduce if the child undergoes adenoidectomy at the same time as the first set of grommets.</p> <p>Adenoid infection or biofilm is linked to glue ear. Grommet insertion as such is only symptomatic relief for children and without concurrent adenoidectomy children are 50% more likely to</p>	Thank you for your comment. The draft scope of this guideline update includes reviews questions on effectiveness of ventilation tubes as well as on adenoidectomy with or without ventilation tubes. The committee will review the evidence on these to make recommendations.

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				<p>require further surgery, grommets, ongoing hearing loss and reduced quality of life.</p> <p>Van den Aardweg MT, 2010 in a Cochrane review of 2712 children and 14 RCT found that Adenoidectomy alone resolved glue ear without grommet insertion (as much as children who had grommet and adenoidectomy). Indeed adenoidectomy and a grommet in one ear resulted in resolution of the glue ear in both sides! The adenoidectomy is the most important part of the treatment.</p> <p>Haggard et al, Clin Oto, 2012, undertook a randomised controlled three-armed trial of Observation or Grommets or Grommets & Adenoidectomy of 376 randomised children of which 253 completed.</p> <p>In this study children who underwent adenoidectomy were found to have better hearing for longer and a 21% reduction of re-insertion of grommets.</p>	

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				<p>Coyte et al NEJM 2001, undertook a retrospective review of 37,316 children, 1995-1997 in Ontario. There they looked at paediatric outcomes after 1st set of Grommets. The children who had concurrent adenoidectomy had a 50% reduction (rr) reinsertion of tympanostomy tubes and a 50% reduction (rr) hospitalisation for acute otitis media P<0.001</p> <p>Adenoidectomy is relatively safe. Tomkinsun et al, Laryngoscope 2012, looked at 5360 curette adenoidectomy patients and the primary haemorrhage rate was 0.4% (22) primary bleed. Much lower than tonsillectomy. And there was no secondary post op bleeding. It is nearly unheard of for a child to re-attend hospital following adenoidectomy unlike tonsillectomy.</p> <p>The summary - glue ear is a disease predominantly mediated by adenoid inflammation (as a modifiable variable) and children who are suffering from glue ear, hearing loss, educational and social needs because of this should have primary adenoidectomy at the same time as grommets.</p>	

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				The NICE guidance is somewhat out of date and not in keeping with the current evidence base.	
Institute of Health Visiting (iHV)	key-issues-and-draft-questions	4.2 Recognition of OME (to help identify when to refer for further investigation)	4.2	<p>Health visitors are highly qualified Specialist Community Public Health Nurses (SCPHN), who have a universal reach supporting families from pregnancy to five years of age (1). This places health visitors in an ideal position to support the health literacy of families to help manage illnesses at home or know when to refer to the GP or specialist services such as audiology and speech and language (SLT) (2)</p> <p>One of the key roles of the health visitor is preventing ill health and 'Making Every Contact Count' (MECC) (3) and health visitors can work with families to reduce their child's chances of developing OME such as advice with the following (4):</p> <ul style="list-style-type: none"> • Parents/carers avoiding cleaning their child's ears with cotton buds as this may damage and irritate the ear canal and pushes wax further into the ear. • Parents/carers to avoid letting soap or shampoo get into their babies/child's ear canal when bathing. 	Thank you for your comment. Because of the important role that health visitors can have in supporting families in recognising, preventing and managing OME, we aim to have a health visitor in the guideline committee.

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				<ul style="list-style-type: none"> • Parents/Carers to try to keep their child's ears dry; if water gets in, to tip it out as soon as possible. • Ensuring babies and children are up to date with their immunisations • Providing advice on smoke free homes; supporting parents/carers with smoking cessation advice and signposting to smoking cessation services.) <p>Prevention of OME starts in pregnancy and health visitors have a central role supporting families with public health interventions to be fit for, during and after pregnancy to reduce the risk of birth complications and childhood illness which can contribute to OME and hearing loss (5).</p> <p>1. https://www.gov.uk/government/publications/health-y-child-programme-0-to-19-health-visitor-and-school-nurse-commissioning#history 2. https://ihv.org.uk/wp-content/uploads/2019/11/7.11.19-Health-Visiting-in-England-Vision-FINAL-VERSION.pdf 3. https://www.makingeverycontactcount.co.uk/</p>	

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				4. https://what0-18.nhs.uk/professionals/gp-primary-care-staff/safety-netting-documents-parents/earache-following-remote-assessment 5. https://www.cdc.gov/ncbddd/hearingloss/facts.html	
Institute of Health Visiting (iHV)	key-issues-and-draft-questions	4.6 Information for children, parents and carers	4.6.1	<p>Parents value quick and easy access to simple, accurate, consistent, explicit safety netting advice on the management of childhood illnesses including OME.</p> <p>2 million children aged 0-5 years attend A&E every year with rates increasing by 24% in the last six years, despite a falling birth rate and improvements in overall child health. The severity of many of these presentations will be relatively minor or self-limiting, and treatment elsewhere or self-care may be more appropriate. These visits tell us that parents are worried and are either unable or unsure how to access the reassurance or advice they need in other ways.</p> <p>An evaluation by 'Healthier Together' found that parents:</p> <ul style="list-style-type: none"> • lack confidence to distinguish self-limiting illnesses from serious ones but believe that clinicians can 	Thank you for your comment and the information provided, that's helpful background information. The guideline committee will review evidence on what information about OME is valued by children and their parents or carers and will make recommendations based on the evidence.

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				<ul style="list-style-type: none"> • can experience a high level of anxiety even when there is a relatively low level of pathology • perceive a lack of communication between professionals and inconsistent advice • living in areas of poverty felt more vulnerable • found that simple information was difficult to find online <p>Implementing effective self-care strategies delivered by health visiting services have been shown to yield significant rewards in the population. When parents received consistent, explicit safety-netting advice they were less likely to re-attend Emergency Departments for self-limiting and minor illnesses . Parents will require information on how to contact their health visiting service for advice as well as signposting to reliable digital sources of information.</p> <p>https://ihv.org.uk/wp-content/uploads/2020/01/HV-Vision-Case-Studies-First-Edition-FINAL-VERSION-21.1.20.pdf A Whole System Approach to Improving Emergency and Urgent Care for Children and Young People</p>	

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				https://www.rcem.ac.uk/docs/Paediatric%20EM%20Guidance/11.%20A%20Whole%20System%20Approach%20to%20Improving%20Emergency%20and%20Urgent%20Care%20for%20CYP.pdf https://www.what0-18.nhs.uk/	
Royal College of Nursing	General	General	General	We do not have any comments to add to this consultation. Thank you for the opportunity to contribute.	Thank you for your comment.
Royal College of Paediatrics and Child Health	Equality considerations	2.1	2.1	One equality consideration is that there is unequal access to grommet operations across the country, (which has been exacerbated by the COVID pandemic) with children waiting variable amounts of time. Some ENT services have been unable to offer any grommet operations since first lockdown in March 2020 through to now (sept 21) whereas other services started offering grommets again (often with a large waiting list) at the end of 2020.	Thank you for your comment. We acknowledge the service delivery pressures, which have worsened during the COVID pandemic. The guideline committee will look at evidence on different options for management of OME, including various non-surgical options including hearing aids and will base the recommendations on the evidence, however, the guideline will not be able to dictate service delivery arrangements for these.
Royal College of Paediatrics and Child Health	General	General	General	The first NICE guidance provides additional guidance for children with Down syndrome, this is not listed in the draft scope.	Thank you for your comment. Children with Down syndrome will be considered, however, we are not planning to conduct a separate evidence review on children with Down syndrome. Instead we will be looking at evidence for various subgroups of children, such as children with Down syndrome, details of which will be determined by the committee at

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					protocol development stage. It should be noted that the current CG60 guideline specifically mentions children with Down syndrome and children cleft palate but excludes "children with other syndromal disorders, such as craniofacial dysmorphism or polysaccharide storage disease, and children with multiple complex needs". The scope for the update guideline proposes to do no such exclusions and therefore the guideline is more inclusive.
Royal College of Paediatrics and Child Health	Why the guideline is needed	1	1	<p>"OME will usually resolve on its own within a few weeks or months. However, the hearing loss can persist, and this can cause..."</p> <p>Perhaps fluctuation should be mentioned again here since this is the most challenging part of OME, and the hearing loss is in fact more likely to fluctuate than persist, so maybe it could read "However, the hearing loss can persist or continue to fluctuate (between unilateral, bilateral and 'normal'), and this can cause..."</p> <p>[Reference: "there are sufficient cases for studies of sequelae or treatment in unilateral and fluctuating OME. Few of these cases would have received medical attention under a bilateral referral criterion."</p>	Thank you for your comment. We have revised the text based on your suggestion.

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				H Stevenson, M Haggard, G Zeilhuis, P Van den Broek, A Schilder, Prevalence of tympanogram asymmetries and fluctuations in otitis media with effusion: implications for binaural hearing. <i>Audiology</i> . May-Jun 1993;32(3):164-74. doi: 10.3109/00206099309072932]	
Royal College of Paediatrics and Child Health	Why the guideline is needed'	1	1	The draft scope says "When OME does not resolve on its own, it can be a recurring or persistent problem that has a significant impact on the day-to-day activities of the child. If this happens then further management will be needed, which could include: - surgical interventions, such as placing grommets (small plastic ventilation tubes) in the eardrum - pharmacological or non-pharmacological interventions." Should 'hearing support' also be listed here? Hearing support is mentioned in the following paragraph so perhaps that is considered to be enough?	Thank you for your comment. We have added hearing support to the list of potential management options, as suggested.
The Royal College of	General	General	General	As an outline of what is going to be looked at, we believe this is a reasonable start. We do not have much to comment on at this stage other than the	Thank you for your comment. We have taken note of your comment about removing current guidance related to cranial osteopathy and other treatments.

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Surgeons of Edinburgh				<p>plan to remove guidance against cranial osteopathy, etc. as treatments for OME. We see no reason to remove this guidance as there is still no evidence these treatments are effective.</p> <p>We will have a lot more to say when the draft guidance is prepared.</p>	<p>We have taken out the last sentence in the paragraph about the existing recommendations being removed. A decision around whether or not the existing recommendations will be removed or could be carried forward without an evidence review will be agreed when the guideline is developed. Regardless, we are not planning to conduct new evidence reviews on these interventions.</p>

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