Otitis media with effusion in under 12s

Consultation on draft guideline - Stakeholder comments table
28/03/23 – 12/05/23

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Stakeholder	Document	Page No	Line No	Comments	Developer's response
Aneurin Bevan University Health Board - Antimicrobial Working Group	Comments form	Q1		Based on the feedback I have received, we are happy with the draft document and draft recommendations.	Thank you for your supportive comment.
Aneurin Bevan University Health Board - Antimicrobial Working Group	Comments form	Q2		Based on the feedback I have received, we do not envisage any significant cost implications for implementation of these draft recommendations.	Thank you for your comment.
Association of Clinical Psychologists UK	Guideline	003	007-010	We welcome this recommendation and the recognition of impact on day-to-day living. Working in partnership with families is far more likely to result in better health literacy and treatment adherence Stewart M, Brown JB, Donner A, McWhinney IR, Oates J, Weston WW, et al. The impact of patient-centered care on outcomes. J Fam Pract 2000, 49(9):796–804. Bauman AE, Fardy HJ, Harris PG. Getting it right: why bother with patient-centred care? Med J Aust 2003, 179(5):253–256	Thank you for your supportive comment and making us aware of this information. The studies that were cited (Stewart et al. 2000 and Bauman et al. 2003) were checked against the inclusion criteria for the evidence reviews but they do not meet the population criteria: children under 12 years with otitis media with effusion.
Association of Clinical Psychologists UK	Guideline	003	018-020	This recommendation could be enhanced by the addition of text "For children with OME without hearing lost, provide reassurance to them, their parents and	Thank you for your comment. This change has been made.

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				carers that it will get better on its own over time and explain that no treatment is necessary and the reasons for this". We know that reassurance alone is not effective at challenging anxiety, and information is also important for families to understand the reasons for no treatment.	
Association of Clinical Psychologists UK	Guideline	004	001-003	Could add 'via their GP' as some families will not be clear on how to seek help should they be concerned.	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they wanted the wording on who should do this to be non-specific in order to cover variations in practice, such as different pathways, across the country. The committee did however change 'medical' to 'professional' to help clarify the recommendation.
Association of Clinical Psychologists UK	Guideline	004	004-020	We welcome this section and the reference to the guideline on babies, children and young people's experience of healthcare. We wonder whether all professionals seeing families for OME will be able to tailor information appropriately as recommended. Could add that referring families to high-quality information available (e.g. online) may support their involvement.	Thank you for your comment. The committee discussed this but decided not to amend the recommendations as they felt that recommendation 1.1.6 already mentions providing information that is tailored to individual needs and in appropriate formats. Also the babies, children and young people's experience of healthcare guideline that

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				Pomey MP, Ghadiri DP, Karazivan P, Fernandez N, Clavel N. Patients as partners: a qualitative study of patients' engagement in their health care. PLoS One. 2015 Apr 9;10(4):e0122499. doi: 10.1371/journal.pone.0122499. PMID: 25856569; PMCID: PMC4391791.	recommendation 1.1.6 links to itself references providing written and digital information in its recommendation 1.2.22. The study that was cited (Pomey et al. 2015) was checked against the inclusion criteria for the Information and support review (Evidence review N) but it did not meet the population criteria: children under 12 years with otitis media with effusion.
Association of Clinical Psychologists UK	Guideline	005	005-009	Given the demands on services and the time between follow-up appointments this may be a difficult recommendation to achieve in practice. Is it worth mentioning the collaboration of the ENT specialist with primary care which patients welcome? https://bmcprimcare.biomedcentral.com/articles/10.1186/s12875-021-01595-6	Thank you for your comment. The committee discussed this but decided not to amend recommendation 1.1.8 as they did not feel that it would be difficult to achieve in practice as it is a fairly basic standard of care. They also felt that although time between appointments might be an issue, the opportunity to ask questions and to allow time for this was important so needed to be recommended. The committee felt that the recommendation did not need amending to mention ENT collaboration with primary care as this was not a theme that had been raised by the Information review (Evidence

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					review N) and no evidence review on collaboration between services or departments was undertaken during development of the guideline. The committee also felt that collaboration should be happening anyway as part of good practice, so did not need adding to the recommendation. The study that was cited in the comment (Davidson et al. 2022) is about general collaboration between services and does not specifically mention patients wanting collaboration between the ENT specialist and primary care. The study that was cited (Davidson et al. 2022) was checked against the inclusion criteria for the evidence reviews but it does not meet the population criteria, children under 12 years with otitis media with effusion.
Association of Clinical Psychologists UK	Guideline	018	031	'The committee recognised that the biggest impact of hearing loss in children is having limited receptivity to education' – this needs more explanation. For children under school age this is often not the case, and even for those children of school age, the biggest	Thank you for your comment. A change has been made based on your suggestion. The text was amended to say 'one of the biggest impacts of hearing loss'. The studies cited (Lederberg and Mobley 1990, Kurtzer-

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				impact for the child may be social or emotional and the biggest impact for parents may be other issues, such as quality of attachment, ability to manage behaviour or impact on family life. e.g. Lederberg, A.R. and Mobley, C.E. (1990), The Effect of Hearing Impairment on the Quality of Attachment and Mother-Toddler Interaction. Child Development, 61: 1596-1604. https://doi.org/10.1111/j.1467-8624.1990.tb02886.x Kurtzer-White, E. and Luterman, D. (2003), Families and children with hearing loss: Grief and coping. Ment. Retard. Dev. Disabil. Res. Rev., 9: 232-235. https://doi.org/10.1002/mrdd.10085 Adrian Davis, Sally Hind, The impact of hearing impairment: a global health problem, International Journal of Pediatric Otorhinolaryngology, Volume 49, Supplement 1,1999,Pages S51-S54, ISSN 0165-5876, https://doi.org/10.1016/S0165-5876(99)00213-X.	White and Luterman 2003, and Davis and Hind 1999) were checked but as a review on the impact of hearing loss on children and their families or carers wasn't conducted none of these references would meet the inclusion criteria for the evidence reviews.
Association of Clinical Psychologists UK	Guideline	019	021-027	We would hope that these recommendations might reinforce and improve practice (rather	Thank you for your comment. The text on how recommendations might affect

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				than not result in much change), given your evidence review highlighted that parents and young people report that their views were often not taken into consideration (p17, lines 7-10). It is the case that children, young people and families continue to experience challenges, sometimes related to limited capacity (for example lack of access, difficulties having a further conversation with consultant or nurse specialist) and sometimes related to staff training and approach. Therefore we would like to see this guidance having a bigger impact on practice by highlighting the need to work in partnership and collaboration with families and young people.	practice is highlighting that the recommendations in the OME guideline on information and advice are not that much of a change in practice in relation to existing NICE guidance which recommends similar things. However, nationally there may be variation in practice and NICE guidance may not have been implemented. So it is hoped that where variation in practice exists the OME recommendations on information and advice will improve practice. The committee were aware of the importance of healthcare professionals working with families and young people and covered this in various recommendations. For example: recommendation 1.1.1 covers health care professionals asking about the parent's or child's concerns and agreeing a plan, 1.1.5 covers discussing management options with parents or children, and 1.1.8 covers healthcare professionals giving parents and children a chance to ask questions at any stage.

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Association of Clinical Psychologists UK	Guideline	General	General	We welcome the recognition in this guidance of a move towards collaboration with families and listening seriously to their concerns and queries and providing adequate information and time to make a collaborative decision. As mentioned in comment 1, this results in better healthcare outcomes overall.	Thank you for your supportive comment.
Association of Paediatric Emergency Medicine	Guideline	007	003	Paragraph 1.2.5 states "If OME is clinically suspected on the basis of the child's clinical history and assessment of the presenting features in recommendations 1.2.1 to 1.2.4, refer for formal assessment". We wondered, to aid the referrer, if there could be some further clarity on referral urgency and to whom the referral should be made e.g. community or hospital ENT specialist, or Audiologist, or any of these.	Thank you for your comment. The committee discussed 'to whom the referral should be made' but decided not to amend the recommendation, as they wanted the wording to be non-specific in order to cover variations in practice, such as different pathways, across the country. No evidence reviews were conducted that covered where care should occur, so community based services were not mentioned in the guidance. The committee discussed 'referral urgency' but decided not to amend the recommendation, as there was no evidence base on how quickly children needed to be seen so the committee felt that this should be left to the professional's judgment.

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British Academy of Audiology	Decision Table		General	Our understanding is that this is meant to be for parents? If so please could this be presented in a more patient friendly way? We suggest it should follow a similar template to the tinnitus decision aid	Thank you for your comment. NICE and NHS England are working together to develop a decision aid on OME. This piece of work will be separate to the development of the OME guideline and won't be published at the same time as the guideline. Due to this it has been decided to reorientate the existing decision table that was part of the OME guideline so that it is aimed at healthcare professionals and provides useful information that might be considered when they are discussing treatment options with patients. Therefore the changes suggested by the stakeholder comment have not been made.
British Academy of Audiology	Guideline		General	There is only very limited reference to groups of high risk, prolonged glue ear, such as children with downs syndrome or cleft lip an palate. We would recommend at least referencing other guidance.	Thank you for your comment. The committee discussed this but felt that the guideline was not intended to cover the management of specific populations, such as those with Downs syndrome or cleft lip or cleft palate, who may be at increased risk of OME. Instead it was intended to cover those presenting with OME in the moment,

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					and each recurrence of OME. In response to another stakeholder comment 'Craniofacial abnormalities, such as Downs syndrome or cleft palate', was added to recommendation 1.2.3 as an example of a presenting feature that might indicate a higher suspicion of OME. NICE guidelines only usually reference other guidance by NICE or accredited bodies, or guidance which has been identified in a systematic search and assessed via AGREEII (please see chapter 8 in the methods manual for further details). Because no guidance on Down syndrome or Cleft lip or Cleft palate related to OME could be located this change has not been made.
British Academy of Audiology	Guideline	007	009	We are concerned that no guidance is given as to what classifies as trained staff. The Academy feels strongly that the only people who should be completing a formal assessment of hearing in the manner expressed in this point should be a member of staff with a formal qualification in audiology. Suggest change to "hearing testing, which	Thank you for your comment. A change has been made based on your suggestion. The committee felt that as untrained staff wouldn't carry out a hearing test it was better to delete 'trained staff' to avoid confusion.

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				should be carried out by staff with a formal qualification in audiology"	
British Academy of Audiology	Guideline	008	Management Section	NICE have moved hearing aids much earlier in the document / guidance and numbered it before grommets, but it is not explicit if this means that hearing aids should now be considered the primary treatment option. If this is the intention, please could this be explicitly stated	Thank you for your comment. The recommendations on hearing aids (1.4.1) and grommets (1.6.1) have the same strength of recommendation: they are both 'consider' recommendations. The order of the whole guideline was based on the general order that the committee felt that assessment, interventions and follow up might happen but this is not an indication that hearing aids are considered the primary treatment option.
British Academy of Audiology	Guideline	008	020	We would suggest the addition of some ear specific hearing thresholds being added to this section	Thank you for your comment. A change has been made based on your suggestion. A definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition, anything >20dB is considered a hearing loss.
British Academy of Audiology	Guideline	011	Grommets section	The onus appears to have been put onto the audiologist to have a conversation regarding grommets and their pros, cons and risks? If so, there needs to be some reference to how training/upskilling for this will be	Thank you for your comment. The committee discussed this but felt that this was not really a change in practice as discussing risks and benefits was a standard part of care and covered in

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				supported? Previously this was a highlights tour as grommets was the primary treatment option, but if this is changing this needs to be deeper than a highlights tour	the 2008 NICE OME guideline (recommendation 1.9.2). They also felt that this conversation might not always involve audiologists: it might involve ENT doctors.
British Academy of Audiology	Guideline	013	009	This is directly against the recently published Patient Initiated Follow Up (PIFU) guidance – please could you revise, we would support one hearing test post grommet insertion but feel a discharge to a PIFU pathway would then be far more appropriate than a year review	Thank you for your comment. The committee discussed this and acknowledged the importance of a PIFU pathway (please refer to the committee's discussion of the evidence section in evidence review M for more detail). However, they also acknowledged that not all hospital trusts have PIFU pathways in place and that PIFU is not always equitable, as some carers or family members may not be able to make use of PIFU due to their geographical or social situation. The committee therefore agreed to amend and reorder the recommendations on follow-up into a bullet point list of what should happen after surgical treatment to ensure that there are options depending on the needs of the patient. These options included both patient initiated follow up

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					and 1-year follow up. The committee also agreed to remove the word 'routine' from the recommendation to clarify that 1-year follow-up does not need to happen in all circumstances and that there are circumstances where another pathway (such as PIFU) might be the better option.
British Academy of Audiology	Guideline	021	Reassessment section	We would recommend this section also includes some recommendations on how often to review a child who is fitted with hearing aids for otitis media with effusion. We would suggest if a child has been fitted with a bone conduction hearing aid, there is little need for regular (3m follow up) however if the child has been fitted with air conduction hearing aids, a 3m follow up is appropriate	Thank you for your comment. As no evidence review was undertaken on how often to review a child who is fitted with hearing aids for OME, the committee could not make recommendations on this. Section 1.3 on reassessment was based on Evidence review C, which investigated the natural history of OME without hearing loss, and Evidence review D, which investigated the natural history of OME with hearing loss.
British Academy of Audiology	Guideline	025	007	We disagree strongly that there will not be substantial changes to costings. At system level it is probably more cost effective to fit a BC aid than grommets, but at service level that will place huge strain on Audiology budgets. If there is going to be a recommendation that BC	Thank you for your comment. It is difficult to ascertain the overall impact on the NHS budget of these recommendations, and this section on how practice might be affected acknowledges that there are potentially

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				aid is first line of treatment there needs to be some exploration as to how this can be funded - E.g. internal recharges to ENT budgets; visible cost for all audiology services etc. If the onus is on Audiology services to manage these without ENT input, there also needs to be consideration of Audiology waiting lists	cost increases as well as savings. Whilst the recommendations make the provision of hearing aids more permissive than in the previous guideline, grommets are still recommended and if there are pressures on particular budgets then this might lead to slower uptake/implementation of the guideline. The role of the NICE guideline committee is to consider cost effectiveness to the whole system. However, it is anticipated that over time the service would adapt to reflect the best evidence on clinical and cost effectiveness. Waiting lists are beyond the scope of the guideline so recommendations cannot be made on this topic.
British Association of Audiovestibular Phyicians	Evidence Review D	017	030	The Committee agrees that the hearing of the child and hearing level are critical. Therefore the accuracy of hearing test is essential. The hearing test must be undertaken by appropriately trained professionals who are regularly undertaking hearing test in children, with appropriate equipment and environment.	Thank you for your comment. The committee felt that as untrained staff wouldn't carry out a hearing test anyway this did not need to be stated in the guidance. 'Hearing test' was added to the terms used section of the guideline to clarify that hearing tests

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				The critical factors are the volume of children and the age of the children tested by each paediatric audiologist which determines whether they are kept up to competencies. It is essential that they test sufficient number of preschool children (children under 5 years) per week. The hearing tests are best undertaken by a paediatric audiology service. The NHS is moving as much diagnostics to community and the hearing tests should be undertaken in community paediatric audiology services. All new referrals from GPs and other professionals with suspected OME (Otitis Media with Effusion) must be referred to the community based paediatric audiology service for a hearing assessment. They should be followed up in the community for repeat hearing test. They could then be referred to ENT for grommets or fitted with hearing aids by the community paediatric service. The impact of the hearing loss on the child varies significantly. It should be the responsibility of the expert in hearing to assess the impact of the hearing loss on a particular child. I have previously read an ENT European consensus document stating that hearing loss	should be age and developmentally appropriate. Clinical competence is beyond the scope of the guideline so is not covered. The committee decided not to amend the relevant recommendations to cover that audiologists should be carrying out the hearing test as this is largely standard clinical practice so did not need to be covered in this detail in the guideline. The committee decided not to amend the relevant recommendations to cover that paediatric audiology services should be used as they were aware of variation in practice, for example adult audiology services have been known to perform hearing tests if they are supporting the ENT team. No evidence reviews were conducted that covered where care should occur, so community based services were not mentioned in the guidance. In response to another stakeholder comment a definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition,

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				with OME could be between 25 dB and 40 dB in the better hearing ear to be referred for grommets. BAAP would support it. It should be the responsibility of the expert in hearing to decide on the impact of hearing on a particular child and refer appropriately.	anything >20dB is considered a hearing loss. The committee felt that by providing a range of options on reassessment in recommendations 1.3.1-1.3.3 they would be providing the necessary guidance to healthcare professionals whilst also allowing for professional judgement on reassessment. Recommendation 1.3.2 gives the option of earlier reassessment if necessary.
British Association of Audiovestibular Phyicians	Evidence Review D	017-018		The committee appears to have discussed 3 month follow up the child is added to the waiting list for grommets when the child's hearing has a significant impact on the child. The ENT waiting list for grommets varies greatly some children waiting over 12 months. I feel the greatest impact of the hearing loss in a child occurs when they are on a waiting list for months. The impact on long waiting times for grommets is much greater than deciding on whether the child should be followed in 3 or 4 months.	Thank you for your comment. One of the recommendations (1.3.2) that resulted from Evidence review D gives the option of earlier intervention than the 3 month reassessment for children who are experiencing hearing difficulties that significantly affect day-to-day living. Although the committee were aware of issues around waiting lists and the impact that this could have on follow up, they were also aware that waiting lists are beyond the scope of the guideline and that they could not therefore make recommendations on this topic.

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British Association of Audiovestibular Phyicians	Evidence Review D	018	022	Follow up – It appears that in the NHS or in wider health care it is rare to have such a stringent follow up interval of 3 months. The evidence to change or keep are both weak. The evidence should be based on accurate hearing tests rather than tympanograms. It should be experts on hearing to decide on the follow up interval and the follow up interval should depend on the impact the hearing loss has on the child.	Thank you for your comment. The committee discussed this but decided not to amend the related recommendations. The committee acknowledged that the available evidence on follow up was not strong and that the recommendations were based on their expert knowledge and experience. Evidence review D investigates the natural history of OME with associated hearing loss. Hearing loss can be confirmed by hearing tests. The population inclusion criteria states that OME would be confirmed by tympanometry. The tympanometry criteria is there to ensure included participants have confirmed OME and are therefore directly applicable to the guideline, which is specifically about OME and not hearing loss in general. The committee felt that by providing a range of options on reassessment in recommendations 1.3.1-1.3.3 they would be providing the necessary guidance to healthcare professionals whilst also allowing for professional

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					judgement on reassessment. Recommendation 1.3.2 gives the option of earlier reassessment if necessary.
British Association of Audiovestibular Phyicians	Evidence Review M	008	021	Children after receiving grommets need not be seen in ENT. They should be followed up by paediatric audiologists who are experts in hearing. They are able to undertake accurate age appropriate hearing tests. They could check whether the grommets are functioning. Children after grommets should be followed up in community paediatric audiology service.	Thank you for your comment. The committee discussed this but decided not to amend the related recommendations to say who should be doing the follow up. The wording used in the relevant recommendations is deliberately non-specific on this in order to cover appropriate variations in practice, such as different pathways, across the country. For example, audiologists might also be capable of conducting age-appropriate hearing tests for children, and this could enable patients to receive timely care without causing issues around resourcing and availability of staff. No evidence reviews were conducted that covered where care should occur, so community based services were not mentioned in the guidance.
British Association of Paediatricians in Audiology	guideline	007	022	Some children may have already been waiting many weeks or months from referral to first appointment in audiology (maybe be longer	Thank you for your supportive comment.

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				when they have been referred to ENT initially and suitable audiology assessment hasn't been done at the same time). If 3 month watchful waiting is then added it could be many months from the original concerns about the child's hearing being raised. We welcome consideration of earlier intervention.	
British Association of Paediatricians in Audiology	guideline	014	017	Evidence for the clinical benefit of amplification for children with OME would be welcome. It would help to have this information for discussion of this option with parents/carers and children. Also helpful for realistic discussion with commissioners	Thank you for your supportive comment about the research recommendation on the clinical and cost effectiveness of hearing aids.
British Association of Paediatricians in Audiology	guideline	015	007	Research into managing hearing loss due to OME in children with craniofacial abnormalities would be welcome. Could the benefits of amplification specifically for this group also be considered? The natural history of OME in these children is likely to be different and more prolonged than in children without such abnormalities	Thank you for your supportive comment. A change has been made based on your suggestion. The population for the research recommendation on hearing aids was amended to include children with craniofacial anomalies, such as Downs syndrome or Cleft palate. See Evidence review J, appendix K for more details. The population for the research recommendation on natural history of OME already included all children regardless of any comorbidity such as

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					Down's syndrome or cleft palate, so did not need amending. See Evidence reviews C and D, appendix K for more details.
British Association of Paediatricians in Audiology	Guideline	General	General	The workforce challenges in paediatric audiology are significant (note recent NDCS listen up report). Timely reviews for these children are important but resources especially staffing might lead to delays	Thank you for your comment. The role of the committee is to consider cost effectiveness to the whole system. It is understood that practice does not have to change immediately, especially in the short term and in the face of service constraints. However, it is anticipated that over time the service would adapt to reflect the best evidence on clinical and cost effectiveness.
Great Western Hospitals NHS Foundation Trust	Guideline	006	021	None of the ENT / Audiology departments or Paediatric Clinical lead knows what a parafunctional sucking habit involves	Thank you for your comment. A change has been made based on your suggestion. 'Parafunctional sucking habit' has been deleted and the remaining text in the bullet point amended to make the language clearer whilst still remaining faithful to the evidence.
Great Western Hospitals NHS Foundation Trust	Guideline	007	022	Consider defining "significantly affect" as there may be a tendency in some areas to over treat at an early stage	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that the current wording gives

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					the right amount of scope for professional interpretation depending on the individual child and their circumstances whilst still providing clarity of meaning.
Great Western Hospitals NHS Foundation Trust	Guideline	008	010	Consider a definition to help ICBs and ENT / Audiology departments agree on when to treat. The need for persistent or bilateral or defined levels of hearing threshold have now all gone.	Thank you for your comment. A change has been made based on your suggestion. A definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition, anything >20dB is considered a hearing loss.
Great Western Hospitals NHS Foundation Trust	Guideline	011	003	No comment on hearing thresholds. No comment on unilateral hearing loss. How do we prevent this becoming a licence to put grommets into almost anyone?	Thank you for your comment. A change has been made based on your suggestion. A definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition, anything >20dB is considered a hearing loss. The committee discussed unilateral hearing loss and felt that although it hasn't specifically been mentioned in recommendation 1.6.1, recommendation 1.3.3 has addressed when grommets (and other interventions) should be considered for

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					children with unilateral hearing loss. Therefore recommendation 1.6.1 did not need to be amended.
Great Western Hospitals NHS Foundation Trust	Guideline	011	005	The risks of grommet insertion need to be reviewed and perhaps published. Perforation rates of up to around 5% for a first insertion of grommets and much higher for subsequent insertions	Thank you for your comment. Specific figures on risk would not usually be included in recommendations. It would detract from the action of the recommendation, discussing risks and benefits, if the specific details of all relevant risks and benefits were listed. Evidence review E on ventilation tubes (for which there is a link below recommendation 1.6.2 in the guideline) includes a summary of the evidence and the committee's discussion of the evidence where risk of grommet insertion and perforation are discussed in more detail. Please note that Evidence review E was based on a Cochrane review and further details on the evidence can be found in that Cochrane review (which is referenced in Evidence review E). Therefore this change has not been made.

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Great Western Hospitals NHS Foundation Trust	Guideline	011	010	An excellent addition, thank you	Thank you for your supportive comment.
Great Western Hospitals NHS Foundation Trust	Guideline	012	001	Recommendations don't discuss middle ear irrigation with saline Review Cochrane Database Syst Rev 2013 Apr 30;(4):CD008512. doi: 10.1002/14651858.CD008512.pub2. Interventions for the prevention of postoperative ear discharge after insertion of ventilation tubes (grommets) in children Mohammed Iqbal Syed 1, Sharon Suller, George G Browning, Michael A Akeroyd	Thank you for your comment. When the protocol for preventing otorrhoea was agreed the committee decided the date cut off would be 2010. The reason for the date cut off was safety of antibiotics was improved from 2015 (e.g., non-ototoxic antibiotics) and the committee wanted to capture studies leading up to that change. The Cochrane review that was cited (Syed et al. 2013) was excluded in the preventing otorrhoea evidence review (Evidence review K) as the included studies in the Cochrane review were checked for relevance but all of them were conducted before 2010. The committee discussed middle ear irrigation with saline but decided not to amend the recommendations as they did not feel that it was standard practice to do this.
Neonatal and Paediatric Pharmacy Group	Guideline	012	002 & 016	Rec 1.6.5 and 1.6.9 - NPPG are aware that some centres are currently still using ciprofloxacin **eye** drops off-label for this	Thank you for your comment. The committee discussed this but decided not to add a recommendation as they

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				indication. This is also common practice when the ciprofloxacin ear drops are unavailable. Would it be useful to include a recommendation that the eye drops could be used off-label in this way if the ear drops are unavailable?	did not feel that it was good practice to promote eye drops used in the ear nationally when a single dose ampoule for use in the ear is available in many centres so was the more appropriate option. The committee were aware of this issue when they discussed the evidence: 'the committee felt that ciprofloxacin 0.2% ear drops in a 0.25 ml single ampoule dose may be the most appropriate option. However, they were aware that in some areas, ciprofloxacin 0.3% eye drops may also be used as a single dose of 3-5 drops (equivalent dose as per above).' See Evidence review K on Preventing otorrhoea for further details.
Neonatal and Paediatric Pharmacy Group	Guideline	012	016	Rec 1.6.9 – Choice of topical antibiotic should consider likely susceptibility of the microorganism. Some children may have had repeated infections and repeated courses of topical antibiotics.	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that the current wording gives the right amount of guidance whilst allowing for professional interpretation depending on the individual child and their circumstances. When the committee originally discussed the

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					evidence behind this recommendation, they agreed that non-ototoxic drops such as ciprofloxacin should be considered based on the evidence of effectiveness of topical antibiotics in treating otorrhoea, as well as their knowledge that non-ototoxic antibiotics would have a lower risk of damaging the ear. See Evidence review L on treating otorrhoea for further details.
Neonatal and Paediatric Pharmacy Group	Guideline	General	General	NPPG welcomes the research recommendations	Thank you for your supportive comment.
NHS England	Guideline	003	018	'without hearing loss'- it is not clear whether this means proven normal hearing on an objective hearing test or whether it simply means without a clear history of hearing loss- as the guideline is aimed at 'health professionals' without stating whether they are in primary or secondary care, this distinction is important	Thank you for your comment. NICE guidelines often have a section on information and advice (Section 1.1) at the start of the guideline as this can be beneficial to parents and carers. Although 'without hearing loss' is first mentioned in the guideline in recommendation 1.1.3, the committee felt that the starting point of the clinical pathway, having a hearing test to assess if children have clinical hearing loss, had been sufficiently laid out in section 1.2 (Recognition and

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					assessment) and in particular recommendations 1.2.5 and 1.2.6. Therefore no changes were made to recommendation 1.1.3.
NHS England	Guideline	004	008	I would qualify 'hearing aids' as bone conducting or air conducting at this stage as there are preconceptions about hearing aids that need to be addressed	Thank you for your comment. Although bone conducting hearing aids and air conducting hearing aids are used elsewhere in the guideline, the more generic 'hearing aids' was purposefully used in this particular recommendation. This is because recommendation 1.1.5 is linked to a decision table. To make the decision table easier to read three main treatment options were highlighted: 'Monitoring & support'; 'Hearing aids'; and 'Grommets'. The second row of the decision table covers 'What is the intervention?' and under the 'hearing aids' column there is an explanation that two different types of hearing aids are available: air conduction or bone conduction. Therefore this change has not been made.

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NHS England	Guideline	004	008-009	'and so on' is a bit too vague a phrase- I'm not sure what else it is supposed to cover and feel it should be removed	Thank you for your comment. This change has been made.
NHS England	Guideline	005	020	Hypersensitivity to loud noises is a common symptom of OME that has not been mentioned	Thank you for your comment. The committee discussed this and decided to not to make this change as they felt that hypersensitivity tends to happen when glue ear is resolved, rather than when the person presently has glue ear.
NHS England	Guideline	005	022	I would dispute the statement that children with OME **often** present with indistinct speech, and if they do present with indistinct speech, it is not nasal/ speaking through nose. The phrase 'nasal speech' has no meaning- it is either hyponasal (caused by a blocked nose) or hypernasal (caused by too much air floe through the nose eg in cleft palate). Neither of these are primarily caused by OME	Thank you for your comment. A change has been made based on your suggestion. The bullet point on 'indistinct speech' has been deleted.
NHS England	Guideline	006	001	I would dispute the statement that children with OME **often** present with frequent earache- Earache would usually imply an active inflammation ie Acute otitis media. A sensation of fullness yes, but pain is not typical of OME.	Thank you for your comment. The committee discussed this and although they understood, and to an extent agreed with the point being made, they also felt that children, especially younger children, might often experience discomfort, or fullness, in

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					the ear but might have trouble expressing this verbally and so they could 'present' with earache. The committee therefore decided to amend the text to 'ear discomfort'.
NHS England	Guideline	006	015	Wheezing is not as far as I am aware a marked of a higher suspicion of OME	Thank you for your comment. The evidence review that was conducted for presenting features associated with OME in children found evidence that showed that wheezing was very specific, but not sensitive, for a diagnosis of OME. Therefore the committee decided to make a recommendation about this. Please see evidence review B for further details on the evidence and the committee's discussion of the evidence.
NHS England	Guideline	006	016	Dyspnoea is not as far as I am aware a marked of a higher suspicion of OME	Thank you for your comment. The evidence review that was conducted for presenting features associated with OME in children found evidence that showed that dyspnoea was moderately specific, but not sensitive, for a diagnosis of OME. Therefore the committee decided to make a recommendation about this. Please see

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					evidence review B for further details on the evidence and the committee's discussion of the evidence.
NHS England	Guideline	006	017	Eczema is not as far as I am aware a marked of a higher suspicion of OME	Thank you for your comment. The evidence review that was conducted for presenting features associated with OME in children found evidence that showed that eczema/atopic dermatitis or IgE-mediated eczema was very specific, but not sensitive, for a diagnosis of OME. Therefore the committee decided to make a recommendation about this. Please see evidence review B for further details on the evidence and the committee's discussion of the evidence.
NHS England	Guideline	006	019	Urticaria is not as far as I am aware a marked of a higher suspicion of OME	Thank you for your comment. The evidence review that was conducted for presenting features associated with OME in children found evidence that showed that urticaria was moderately specific, but not sensitive, for a diagnosis of OME. Therefore the committee decided to make a recommendation about this. Please see evidence review B for further details on

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					the evidence and the committee's discussion of the evidence.
NHS England	Guideline	006	022	Conjunctivitis is not as far as I am aware a marked of a higher suspicion of OME	Thank you for your comment. The evidence review that was conducted for presenting features associated with OME in children found evidence that showed that conjunctivitis was very specific, but not sensitive, for a diagnosis of OME. Therefore the committee decided to make a recommendation about this. Please see evidence review B for further details on the evidence and the committee's discussion of the evidence.
NHS England	Guideline	006	024-025	Use of a double negative is very confusing and should be rewritten	Thank you for your comment. The evidence showed that these presenting features were moderately sensitive but not specific, meaning that the absence of the presenting feature might reduce the likelihood that the patient has OME. However, based on the evidence, it would not be correct to say the reverse is true (i.e. that the presence of these presenting features might increase likelihood of OME). Therefore the committee agreed to amend some of

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					the wording of the recommendation to make it clearer, while still remaining faithful to what the evidence actually showed.
NHS England	Guideline	006	028	'adenoid hypertrophy or history of adenoidectomy' is contradictory and incorrect and confusing given the double negative in the opening statement. A history of having had an adenoidectomy has been demonstrated to reduce the risk of further OME	Thank you for your comment. The committee discussed this and decided to amend some of the wording of the recommendation to make it clearer. However, as the evidence showed that these presenting features were moderately sensitive but not specific, meaning that the absence of the presenting feature might reduce the likelihood that the patient has OME, they felt that making the recommendation more grammatically sensible would mean that they were not being faithful to what the evidence actually showed. Therefore, the double negative in the recommendation was not removed. The committee did agree to replace a 'history of adenoidectomy' with 'a history of adenoid hypertrophy', as it was felt that making this change, along with some changes to the stem of

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					the recommendation, would make the recommendation clearer.
NHS England	Guideline	006 (box)	045	Who is it for? Says children uunder 12 years old with otitis media- should read otitis media with effusion- the two are related but different entities and this guideline only applies to OME	Thank you for your comment. This change has been made.
NHS England	Guideline	009	009	Format: 'this type of device….' Should be given its own bullet point	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that although bone conduction may be considered due to contraindications to using a air hearing aid there is the possibility that these devices might not be tolerated. The committee were aware that headbands on bone conducting devices can be a significant issue for children, meaning that they will not tolerate them.
NHS England	Guideline	012	010	I would suggest deleting the word post-operative- this suggests that the statement refers to immediate post operative issues, where I think what is meant is any episode of otorrhoea following grommet insertion and prior to extrusion of the grommets- that could be upto 2 years post-operatively	Thank you for your comment. This change has been made.

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NHS England	Guideline	012	017	I would suggest deleting the word post-operative- this suggests that the statement refers to immediate post operative issues, where I think what is meant is any episode of otorrhoea following grommet insertion and prior to extrusion of the grommets- that could be upto 2 years post-operatively	Thank you for your comment. This change has been made.
NHS England	Guideline	General	General	I think that the guideline should make it clear that it does not cover the treatment of Acute Otitis Media, Recurrent Acute otitis media (RAOM) (that can occur in association with OME) or chronic otitis media	Thank you for your comment. A change has been made based on your suggestion. The text prior to the first recommendation was amended to make it clear that the guideline does not cover the management of acute otitis media or chronic otitis media. However, the committee felt that recurrent acute otitis media didn't also need to be mentioned as this was sufficiently covered by acute otitis media, so this change wasn't made.
Royal College of General Practitioners	General			The RCGP has reviewed the draft guidance for the Otitis media with effusion in under 12s consultation and have no comments to share. It was felt that this was a good document.	Thank you for your supportive comment.
Royal College of Speech and Language Therapists	Guideline	005	004	Children are often referred to audiology due to concerns about their speech, language or communication. As noted in recommendation	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as

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				1.2.1, indistinct speech and delayed speech and language may occur as features of OME but may also co-occur due to other factors. Speech and language therapists carry out assessment to inform differential diagnosis and appropriate advice and intervention. RCSLT therefore suggests the following bullet point is added to 1.1.7. • **Considering referral to speech and language therapy where there are concerns about speech and language development.**	they felt that recommendation 1.1.7 was about healthcare professionals advising parents and carers about practical ways that parents and carers can support their child, so the committee felt that it was inappropriate to cover referral for speech and language therapy in this recommendation.
Royal College of Speech and Language Therapists	Guideline	005	022	Nasal speech may be one element of indistinct speech associated with OME due to the association between palatal dysfunction and OME. However, indistinct speech in OME is much more likely to be related to errors in production of consonants in speech e.g. disordered or delayed patterns. RCSLT would suggest this bullet point is clarified as follows: • **indistinct speech (e.g. omitting or substituting consonants, nasal/speaking through nose)**	Thank you for your comment. The committee discussed this and decided not to make this change as they felt that 'omitting or substituting consonants' was already covered by the following bullet point on 'delayed speech and language development'. The terminology of 'nasal, speaking through nose' was queried by another stakeholder, who suggested it is either 'hyponasal' or 'hypernasal' and disputing that these were primarily caused by OME. The stakeholder also disputed that children with OME often

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					present with indistinct speech. The committee discussed this and decided to delete the bullet point on 'indistinct speech (nasal, speaking through nose)'.
Royal College of Speech and Language Therapists	Guideline	006	008-023	Children with cleft palate are more likely to experience OME and fluctuating conductive hearing loss than other children, therefore RCSLT recommends that **cleft palate** is added to this list.	Thank you for your comment. A change has been made based on your suggestion. The text was amended with craniofacial anomalies added to the list and cleft palate given as an example of this.
Royal College of Speech and Language Therapists	Guideline	007	017-021	Children with cleft palate are more likely to experience OME and fluctuating conductive hearing loss than other children. Clinical Standards for Cleft Palate in England and Wales state that 'All children with a cleft palate should have their hearing assessed by a clinician trained in paediatric audiology before the gestational age of 10 months (in addition to the national newborn hearing screen within the first few days of life). They should receive follow-up audiological care and appropriate audiometric assessments, not less frequently than once a year for the first 3 years, again at school entry and at 5 years and 10 years of age'	Thank you for your comment. The committee discussed this but decided not to add a recommendation on reassessment for children who are at increased risk of OME and conductive hearing loss. They felt that the guideline was not intended to cover the management of specific populations, such as those with cleft palate, who may be of increased risk of OME but instead it was intended to cover those presenting with OME in the moment, and each recurrence of OME. In response to another stakeholder comment cleft palate was added to recommendation 1.2.3 as an example

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				NHS England reference: https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf NHS Wales reference: https://whssc.nhs.wales/commissioning/whssc-policies/all-policy-documents/cleft-lip-and-or-palate-including-non-cleft-velopharyngeal-dysfunction-all-ages-cp186 RCSLT suggests that there should be a clearer recommendation for reassessment for children who are at increased risk of OME and conductive hearing loss, regardless of whether this is unilateral.	of a presenting feature that might indicate a higher suspicion of OME.
Royal College of Speech and Language Therapists	Guideline	008	004-006	There is evidence that parents of children born with a cleft palate do not always recognise their child's hearing difficulties (McAndrew, 2020). If children are discharged after one normal hearing test there is a risk that they will not seek re-referral even though the chances of them having a fluctuating conductive hearing loss are increased. RCSLT suggests that there should be a clearer recommendation for reassessment for children who are at increased risk of OME and	Thank you for your comment. The committee discussed this but decided not to add a recommendation on reassessment for children who are at increased risk of OME and conductive hearing loss, regardless of parental concern. The committee felt that this issue was not just related to cleft palate, as parents of children who do not have cleft palate may also not always recognise their child's hearing difficulties. They also felt that the

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				conductive hearing loss, regardless of parental concern. Reference: McAndrew, L., 2020. Parental judgement of hearing loss in infants with cleft palate. The Cleft Palate-Craniofacial Journal, 57(7), pp.886-894.	guideline was not intended to cover the management of specific populations, such as those with cleft palate, who may be of increased risk of OME but instead it was intended to cover those presenting with OME in the moment, and each recurrence of OME. The committee felt that recommendations 1.3.1 to 1.3.3 gave sufficient guidance on assessing or reassessing those presenting with OME in the moment, and each recurrence of OME, so did not need amending. Parental judgment of hearing loss was not specified in any of the review protocols so consequently the review that was cited (McAndrew 2020) would not have met the inclusion criteria for the reviews.
Royal College of Speech and Language Therapists	Guideline	011	010-011	Thank you for making reference to palatal abnormalities. Cleft teams continue to see children for whom adenoidectomy results in velopharyngeal dysfunction (VPD) which was not present prior to surgery. This most often occurs in children who have an undiagnosed occult submucous cleft palate. RCSLT suggests that this recommendation should be	Thank you for your comment. A change has been made based on your suggestion. The text was amended to say 'unless assessment indicates'.

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				strengthened to include the expectation for ENT surgeons to look for features of submucous cleft palate before conducting adenoidectomy, with a recognition that occult submucous cleft palates may not have been previously identified. e.g. When planning grommets for management of OME, consider adjuvant adenoidectomy unless **case history or examination indicates** an abnormality with the palate.	
Royal College of Speech and Language Therapists	Guideline	012	012-015	Thank you for making reference to velopharyngeal insufficiency. Cleft teams continue to see children for whom adenoidectomy results in velopharyngeal dysfunction (VPD) which was not present prior to surgery. This most often occurs in children who have an undiagnosed occult submucous cleft palate. There are also cases where there is no palatal abnormality but adenoidectomy leaves a large pharyngeal space resulting in VPD. RCSLT suggests that those advising about risk of VPD should make the child/family/carers aware that this might mean further surgery and/or significant changes to their speech.	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that 'velopharyngeal insufficiency' covers 'velopharyngeal dysfunction'. Therefore the existing recommendation regarding discussions about benefits and risks of adenoidectomy could cover the points raised in the comment so no amendments were necessary.

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Royal College of Speech and Language Therapists	Guideline	013	006-016	Cleft teams continue to see children for whom adenoidectomy results in velopharyngeal dysfunction (VPD) which was not present prior to surgery. RCSLT suggests a recommendation should be added here under 'Follow up after surgical treatment': **if concerns arise about changes in speech post adenoidectomy, families should be signposted to their local, regional cleft team.**	Thank you for your comment. The committee discussed this but decided not to add the suggested recommendation as they felt that cleft teams might be inundated with inappropriate referrals. The committee also felt that if there were concerns post adenoidectomy then children or their families probably shouldn't go straight to the cleft team but should perhaps contact the ENT team who undertook the surgery.
Royal College of Speech and Language Therapists	Guideline	028	023-027	There has been a recent systematic review for children born with a cleft palate which was not included in the evidence review. This indicated that earlier ventilation tube placement results in similar outcomes to children without cleft palate undergoing ventilation tube insertion and that this has better outcomes than later ventilation tube insertion. RCSLT suggests that the committee review this evidence and decide whether it should be acknowledged in the guidelines. Felton, M., Lee, J.W., Balumuka, D.D., Arneja, J.S. and Chadha, N.K., 2018. Early placement of ventilation tubes in infants with cleft lip and	Thank you for your comment and making us aware of this study. Evidence review E on Ventilation tubes was based on a review conducted by the Cochrane ENT group that investigated the effectiveness of ventilation tubes for OME in children (see Evidence review E for further details). In the protocol, only primary evidence (randomised controlled trials, quasi-randomised trials, and cross-over randomised controlled trials) were included. Therefore, the study cited (Felton et al. 2018), which was a

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				palate: a systematic review. Otolaryngology–Head and Neck Surgery, 158(3), pp.459-464.	systematic review, would not have been included as evidence in the OME guideline as it did not meet the inclusion criteria. The included studies in the study cited (Felton et al. 2018) were also not included because they also don't meet the inclusion criteria: none of them are randomised controlled trials, quasi-randomised trials, or cross-over randomised controlled trials.
University of Cambridge – SOUND lab	Decision table	General	General	Focus group felt this was a lot of information to provide to children, parents, carers but would be useful to guide conversations. The group felt that the wording around hearing aids being 'less effective' could be reworded to describe close monitoring is necessary as hearing changes, therefore parents should monitor with child at home, and report any changes to reactions to sounds e.g sound sensitivity/loudness discomfort.	Thank you for your comment. NICE and NHS England are working together to develop a decision aid on OME. This piece of work will be separate to the development of the OME guideline and won't be published at the same time as the guideline. Due to this it has been decided to reorientate the existing decision table that was part of the OME guideline so that it is aimed at healthcare professionals and provides useful information that might be considered when they are discussing treatment options with patients. A change has been made based on your suggestion. The text in the row entitled

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					'What day to day issues are there for children and parents or carers?' was amended to say 'close monitoring may be necessary as hearing changes. Parents and children could be asked to monitor changes in hearing at home and report any changes, such as reactions to sounds, sound sensitivity, loudness or discomfort'.
University of Cambridge – SOUND lab	Guideline	003	018-019	Focus group feels parents should also be told that hearing loss can occur for example if they become more congested.	Thank you for your comment. The committee discussed this but decided not to amend the recommendation. They felt that providing reassurance and explaining why no treatment is necessary, which are mentioned by the recommendation, could include telling parents about the fluctuating nature of hearing loss and that it could be affected by factors such as congestion. The committee also felt that the fluctuating nature of hearing loss had been covered elsewhere in the guideline. Recommendation 1.1.4 advises parents or carers to seek help if there are future concerns about hearing.

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University of Cambridge – SOUND lab	Guideline	004	008	We agree with the conversations to cover management but feel this line should explicitly state 'autoinflation' as referred to in the decision table but not mentioned in the guideline until section 1.5.	Thank you for your comment. This change has been made.
University of Cambridge – SOUND lab	Guideline	007	009	The focus group felt 'hearing test' is too vague and should recommend a gold standard of testing ie ear specific with bone conduction and any masking indicated.	Thank you for your comment. No evidence reviews were conducted that covered what is the most effective hearing test, so the committee could not make recommendations on this. The committee also felt that as professionals should always be using the gold standard as part of current practice the level of detail in the recommendation was sufficient. Therefore no changes were made to the recommendation.
University of Cambridge – SOUND lab	Guideline	007	020	Our interpretation is that the guidance is suggesting reassessment if a child has bilateral Otitis Media with Effusion (OME) with related hearing loss. We believe this needs to state "bilateral OME with related hearing loss" and "unilateral OME with related hearing loss" or similar if this is intended to be the guidance.	Thank you for your comment. This change has been made.

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University of Cambridge – SOUND lab	Guideline	007	021	We are concerned that "consider reassessment" is vague and may lead to continued variability in service offers. The majority of members in our clinician focus group who reviewed the guidance interpreted this to be 'discharge' where some felt this meant consider delaying review even after reading the rationale.	Thank you for your comment. NICE uses standard terminology to reflect the strength of the evidence and 'consider' is used when the evidence is weak or uncertain. In this instance the available evidence on resolution of OME-related hearing loss was varied and of low quality. Based on their experience the committee felt that due to the fluctuating nature of hearing loss, especially in the context of unilateral OME, reassessment may, depending on individual circumstances, be appropriate sometimes but not in every instance. Therefore the use of 'consider reassessment' was justified and the recommendation was not amended.
University of Cambridge – SOUND lab	Guideline	007	022-023	Some expansion on the term "significant affect" required so that the reader is clear on the terminology. Particularly import for a new workforce or workforce not familiar with NICE/UK guidelines. This requires a significant shift in thinking from ENT services and we are concerned about whether our ENT colleagues will agree to adopt this recommendation. Given current waiting times in the pathways, this will	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that the current wording gives the right amount of scope for professional interpretation depending on the individual child and their circumstances whilst still providing clarity of meaning. The role of the NICE

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				require additional resource/funding to support. Is there a process for accessing the funding	committee is to consider cost effectiveness to the whole. It is anticipated that over time the service would adapt to reflect the best evidence on clinical and cost effectiveness. Access for funding for assessment, or reassessment, of OME in under 12's is beyond the scope of the guideline.
University of Cambridge – SOUND lab	Guideline	008	008	The focus group felt there should be more advice around sound localisation and speech in noise.	Thank you for your comment. The committee discussed 'sound localisation and speech in noise' but decided not to amend the recommendations as they felt that spatial hearing and localisation are not routinely assessed and wouldn't affect treatment for OME.
University of Cambridge – SOUND lab	Guideline	008	009	We are concerned with this recommendation because patients will potentially remain on audiology caseload longer and middle ear health will not be reviewed by ENT.	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that this depends on the clinical judgement of the audiologist. If there are concerns about the patient then the audiologist can schedule a further reassessment or refer to ENT if they think it is appropriate to do so.

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University of Cambridge – SOUND lab	Guideline	008	018-019	Not all services have access to both air and bone conduction devices. Will there be a review of funding for support/management of OME in under 12's? Bone conduction devices are considerably more expensive than air condition and as such many services have limited access to the intervention despite the potential gains from the less frequent follow-up that is required.	Thank you for your comment. The recommendation the comment is related to highlights effective treatment options. Both air and bone conduction devices were considered effective treatment options. The role of the NICE committee is to consider cost effectiveness to the whole system. It is anticipated that over time the service would adapt to reflect the best evidence on clinical and cost effectiveness. A review of funding for the support or management of OME in under 12's is beyond the scope of the guideline.
University of Cambridge – SOUND lab	Guideline	008	022	The focus group suggested there should be a definition on 'stable' to support decision making.	Thank you for your comment. A change has been made based on your suggestion. 'Stable' was originally included in recommendation 1.4.2 to counter recommendation 1.4.3 where bone conduction devices are recommended for people with 'fluctuating' hearing levels. The committee discussed this comment but they did not feel that they could sufficiently define 'stable', the only terminology they felt was suitable was

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					'not fluctuating'. Therefore the text was amended to 'not fluctuating' to help clarify the recommendation.
University of Cambridge – SOUND lab	Guideline	013	010	The focus group thought that it should be made clear that you are trying to identify reoccurring unidentified hearing loss.	Thank you for your comment. A change has been made based on your suggestion. The text was amended to clarify that what was meant was reoccuring hearing loss that could be missed.
University of Cambridge – SOUND lab	Guideline	013	014-016	This recommendation is a different approach to line 9-10. Is the recommendation either or both?	Thank you for your comment. A change has been made based on your suggestion. The committee agreed to amend and reorder the recommendations in this section into a bullet point list of what should happen after surgical treatment to ensure that there are options depending on the needs of the patient. These options include patient initiated follow up and 1-year follow up. The committee also agreed to remove the word 'routine' from the recommendation to clarify that 1-year follow-up does not need to happen in all circumstances and that there are circumstances where another pathway might be the better option. So

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					either patient initiated follow up or 1-year follow up could be used.
University of Cambridge – SOUND lab	Guideline	013	017	Should this section define "hearing loss"? There is no British Society of Audiology or any other descriptor included here	Thank you for your comment. A change has been made based on your suggestion. A definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition, anything >20dB is considered a hearing loss.
University of Cambridge – SOUND lab	Guideline	021	026	It should be consistent and clear throughout document. This implies Unilateral OME with related hearing loss but does not clearly specify	Thank you for your comment. A change has been made based on your suggestion. The text was amended to specify that unilateral OME with related hearing loss was meant. The rest of the document was also checked where unilateral OME was mentioned, and where relevant, the text was amended to specify that related hearing loss was meant.
University of Cambridge – SOUND lab	Guideline	022	002	We interpret this as bilateral OME with related hearing loss and believe that hearing should be reassessed.	Thank you for your comment. A change has been made based on your suggestion. The text was amended to specify that bilateral OME with related hearing loss was meant.

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University of Cambridge – SOUND lab	Guideline	General	General	We note there is not a minimum criteria for intervention, previous guideline defined minimum hearing loss. With removal of this we assume this is down to clinical judgement. Is that the intention?	Thank you for your comment. A change has been made based on your suggestion. A definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition, anything >20dB is considered a hearing loss.
University of Cambridge – SOUND lab	Guideline	Research recommendations	Research recommendations	Research recommendations – The groups felt that the first 4 recommendations should be priorities for research. Comment would be to include education and quality of life benefits of hearing aids. We note the recommendation for research into specific populations, more at risk of OME, on acceptability and effectiveness of various treatment strategies, has been removed despite evidence review still indicating insufficient research in this area. The focus group feels this should still be a research recommendation.	Thank you for your comment. 'Quality of life' is already an outcome for the research recommendation on hearing aids. The educational benefits of hearing aids are also already covered by the outcomes 'listening skills', 'receptive language skills', and 'psychological development' in the research recommendation on hearing aids (see evidence review J, appendix K for full details). With regards to general information needs and education on OME, the qualitative review on information and advice found plenty of evidence which informed recommendations and so no research recommendation was made (see evidence review N). In terms of research into treatments for specific

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					populations who are more at risk of OME, a research recommendation was made on the effectiveness of grommets for managing OME with associated hearing loss for children with craniofacial abnormalities, including children with Down syndrome or Cleft palate (see evidence review E, appendix K for full details). Children with craniofacial abnormalities were also explicitly mentioned as a population to include in the research recommendations on hearing aids and natural history (see appendix K of evidence reviews J and C, respectively, for full details). However, a research recommendation exclusively on various treatment strategies for specific populations (such as those with Down syndrome or Cleft palate) cannot be made as an evidence review on this was not conducted in the current update. Research recommendations can only be based on the evidence reviews carried out during guideline development because a full evidence review is necessary to know there is no, or little, evidence that meets the review

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					criteria, in which case there is a good justification to make research recommendations.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Decision table			(1) The decision aid mentions making things louder and clearer. It is not obvious why "clearer" is included since OME and conductive hearing loss results in reduced audibility. Suggest wording is: "Makes speech more audible and so improves speech understanding" (2) Clarify wording that grommets become less effective at 6 to 9 months **after insertion** and not after 6 to 9 months **of age**. Move apostrophe so "the hearing aid's setting reads the hearing aids' setting.	Thank you for your comment. Changes have been made based on your suggestion. The text was amended to say 'Makes speech more audible and so improves speech understanding, or speech access in younger children'. The text was amended to clarify that grommets become less effective at 6 to 9 months after insertion. The apostrophe has been amended as suggested.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	003	017	The final bullet in section 1.1.2 could be expanded to read: "its possible impact on the child's hearing, listening, language development, behaviour, and emotional and social wellbeing **which can persist after the OME resolves, unless specifically remediated**" (See Graydon et al, Ear Hear 2017, 38, 621-7 for evidence that 20% of	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they felt that this level of detail was not required. The action of providing information on the possible impact of OME on the child could include the information in the stakeholder comment, as well as other relevant

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				children have ongoing spatial hearing difficulties).	details, but did not need to be stated in the recommendation. The study that was cited (Graydon et al. 2017) was checked against the inclusion criteria for the evidence reviews but it does not report any of the outcomes of interest, so wouldn't have been included.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	003	018	Here, and elsewhere, the document refers to "hearing loss" and "hearing tests". Without a definition, readers will assume this means "decibels hearing loss" i.e., reduced sensitivity/audibility and "pure tone audiometry" although may still be unsure what the definition of "without hearing loss" means. Perhaps the document should refer to the more important aspect on treatment of "hearing difficulty" i.e., managing limitations in everyday functioning? Relevant tests would extend beyond PTA and decibel hearing loss to include speech-in-noise measures (see research recommendation about the need for normative reference data) and self-report functioning. Similar comment applies elsewhere including page 2, line 1 and line 5.	Thank you for your comment. A change has been made based on your suggestion. A definition of 'hearing loss' has been added to the terms used section of the guideline. In line with the current WHO definition, anything >20dB is considered a hearing loss. The committee discussed 'hearing difficulty' but decided not to amend the recommendations to cover 'hearing difficulty' or tests relevant to this. They felt that there was a big difference between 'hearing difficulty' and 'hearing loss', and that they would not act on 'hearing difficulties' unless it was >20dB.
University of Manchester	Guideline	007	009	Perhaps further explanation of "hearing testing" would be useful if this refers to more than	Thank you for your comment. The committee discussed this but decided

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(Manchester Centre for Audiology and Deafness (ManCAD))				hearing thresholds via PTA, or equivalent. Expanding the text to the following may be sufficient: "assessment of hearing impairment/sensitivity and disability/functioning." Perhaps inclusion of localisation, a not infrequent difficulty reported by parents, should be specifically mentioned too. Otherwise, there is a danger that the document might look dated and focused on assessment of pure tone hearing thresholds. It is the limitations to everyday functioning that is important, irrespective of pure tone thresholds. The wording on lines 22-23 is better i.e., hearing difficulty that significantly affect day-to-day living but it isn't clear how this is to be determined.	not to amend the recommendation as they felt that the main aim of the recommendation is to find hearing loss to treat rather than finding developmental issues so they would not usually include this in a hearing assessment. They also felt that they would not be looking at localisation since if there was a hearing loss it would be treated anyway. In light of another stakeholder comment the committee amended the recommendation to clarify that hearing tests should be age and developmentally appropriate, to cover for example that a PTA would not be carried out in some children as it's not developmentally appropriate. In light of a further stakeholder comment the committee decided not to amend the recommendations to cover 'hearing difficulty' or tests relevant to this. They felt that there was a big difference between 'hearing difficulty' and 'hearing loss', and that they would not act on 'hearing difficulties' unless it was

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					>20dB, which was the definition they decided to use for hearing loss.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	008	004	Does "hearing is normal" refer to pure tone hearing thresholds or where there is no significant impact on day-to-day living?	Thank you for your comment. The committee discussed this and felt that 'hearing is normal' refers to pure tone hearing thresholds. When impact on day-to-day living has been meant in the guideline then that text was used. In response to another stakeholder comment the committee decided to amend 'hearing is normal' to 'no associated hearing loss' to be consistent with later recommendations.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	008	017	The individual management options read in isolation but some of these could be combined e.g., use of amplification while waiting surgery. Likewise, perhaps it should be clarified that auto-inflation is not required after grommets.	Thank you for your comment. The recommendations on management options are listed in isolation as the evidence reviews on which they are based investigated the effectiveness of individual management options, for example Evidence review I investigated auto-inflation, whilst Evidence review J investigated hearing aids. An evidence review comparing management options was not undertaken. It is expected that healthcare professionals will use their professional judgement to decide when

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					combinations of management options should be used. The committee discussed clarifying that auto-inflation is not required after grommets but decided not to amend the recommendations to cover this as they felt that this was standard practice and that this level of detail was not required in the recommendations.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	008	022	1) What is the definition of "stable" and 2) How will it be possible to determine if hearing is stable if reassessment only occurs after 3 months (as stated on page 7, line 20)	Thank you for your comment. A change has been made based on your suggestion. 'Stable' was originally included in recommendation 1.4.2 to counter recommendation 1.4.3 where bone conduction devices are recommended for people with 'fluctuating' hearing levels. The committee discussed this comment but they did not feel that they could sufficiently define 'stable', the only terminology they felt was suitable was 'not fluctuating'. Therefore the text was amended to 'not fluctuating' to help clarify the recommendation. Recommendation 1.3.1, on reassessment after 3 months, is

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					followed by recommendation 1.3.3, which covers what should happen at the reassessment and afterwards. Recommendation 1.3.3 links to either discharge, interventions, or reassessment of hearing after a further 3 months. This process, of 3 months assessment leading to either discharge, intervention or further reassessment could continue as long as is necessary. This should allow enough time to determine if hearing is 'not fluctuating'. As this was covered by the recommendations no change was made.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	009	017	The section heading is "non-surgical management" but the previous section (page 8, line 17) on hearing aids is also non-surgical. Should this section include behavioural management such as communication training (for parents) and listening strategies (or/and does there need to be a research recommendation on the effectiveness of these?).	Thank you for your comment. Although hearing aids can be classed as non-surgical management the committee felt that as it is one of the main treatment options it made clinical sense to have a separate section on management of hearing loss rather than having the recommendations in a general section where it might not be immediately clear that readers should look for this information. As no

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					evidence review was conducted on what types of behavioural management are effective the committee could not make recommendations about these in the guideline. Listening strategies was mentioned in recommendation 1.1.5 but this was as an example of management options that could be discussed with children, parents and carers. Research recommendations can only be based on the evidence reviews in the guideline. Carrying out a full evidence review shows that there is no, or little, evidence that meets the review criteria. In which case there is a good justification to make relevant research recommendations. As no evidence review was conducted on what types of behavioural management are effective no research recommendations can be made on this topic. The committee decided not to make a research recommendation related to the Information review (the review from which recommendation 1.1.5 came from) as the qualitative review on Information and advice (Evidence review N) found plenty of evidence.

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University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	013	007	What sort of hearing test, and then what (after hearing test)?	Thank you for your comment. A change has been made based on your suggestion. 'Hearing test' was added to the terms used section of the guideline to clarify that hearing tests should be age and developmentally appropriate. Therefore the committee decided not to add further details on what sort of hearing test should be performed to this recommendation. In response to your comment and other comments the committee agreed to amend and reorder the recommendations in the section on 'Follow up after surgical treatment' into a bullet point list of what should happen after surgical treatment to ensure that there are options depending on the needs of the patient.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	014	008	This section on monitoring and support refers to watchful waiting and active monitoring. Waiting could mean doing nothing and this is different from active monitoring.	Thank you for your comment. The committee discussed this and felt that the intention was to try to redefine 'watchful waiting' as being an active intervention, 'active monitoring'. They felt that as 'watchful waiting' is a term still used in current practice it was important to reference the old

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					terminology to link the two concepts. 'Watchful waiting' was therefore retained but the text was amended to clarify that this was the terminology that was previously used.
University of Manchester (Manchester Centre for Audiology and Deafness (ManCAD))	Guideline	017	014	The research recommendations do not appear to take into account that • Snapshots of auditory function at 3-month visits provide limited information. Parents frequently report being exasperated at long delays between consultations, only to be told there is no problem on that particular day. Research priorities expressed by parents including overcoming this problem and they have expressed a willingness to engage in active monitoring at home, perhaps ecological momentary assessment of daily functioning as well as remote/online assessments. Solutions already exist that potentially make this feasible e.g., Sound Scouts. There are also developments in DIY otoscopy and tests to identify presence of OME.	Thank you for your comment. The research recommendation on the natural history of OME, with and without hearing loss, has the following outcomes: "Time to resolution of current episode of OME", "Time to progression of OME-related hearing loss", "Time to resolution of OME-related hearing loss", and "Time to resolution of OME causing hearing loss". The research recommendation should therefore help identify the best timing for assessment. See Evidence reviews C and D, appendix K for further details. The committee discussed 'spatial hearing and localisation' but decided not to amend the recommendations as they felt that spatial hearing and localisation are not routinely assessed and wouldn't affect treatment for OME. Research recommendations can only be based

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				• Problems with spatial hearing and localisation have not been addressed in the guideline or as a research recommendation. The former is known to persist in around 20% of cases after repeated or protracted OME has resolved during the first five years of life (Graydon et al, Ear Hear 2017, 38, 621-7. Since hearing assessment should extend beyond pure tone hearing thresholds, there is a need to determine normative data for different age groups and different (speech) tests.	on the evidence reviews in the guideline. Carrying out a full evidence review shows that there is no, or little, evidence that meets the review criteria. In which case there is a good justification to make relevant research recommendations. As 'spatial hearing and localisation' are not covered by any of the evidence reviews in the OME guideline, research recommendations cannot be made on those topics. No evidence review was conducted on what a hearing assessment should include or diagnosis, so no recommendations or research recommendations were made related to assessment beyond pure tone hearing thresholds or normative data for different age groups and different (speech) tests. The study that was cited (Graydon et al. 2017) was checked against the inclusion criteria for the evidence reviews but it does not report any of the outcomes of interest, so wouldn't have been included.

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Welsh Government - Audiology Standing Specialist Advisory Group	Decision table	Table		**Bone conduction devices are worn on a headband and transmit sounds using vibration through the bones of the skull.** Your child may need an initial audiology appointment to fit the aid or **device** **Comment:** It is better to use the term of bone conduction hearing aids, rather than bone conduction devices or device	Thank you for your comment. When developing the guideline the committee decided to specifically avoid the term 'bone conduction hearing aids' as they felt that in addition to bone conduction hearing aids it might be beneficial to consider devices linked to bone conduction that may not necessarily be classed as hearing aids. The committee decided to use the collective term 'bone conduction devices' to cover both bone conduction hearing aids and bone conduction devices. The use of this terminology was also highlighted in the terms used section of the guideline. Therefore this change has not been made.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	003	001-003	Recommendation 1.1.4 For children with OME without hearing loss, advise them and their parents and carers to seek **medical** help again if they have future concerns about **hearing**. **Comment:** It is better to replace the word of 'medical' by audiological or/and add 'Audiology'.	Thank you for your comment. The committee discussed this but decided not to amend the recommendation to say who should do this as they wanted the wording to be non-specific in order to cover variations in practice, such as different pathways, across the country. The committee did however change

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					'medical' to 'professional' to help clarify the recommendation.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	003	004-009	Recommendation 1.1.5 • Discuss management options with children with confirmed OME and hearing loss, and their parents and carers. Use decision **table 1** to guide and inform the conversation, and cover… **Comment:** Because of only one table in the document, delete **'1'**	Thank you for your comment. A change has been made based on your suggestion. The text in the recommendation was amended to just say 'table'. However, 'Table 1' was not amended where the table is located (Supplement 4) as it is NICE style to number all tables.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	003	004-009	Recommendation 1.1.5 • the benefits, risks and practical considerations of each option [monitoring and support, hearing aids, grommets (ventilation tubes) and **so on**] **Comment:** delete **'and so on'**	Thank you for your comment. This change has been made.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	003	027	Recommendation 1.1.7 **limiting** background noise **Comment:** Replace limiting by minimising	Thank you for your comment. This change has been made.

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Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	004	001-004	Terms used in this guideline Bone conduction devices A collective term that covers bone conduction hearing aids as well as bone conduction hearing implants. Bone conduction devices transfer sound by bone vibration directly to the cochlea, bypassing the outer and the middle ear. **Comment:** It is better to use the term of bone conduction hearing aids, rather than bone conduction devices.	Thank you for your comment. When developing the guideline the committee decided to specifically avoid the term 'bone conduction hearing aids' as they felt that in addition to bone conduction hearing aids it might be beneficial to consider devices linked to bone conduction that may be not necessarily be classed as hearing aids. The committee decided to use the collective term 'bone conduction devices' to cover both bone conduction hearing aids and bone conduction devices. Therefore this change has not been made.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	006	002	Recommendation 1.2.1 tinnitus **Comment:** It would be better to move it to 1.2.2 (symptoms associated with OME)	Thank you for your comment. The committee discussed this but decided not to amend the recommendations. They felt that recommendation 1.2.1 was mainly focused on presenting features related to the ear or hearing, whilst recommendation 1.2.2 was mainly focussed on other factors associated with OME. Therefore they agreed it was better to keep tinnitus in recommendation 1.2.1.

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Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	006	028	Recommendation 1.2.4 • **adenoid hypertrophy** or history of adenoidectomy (Be aware that OME is less likely if the child does not have any of the following features) **Comment:** It seems not practical to observe the feature of adenoid hypertrophy, particularly in young children.	Thank you for your comment. The committee discussed this recommendation and felt that although adenoid hypertrophy may not be practical to observe, particularly in young children, it was important to cover adenoid hypertrophy in the recommendation. The evidence showed that adenoid hypertrophy was moderately sensitive but not specific, meaning that the absence of adenoid hypertrophy might reduce the likelihood that the patient has OME. The committee agreed to replace a 'history of adenoidectomy' in the recommendation with 'a history of adenoid hypertrophy', as it was felt it would be easier for health professionals to implement if they were unable to observe adenoid hypertrophy but a history of adenoid hypertrophy was known.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	007	012	Recommendation 1.2.6 Formal assessment should include • tympanometry. **Comment:**	Thank you for your comment. The committee discussed this but decided not to amend the recommendation as they did not feel that specifying the type

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				It would be better to highlight different types of tympanometry, i.e., single 226Hz low frequency,1000Hz high frequency and Wideband tympanometry	of tympanometry would be useful to healthcare professionals. The type of typanometry would depend upon the individual undergoing the assessment and their circumstances. The committee also felt that some of the examples of different types of tympanometry that were mentioned in the comment might not be appropriate for children or weren't widely used.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	008-009		Recommendation 1.4.1 Consider air conduction hearing aids or **bone conduction devices** for children with OME-related hearing loss 1.4.2 This type of device would be better tolerated or is preferred, for example by avoiding the need for a headband as is used with **bone conduction devices**. 1.4.3 Consider **bone conduction devices** 1.4.4 **other hearing devices** **Comment:** It is better to use the term of bone conduction hearing aids, rather than bone conduction devices.	Thank you for your comment. When developing the guideline the committee decided to specifically avoid the term 'bone conduction hearing aids' as they felt that in addition to bone conduction hearing aids it might be beneficial to consider devices linked to bone conduction that may be not necessarily be classed as hearing aids. The committee decided to use the collective term 'bone conduction devices' to cover both bone conduction hearing aids and bone conduction devices. The use of this terminology was also highlighted in the terms used section of the guideline.

Otitis media with effusion in under 12s

Consultation on draft guideline - Stakeholder comments table
28/03/23 – 12/05/23

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					Therefore this change has not been made.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	014-017		Recommendations for research **Comment:** We would like to recommend to conduct a translational research of applying innovative technology for digital self-hearing test and AI automated diagnosis of children with OME in primary care setting	Thank you for your comment. NICE's methodology means that a research recommendation cannot be made on this topic. Research recommendations can only be based on the evidence reviews in the guideline. Carrying out a full evidence review shows that there is no, or little, evidence that meets the review criteria. In which case there is a good justification to make relevant research recommendations. As the topics mentioned in the stakeholder comment do not match any of the evidence reviews in the OME guideline, research recommendations cannot be made on those topics. NICE is planning to carry out a review of horizon scanning and will be giving stakeholders the opportunity to contribute to this work. This may be something your organisation would like to contribute to.
Welsh Government - Audiology Standing	Guideline	036	026-027	Context	Thank you for your comment. A change has been made based on your

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Specialist Advisory Group				OME is particularly common in children with **craniofacial anomalies**, for example children with **Down's syndrome** or cleft palate….. **Comment:** Down syndrome can be considered to have a craniofacial feature, rather than craniofacial anomaly	suggestion. The text was amended so that craniofacial feature was added, however the committee felt that it was also useful to retain craniofacial anomaly as this terminology is still used by healthcare professionals.
Welsh Government - Audiology Standing Specialist Advisory Group	Guideline	037	014-016	There are also communication problems between services, with paediatric audiology services often not aware of surgical delays. **Comment:** It would be better to provide a positive recommendation, such as 'Efforts to improve communication between services could ensure that paediatric audiology services are informed and able to provide optimal care.'	Thank you for your comment. A change has been made based on your suggestion. The text in the context section was amended to say 'Communication between audiological and surgical services could be improved'.