

SURGICAL MANAGEMENT OF OME draft guideline consultation: registered stakeholder comments & responses

Order No	Organisation	Document	Section No	Line No	Comments	Response
1	Addenbrooke's NHS Trust				This organisation was approached but did not respond	
2	Association of Medical Microbiologists				This organisation was approached but did not respond	
3	Barnsley Hospital NHS Foundation Trust				This organisation was approached but did not respond	
4	Bedfordshire PCT				This organisation was approached but did not respond	
5	Berkshire Healthcare NHS Trust				This organisation was approached but did not respond	
6	Bolton Council				This organisation was approached but did not respond	
7	Bradford Hospitals NHS Trust				This organisation was approached but did not respond	
8	British Association of Otolaryngologists Head & Neck Surgeons				This organisation was approached but did not respond	
9.0	British Association for Paediatric Otorhinolaryngology	FULL	General	ALL	A pragmatic and well presented guideline	Thank you
9.1	British Association for Paediatric Otorhinolaryngology	FULL	General	ALL	<p>BAPO has significant concerns about the approach the GDG has taken to adenoidectomy. If evidence is lacking, guidance should state this but take a neutral stance. The converse approach has been taken by the GDG on hearing provision, where evidence is also lacking.</p> <p>The GDG should emphasis that adenoidectomy is frequently indicated in the age group undergoing VT insertion for other co morbidity and that it is often appropriate to remove the adenoid at the time of VT insertion for reasons other than OME. The approach in the guideline is likely to be misinterpreted so that VT's + A's is disallowed by commissioners as "ineffective practice".</p>	<p>We understand BAPO's concern in this matter. The <u>published</u> evidence is not sufficiently robust to recommend routine adjuvant adenoidectomy for every child with OME and persistent bilateral hearing loss. Adenoidectomy might be associated with severe complications, and to recommend it for every child would require a higher level of evidence than provision of hearing aids, which is inherently less hazardous.</p> <p>Nevertheless we accept that there is a place for adjuvant adenoidectomy in the presence of frequent and/or persistent upper respiratory tract symptoms and this has been included in the guideline. The recommendation on VT + adenoidectomy is quite explicit and unlikely to be misinterpreted as "ineffective practice".</p> <p>The recommendation is quite clear and there is no need for using upper case/bold.</p> <p>Appropriate changes have been made.</p>
9.2	British Association for Paediatric Otorhinolaryngology	FULL	20	26	Suggest "not" in upper case bold i.e. NOT	
9.3	British Association for Paediatric Otorhinolaryngology	FULL	20	28	Suggest topical or systemic antihistamines instead of "antihistamines"	
9.4	British Association for Paediatric Otorhinolaryngology	FULL	20	29	Suggest topical or systemic decongestants instead of "decongestants"	Appropriate changes have been made.
9.5	British Association for Paediatric Otorhinolaryngology	FULL	22-23	37 - 9	<p>Current practice of recommending adenoidectomy with VT's for recurrent OME follows US guideline from AAO-HNS and AAFPH. Also, many children have symptoms of recurrent URTI and nasal obstruction that is concurrent with persisting OME and benefits from adenoidectomy.</p> <p>It is likely that the adenoid is the source of the biofilm infection resulting in upregulation of mucin genes and effusion formation in the middle ear. If the evidence is</p>	<p>Your point is well appreciated. The guideline does not advice 'against adenoidectomy' but recommends it to be performed along with VT insertion only in certain group of children with OME. Please also see the response to comment 9.1.</p> <p>It is probable that under the US healthcare system, children with OME are treated at an earlier stage than in the UK.</p>

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					not yet available, this should be discussed; BAPO believe that the guideline should not advise against adenoidectomy if evidence is lacking, but convey a more neutral message. Absence of evidence is not evidence against the intervention.	
9.6	British Association for Paediatric Otorhinolaryngology	FULL	24-27	All	The care pathways are very helpful	Thank you.
9.7	British Association for Paediatric Otorhinolaryngology	FULL	24-27	All	When surgery is indicated, will the active observation be part of the 18 week pathway, or will the "clock stop" for this period? There are major problems in achieving timely surgical intervention following active observation and current DH practice disallows placing a child on a surgical waiting list with a provisional decision to operate based on the outcome at the end of active observation. The guidance must include such advice to facilitate implementation of the guidance with commissioners and providers.	The 18 week clock stops once active observation commences.
9.8	British Association for Paediatric Otorhinolaryngology	FULL	25	All	Please delete "exceptional" from "routine adjuvant adenoidectomy". By definition, upper respiratory tract symptoms are very common in this age group. There is no evidence to support the use of the qualifying adjective "exceptional"	The word has been deleted.
9.9	British Association for Paediatric Otorhinolaryngology	FULL	26	All	There are major compliance problems with children who have Down syndrome using hearing aids.	The GDG had discussed the benefits and harm of hearing aids (including compliance) in children with Down's syndrome before recommending them.
9.10	British Association for Paediatric Otorhinolaryngology	FULL	28	7	Please include UK prevalence/incidence data	We were unable to get authentic data for incidence/prevalence in the UK.
9.11	British Association for Paediatric Otorhinolaryngology	FULL	29	50	Clinical observation indicates that the children with OME who have significant balance symptoms are those in a younger age group, just learning to walk. This study will have missed this group by looking at children in an older age group.	Your point is well appreciated. The GDG were aware of the limited clinical relevance of the study results. They have included 'balance difficulties' in the list of suspected features of OME in spite of the study's failure to find strong evidence of balance problems in (older) children.
9.12	British Association for Paediatric Otorhinolaryngology	FULL	30	50-51	See comments above for pp 22-23 and p 25	Please see response to comments 9.1 and 9.8.
9.13	British Association for Paediatric Otorhinolaryngology	FULL	31	7	See comments above for pp 22-23 and p 25	Please see response to comments 9.1 and 9.8.
9.14	British Association for Paediatric Otorhinolaryngology	FULL	34	10-15	Is there evidence that tuning fork testing is reliable and reproducible in 2 year old children?	No evidence was identified on the reliability or reproducibility of tuning fork tests in 2 year old children.
9.15	British Association for Paediatric Otorhinolaryngology	FULL	47	50-51	Does this translate to the same hearing thresholds as normal children without OME? i.e. treatment with VT's brings children with OME to a normal hearing threshold at 12-18 month as if they had no treatment (and also no OME)?	No. It implies improvement in the hearing levels from the baseline levels measured at the time of diagnosis. The text has been modified to make it clear.
9.16	British Association for Paediatric Otorhinolaryngology	FULL	52	32-33	What is the statistical risk of haemorrhage and re-operation/extended stay in hospital following	The statistical risk is given in Table C.6. Whilst, the GDG is the source of this estimate, it is in a similar

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					adenoidectomy?	ballpark to that reported for bleeding significant enough to cause a return to the operating theatre. http://www.emedicine.com/ent/topic316.htm
9.17	British Association for Paediatric Otorhinolaryngology	FULL	52	36-37	By definition, most children in this age group do have upper respiratory symptoms. The guideline should say that evidence is lacking to support adenoidectomy for the surgical management of OME, but that by definition, the group of children requiring VT's for OME often have parallel indications for adenoidectomy and that it is appropriate to perform the two procedures under the same anaesthetic if indicated.	Severe is defined as a bleed requiring either a return to the operating theatre and/or an overnight stay in hospital. We agree with your comment and appropriate changes have been made.
9.18	British Association for Paediatric Otorhinolaryngology	FULL	52-53	46-7	Ideal advice, but good quality RCT's are unlikely to be achievable. The attrition from the control group to treatment arm was well demonstrated in the UK TARGET trial. Parents are unlikely to keep their child for two years in a control group.	We disagree with your comment. It is quite possible to conduct good quality RCT's comparing the short and long-term effectiveness of ventilation tubes alone with ventilation tube and adjuvant adenoidectomy. Attrition is a potential problem with any trial, but it can always be minimized.
9.19	British Association for Paediatric Otorhinolaryngology	FULL	53	49	Has Ian Williamson at Southampton University been asked to submit data from primary care OME/intranasal steroid study? P59 Line 10 – will this be published in time to include in the guideline?	The evidence on effectiveness of intranasal steroids in OME has not been published yet as the data is being collected. In the absence of evidence in favour of the intervention, we have recommended it not to be used.
9.20	British Association for Paediatric Otorhinolaryngology	FULL	53	50-51	Reference missing	The study is a part of the systematic review and this has been referenced adequately. Kindly see the review (Ref ID 60) for more details.
9.21	British Association for Paediatric Otorhinolaryngology	FULL	54	1	Reference missing	The study is a part of the systematic review and this has been referenced adequately. Kindly see the review (Ref ID 60) for more details.
9.22	British Association for Paediatric Otorhinolaryngology	FULL	55	45	Was this an older age group?	Age of the children ranged from 3-16 years in the five trials included for this systematic review. Kindly see the evidence table for more information.
9.23	British Association for Paediatric Otorhinolaryngology	FULL	57	22	This contradicts the guidance for the care pathway for children with Down syndrome? If there is no good-quality evidence for hearing aids, why are they recommended while there is no good-quality evidence for adjuvant adenoidectomy and this is not recommended?	Please see the response to comment 9.1
9.24	British Association for Paediatric Otorhinolaryngology	FULL	59	15-21	Why has the GDG decided to recommend hearing aids in the absence of evidence? May we review the health economics data comparing single intervention VT's with bilateral hearing aid issue, follow-up consultations, maintenance, batteries, repairs, replacement and	Please see the response to comment 9.1 for the first part of your question. In accordance with the NICE Guidance Manual parental travel and loss of income are not considered and the

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					parental travel and loss of income to continue attending a paediatric audiology clinics? What data are the GDG estimates based on; would it be possible to get more accurate data from a paediatric audiology clinical service within the NHS?	costs are measured from the perspective of the NHS and personal social services http://www.nice.org.uk/niceMedia/pdf/GuidelinesManualChapter8.pdf . We feel that the costing method is adequately explained in the Health Economics appendix. The costing of hearing aids was based on information received from members of the GDG who work within a paediatric audiology clinical service within the NHS. In the absence of any clear indication of the existence of better data or flaws in the method, we believe the estimate derived is reasonable.
9.25	British Association for Paediatric Otorhinolaryngology	FULL	61	49-50	There are major parental difficulties in maintaining hearing aid compliance for children with Down syndrome	Please see the response to comment 9.9
9.26	British Association for Paediatric Otorhinolaryngology	FULL	64	8-9	This issue also applies to the parents of children with Down syndrome, but is not included in the discussion of hearing aid provision	Agreed and appropriate changes made in the text.
9.27	British Association for Paediatric Otorhinolaryngology	FULL	69-70	ALL	Presumably this assumes bilateral hearing aid provision – should be stated	This is already stated in Table C.1.
9.28	British Association for Paediatric Otorhinolaryngology	FULL	71	23-34	This is an unacceptably biased statement with a financial sub text that should not be included in a clinical guideline. It is within a “description” section, but is clearly an economic pointer. It suggests that if commissioners reduce access to the choice of surgical treatment, parents will be forced to accept hearing aid provision for their child even if they had expressed a wish for surgery. The statement contradicts the guideline that has already concluded that there is lack of evidence to support the benefit of hearing aid issue for the management of OME. Please delete	The health economist does not accept there is any financial sub-text. The economic analysis goes on to suggest that surgery may be justified on cost-effective grounds. Therefore, there is no suggestion that commissioners reduce access to the choice of surgical treatment, because hypothetically the acceptability of hearing aids might (or might not) be higher if surgery was not provided by the NHS. The statement does not make any reference to the effectiveness of hearing aids and there is no contradiction with the evidence base discussed by the guideline elsewhere. Nevertheless, we accept that this hypothetical discussion is not central to the analysis and we have deleted it.
9.29	British Association for Paediatric Otorhinolaryngology	FULL	71	36	What is the statistical risk of severe bleeding? How is “severe” defined? RCS Clinical Effectiveness team may have some data on this from UK NPAT	The statistical risk is given in Table C.6. Whilst, the GDG is the source of this estimate, it is in a similar ballpark to that reported for bleeding significant enough to cause a return to the operating theatre. http://www.emedicine.com/ent/topic316.htm Severe is defined as a bleed requiring either a return to the operating theatre and/or an overnight stay in

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						hospital. A footnote will be added to this effect.
9.30	British Association for Paediatric Otorhinolaryngology	FULL	72	ALL	What is the loss rate for children issued with hearing aids?	This information is given in Table C.7.
9.31	British Association for Paediatric Otorhinolaryngology	FULL	73	4	This is data from a trainee presentation – is there a better quality reference source?	We've added a better quality reference source. Randall DA, Hoffer ME. Complications of tonsillectomy and adenoidectomy. Otolaryngol Head Neck Surg 1998; 118:61-8
9.32	British Association for Paediatric Otorhinolaryngology	FULL	74	ALL	Using so many GDG estimates invalidates the quality and impact of the guidance derived from these estimates	This will to some extent depend on the accuracy of the estimates! Ideally we use published data but where this isn't available a GDG estimate is the 'best available evidence'. Sensitivity analysis is used to assess the importance of the uncertainty surrounding any particular parameter value.
9.33	British Association for Paediatric Otorhinolaryngology	FULL	77	ALL	The incremental cost of VT+ads fails to account for savings in primary care derived from reduced frequency of attendance due to lower rate of recurrent URTI's, reduced inappropriate prescription costs and loss of parental income due to care for children off school. This organisation was approached but did not respond	The GDG felt there was no published evidence showing a lower rate of recurrent URTI's with VT+ads. Furthermore, the NICE Guidelines Manual states that only cost to the NHS and personal social services should be included in any analysis.
10	British Association of Community Doctors in Audiology (BACDA)				This organisation was approached but did not respond	
11	British Association of Teachers of the Deaf (BATOD)				This organisation was approached but did not respond	
12	British Homeopathic Association	NICE	general		It should be noted that doctors trained in homeopathy often treat children with OME (in both primary and secondary care). Clinical observational studies suggest this can avert the need for surgical intervention. More research in this area would be desirable. There is one pragmatic RCT that shows a significantly higher proportion of children receiving homeopathy had normal tympanograms at 12 months compared with those on standard care (Harrison, Fixsen & Vickers, 1999). This organisation was approached but did not respond	Thank you for your comment. The single pilot RCT (referenced by you) and its results were discussed by the GDG but they found it to be insufficient evidence for making a recommendation or a research recommendation.
13	British National Formulary (BNF)				This organisation was approached but did not respond	
14	Calderdale PCT				This organisation was approached but did not respond	
15.0	CASPE Research	NICE	General		These comments are made from the perspective of drafting audit criteria for NICE guidance. The comments are therefore restricted to considering the key priorities for implementation, and whether these are phrased in such a way as to facilitate audit of the implementation of the guidance.	Thank you for your comments.
15.1	CASPE Research	NICE	5	Key priority 1	To aid audit, could 'developmentally appropriate' hearing tests be more fully defined?	The wording of the recommendation has been changed.

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15.2	CASPE Research	NICE	5	Key priority 2	If it is the intention that all children who meet these criteria should have surgical treatment, then could this recommendation be worded more effectively? At present the inclusion of the 'considered' qualifier does not allow for audit of this recommendation.	It is guidance for health care professionals and we cannot be more emphatic.
15.3	CASPE Research	NICE	6	Key priority 6	Use of the word 'majority' makes audit of this key priority for implementation very difficult to achieve. As such, could it be worded differently?	Appropriate changes have been made.
16	Charing Cross Hospital				This organisation was approached but did not respond	
17	Chase Farm Hospital				This organisation was approached but did not respond	
18	Commission for Social Care Inspection				This organisation was approached but did not respond	
19	Connecting for Health				This organisation was approached but did not respond	
20	Cornwall & Isles of Scilly PCT				This organisation was approached but did not respond	
21	Department of Health				This organisation responded and said that they have no comments to make	Thank you.
22	Department of Health, Social Security and Public Safety of Northern Ireland				This organisation was approached but did not respond	
23	Derriford Hospital				This organisation was approached but did not respond	
24	Downs Syndrome Medical Interest Group (DSMIG)				This organisation was approached but did not respond	
25	Dudley Group of Hospitals NHS Trust				This organisation was approached but did not respond	
26	East & North Herts PCT & West Herts PCT				This organisation was approached but did not respond	
27	Glan Clwyd District General Hospital				This organisation was approached but did not respond	
28	Health Commission Wales				This organisation was approached but did not respond	
29	Healthcare Commission				This organisation was approached but did not respond	
30	Home Office				This organisation was approached but did not respond	
31.0	Kettering General Hospital	Surgical Management of OME Not recommended treatment	9	151.1	In younger children who are not suitable for grommets, I use a long term low dose antibiotic with great success. EG one dose Amoxil daily for up to 3 months at a time. Parents are happier to use this option at this age group.	The published evidence on antibiotics was reviewed and there was no evidence to suggest that these were effective in treating OME in children.
31.1	Kettering General Hospital	Adenoid	13		Adenoids should be removed if symptoms of	This is explicit from the recommendation.

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		decto my			obstruction co-exist eg mouth breathing, snoring.	
32	Leeds PCT				This organisation was approached but did not respond	
33	Leeds Teaching Hospitals NHS Trust				This organisation was approached but did not respond	
34	Lincolnshire PCT				This organisation was approached but did not respond	
35	Medicines and Healthcare Products Regulatory Agency (MHRA)				This organisation was approached but did not respond	
36	Medway NHS Trust				This organisation was approached but did not respond	
37	Milton Keynes PCT				This organisation was approached but did not respond	
38	Morecombe Bay Health Trust				This organisation was approached but did not respond	
39	MRC Multicentre Otitis Media Study Group				This organisation was approached but did not respond	
40	National Deaf Childrens Society				This organisation was approached but did not respond	
41	National Patient Safety Agency				This organisation was approached but did not respond	
42	National Public Health Service - Wales				This organisation responded and said that they have no comments to make	Thank you.
43	NCCHTA	Full			1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)	
43	NCCHTA	Full			None. Within the limits of my clinical understanding, it appears to address the scope fully. An excellent and thorough piece of work	Thank you.
43	NCCHTA	Full			2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines)	
43	NCCHTA	Full	45	35	Some risk of bias through literature being identified through GDG members if these were not otherwise identified through the search strategy. This is not to throw pragmatism out of the window if important articles are poorly indexed, but it might be preferable to use the indexing of papers identified by GDG members to improve the search strategy in an attempt to identify other obscure references. More detail should be given about the extent and import of the literature included but not identified by the searches.	The sentence in line 35 relates predominantly to the studies on effectiveness of various treatments (surgical and non-surgical) in children with Down's syndrome and cleft palate. It is rare for every search, no matter how good they are, to pick up every relevant paper. Not all papers are indexed by the bibliographic databases, and some papers are poorly indexed so that retrieval (even using an optimum combination of free text and MeSH terms) is difficult. The GDG members, and the consultation which invites input from registered stakeholders, act as a 'safety net' to pick up material of this kind. When papers are suggested in this way it should not throw the legitimacy of the searches into doubt.
43	NCCHTA	Full			2.2 Please comment on the health economics and/or statistical issues depending on your area	

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									of expertise.	
43	NCCHTA		Full						I am a medical statistician and have commented mainly on the clinical evidence, especially with reference to RCTs and meta-analysis as these are my areas of expertise.	
43	NCCHTA		Full						In general the statistical aspects of the report have been handled competently. I have some specific comments on the reporting and interpretation of some studies which are given in detail below. These comments are mainly of a "tightening up" nature and I do not believe that any of these points have a major impact on the conclusions of the report or the guidelines developed	Thank you.
43	NCCHTA		Full						3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?	
43	NCCHTA		Full						Both justified and complete, with appropriate comment on areas where the evidence base is absent or unsatisfactory.	Thank you.
43	NCCHTA		Full						3.2 Are any important limitations of the evidence clearly described and discussed?	
43	NCCHTA		Full						Yes. The evidence has for the most part been well described and discussed. I have made some specific comments on interpretation below which may need to be addressed, but overall the work is thorough and has been very well done	Thank you.
43	NCCHTA		Full						4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.	
43	NCCHTA		Full						The report is well written, well presented and easy to understand. I have made some comments below on ambiguities of meaning and points which might receive more or less emphasis. The recommendations flow clearly from the discussion of the evidence and appear very reasonable.	Thank you.
43	NCCHTA		Full						4.2 Please comment on whether the research recommendations, if included, are clear and justified.	
43	NCCHTA		Full	23	4-5				Follow-up beyond 2 years may be important for behavioural/developmental outcomes – especially with the potential for conduct disorders and diagnoses such as ADHD as well as increasing use of long-term drug	Though it might be important to follow-up children beyond 2 years for the specified outcomes, it will not be a practical time-frame under field conditions considering the costs, attrition rate, and acceptability

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					treatments for behavioural problems.	to parents/carers and children. Nevertheless the recommendation does not prevent trials to follow-up beyond 2 years and from using different instruments to collect information.
43	NCCHTA	Full	23	4-5	Long-term follow-up via NHS number and GPs (respiratory/hearing/behavioural diagnoses and treatments), the school system (educational and behavioural) and the criminal justice system should be feasible for measuring long-term outcomes in a large pragmatic trial.	Please see the above response.
43	NCCHTA	Full	23	44-50	Why no recommendation for a (large, pragmatic, long-term) RCT comparing surgery vs hearing aids? This would appear to be the most critical omission from the evidence-base.	The use of hearing aids is a temporising intervention to alleviate the conductive hearing loss produced by OME and the major issues with its use are compliance and acceptability. It might not be possible to conduct a large RCT comparing surgery and the provision of hearing aids, but it could be the subject of a comparative study or multi-centre audit.
43	NCCHTA	Full			Please make any additional comments you want the NICE Guideline Development Group to see	
43	NCCHTA	Full	46	7-8	This sentence is ambiguous. It appears to refer to the way that duration of OME was defined for the purposes of the systematic review. It is standard to measure the duration of disease from the date of entry into a study for practical and scientific reasons. It has nothing to do with follow-up varying across studies.	Thank you. The sentence has been changed as per your suggestion.
43	NCCHTA	Full	46	7-8	If my interpretation of the sentence is correct, the first clause ("Owing to...") should be deleted and "study inception" should read "entry into the study". There may be other issues relating to differences between recruitment methods across. In this case, the problem and solution need to be described more clearly. I cannot see how this can be an issue with follow-up.	Please see the above response.
43	NCCHTA	Full	47	24-25	Need to clarify what is meant by "none of these had an independent effect on outcome". It appears to mean that none of them predicted poor outcome in a univariable analysis but did appear to do so in a multivariable analysis, which would be unusual; if this is the case it should be stated clearly	None of these refers to the subgroups of children or variables which were identified as poor predictors for the outcome 'mean time spent with effusion' using regression analysis. This has been clarified further by making appropriate changes in the text. The variables referred in the following paragraphs relate to the other two outcomes - mean hearing level and language development.
43	NCCHTA	Full	47	24-25	If it means that there was no interaction between these effects and the treatments given (which it may not, as day care is identified as a possible effect modifier in the next paragraph, line 30), this must still be interpreted carefully. If a prognostic factor does not	Please see the above response.

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43	NCCHTA	Full	47	32 & 37	<p>show an interaction in terms of relative benefit (eg RR), there <i>must</i> be an interaction in terms of absolute benefit (eg absolute difference in % recovering), and vice versa. (More on this below.)</p> <p>Must specify which outcome measurement was used to calculate p-values for interaction. The absolute differences given in the text imply that the interaction effect is based on these. The implication of an interaction is that the treatment is more or less beneficial for some groups – but when the factor under consideration is an indicator of prognosis this needs to be interpreted carefully. It is often the case that a treatment has the same relative effect across groups but this means that poorer prognosis patients therefore gain much more in absolute terms.</p>	<p>In both the lines 32 and 37, the outcome was mean hearing levels and it is evident from the text.</p> <p>We agree with the second part of your comment. Though clinical improvement in hearing level is more important than absolute gain, a major drawback of the evidence for OME was the preponderance of trials evaluating absolute gain in hearing levels as the major/only outcome. At the same time these two outcomes are not very different from each other. It is obvious that a higher absolute gain in hearing levels will usually lead to an improved clinical benefit provided there is no underlying other cause of hearing loss.</p>
43	NCCHTA	Full	47	32 & 37	<p>Once this is clarified, the question then becomes which is the more important consideration – absolute benefit in terms of decibels lost, or prevention of clinically relevant hearing loss regardless of how big the absolute loss is for the individual, or somewhere in between?</p>	<p>Please see the above response.</p>
43	NCCHTA	Full	47	32 & 37	<p>[Consider, for example tamoxifen for the prevention of breast cancer (using some simple numbers for convenience). RCTs suggest that prophylactic tamoxifen halves the lifetime risk of breast cancer (RR=0.5 for low and high risk individuals), but this is only a reduction of ~2% (NNT=50) for the general population (4% baseline risk) whilst it is a 40% (NNT=2.5) for those with a family history of breast and/or ovarian cancer (80% baseline risk).</p>	<p>Please see the above response.</p>
43	NCCHTA	Full	47	32 & 37	<p>Whether or not there is a statistical interaction depends on whether you use a relative or absolute measure of risk to do the test – there has to be an interaction for at least one of them if the factor has an impact on prognosis. Whether or not the interaction found is relevant to decision-makers depends on the specific clinical situation and outcomes.]</p>	<p>Please see the above response.</p>

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43	NCCHTA	Full	48	23-28	The review included studies in children with both unilateral and bilateral OME, but the description does not appear to include any designs suitable for children with unilateral OME?	Agreed. This has been further clarified by adding a sentence under 'Review findings'.
43	NCCHTA	Full	48	23-28	Did these studies allow hearing aids in the control arm? Need some clarification on hearing aids and whether they were included/allowed/disallowed in any study, and whether any such on-study restrictions prevented a clinically realistic comparison from being made.	None of the included trials had allowed hearing aids in the control group. Please see the review (Ref ID 51) for more details.
43	NCCHTA	Full	48	25-28 & 49-51	It may be worth commenting that trials which randomised ears cannot measure behavioural or developmental outcomes in a way that is relevant to the real world.	Apart from behavioural or developmental outcomes, it is also true for the other outcomes like improvement in hearing levels. This has been highlighted under 'translation from evidence to recommendations'.
43	NCCHTA	Full	48	25-32	The inclusion/exclusion criteria reported for the review are poorly worded – no review can include “all RCTs” as it is impossible to know whether all RCTs were identified. They also did not include all RCTs making these comparisons, as stated, because some types of ventilation tube were excluded as, it appears, were studies not confirming OME diagnosis by the stated methods.	Agreed. Appropriate changes have been made.
43	NCCHTA	Full	49	10-12	This is a difficult outcome measure to interpret across timepoints. If my non-clinical understanding is correct, as OME resolves over time for an increasing proportion of both groups, the % difference in time spent with effusion will decrease at later timepoints regardless of whether the treatment effect stays constant or not. If we extended follow-up to lifetime, the effect should more or less disappear because of the huge amount of time spent effusion-free by a large proportion of both groups.	Your comment is well appreciated. The evidence has shown ventilation tube insertions to be beneficial (in terms of hearing gain) for a short period of time only, that is, till 12 months.
43	NCCHTA	Full	49	10-12	If possible, these sorts of outcome measures should be translated to something more clinically relevant and intuitive for children and parents to understand.	A separate version of the guideline will be published for the children and their parents - Understanding NICE guidance.
43	NCCHTA	Full	49	25-26	Was this a trial of BVTi alone vs BVTi+adenoidectomy, or a trial of BVTi+adenoidectomy vs watchful waiting?	The trial had compared four different interventions (myringotomy alone, bilateral VT alone, myringotomy+adenoid and bilateral VT+adenoid). Here the results are given for bilateral VT vs. bilateral VT+adenoidectomy. Please see the relevant study for more details.
43	NCCHTA	Full	49	33-35	Is this comment based on an indirect comparison between groups of trials? If so, the comment appears	The sentence has been further clarified in the text.

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					unwarranted given the clinical and statistical heterogeneity (for the reasons later discussed on page 52). There is no direct evidence as to the relative size of the effect for the combined procedure.	
43	NCCHTA	Full	49	33-35	If it refers to a within trial comparison, this implies that the BVTi+adenoidectomy group did worse than the BVTi alone group – in which case, this needs to be stated clearly.	Please see the above response.
43	NCCHTA	Full	55	24	Was this statistical heterogeneity present when RR (relative risk) was used instead of RD (risk difference)? Clinical heterogeneity would cause statistical heterogeneity using RD even if there was no heterogeneity when summarized as RR. (See comments on interaction, above).	The study has given the results in terms of RD only and the data is insufficient to calculate relative risk.
43	NCCHTA	Full	57	21-26	Whilst this is not high quality evidence, it would be useful to compare the extent of improvements reported over time in behavioural/developmental outcomes with those reported in the surgical and non-surgical arms of the RCTs used to consider the outcomes of surgery. This is implicitly taken into account by the GDG recommendations on hearing aids.	There is insufficient data for making the comparison.
43	NCCHTA	Full	57 & 58	46-47 & 1-4	This is an enormous bias when absolute differences are used as the outcome measure, as we know from other studies that this factor does influence outcomes measured as absolute differences.	Agreed. It is one of the reasons for rating this evidence as EL 1-. It was the only study identified on the effectiveness of homeopathy and was included in spite of all its limitations.
43	NCCHTA	Full	57 & 58	46-47 & 1-4	The criticism of this study should also be a little more strident given that it does not strictly qualify as an RCT (it is not possible to randomise if allocation concealment is absent). The statement in the summary is unwarranted – a study of this low quality cannot “show” anything at all.	Please see the above response.
43	NCCHTA	Full	58	19 & 37	I'd never describe a trial that failed to use ITT as “fair-quality”. It is an unforgivable omission that makes randomisation essentially pointless. The number of, and reasons for, exclusions from analysis should be stated to allow the reader to judge how serious the bias might be.	The subjectivity of quality rating has been removed. Please see the revised evidence summary.
44	NHS Plus				This organisation was approached but did not respond	
45	NHS Quality Improvement Scotland				This organisation was approached but did not respond	
46	North Tees PCT				This organisation was approached but did not respond	
47	Obesity Management Association				This organisation was approached but did not respond	

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48	OCD-Today			This organisation was approached but did not respond	
49	PERIGON Healthcare Ltd			This organisation was approached but did not respond	
50	PRIMIS+			This organisation was approached but did not respond	
51	Royal College of General Practitioners			This organisation was approached but did not respond	
52.0	Royal College of Nursing	FULL	General	The timing of the 3 month observation period may be important especially during the winter months. For example if a child is seen in November, the 3 month period will be February, should this be considered as it is recognised that there is an increase in OME during the winter months?	Thank you for your comments. The 3 month period of active observation is still required as resolution may occur in the winter months.
52.1	Royal College of Nursing		General	Who is expected to perform formal assessment on those children who do not have Downs or cleft palate? Is this the GP, HV or school nurse and will they be given additional training?	It is outside our domain to comment on the service delivery as there is great variation in the services across the UK.
52.2	Royal College of Nursing		General	Is it this professional who monitors the 3 month period or are they referred to specialist centre for monitoring? As it is known the condition will self resolve in many children is there a minimum age in which surgical intervention is recommended?	If surgical intervention is required for any child then it should be given irrespective of the age.
53.0	Royal College of Paediatrics and Child Health	NICE	General	The document is mainly clear and helpful.	Thank you.
53.1	Royal College of Paediatrics and Child Health	NICE	Title and P4, line1	The title refers to “ surgical ” management of OME but the guidelines “offers best practice advice on the care of children with OME” and gives advice on non-surgical management also.	It would not have been possible to provide guidance on the surgical management of OME without giving some consideration to the non-surgical interventions.
53.2	Royal College of Paediatrics and Child Health	NICE	P 5	Under ‘Diagnosis’, it would be useful to suggest “bone conduction thresholds should be ascertained whenever possible”. This is in line with standard BSA procedure.	Bone conduction thresholds are routinely assessed during hearing tests and do not need to be written separately. Please also see the definition of PTA in the glossary.
53.3	Royal College of Paediatrics and Child Health	NICE	P5	Under ‘which children benefit’, it would useful to add that “period of observation may be prolonged over 3 months despite hearing loss as described if parents and professionals consider appropriate” i.e., no obvious impact on development/progress (although this is perhaps obvious?).	We agree that this is obvious.
53.4	Royal College of Paediatrics and Child Health	NICE	P5	Under “Effectiveness of Surgical Procedures”, we suggest adding a comment to the effect of “a post-operative hearing test should be performed an all children” - see P8 1.2 12 below.	A separate recommendation on post-operative follow-up and hearing assessment has been added.

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53.5	Royal College of Paediatrics and Child Health	NICE	P8, 1.2.12		We think this should be clearer e.g. "OME can be superimposed on sensorineural and/or permanent conductive hearing losses. Hence need to carry out pre and post grommet hearing assessment with bone conduction when appropriate."	The recommendation has been reworded.
53.6	Royal College of Paediatrics and Child Health	NICE	P23 And P24		The flow diagrams seem to imply that regular assessment should only take place if there are features that are suggestive of OME, whereas they should all have regular review anyway (as stated in text). Perhaps the guideline also needs to include the outcome option of persisting OME but with no obvious impact on development/education, in which case monitoring should continue.	Agreed and appropriate changes made.
53.7	Royal College of Paediatrics and Child Health	NICE	P10 1.5.1.3		We suggest replacing "Hearing aids should be offered" with "Hearing aids should be considered", as it will not be appropriate for all and terminology is then in keeping with that used in 1.3.2.1 (i.e., "considered for surgical treatment").	The wording has been changed and now it does not suggest offering it to 'all children'.
53.8	Royal College of Paediatrics and Child Health	Full	22 of 150	25	It may be appropriate to mention local protocols agreed with the cleft palate team on 'Hub and Spoke' model.	Disagree. The wording of the recommendation is self-explanatory.
53.9	Royal College of Paediatrics and Child Health	Full	27 of 150	Fig 2.4.3	First Large Box: Maybe it should read 'regular formal assessment by local ENT/paediatric audiology', as many of these children will be too young for PTA in ENT settings, unless specialised audiology is in place at the time of the ENT clinic. The local audiology, paediatric and education services (<i>ie. the local multidisciplinary team</i>) are also involved, as well as the specialist cleft team.	Agreed and appropriate changes made.
53.10	Royal College of Paediatrics and Child Health	Full	32 of 150	1 - 2	External examination for dysmorphisms, which may contribute to an aetiological diagnosis predisposing to OME (or other type of conductive loss), should be carried out, for example, Branchio Oto Renal Syndrome, or even chromosome 22 conditions.	It has already been clarified in the 3 rd paragraph of introduction – "Otoscopy shouldand examination of the nose and throat will help in the assessment of any factors predisposing to OME".
53.11	Royal College of Paediatrics and Child Health	Full	32 of 150	3	'A clinical hearing assessment may also be helpful'. We are unclear what this is referring to (e.g., Whisper test? Or Tuning fork tests?).	Agreed. The sentence has been deleted.
53.12	Royal College of Paediatrics and Child Health	Full	44	35	The wording should be changed to 'Emphasise' not 'emphasis'.	Agreed
53.13	Royal College of Paediatrics and Child Health	Full	44	38	'It will not always be achievable'. We disagree with this comment, however it needs highly trained testers.	Agreed. The sentence has been deleted.
54	Royal College of Pathologists				This organisation was approached but did not respond	
55.0	Royal College of Physicians of London	Full	1.1 p15	8	This organisation was approached but did not respond	Thank you for your comments. The next sentence (line 9) answers your query – "OME is known to be a fluctuating condition with symptoms that vary with time and age".

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55.1	Royal College of Physicians of London	Full	1.5 p16	34	This list should include General Practitioners, practice and school nurses and health visitors.	Agreed and the list has been expanded.
55.2	Royal College of Physicians of London	Full	1.6 p17	4	Why was there no public health consultant/commissioner representation?	Though there was an opportunity to apply for GDG membership (through advertisement and information to all stakeholder organizations), none of the public health consultant/commissioner applied for it.
55.3	Royal College of Physicians of London	Full	2.1 p20	4-19	Strongly agree that there has to be a holistic assessment.	Thank you.
55.4	Royal College of Physicians of London	Full	20 p2.1	20-22	It is difficult to agree with this statement for a condition which resolves in the majority of children. If there are additional problems, further to the abnormal hearing problems, then this advice would be acceptable. At this time many parents would not opt for an operation.	All the evidence points to parent's concerns regarding hearing and as such hearing loss on its own cannot be disregarded as the sole criterion.
55.5	Royal College of Physicians of London	Full	2.2 p21	23	A more explicit description would help – especially palatal examination and examination of nose and craniofacial region.	Disagree. These fall under routine clinical/ENT examination and do not require to be written separately.
55.6	Royal College of Physicians of London	Full	p21	32	Advice should be given at first visit about good hearing tactics and written information given to parents to be copied to nursery or school staff.	Health care professionals are free to give relevant information and advice in an appropriate manner.
55.7	Royal College of Physicians of London	Full	p21	41	Why not include this advice as part of the general statement about who would benefit?	Please see the above response.
55.8	Royal College of Physicians of London	Full	2.3 p22	38-40	Agree.	Thank you.
55.9	Royal College of Physicians of London	Full	p23	11-30	This is of great national importance. It is of interest that a very similar recommendation was made in the Effective Health Care Bulletin 1992 no 4 page 10.	Your point is appreciated.
55.10	Royal College of Physicians of London	Full	p23	44-47	Strongly agree.	Thank you.
55.11	Royal College of Physicians of London	Full	2.4 p25		The non-surgical box could include FM systems.	No evidence was reviewed for FM systems.
55.12	Royal College of Physicians of London	Full	3.1 p31	7	Why not include obstructive sleep apnoea (OSA)?	Outside the scope.
55.13	Royal College of Physicians of London	Full	p31	13	Downs syndrome children should also be assessed for OSA.	Outside the scope.
55.14	Royal College of Physicians of London	Full	p31	34	Strongly agree.	Thank you.
55.15	Royal College of Physicians of London	Full	3.2 p31	49	Requires clarification about who should perform this clinical examination to elicit the information required.	It is outside our domain to comment on the service delivery as there is great variation in the services across the UK.
55.16	Royal College of Physicians of London	Full	p32	1	And palatal examination.	It falls under ENT examination.
55.17	Royal College of Physicians of London	Full	3.2 p32	18-22	This is a hypothetical statement on which the main recommendation is based – and there is very little evidence presented to back this up.	We strongly disagree with your comment. The statement in the introduction was made on the information/experience of the experts in the GDG, while the main recommendation is derived from the evidence presented.

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55.18	Royal College of Physicians of London	Full	3.2.3 p34	54-55	The lack of good quality evidence on the diagnostic value of pure tone audiometry (PTA) weakens the main recommendation of the guidance.	Disagree. Lack of published evidence for a particular condition does not imply that the reliability of the test is not good.
55.19	Royal College of Physicians of London	Full	3.2.7 p44	46	Why not include obstructive sleep apnoea (OSA)?	Outside the scope.
55.20	Royal College of Physicians of London	Full	p45	4-5	It would be useful to list possible other causes.	Agreed and appropriate changes made.
55.21	Royal College of Physicians of London	Full	3.3 p45	13	What about atopy?	Outside the scope.
55.22	Royal College of Physicians of London	Full	p45	23	One of the main reasons for surgery is really to provide a window of opportunity to observe the child's hearing and developmental progress with improved hearing levels	We strongly disagree.
55.23	Royal College of Physicians of London	Full	p46	40-41	We believe that the evidence as quoted in lines 34 and 35 give a much stronger argument for having a period of observation of 6 to 9 months for children with no additional problems as recommended in the American Academy of Family physician guidelines 2004.	It is probable that under the US healthcare system, children with OME are treated at an earlier stage than in the UK where children present with a more severe or persistent OME. Waiting for more than 3 months would be detrimental for their hearing levels and overall health.
55.24	Royal College of Physicians of London	Full	3.3.2 p48	7-12	We believe that the evidence as quoted in lines 34 and 35 give a much stronger argument for having a period of observation of 6 to 9 months for children with no additional problems as recommended in the American Academy of Family physician guidelines 2004. Children should be considered for grommets if they have raised hearing levels and additional problem(s).	Kindly see the response to above comment 55.23.
55.25	Royal College of Physicians of London	Full	3.3.3 p51	2	It would be helpful to have figures for incidence of cholesteatoma both post grommet insertion and in patients who never had grommets.	Kindly see the recommendations under section 'factors predicting benefit from surgical intervention' for response to your second part of the question.
55.26	Royal College of Physicians of London	Full	p51	31	Is there any evidence of levels of hearing loss associated with these complications?	Cholesteatoma is considered to be a complication of the disease process rather than of any intervention and its incidence was not looked for.
55.27	Royal College of Physicians of London	Full	p51	43-51	There are too many assumptions to justify economic analysis. Was the cost of hearing aid intervention realistic?	We did not look into this topic.
						The first point is a very general assertion. What constitutes "too many"?
						It would be more helpful to have specific feedback on which assumptions are considered deficient or flawed.
						GDG estimates of parameter values are the best available evidence in the absence of published data.
						Stakeholders have not suggested alternatives for any parameter values, which suggest they don't have better evidence. Furthermore, sensitivity analysis is used to assess the importance of certain assumptions to the model's results.

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						<p>The quality of the evidence (clinical or economic) does not obviate the need to make a decision between alternative courses of actions. The assumptions may reflect limitations in the data but resource allocation is unlikely to be improved by ignoring the best available evidence altogether.</p> <p>The costing of the hearing aid intervention was based on information provided by experts on the GDG. We consider it a reasonable estimate based on the best available evidence at our disposal. No alternative information/evidence/data was provided by the stakeholders in order to derive a more 'realistic' estimate.</p> <p>What constitutes "too many assumptions"?</p> <p>It would be more helpful to have specific feedback on which assumptions are considered deficient or flawed.</p> <p>The statement reflects the results of the economic model described in appendix C. References and caveats are made with respect to the limitations of the data but that does not mean that a decision with resource implications for the NHS can be avoided. If the stakeholder thinks the costing isn't realistic it would be helpful if they stated the reasons why.</p> <p>The costing is described in detail in appendix C. The GDG experts did not dissent from the assumptions and data used to derive the costs used in the model. No evidence was identified.</p> <p>The text is self-explanatory.</p> <p>The GDG experts who work in this field considered this to be highly unrealistic and not reflecting current practice. We agree that there are measures that could be undertaken to mitigate the hearing loss and this is covered elsewhere in the guideline.</p> <p>However, we don't think that its inclusion in the model is necessary as it would have no impact on costs or hearing level. All the strategies include some kind of review or follow-up. This is described in the description of the four</p>
55.28	Royal College of Physicians of London	Full	p51	56	Disagree – too many assumptions.	
55.29	Royal College of Physicians of London	Full	p57	31	Was the costing realistic?	
55.30	Royal College of Physicians of London	Full	p61	32	Is there any evidence available on the incidence of choleostoma in downs syndrome children who have and have not received grommets?	
55.31	Royal College of Physicians of London	Full	4.1 p65	14	Change the wording to state that Information needs to be unbiased.	
55.32	Royal College of Physicians of London	Appendix C	71	15	Children would need review every 6 to 8 weeks as hearing levels fluctuate.	
55.33	Royal College of Physicians of London	Appendix C	71	39-40	Good hearing tactics by parents and teachers as well as introduction of hearing aids could be implemented.	
55.34	Royal College of Physicians of London	Appendix C	72	6	What about the cost of paediatric /Audiological physician assessment in intervening periods?	

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55.35	Royal College of Physicians of London	Appendix C	73	1	This table should include cholesteatoma?	strategies. The costs of this follow-up are factored into the costs of each strategy (using the unit costs listed in Table C.3)
55.36	Royal College of Physicians of London	Appendix C	79	12-18	We are not positive that the assumption that this is a cost effective intervention is correct.	The GDG's view is that it is a complication of the condition rather than a complication of ventilation tube insertion.
55.37	Royal College of Physicians of London	Appendix D			General comment – There does not seem to be any mention of the American Academy of Family Physicians clinical practice guideline: otitis media with effusion .2004	Given the caveats which are clearly stated it is clear that the authors of the report are not “positive” either. However, they consider that it is reasonable to recommend VT on cost-effectiveness grounds given the best available evidence.
56.0	Royal College of Speech and Language Therapists	NICE			The style and format are appropriate.	Appendix D gives the evidence tables of all the studies included as evidence for drafting recommendations. The AAFP guideline was not used as evidence.
56.1	Royal College of Speech and Language Therapists	NICE	Page 8 1.3.2.1 1.3.2.1		Impact may be a more significant factor than whether hearing loss is more than / less than 25-30dBHL	Thank you.
56.2	Royal College of Speech and Language Therapists	NICE version	Pages 5 and 6		The reference points to the guidance notes from page 7 associated with each section on pages 5 and 6 were put in bold at the end of each section here. It wasn't initially clear what these reference points referred to. It may be better to put in parentheses with 'see' or 'refer to' e.g., (see/refer to 1.2.1.1)	Impact is relatively subjective and difficult to measure, and hence we have included both objective (hearing levels) and/or subjective (impact) criterion to be considered.
57	Royal College of Surgeons of Edinburgh				This organisation was approached but did not respond	Please note that these reference points will not be there in the final version.
58	Royal United Hospital				This organisation was approached but did not respond	
59	SACAR				This organisation was approached but did not respond	
60	Sandwell PCT				This organisation was approached but did not respond	
61	Scottish Intercollegiate Guidelines Network (SIGN)				This organisation was approached but did not respond	
62	Sheffield PCT				This organisation was approached but did not respond	
63	Sheffield Teaching Hospitals NHS Foundation Trust				This organisation was approached but did not respond	
64	Social Care Institute for Excellence (SCIE)				This organisation was approached but did not respond	
65	Suffolk Health Care Ltd				This organisation was approached but did not respond	
66	The Afiya Trust				This organisation was approached but did not respond	
67	UK Clinical Pharmacy Association				This organisation was approached but did not respond	
68	University Hospital Birmingham NHS Foundation Trust				This organisation was approached but did not respond	

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69	University Hospital Birmingham NHS Trust	This organisation was approached but did not respond
70	University of North Durham	This organisation was approached but did not respond
71	Walsall PCT	This organisation was approached but did not respond
72	Welsh Assembly Government	This organisation was approached but did not respond
73	Welsh Otorhinolaryngology Association	This organisation was approached but did not respond
74	Welsh Scientific Advisory Committee (WSAC)	This organisation was approached but did not respond
75	Western Cheshire Primary Care Trust	This organisation was approached but did not respond
76	Wiltshire PCT	This organisation was approached but did not respond
77	York NHS Trust	This organisation was approached but did not respond