

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review consultation document

Review of Clinical Guideline (CG) – CG60: Surgical management of otitis media with effusion in children

1. Background information

Guideline issue date: 2008

3 year review: 2011

National Collaborating Centre: National Collaborating Centre for Women's and
Children's Health

2. Consideration of the evidence

Literature search

From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 16 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline and were all in line with current recommendations:

- Diagnosis of OME
- Effectiveness of various surgical and non-procedures in children with OME
- Predicting which children with OME will benefit from surgical intervention
- Economic analysis and quality of life measures for OME

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- Management of otitis media with effusion (OME) in children with cleft palate

Three Cochrane systematic reviews relating to the scope of the guideline were identified. Their conclusions were all in line with current recommendations in CG60: Surgical management of otitis media with effusion in children:

- An update review found limited evidence to indicate that screening a general population for asymptomatic children for OME would lead to better language and behavioural outcomes.
- A second update review into the use of grommets for hearing loss and OME identified four new references all pertaining to longer-term follow-up reports of studies already included in the previous review which formed part of the evidence based for the CG60 guideline. The review concluded that the effect of tympanostomy tubes on hearing was small and diminished after six to nine months by which time natural resolution also leads to improved hearing in the non-surgically treated children. No effect on speech and language development had been shown. However, there was some indication that children with the poorest hearing levels at the outset had the greatest chance of persistence of middle ear fluid and hearing loss.
- A Cochrane review on adenoidectomy for otitis media in children indicated that there was a significant benefit of adenoidectomy as far as the resolution of middle ear effusion in children with OME is concerned. However, the benefit to hearing was small. The trials included were too heterogeneous to include in the meta-analysis and there was a significant loss to follow up in most studies.

One clinical question relating to children with cleft palate or Down's syndrome was developed based on the clinical areas above, the qualitative feedback from other NICE departments and the views expressed by the Guideline Development Group, for a more focused literature search. The result of the focused search is summarised in the table below. All references identified through the initial intelligence gathering, high-level RCT search and the focused search can be viewed in [Appendix 1](#).

Clinical area 1: Management of OME in children with cleft palate and Down's syndrome		
Clinical question	Summary of evidence	Relevance to guideline recommendations
<p>Q: What is the most effective intervention for children with Down's syndrome or cleft palate to manage otitis media with effusion (OME)?</p> <p>Relevant section of guideline (Section 3.4 Management of OME in children with Down's syndrome and 3.5 Management of OME in</p>	<p>Through the focused search seven studies relevant to the clinical question were identified.</p> <p><u>Children with cleft palate</u> (six studies)</p> <p>Five studies were identified regarding the timing of ventilation tubes insertion in relation to cleft palate closure:</p> <ul style="list-style-type: none"> • A systematic review concluded that there is currently insufficient evidence on which to base the clinical practice of early routine ventilation tube placement during cleft palate closure in these children. • One very small RCT investigating the long term (20 years) effect of ventilation tube insertion in children with cleft palate and OME found no clear benefit of ventilation tubes in this population. 	<p>No new evidence was identified which would change the direction of current guideline recommendations.</p>

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<p>children with cleft palate)</p> <p>Recommendations</p> <p>Recommendations on children with cleft palate</p> <p>The care of children with cleft palate who are suspected of having OME should be undertaken by the local otological and audiological services with expertise in assessing and treating these children in liaison with the regional</p>	<ul style="list-style-type: none"> • Two observational studies comparing insertion of ventilation tubes as routine at the time of cleft palate surgery to ventilation tubes managed conservatively both found no difference in hearing outcomes on the basis of time of insertion. However, one study reported recurrent middle ear disease, tympanic membrane abnormalities, and the total number of ventilation tube insertions were significantly higher in the routine ventilation tube group. • A small prospective observational study found that post-operative otorrhea after ventilation tube placement prior to cleft palate repair is higher than the incidence after cleft palate repair. However, the average speech reception threshold was lower for the infants with ventilation tubes inserted after cleft palate repair. <p>In addition a retrospective record review assessed the profile and outcomes of children with cleft palate. The study aimed to advise families of children with cleft palate on the benefit of tympanostomy tubes (ventilation tubes), hearing issues and risks of multiple sets of tubes. The study concluded that whilst the majority of children with cleft palate do not</p>	
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<p>multidisciplinary cleft lip and palate team.</p> <p>Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.</p> <p>Insertion of ventilation tubes should be offered as an alternative to hearing aid.</p> <p>Recommendations on children with Down's syndrome</p>	<p>have middle ear fluid at birth most children will develop OME with conductive hearing loss. In addition, the risks of complications from ventilation tubes in cleft palate patients were few and manageable using standard sized ear tubes.</p> <p><u>Down's syndrome (one study)</u></p> <p>A small retrospective case analysis of the use bone anchored hearing aids in children with Down's syndrome after conventional hearing aids and/or ventilation tubes have been considered or already failed, indicated that these devices significantly improved quality of life and showed a high level of patient/carers satisfaction.</p> <p>The guideline recommends that insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment. No evidence that contradicts this recommendation has been found in the focussed search.</p> <p>Hearing aids are recommended for children with Down's syndrome and</p>	
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<p>The care of children with Down's syndrome who are suspected of having OME should be undertaken by a multidisciplinary team with expertise in assessing and treating these children.</p> <p>Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.</p> <p>Before ventilation tubes are offered as an alternative to hearing aids for treating OME in</p>	<p>OME with hearing loss. Limited evidence relating to one very small case series study for the use of bone anchored hearing aids within this population has been identified. This intervention has not previously been specifically addressed in the guideline. No evidence that contradicts this recommendation has been found in the focussed search.</p>	
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<p>children with Down's syndrome, the following factors should be considered:</p> <ul style="list-style-type: none"> • the severity of hearing loss • the age of the child • the practicality of ventilation tube insertion • the risks associated with ventilation tubes • the likelihood of early extrusion of ventilation 		
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tubes.		
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Several ongoing clinical trials (publication dates unknown) were identified focusing on surgical procedures (adenoidectomy and tympanostomy), pharmacological treatments for infections post surgery and medical techniques. The results of these trials have not been published at this time but may contribute towards the evidence base relating to surgical management of OME in the next update review.

No evidence was identified that was relevant to research recommendations in the original guideline.

In conclusion, no identified new evidence contradicts current guideline recommendations.

Guideline Development Group and National Collaborating Centre perspective

A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Six responses were received with respondents highlighting issues relating to implementation and interpretation of the guideline by PCTs and commissioners which were not in line with the recommendations or local clinical judgement. There was also an indication that ENT surgeons were now routinely offering a non surgical choice in line with the guideline which had led to far more hearing aid fittings. It was stressed that, if this option was not well tolerated, then grommet insertion was also undertaken in the same patient which was having a cost implication.

Suggestions were also made regarding potential cost savings. This included conducting initial reviews in an audiologist led clinic leading to greater capacity for the consultant clinics and better co-ordination of grommet insertion and cleft palate closure (if both are required) which would be more cost effective and better for the child / family.

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The TARGET trial (Trial of Alternative Regimens in Glue Ear Treatment) which was carried out in the late 1990s and an intervention trial (unspecified) were highlighted as future potential sources for new evidence with as yet unpublished data. No published literature relating to the scope of the guideline was specified through the GDG feedback which contradicted current guideline recommendations.

A potential for inequalities regarding children with cleft palate was identified relating to delays in grommet insertion for OME at primary closure of the cleft palate due to a lack of capacity in both location and time. This feedback contributed towards the development of the clinical question for the focused search.

The majority of respondents felt that there is insufficient variation in current practice supported by adequate evidence at this time to warrant an update of the current guideline.

Implementation and post publication feedback

In total nine enquiries were received from post-publication feedback, most of which were routine. This feedback contributed towards the development of the clinical questions as described above.

Routine implementation feedback is not collected regarding the outcomes from this clinical guidance. However, implementation feedback from GDG members indicated that PCTs were using the guideline as means of setting 'cut off' limits for treatment. It was suggested that this may not always be in line with the recommendations and /or allowing for clinical judgements relating to level of hearing loss and the need for adenoidectomy in some cases with frequent or persistent upper respiratory tract infections.

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No new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

Relationship to other NICE guidance

The following NICE guidance is related to CG60: Surgical management of otitis media with effusion in children

Guidance	Review date
Related NICE guidance not included in CG60	
IPG328: Suction diathermy adenoidectomy Dec 2009	

Anti-discrimination and equalities considerations

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of diagnosis, treatment and management of OME in children (aged up to 12 years) with suspected hearing loss. This specifically includes children with all types of cleft palate and children with Down's syndrome. The guideline covers care in primary and secondary care, including both community and hospital settings.

Conclusion

Through the process no additional areas were identified which were not covered in the original guideline scope or would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations. The

surgical management of otitis media with effusion in children guideline should not be updated at this time.

3. Review recommendation

The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

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Appendix I

Browning, G. G., Rovers, M. M., Williamson, I., Lous, J., & Burton, M. J. 2010, "Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. Cochrane Database of Systematic Reviews: Reviews 2010 Issue 10 John Wiley & Sons, Ltd Chichester, UK DOI: 10.1002/14651858.CD001801.pub3," Chichester (UK): John Wiley & Sons, Ltd.

British Association of Otorhinolaryngologists - Head & Neck Surgeons (BAO-HNS) (2009) OME (glue ear) /adenoid and grommet position paper ENT UK 2009

Casselbrant, M.L., Mandel, E.M., Rockette, H.E., Kurs-Lasky, M., Fall, P.A., & Bluestone, C.D. 2009. Adenoidectomy for otitis media with effusion in 2-3-year-old children. *International Journal of Pediatric Otorhinolaryngology*, 73, (12) 1718-1724

Chianese, J., Hoberman, A., Paradise, J.L., Colborn, D.K., Kearney, D., Rockette, H.E., & Kurs-Lasky, M. 2007. Spectral gradient acoustic reflectometry compared with tympanometry in diagnosing middle ear effusion in children aged 6 to 24 months. *Archives of Pediatrics & Adolescent Medicine*, 161, (9) 884-888

Civelek, B., Celebioglu, S., Sagit, M., & Akin, I. 2007. Ventilation tubes in secretory otitis media associated with cleft palate: A retrospective analysis. *Turkish Journal of Medical Sciences*, 37, (4) 223-226

Curtin, G., Messner, A.H., & Chang, K.W. 2009. Otorrhea in infants with tympanostomy tubes before and after surgical repair of a cleft palate. *Archives of Otolaryngology -- Head & Neck Surgery*, 135, (8) 748-751

Dakin, H., Petrou, S., Haggard, M., Bengt, S., & Williamson, I. 2010. Mapping analyses to estimate health utilities based on responses to the OM8-30 Otitis Media Questionnaire. *Quality of Life Research*, 19, (1) 65-80

Griffin G, Flynn CA, Bailey RE, Schultz JK. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD003423. DOI: 10.1002/14651858.CD003423.

Hall, A.J., Maw, A.R., & Steer, C.D. 2009. Developmental outcomes in early compared with delayed surgery for glue ear up to age 7 years: a randomised controlled trial. *Clinical Otolaryngology*, 34, (1) 12-20

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Hornigold, R., Morley, A., Glore, R.J., Boorman, J., & Sergeant, R. 2008. The long-term effect of unilateral t-tube insertion in patients undergoing cleft palate repair: 20-year follow-up of a randomised controlled trial. *Clinical Otolaryngology*, 33, (3) 265-268

Kanemaru, S.-I., Nakamura, T., Yamashita, M., Magrfov, A., Omori, K., & Ito, J. 2007. 5-Fluorouracil ointment for the treatment of otitis media with effusion. *Laryngoscope*, 117, (2) 215-219

Lous, J. 2008. Which children would benefit most from tympanostomy tubes (grommets)? A personal evidence-based review. *International Journal of Pediatric Otorhinolaryngology*, 72, (6) 731-736

McDermott, A.L., Williams, J., Kuo, M.J., Reid, A.P., & Proops, D.W. 2008. The role of bone anchored hearing aids in children with Down syndrome. *International Journal of Pediatric Otorhinolaryngology*, 72, (6) 751-757

MRC Multi-centre Otitis Media Study Group 2009. Air-conduction estimated from tympanometry (ACET) 1: relationship to measured hearing in OME. *International Journal of Pediatric Otorhinolaryngology*, 73, (1) 21-42

Petrou, S., Dakin, H., Abangma, G., Benge, S., & Williamson, I. 2010. Cost-utility analysis of topical intranasal steroids for otitis media with effusion based on evidence from the GNOME trial. *Value in Health*, 13, (5) 543-551

Phua, Y.S., Salkeld, L.J., & de Chalain, T.M. 2009. Middle ear disease in children with cleft palate: protocols for management. *International Journal of Pediatric Otorhinolaryngology*, 73, (2) 307-313

Ponduri, S., Bradley, R., Ellis, P.E., Brookes, S.T., Sandy, J.R., & Ness, A.R. 2009. The management of otitis media with early routine insertion of grommets in children with cleft palate -- a systematic review. [Review] [42 refs]. *Cleft Palate-Craniofacial Journal*, 46, (1) 30-38

Schoem, S.R., Willard, A., & Combs, J.T. 2010. A prospective, randomized, placebo-controlled, double-blind study of montelukast's effect on persistent middle ear effusion. *Ear, Nose and Throat Journal*, 89, (9) 434-437

Shishegar, M. & Hoghoghi, H. 2007. Comparison of adenoidectomy and myringotomy with and without tube placement in the short term hearing status of children with otitis media with effusion: a preliminary report. *Iranian Journal of Medical Sciences*, 32, (3) 169-172

Simpson, S.A., Thomas, C.L., van der Linden, M.K., Macmillan, H., van der Wouden, J.C., & Butler, C. 2007. Identification of children in the first four years of life for early treatment for otitis media with effusion. *Cochrane database of systematic reviews (Online)* (1) CD004163

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Szabo, C., Langevin, K., Schoem, S., & Mabry, K. 2010. Treatment of persistent middle ear effusion in cleft palate patients. *International Journal of Pediatric Otorhinolaryngology*, 74, (8) 874-877

van den Aardweg, M.T., Schilder, A.G., Herkert, E., Boonacker, C.W., & Rovers, M.M. 2010. Adenoidectomy for otitis media in children. *Cochrane database of systematic reviews (Online)* (1) CD007810

Williamson, I., Benge, S., Barton, S., Petrou, S., Letley, L., Fasey, N., Haggard, M., & Little, P. 2009. Topical intranasal corticosteroids in 4-11 year old children with persistent bilateral otitis media with effusion in primary care: double blind randomised placebo controlled trial. *BMJ*, 339, b4984

Williamson, I., Benge, S., Barton, S., Petrou, M., Letley, L., Fasey, N., Abangma, G., Dakin, H., & Little, P. 2009. A double-blind randomised placebo-controlled trial of topical intranasal corticosteroids in 4- to 11-year-old children with persistent bilateral otitis media with effusion in primary care. *Health Technology Assessment (Winchester, England)*, 13, (37) 1-144