

Surgical management of otitis media with effusion

NICE guideline

Draft for consultation, October 2007

<p>If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.</p>
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Introduction

Otitis media with effusion (OME) is a condition characterised by a collection of fluid within the middle ear without signs of acute inflammation. It is most common in young children, with a bimodal peak at 2 and 5 years of age. Eighty percent of children will have had a least one episode of OME by the age of 10 years. At age 7–8 years, about 8% of children will have middle ear effusions; this incidence increases in winter. The mean duration of effusions is 6–10 weeks but some cases are more persistent. OME is known to be a fluctuating condition with symptoms that vary with time and with age. The main symptom of OME is impaired hearing because the middle ear effusion causes a conductive hearing loss by reflection of the sound energy at the air-fluid interface. The diagnosis is based on suspicion of hearing loss, clinical history, clinical examination of the ears and appropriate audiometry and tympanometry. While most cases of OME will resolve spontaneously, some children will need intervention because of the effects of hearing loss. This intervention may take the form of educational and social action or the provision of a hearing aid to minimise the impact of the hearing loss. No non-surgical treatment has yet been shown conclusively to be of benefit. Surgical management usually takes the form of myringotomy and insertion of a ventilation tube (grommet), with or without adenoidectomy. Children with cleft palate are particularly susceptible to OME because of the impaired function of the eustachian tube that results from the palatal anomaly, which in turn leads to a failure of middle ear ventilation. Similarly, children with Down syndrome have a high incidence of OME, partly because of their impaired immunity and mucosal abnormality, with resulting susceptibility to ear infection. These groups of children need particular surveillance for OME so that proper action can be taken. This guideline attempts to bring together the evidence related to surgical management, and to advise on best and safest practice; treatment decisions need to balance potential benefits against potential risks, reflecting the fact that the degree of benefit usually depends upon the severity and persistence of the condition.

Patient-centred care

This guideline offers best practice advice on the care of children with otitis media with effusion (OME).

Treatment and care should take into account children needs and preferences and those of their parents or carers. Parents or carers of children with OME should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If parents or carers do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – ‘Reference guide to consent for examination or treatment’ (2001) (available from www.dh.gov.uk). Healthcare professionals should also follow a code of practice accompanying the Mental Capacity Act (summary available from www.dca.gov.uk/menincap/bill-summary.htm).

If the patient is under 16, healthcare professionals should follow guidelines in ‘Seeking consent: working with children’ (available from www.dh.gov.uk).

Good communication between healthcare professionals and the parents and carers of children with OME is essential. It should be supported by evidence-based written information tailored to the patient’s needs. Treatment and care of children with OME, and the information parents and carers are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Parents and carers should have the opportunity to be involved in decisions about the patient’s treatment and care.

Parents and carers should also be given the information and support they need.

Key priorities for implementation

Diagnosis

- Formal assessment of a child with suspected OME should include:
 - clinical history taking, focusing on:
 - ◇ poor listening skills
 - ◇ indistinct speech or delayed language development
 - ◇ inattention and behaviour problems
 - ◇ hearing fluctuation
 - ◇ recurrent ear infections or upper respiratory tract infections
 - ◇ balance problems and clumsiness
 - ◇ school progress
 - clinical examination, focusing on:
 - ◇ otoscopy
 - ◇ upper respiratory health
 - ◇ general developmental status
 - hearing testing, which should be carried out by trained staff using developmentally appropriate hearing tests and calibrated equipment
 - tympanometry. **1.2.1.1**

Which children will benefit from surgical treatment

- Children with bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where HL not available) should be considered for surgical treatment. **1.3.2.1**

Effectiveness of surgical procedures

- Once a decision has been taken to offer surgical treatment for OME in children, the insertion of ventilation tubes is recommended. Adenoidectomy is not recommended in the routine surgical treatment of OME in the absence of upper respiratory tract symptoms. **1.4.1.1**

Effectiveness of non-surgical interventions

- The following treatments are not recommended for treatment of OME:
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- systemic steroids
 - antihistamines
 - decongestants
 - antibiotics
 - homeopathy
 - cranial osteopathy
 - acupuncture
 - dietary modification
 - immunostimulants
 - massage
 - probiotics. **1.5.1.1**
- Hearing aids should be offered to children with OME as an alternative to surgical treatment. **1.5.1.3**

Children with Down syndrome

- Hearing aids should be offered to the majority of children with Down syndrome and OME with hearing loss. **1.6.1.2**

Children with cleft palate

- Insertion of ventilation tubes at primary closure of the cleft palate should only be performed after careful otological and audiological assessment. **1.7.1.2**

1 Guidance

The following guidance is based on the best available evidence. The full guideline ([add hyperlink]) gives details of the methods and the evidence used to develop the guidance (see section 5 for details).

1.1 *Clinical presentation*

1.1.1 How OME presents

1.1.1.1 Suspicion of OME should lead to broad-based assessment.

Features that raise suspicion include:

- hearing difficulty, e.g. mishearing when not looking at you, difficulty in a group, asking for things to be repeated
- indistinct speech or delayed language development
- repeated ear infections or earache
- history of recurrent upper respiratory tract infection or frequent nasal obstruction
- behavioural problems, particularly lack of concentration or attention, or being withdrawn
- poor school progress
- less commonly, balance difficulties (e.g. clumsiness), tinnitus and intolerance of loud sounds.

1.1.1.2 Parental concerns about features suggestive of OME should be taken seriously and lead to assessment.

1.1.1.3 All children with Down syndrome and all children with cleft palate should be assessed regularly for OME.

1.2 *Diagnosis of OME*

1.2.1 Diagnosing OME

1.2.1.1 Formal assessment of a child with suspected OME should include:

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- clinical history taking, focusing on:
 - poor listening skills
 - indistinct speech or delayed language development
 - inattention and behaviour problems
 - hearing fluctuation
 - recurrent ear infections or upper respiratory tract infections
 - balance problems and clumsiness
 - school progress
- clinical examination, focusing on:
 - otoscopy
 - upper respiratory health
 - general developmental status
- hearing testing, which should be carried out by trained staff using developmentally appropriate hearing tests and calibrated equipment
- tympanometry.

1.2.1.2 The possibility of other causes of hearing loss should be borne in mind when assessing a child with suspected OME.

1.3 *Management of OME*

1.3.1 Timing of clinical intervention

1.3.1.1 The persistence of bilateral OME and hearing loss should be confirmed over a period of at least 3 months before active intervention is considered.

1.3.1.2 During the observation period, advice on educational and behavioural strategies to minimise the effects of that loss should be offered to parents and carers.

1.3.2 Which children will benefit from surgical treatment

1.3.2.1 Children with bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse

averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where HL not available) should be considered for surgical treatment.

- 1.3.2.2 Exceptionally, healthcare professionals may need to consider surgical treatment in children with persistent bilateral OME with a hearing loss less than 25–30 dBHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.

1.4 *Effectiveness of surgical procedures*

1.4.1 When to insert ventilation tubes

- 1.4.1.1 Once a decision has been taken to offer surgical treatment for OME in children, the insertion of ventilation tubes is recommended. Adenoidectomy is not recommended in the routine surgical treatment of OME in the absence of upper respiratory tract symptoms.

1.5 *Effectiveness of non-surgical interventions*

1.5.1 Non-surgical treatment

- 1.5.1.1 The following treatments are not recommended for treatment of OME:
- systemic steroids
 - antihistamines
 - decongestants
 - antibiotics
 - homeopathy
 - cranial osteopathy
 - acupuncture
 - dietary modification
 - immunostimulants
 - massage
 - probiotics.

1.5.1.2 Autoinflation may be considered during the watchful waiting period for older children who are more likely to be compliant.

1.5.1.3 Hearing aids should be offered to children with OME as an alternative to surgical treatment.

1.6 *Management of OME in children with Down syndrome*

1.6.1 Children with Down syndrome

1.6.1.1 Children with Down syndrome who are suspected of having OME should be managed by a multi-disciplinary team with expertise in assessing and treating these children.

1.6.1.2 Hearing aids should be offered to the majority of children with Down syndrome and OME with hearing loss.

1.6.1.3 When ventilation tubes are offered as an alternative to hearing aids for treating OME in children with Down syndrome, the following factors should be considered:

- the severity of hearing loss
- the age of the child
- the feasibility of ventilation tube insertion
- the risks associated with ventilation tubes
- the likelihood of early extrusion of ventilation tubes.

1.7 *Management of OME in children with cleft palate*

1.7.1 Children with cleft palate

1.7.1.1 Children with cleft palate who are suspected of having OME should be managed by the local otological and audiological services with expertise in assessing and treating these children in liaison with the multi-disciplinary cleft team.

1.7.1.2 Insertion of ventilation tubes at primary closure of the cleft palate should only be performed after careful otological and audiological assessment.

1.7.1.3 Insertion of ventilation tubes may be offered as an alternative to hearing aids in children with cleft palate who have OME.

1.8 *Information for children, parents and carers*

1.8.1 Giving information to children, parents and carers

1.8.1.1 Information should be given on the nature and effects of OME and its usual natural resolution.

1.8.1.2 Parents/carers and children should be given the opportunity to discuss both the surgical and non-surgical options for treatment of OME and the benefits and risks of each.

1.8.1.3 Verbal information about OME should be supplemented by written information appropriate to the stage of the child's management.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from guidance.nice.org.uk/page.aspx?o=439690.

How this guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information in the booklet: 'The guideline development process: an overview for stakeholders, the public and the NHS' (third edition, published

April 2007), which is available from www.nice.org.uk/guidelinesprocess or by telephoning 0870 1555 455 (quote reference N1233).

3 Implementation

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health', issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/CGXXX).

[NICE to amend list as needed at time of publication]

- Slides highlighting key messages for local discussion.
- Costing tools:
 - costing report to estimate the national savings and costs associated with implementation
 - costing template to estimate the local costs and savings involved.
- Implementation advice on how to put the guidance into practice and national initiatives that support this locally.
- Audit criteria to monitor local practice.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 ***Effectiveness of surgical procedures for treating OME***

There is a need for good-quality randomised controlled trials comparing the short- and long-term effectiveness of ventilation tubes alone with ventilation

tubes plus adenoidectomy for the treatment of persistent bilateral OME in children.

Why this is important

Adjuvant adenoidectomy along with ventilation tube insertion is routinely performed in many countries for recurrent episodes of OME and chronic persistent OME, but the practice is not backed by robust scientific evidence. There have been a good number of trials that have compared ventilation tube insertion alone with ventilation tubes plus adenoidectomy, but great variation in the study designs, population characteristics, outcomes measured and duration of follow-up among the trials have made it difficult to come to any definite conclusion on the benefit of adjuvant adenoidectomy. There is a need for good-quality randomised controlled trials on larger samples than hitherto, addressing their power deficit for measuring the additional benefits from adenoidectomy in the proportion of time with ear fluid and any corresponding benefits in hearing level. For this, the trials need to follow up children beyond 6–12 months after ventilation tube insertion as a high proportion of tubes would have fallen out during this time period, and so any advantage that may exist for adjuvant adenoidectomy becomes in principle demonstrable. Up to 2 years is a practicable follow-up period for formal outcome measurement, without high sample attrition. The trials should also evaluate any benefits to respiratory and general health; these are expected from benefits seen in other ENT disease, but not so far demonstrated in uncomplicated OME. However, additional benefits to healthcare (such as re-insertions of ventilation tubes) can also be documented and would add precision to the cost-effectiveness or cost-utility comparisons.

4.2 *Presentation of OME*

A combination of randomised trials, cohort studies and qualitative research is needed to accurately measure the developmental impact of persistent bilateral OME in children.

Why this is important

This scientific issue is core to many of the aspects of chronic OME that the GDG considered. Clinically, it has implications both for the baseline assessment (indications for intervention) and appropriate outcomes in the studies. The GDG felt hampered by the almost exclusive predominance of hearing level as outcome measure in the available trials. A diversity of approaches (such as validated questionnaires and objective reports) to measure the developmental outcomes should be incorporated in statistically well-controlled longitudinal studies to overcome this problem. The value of such a study relative to research costs might be maximised by bolting it on to a larger population cohort study, for example as a subset selected on a stratified basis. The GDG noted an embedded trial¹ (of good quality but with a small sample size) of ventilation tubes with speech recognition in noise as an objective outcome for hearing: this study showed a greater benefit in children who had a larger baseline deficit on the same test. This result is promising for linking the rationales for sequelae and for treatment, but it needs to be generalised via a larger sample and adequately powered stratification, for example by age. Other markers of developmental impact between hearing (narrow, probably short-term) and speech/language, behaviour, etc. (broad, probably long-term) should also be considered, and the possibility that facets of OME other than hearing could contribute to developmental outcomes should not be ignored.

4.3 OME in children with Down syndrome and children with cleft palate

Studies and national audit should evaluate the acceptability, effectiveness and consequences of the various treatment strategies for OME in children with Down syndrome and children with cleft palate.

Why this is important

The GDG noted particular difficulties in organising research with children with Down syndrome and those with cleft palate, and this seems to contribute to

¹ MRC Multicentre Otitis Media Study Group. Speech reception in noise: an indicator of benefit from otitis media with effusion surgery. *Clinical Otolaryngology and Allied Sciences* 2004;29:497–504.
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the lack of high-quality evidence for the questions of this guideline.

Randomised controlled trials may not necessarily be the most cost-effective investment, and if undertaken would need to be conducted on a multicentre basis. However, high-quality designed national audits with statistical control for baseline characteristics would enable a fuller understanding of natural histories and sub-types, particularly in cleft palate, and could provide an informative and unbiased account of the consequences of locally varying management practices.

5 Other versions of this guideline

5.1 *Full guideline*

The full guideline, 'Surgical management of otitis media with effusion', contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Women's and Children's Health, and is available from [NCC website details to be added], our website (www.nice.org.uk/CGXXXfullguideline) and the National Library for Health (www.nlh.nhs.uk). **[Note: these details will apply to the published full guideline.]**

5.2 *Quick reference guide*

A quick reference guide for healthcare professionals is available from www.nice.org.uk/CGXXXquickrefguide

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1XXX). **[Note: these details will apply when the guideline is published.]**

5.3 *'Understanding NICE guidance'*

Information for patients and carers ('Understanding NICE guidance') is available from www.nice.org.uk/CGXXXpublicinfo

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1XXX). **[Note: these details will apply when the guideline is published.]**

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6 Related NICE guidance

Published

[Short title of guideline, then colon, then full title]. NICE clinical guideline [number] ([year]). Available from www.nice.org.uk/CGXXX

[Title of appraisal]. NICE technology appraisal guidance [number] ([year]). Available from www.nice.org.uk/TAXXX

[Title of interventional procedure]. NICE interventional procedure guidance [number] ([year]). Available from www.nice.org.uk/IPGXXX

[Title of public health intervention guidance]. NICE public health intervention guidance [number] ([year]). Available from www.nice.org.uk/PHIXXX

[Title of public health programme]. NICE public health programme guidance [number] ([year]). Available from www.nice.org.uk/PHPXXX

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- [Short title of guideline, then colon, then full title]. NICE clinical guideline [number] ([year]). Available from www.nice.org.uk/CGXXX
- [Title of appraisal]. NICE technology appraisal guidance [number] ([year]). Available from www.nice.org.uk/TAXXX
- [Title of interventional procedure]. NICE interventional procedure guidance [number] ([year]). Available from www.nice.org.uk/IPGXXX
- [Title of public health intervention guidance]. NICE public health intervention guidance [number] ([year]). Available from www.nice.org.uk/PHIXXX
- [Title of public health programme]. NICE public health programme guidance [number] ([year]). Available from www.nice.org.uk/PHPXXX

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7 Updating the guideline

NICE clinical guidelines are updated as needed so that recommendations take into account important new information. We check for new evidence 2 and 4 years after publication, to decide whether all or part of the guideline should be updated. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

Appendix A: The Guideline Development Group

Peter Bull

GDG Chair, Consultant ENT Surgeon, Sheffield Children's Hospital

Helen Barrow

Patient/consumer representative

Gareth Davies

Patient/consumer representative, Chief Executive - Cleft Lip and Palate Association

Sarita Fonseca

Consultant Paediatrician, St George's Hospital, London

Mark Haggard

GDG Expert Adviser, Professor of Experimental Psychology, Clinical Triallist and Methodologist, Addenbrooke's Hospital, Cambridge

John Hart

General Practitioner, Kettering

Teresa Loxley

Senior Paediatric Audiologist, Head of Audiology Services, Sheffield Children's NHS Foundation Trust,

Wanda Neary

Consultant Community Paediatrician (Paediatric Audiology), Warrington

Kenneth Pearman

Consultant ENT Surgeon, Birmingham Children's Hospital

Ewa Raglan

Consultant Audiovestibular Physician, Great Ormond Street Hospital, London

Patrick Sheehan

Consultant ENT Surgeon, North Manchester General Hospital

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Jo Williams

Advanced Nurse Practitioner, Birmingham Children's Hospital

Ian Williamson

Senior Lecturer in Primary Medical Care, University of Southampton

Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

[NICE to add]

[Name; style = Unnumbered bold heading]

[job title and location; style = NICE normal]

Appendix C: The algorithms







