



*National Institute for
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Surgical management of otitis media with effusion in children

NICE clinical guideline 60

Developed by the National Collaborating Centre for Women's and Children's Health

NICE clinical guideline 60

Surgical management of otitis media with effusion in children

Ordering information

You can download the following documents from www.nice.org.uk/CG060

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide – a summary of the recommendations for healthcare professionals.
- ‘Understanding NICE guidance’ – information for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and reviews of the evidence they were based on.

For printed copies of the quick reference guide or ‘Understanding NICE guidance’, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N1461 (quick reference guide)
- N1462 (‘Understanding NICE guidance’).

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drugs they are considering.

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Contents

Introduction	4
Patient-centred care.....	6
Key priorities for implementation.....	7
1 Guidance	9
1.1 Clinical presentation	9
1.2 Diagnosis of OME.....	10
1.3 Appropriate time for intervention.....	10
1.4 Children who will benefit from surgical intervention	11
1.5 Surgical interventions	11
1.6 Non-surgical interventions	11
1.7 Management of OME in children with Down’s syndrome.....	12
1.8 Management of OME in children with cleft palate.....	12
1.9 Information for children, parents and carers	13
2 Notes on the scope of the guidance	14
3 Implementation	14
4 Research recommendations	15
4.1 Effectiveness of surgical procedures for treating OME	15
4.2 Presentation of OME	16
4.3 OME in children with Down’s syndrome and children with cleft palate	16
5 Other versions of this guideline.....	17
5.1 Full guideline	17
5.2 Quick reference guide.....	17
5.3 ‘Understanding NICE guidance’	17
6 Related NICE guidance	18
7 Updating the guideline	18
Appendix A: The Guideline Development Group	19
Appendix B: The Guideline Review Panel	21
Appendix C: The algorithms.....	22

Introduction

Otitis media with effusion (OME) is a common condition of early childhood in which an accumulation of fluid within the middle ear space causes hearing impairment. The hearing loss is usually transient and self-limiting over several weeks, but may be more persistent and lead to educational, language and behavioural problems.

OME may be overlooked because of the insidious nature of the condition, and suspicion of hearing loss in children must be acted upon effectively. In most instances of uncomplicated OME, no intervention is required because the fluid clears spontaneously and the hearing recovers.

A period of observation of the hearing loss over 3 months (with accurate audiometry), and its impact on the child's development, is recommended in order to determine whether resolution occurs or if further treatment is needed. This may require better and more timely access to paediatric audiology services than is currently available in some areas.

Persistence of hearing loss with adverse effects on the child will require further action, which may include surgery. Once a decision is taken to offer surgery following the period of active observation, it is important that there is a minimum of delay in performing it. Similarly, it should be recognised that if surgery is not recommended, there is still a continuing need for expert review. However, there are also resource implications in the non-surgical management of OME, particularly if a hearing aid is fitted.

Children with Down's syndrome and those with cleft palate are particularly susceptible to OME and require special consideration. Middle ear effusions in these children are very common and are also likely to occur at an earlier age and be more persistent. Early and continuing specialist assessment is beneficial for these children.

This guideline makes recommendations specifically on the surgical management of OME in children under the age of 12 years, but also considers other forms of management. The recommendations are based on the best

available published evidence and GDG consensus. Parents and carers often receive well meant but erroneous advice on a variety of non-surgical treatments for OME. This guideline explains the nature of the condition and when surgery is appropriate. The guidance may also allay anxieties over the use of active observation to allow natural resolution of OME to occur and thereby avoid the need for surgery.

The view has been expressed that surgery for OME is 'inessential'. This guideline provides a balanced, multidisciplinary opinion on the effects of hearing loss and the need for surgical management of OME based on current evidence. The guideline will also aid healthcare professionals and parents/carers in the practical management of the condition. It should also assist purchasers of healthcare to make cost-effective and unbiased arrangements for the management of this condition, thereby giving maximum benefit to children while minimising the risks of intervention.

Implementation of this guideline should not require a major change in what is already current practice in many areas. However, it will require acceptance on the part of purchasers of healthcare that the management of children with OME can be complex and long term and will also require specialist resources.

Patient-centred care

This guideline offers best practice advice on the care of children with OME.

Treatment and care should take into account children's needs and preferences together with those of their parents or carers. Parents or carers of children with OME should be given the opportunity to make informed decisions about their child's 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 the code of practice accompanying the Mental Capacity Act (summary available from www.publicguardian.gov.uk).

Healthcare professionals should be aware of the issues of working with children under 16 years of age and as such should follow the guidelines found in 'Seeking consent: working with children' (available from www.dh.gov.uk).

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

Parents or carers should have the opportunity to be involved in decisions about the patient's treatment and care. They should also be given the information and support they need.

Key priorities for implementation

Diagnosis of OME

- 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
 - ◇ poor educational progress
 - clinical examination, focusing on:
 - ◇ otoscopy
 - ◇ general upper respiratory health
 - ◇ general developmental status
 - hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
 - tympanometry.

Children who will benefit from surgical intervention

- Children with persistent 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 dBHL not available) should be considered for surgical intervention.

Surgical interventions

- Once a decision has been taken to offer surgical intervention for OME in children, insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

Non-surgical interventions

- The following treatments are not recommended for the management of OME:
 - antibiotics
 - topical or systemic antihistamines
 - topical or systemic decongestants
 - topical or systemic steroids
 - homeopathy
 - cranial osteopathy
 - acupuncture
 - dietary modification, including probiotics
 - immunostimulants
 - massage.

- Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.

Management of OME in children with Down's syndrome

- Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.

Management of OME in children with cleft palate

- Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.
- Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

1 Guidance

The following guidance is based on the best available evidence. The full guideline (www.nice.org.uk/nicemedia/pdf/CG060FullGuideline.pdf) gives details of the methods and the evidence used to develop this guidance (see section 5 for details).

1.1 *Clinical presentation*

1.1.1 Concerns from parents/carers or from professionals about features suggestive of OME should lead to initial assessment and referral for formal assessment if considered necessary. These features include:

- hearing difficulty (for example, 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 infections or frequent nasal obstruction
- behavioural problems, particularly lack of concentration or attention, or being withdrawn
- poor educational progress
- less frequently, balance difficulties (for example, clumsiness), tinnitus and intolerance of loud sounds.

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

1.2 *Diagnosis of OME*

1.2.1 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
 - poor educational progress
- clinical examination, focusing on:
 - otoscopy
 - general upper respiratory health
 - general developmental status
- hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
- tympanometry.

1.2.2 Co-existing causes of hearing loss (for example, sensorineural, permanent conductive and non-organic causes) should be considered when assessing a child with OME and managed appropriately.

1.3 *Appropriate time for intervention*

1.3.1 The persistence of bilateral OME and hearing loss should be confirmed over a period of 3 months before intervention is considered. The child's hearing should be re-tested at the end of this time.

1.3.2 During the active observation period, advice on educational and behavioural strategies to minimise the effects of the hearing loss should be offered.

1.4 *Children who will benefit from surgical intervention*

1.4.1 Children with persistent 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 dBHL not available) should be considered for surgical intervention.

1.4.2 Exceptionally, healthcare professionals should consider surgical intervention 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.

1.5 *Surgical interventions*

1.5.1 Once a decision has been taken to offer surgical intervention for OME in children, the insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

1.5.2 Children who have undergone insertion of ventilation tubes for OME should be followed up and their hearing should be re-assessed.

1.6 *Non-surgical interventions*

1.6.1 The following treatments are not recommended for the management of OME:

- antibiotics
- topical or systemic antihistamines
- topical or systemic decongestants
- topical or systemic steroids
- homeopathy
- cranial osteopathy
- acupuncture
- dietary modification, including probiotics

- immunostimulants
- massage.

1.6.2 Autoinflation may be considered during the active observation period for children with OME who are likely to cooperate with the procedure.

1.6.3 Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.

1.7 *Management of OME in children with Down's syndrome*

1.7.1 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.

1.7.2 Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.

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

- 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 tubes.

1.8 *Management of OME in children with cleft palate*

1.8.1 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 multidisciplinary cleft lip and palate team.

- 1.8.2 Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.
- 1.8.3 Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

1.9 *Information for children, parents and carers*

- 1.9.1 Parents/carers and children should be given information on the nature and effects of OME, including its usual natural resolution.
- 1.9.2 Parents/carers and children should be given the opportunity to discuss options for treatment of OME, including their benefits and risks.
- 1.9.3 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 www.nice.org.uk/nicemedia/pdf/Finalscope040707smOME.pdf.

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 from NICE publications (phone 0845 003 7783 or emailing publications@nice.org.uk and 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 nationally 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/CG060).

- 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.
- Audit support 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 documenting the effect of adjuvant adenoidectomy with ventilation tubes compared to ventilation tubes alone in the management of persistent bilateral OME in children. Trials should be sufficiently powered (large) to accurately document a probably small but continuing difference due to adjuvant adenoidectomy, and to identify subgroups that would particularly benefit from surgical intervention.

Why this is important

Despite a lack of robust scientific evidence, adjuvant adenoidectomy with ventilation tube insertion is routinely performed for recurrent or chronic persistent OME. There is, therefore, a need for good quality, randomised controlled trials with large samples which address the power deficit in measuring any additional difference derived from adjuvant adenoidectomy. In particular, the proportion of time spent with middle ear fluid and any corresponding benefit to hearing should be investigated. The trials need to follow up study participants beyond 6–12 months after ventilation tube

insertion. This is because a high proportion of tubes would have fallen out during this period, and therefore any advantage that may exist for adjuvant adenoidectomy would become, in principle, demonstrable. Up to 2 years is a feasible follow-up period without high sample attrition. Further trials should also evaluate benefit to children's respiratory and general health, and additional benefits (for example, re-insertion of ventilation tubes) which would add precision to 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

Current studies are limited by the almost exclusive predominance of hearing level as an outcome measure. Developmental outcomes can be measured using various approaches (for example, validated questionnaires and objective reports) and incorporated into well-controlled longitudinal studies, which, to maximise their value, could form part of a larger population cohort study. One particular embedded trial¹ used speech reception in noise as a measure of auditory disability, and reported a greater benefit in children with larger baseline deficits on the same test. Such a result is promising for linking sequelae with treatment, but needs to be generalised via a larger sample size and adequately powered stratification. Other markers of developmental impact between hearing (narrow, probably short-term) and speech/language and behaviour (broad, probably long-term) should also be considered.

4.3 *OME in children with Down's 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's syndrome and children with cleft palate.

¹ MRC Multicentre Otitis Media Study Group (2004) Speech reception in noise: an indicator of benefit from otitis media with effusion surgery. *Clinical Otolaryngology and Allied Sciences* 29: 497–504.

Why this is important

There are particular difficulties in organising research of children with Down's syndrome and those with cleft palate. These problems have contributed to the lack of high-quality evidence in these populations. Randomised controlled trials are not necessarily the most cost-effective investment, and would need to be conducted on a multicentre basis. In contrast, high-quality and well-designed national audits with appropriate statistical control for baseline characteristics would enable a fuller understanding of the natural history of these disorders and their subtypes, particularly in children with cleft palate. Such studies may also provide an informative and unbiased account of the consequences of different management practices that may vary by region.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Surgical management of otitis media with effusion in children', 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 www.ncc-wch.org.uk, our website (www.nice.org.uk/nicemedia/pdf/CG060FullGuideline.pdf) and the National Library for Health (www.nlh.nhs.uk).

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available from www.nice.org.uk/CG060quickrefguide.

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1461).

5.3 'Understanding NICE guidance'

Information for patients and carers ('Understanding NICE guidance') is available from www.nice.org.uk/CG060publicinfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1462).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about OME.

6 Related NICE guidance

There is no related guidance for this guideline. For a full list of NICE guidance visit www.nice.org.uk.

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

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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.

John Hyslop (Chair)

Consultant Radiologist, Royal Cornwall NHS Trust

Jonathan Hopper

Medical Director (UK and Ireland), ConvaTec

John Seddon

Lay Representative

Appendix C: The algorithms

There are care pathways for the surgical management of OME in children under 12 years, and in children with Down's syndrome and cleft palate, on pages 5–7 of the quick reference guide at www.nice.org.uk/CG060quickrefguide