

# Greater Manchester EUR Policy Statement on:

## Surgical drainage of the middle ear (with or without the insertion of grommets)

GM Ref: GM015

Version: 2.0 (21 Mar 2018)



## Commissioning Statement

<b>Surgical drainage of the middle ear (with or without the insertion of grommets)</b>	
<b>Policy Exclusions</b> <b>(Alternative commissioning arrangements apply)</b>	<p>Funding approval is <u>not</u> needed for the following:</p> <p><b>Suspected Cholesteatoma</b></p> <p><b>NOTE:</b> If there is a persistent, foul-smelling discharge suggestive of a possible cholesteatoma, arrange referral to an ear, nose, and throat specialist for people who have:</p> <ul style="list-style-type: none"> <li>• A <a href="#">characteristic appearance of a cholesteatoma</a> on visualization of the tympanic membrane</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• A persistent occlusion of the external auditory canal with purulent discharge preventing visualization of the tympanic membrane despite <a href="#">appropriate treatment</a>.</li> </ul> <p><b>Arrange emergency admission</b> for people who also have:</p> <ul style="list-style-type: none"> <li>• A facial nerve palsy or vertigo.</li> <li>• Other neurological symptoms (including pain) or signs that could be associated with the development of an intracranial abscess or meningitis.</li> </ul> <p><b>Chronic Suppurative Otitis Media (CSOM)</b></p> <p>Urgent referral for admission should be made for people with signs of infection beyond the ear, e.g. post auricular swelling or tenderness, headache, facial paralysis, or vertigo.</p> <p>If CSOM is suspected, referral to an ear, nose, and throat specialist (for diagnosis, treatment, and follow up) should be made:</p> <ul style="list-style-type: none"> <li>• The ears should not be swabbed.</li> <li>• Treatment should not be initiated.</li> <li>• Reassurance should be given that any hearing will usually return when the perforation heals, but a hearing test may be done in secondary care.</li> </ul> <p>Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).</p>
<b>Fitness for Surgery</b>	<p><b>NOTE:</b> All patients should be assessed as fit for surgery before going ahead with treatment, even though funding has been approved.</p>
<b>Policy Inclusion Criteria</b>	<p>This policy applies to children under the age of 12 years (in line with NICE CG60). Adults with symptoms suggestive of otitis media with effusion (OME) should be referred for investigation. An IFR form with details of clinical exceptionality is required for children over the age of 12 years.</p> <p><b>Otitis media with effusion (OME) assessment</b></p> <p>Referral for assessment for surgery for children with OME can be made if:</p> <ul style="list-style-type: none"> <li>• The child has Down's Syndrome or has a cleft palate.</li> <li>• The child has had a developmentally appropriate hearing test confirming hearing loss and there are functional issues (including but not limited to speech and</li> </ul>

language development). This should be evidenced by the hearing test result and/ or a corroborating statement from the child's school / nursery etc.

- Significant hearing loss persists on two documented occasions.
- The tympanic membrane is structurally abnormal.
- An alternative diagnosis is suspected.

#### **Persistent bilateral OME with a hearing level in the better ear of 25–30 dBHL or worse**

Surgical drainage of the middle ear is commissioned for 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.

#### **Funding Mechanism**

Monitored Approval: Referrals may be made in line with the criteria without seeking funding. **NOTE:** May be the subject of contract challenges and/or audit of cases against commissioned criteria.

#### **Persistent bilateral OME with a hearing loss less than 25–30 dBHL**

Commissioned for 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.

**NOTE:** The decision as to whether or not grommets are also needed is a clinical one based on the individual case and is at the discretion of the clinician, provided the child meets the criteria for surgical drainage.

#### **Funding Mechanism**

Individual prior approval provided the patient meets the above criteria. Requests should be submitted with all relevant supporting evidence, which must be provided with the request.

**NOTE:** If a hearing test result is not available, the result of an age / ability appropriate hearing test should be included with the request.

#### **Concurrent Adenoidectomy**

Adenoidectomy for the management of otitis media is not routinely commissioned but can be performed at the same time as OME surgery if it is indicated for a comorbidity. The request should include details of the indication for adenoidectomy as well as those for drainage of the middle ear.

#### **Funding Mechanism**

Individual prior approval provided the patient meets the above criteria. Requests should be submitted with all relevant supporting evidence, which must be provided with the request.

#### **Acute Otitis Media (AOM)**

Referral for assessment for surgery for children with persistent OR recurrent AOM can be made if all other standard treatments have been tried and failed (see NICE CKS AOM summary in the evidence review for details) with clear information provided on why this case is clinically exceptional.

	<p><b>Funding Mechanism</b></p> <p>Individual funding request (exceptional case) approval: Requests should be submitted with all relevant supporting evidence, which <u>must</u> be provided with the request.</p>
<p><b>Clinical Exceptionality</b></p>	<p>Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.</p> <p>Exceptionality means ‘a person to which the general rule is not applicable’. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:</p> <ul style="list-style-type: none"> <li>• Significantly different to the general population of patients with the condition in question.</li> </ul> <p><b><i>and as a result of that difference</i></b></p> <ul style="list-style-type: none"> <li>• They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.</li> </ul>

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## Policy Statement

Greater Manchester Shared Services (GMSS) Effective Use of Resources (EUR) Policy Team in conjunction with GM EUR Steering Group have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMSS has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

## Equality & Equity Statement

GMSS/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMSS/CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMSS/CCG will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMSS Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMSS evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact [policyfeedback.gmscu@nhs.net](mailto:policyfeedback.gmscu@nhs.net).

## Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

## Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

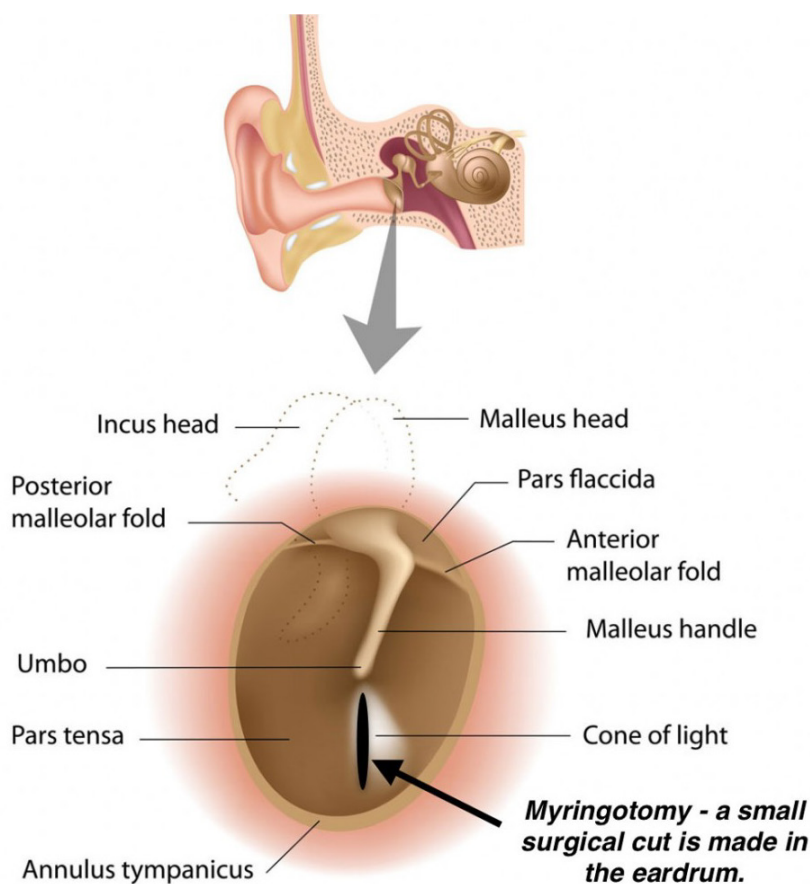
## Rationale behind the policy statement

The evidence suggests that myringotomy with or without the insertion of grommets is only effective in a select group of patients. Activity levels suggest that there is more activity than would be expected if this group alone were being treated. This is an invasive procedure requiring anaesthetic so it should be restricted to those individuals most likely to benefit from having it carried out.

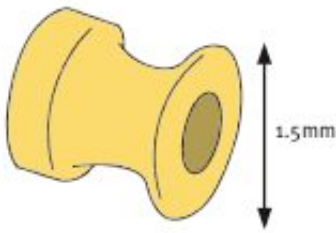
This policy aims at ensuring this treatment is targeted at those individuals most likely to benefit from the procedure and to avoid unnecessary risk to those in whom there is likely to be little to no benefit from the procedure.

## Treatment / Procedure

**Drainage of the middle ear or Myringotomy** is a surgical procedure used in the treatment of Otis Media in which a small incision is made in the eardrum (the tympanic membrane), usually in both ears. It can also be called myringocentesis, tympanotomy, tympanostomy, or paracentesis of the tympanic membrane. Fluid in the middle ear can be drawn out through the incision.



**Grommets or tympanostomy tubes** are small tubes open at both ends that are inserted into the incisions in the eardrums during myringotomy. They come in various shapes and sizes and are made of plastic, metal, or both. They are left in place until they fall out by themselves or occasionally they may need to be removed by a clinician.



## Epidemiology and Need

**Otitis Media with Effusion (OME)** is a common condition of early childhood in which a build-up of fluid in the middle ear space can cause 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. It is most common in young children, with a bimodal peak at 2 and 5 years of age; 80% of children will have had at least one episode of OME by the age of 10 years.

In most instances of uncomplicated, straightforward OME, no intervention is required because the fluid clears spontaneously.

**Acute otitis media (AOM)** is defined as the presence of inflammation in the middle ear associated with an effusion, and accompanied by the rapid onset of symptoms and signs of an ear infection.

- It is a common condition that can be caused by both viruses and bacteria.
- AOM occurs frequently in children but is less common in adults.
- It most commonly affects children younger than 10 years of age (more than 75% of cases), especially those who are subject to passive smoking, attend daycare or nursery, are formula-fed, or have craniofacial abnormalities (such as Down's Syndrome or cleft palate).
- It is more common in males than females.

**Chronic Suppurative Otitis Media (CSOM)** is defined as 'a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges (otorrhoea) through a tympanic perforation'. CSOM is assumed to be a complication of acute otitis media (AOM).

The World Health Organisation definition states that AOM is considered to be CSOM after at least 2 weeks of discharge, whereas some experts suggest that more than 6 weeks of discharge is the cut-off point.

The true prevalence of CSOM is unknown, but in the UK it is estimated to be less than 1%.

## Adherence to NICE Guidance

This policy adheres fully to the recommendations made in NICE CG60.

## Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

## Date of Review

Five years from the date of the last review, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All



available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

## Glossary

Term	Meaning
Acute Otitis Media (AOM) / Otitis Media	The presence of inflammation in the middle ear accompanied by the rapid onset of symptoms and signs of an ear infection.
Cholesteatoma	An uncommon condition where a cyst-like growth develops in the ear. It can be a birth defect (congenital problem) but usually occurs as a complication of chronic (long-standing) ear infection. The most common symptoms are loss of hearing and a foul-smelling discharge from the ear.
Chronic Suppurative Otitis Media (CSOM)	Recurrent or persistent discharge (otorrhoea) through a perforation in the tympanic membrane, and can lead to thickening of the middle-ear mucosa and mucosal polyps. It usually occurs as a complication of persistent acute otitis media with perforation in childhood. Occasionally it can lead to fatal intracranial infections and acute mastoiditis, especially in developing countries.
Comorbidity	The presence of one or more additional disorders (or diseases) co-occurring with a primary disease or disorder; or the effect of such additional disorders or diseases. The additional disorder may also be a behavioral or mental disorder.
Concurrent Adenoidectomy	A surgical procedure performed to remove the adenoids. (Adenoids are a mass of lymphoid tissue located behind the nasal passages) at the same time as another surgical procedure.
Grommets	A tube surgically implanted in the eardrum to drain fluid from the middle ear.
Invasive procedure	A medical procedure in which the body is "invaded" or entered by a needle, tube, device or scope. Invasive procedures can include anything from the simple needle prick for a blood test or shot, to inserting a tube, device or scope, to major surgeries.
Myringotomy / drainage of the middle ear	A surgical incision into the eardrum, to relieve pressure or drain fluid.
NICE	National Institute for Health and Care Excellence
NICE CG	Clinical Guidance
NICE CKS	Clinical Knowledge Summaries
Otitis Media with effusion (OME)	Otitis media with effusion (OME), also known as 'glue ear', is a condition characterized by a collection of fluid within the middle ear space without signs of acute inflammation.
Otorrhoea	A discharge from the ear
Postauricular	An anatomical term for "behind the ear"
Tympanic membrane	The anatomical term for the ear drum

## References

- Greater Manchester Effective Use of Resources Operational Policy
- RCS ENT UK Commissioning Guide Otitis Media with Effusion

## Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	16/03/2016
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	14/02/2017
Greater Manchester Association Governing Group	07/03/2017
Bury Clinical Commissioning Group	05/04/2017
Bolton Clinical Commissioning Group	24/03/2017
Heywood, Middleton & Rochdale Clinical Commissioning Group	07/03/2017
Central Manchester Clinical Commissioning Group	15/03/2017
North Manchester Clinical Commissioning Group	15/03/2017
Oldham Clinical Commissioning Group	07/03/2017
Salford Clinical Commissioning Group	07/03/2017
South Manchester Clinical Commissioning Group	15/03/2017
Stockport Clinical Commissioning Group	07/03/2017
Tameside & Glossop Clinical Commissioning Group	07/03/2017
Trafford Clinical Commissioning Group	21/03/2017
Wigan Borough Clinical Commissioning Group	03/05/2017

## Appendix 1 – Evidence Review

### Surgical drainage of the middle ear (with or without the insertion of grommets) GM015

#### Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; BMJ Clinical Evidence; and the relevant Royal College websites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

Database	Result
NICE	NICE CG60: Otitis media with effusion in under 12s: surgery (Published: Feb 2008)
NHS Evidence and NICE CKS	<ul style="list-style-type: none"> <li>• NICE CKS: Otitis media with effusion</li> <li>• NICE CKS: Otitis media - acute</li> <li>• NICE CKS: Otitis media - chronic suppurative</li> </ul>
SIGN	SIGN 66: Diagnosis and management of childhood otitis media in primary care, Issued: Feb 2003 (currently withdrawn as the evidence review is more than 10 years old)
Cochrane	<ul style="list-style-type: none"> <li>• Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children, Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ</li> <li>• Adenoidectomy for otitis media in children, van den Aardweg MTA, Schilder AGM, Herkert E, Boonacker CWB, Rovers MM</li> </ul>
BMJ Clinical Evidence	<ul style="list-style-type: none"> <li>• Chronic suppurative otitis media, <i>Peter Morris</i>, Search date: May 2010</li> <li>• Otitis media with effusion in children, <i>Ian Williamson</i>, Search date: March 2010</li> <li>• Acute otitis media in children, <i>Roderick P. Venekamp, Roger A.M.J. Damoiseaux, and Anne G.M. Schilder</i>, Search date: October 2013</li> </ul>
General Search (Google)	Not done due to the number of NICE and BMJ documents found
Medline / Open Athens	Not done due to the number of NICE and BMJ documents found
Other	RCS ENT UK Commissioning Guide: Otitis Media with Effusion (Oct 2013)

#### Summary of the evidence

The evidence for the effectiveness of surgical drainage of the middle ear with or without the insertion of grommets is limited. There is some evidence that it is an effective intervention in children with persistent hearing loss 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). Exceptionally it can be effective with lower levels of hearing loss but only if that loss is having a marked effect on the child's developmental, social or educational status. There is no evidence for adenoidectomy in the treatment of Otitis Media.

## The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

### 1. LEVEL 1: EVIDENCE BASED GUIDELINE: NICE CLINICAL GUIDELINE NICE CG60: Otitis media with effusion in under 12s: surgery (Published: Feb 2008)

#### 1 Guidance

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop this guidance.

#### 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.
- 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
  - 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 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. LEVEL: N/A**

### **RCS ENT UK Commissioning Guide: Otitis Media with Effusion (Oct 2013)**

OME may be overlooked because of the insidious nature of the condition and suspicion of hearing loss in children must be acted on effectively. Consequently, if parents, carers or professionals have concerns that a child might have hearing loss due to OME, then an initial assessment should be undertaken followed by a more formal assessment to confirm the diagnosis. See the National Institute for Health and Clinical Excellence (NICE) clinical guideline CG60 quick reference guide for further information on care pathways, including prevention, recognition, initial and formal assessment and access to effective interventions. Commissioners should ensure that all the component parts of the integrated pathway are in place and working well to enable effective and equitable outcomes.

NICE clinical guideline CG60 on surgical management of OME recommends that persistent bilateral OME and hearing loss should be confirmed over a period of three months before intervention is considered, and that a child's hearing should be re-tested at the end of this time. Commissioners will need to ensure there is timely access to and sufficient service capacity for hearing assessments suitable for the stage of development of the child presenting with OME.

The integrated care pathway should include prevention through public health programmes to decrease exposure to cigarette smoke during infancy and childhood.

Primary care practitioners should be competent to recognise hearing impairment associated with OME.

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

The quality dashboard provides an overview of activity commissioned by CCGs from the relevant pathways and indicators of the quality of care provided by surgical units.

The quality dashboard is available via the Royal College of Surgeons website.

## **3. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARY**

### **NICE CKS: Otitis media with effusion**

#### **Summary**

- Otitis media with effusion (OME), also known as 'glue ear', is a condition characterized by a collection of fluid within the middle ear space without signs of acute inflammation.
- It is the most common cause of hearing impairment in childhood.
- Symptoms vary with time and age. The hearing loss usually resolves over several weeks or months, but may be more persistent and, if bilateral, may lead to educational, language, and behavioural problems.

- The presence of coexisting medical conditions may increase the impact of OME on the child (e.g. hearing loss otherwise unrelated to OME, uncorrectable visual impairment, speech and language delay or disorder, and other causes of developmental delay).
- OME is most common in young children aged between 1 and 6 years, especially in the in the winter months.
- The exact cause of OME is uncertain, but over 50% of cases are thought to follow an episode of acute otitis media, especially in children under 3 years of age. Persistence of OME may occur because of one or more of the following:
  - Impaired Eustachian tube function causing poor aeration of the middle ear.
  - Low-grade viral or bacterial infection.
  - Persistent inflammatory reaction.
  - Adenoidal infection or hypertrophy.
- OME is more common in children cleft palate, Down's syndrome, cystic fibrosis, primary ciliary dyskinesia, and allergic rhinitis.
- Several environmental factors (such as low socioeconomic group and frequent upper-respiratory infections) may increase the chance of children developing OME. Parental smoking increases the risk of OME.
- Complications include:
  - Conductive hearing loss.
  - Educational, developmental, behavioural, and social difficulties.
  - Chronic damage to the tympanic membrane.
- Screening children in the general population is of no value in identifying children with OME. However, children with Down's syndrome or a cleft palate should be regularly assessed for OME by a specialist.
- Suspicion of OME is based on suspected hearing loss, clinical history, and examination, and is confirmed with audiometry and tympanometry, as appropriate.
- Diagnosis involves taking a detailed history; examining the ears; considering the need for a wider examination of the respiratory system, including the nose and throat; and excluding alternative diagnoses (e.g. acute otitis media, foreign body, impacted wax, and balance disorders).
- Spontaneous resolution of OME is common, so for most children a period of active observation over 6–12 weeks is appropriate management. If signs and symptoms persist, the child should be referred for a hearing test or to a specialist in ear, nose, and throat (ENT) if direct referral for audiometry is not available.
- Referral to ENT should also be made if:
  - The child has Down's syndrome or has a cleft palate.
  - Hearing loss is severe and/or associated with a significant impact on the child's quality of life.
  - Significant hearing loss persists on two documented occasions.
  - The tympanic membrane is structurally abnormal.
  - An alternative diagnosis is suspected.
  - There is a persistent, foul-smelling discharge suggestive of a possible cholesteatoma - referral should be urgent (within 2 weeks).

#### **4. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARY**

##### **NICE CKS: Otitis media - acute**

##### **Summary**

- Acute otitis media (AOM) is defined as the presence of inflammation in the middle ear associated with an effusion, and accompanied by the rapid onset of symptoms and signs of an ear infection.
- It is a common condition that can be caused by both viruses and bacteria.
- AOM occurs frequently in children but is less common in adults.

- It most commonly affects children younger than 10 years of age (more than 75% of cases), especially those who are subject to passive smoking, attend daycare or nursery, are formula-fed, or have craniofacial abnormalities (such as Down's syndrome or cleft palate).
- It is more common in males than females.
- Complications of AOM include recurrence of infection, hearing loss, tympanic membrane perforation, and rarely, mastoiditis, meningitis, intracranial abscess, sinus thrombosis, and facial nerve paralysis.
- In older children and adults, AOM usually presents with earache. Younger children may pull or rub their ear, or may have non-specific symptoms such as fever, irritability, crying, poor feeding, restlessness at night, cough, or rhinorrhoea.
- On examination the tympanic membrane is distinctly red, yellow, or cloudy and may be bulging.
- Pain and fever should be managed with paracetamol or a nonsteroidal anti-inflammatory drug (such as ibuprofen).
- Most people with AOM will not need antibiotic treatment as symptoms usually resolve spontaneously within a few days. However, antibiotics may be necessary for:
  - People who are systemically unwell.
  - People who have had symptoms for 4 days or more and are not improving.
  - Children younger than 2 years of age with infection in both ears.
  - Children with perforation and/or discharge in the ear canal.
- If an antibiotic is required, a 5-day course of amoxicillin is recommended first-line. Erythromycin or clarithromycin are alternatives for people who are allergic to penicillin.
- The following groups of people should be admitted to hospital for immediate specialist assessment:
  - Children younger than 3 months of age with a temperature of 38°C or more.
  - People with suspected complications of AOM, such as meningitis, mastoiditis, or facial nerve paralysis.
- Management of persistent or recurrent AOM involves:
  - Reassessing the person.
  - Considering the need for paediatric or ENT referral or admission, depending on the clinical situation.
  - Considering a first-line antibiotic (if not already prescribed) or a second-line antibiotic if the initial treatment was ineffective.
- Measures to prevent recurrent AOM include:
  - In children — avoiding exposure to passive smoking, use of dummies, and flat, supine feeding; and ensuring that children have had a complete course of pneumococcal vaccinations as part of the routine childhood immunization schedule.
  - In adults — avoiding smoking and/or passive smoking.

## 5. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARY

### NICE CKS: Otitis media - chronic suppurative

#### Summary

- Chronic suppurative otitis media (CSOM) is defined as 'a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges (otorrhoea) through a tympanic perforation'.
- CSOM is assumed to be a complication of acute otitis media (AOM).
  - The World Health Organization definition states that AOM is considered to be CSOM after at least 2 weeks of discharge, whereas some experts suggest that more than 6 weeks of discharge is the cut-off point.
- The true prevalence of CSOM is unknown, but in the UK it is estimated to be less than 1%.
- If left untreated, infection in CSOM may spread extracranially (causing facial paralysis, mastoiditis, or cholesteatoma) or intracranially (causing meningitis or a cerebral abscess), although this is rare (0.7% to 3.2%).



- A tympanic perforation will usually close spontaneously, but may persist, leading to permanent hearing loss and (in children) problems with language development.
- Symptoms that support a diagnosis of CSOM are:
  - Ear discharge (for more than 2 weeks) without pain and fever.
  - A history of AOM (ear pain, fever, and irritability), a history of ear trauma, or a previous glue ear and grommet insertion.
  - A painless ear examination (unlike AOM or acute otitis externa), with evidence of tympanic membrane perforation.
  - Possible hearing loss.
- Assessment should include:
  - Checking for postauricular swelling (tenderness), facial paralysis, or vertigo and signs or symptoms of intracranial infection (requiring admission).
  - Asking about hearing loss and, if appropriate, the effect of CSOM on daily activities (e.g. school or work) and language development.
  - Excluding alternative causes for persistent ear discharge such as otitis externa (suggested by an inflamed, eczematous canal without a perforation), a foreign body (particularly in children), impacted ear wax, and neoplasm (ear canal swelling that bleeds on contact).
- Admission should be made for people with signs of infection beyond the ear, e.g. postauricular swelling or tenderness, headache, facial paralysis, or vertigo.
- If CSOM is suspected, referral to an ear, nose, and throat specialist (for diagnosis, treatment, and follow up) should be made:
  - The ears should not be swabbed.
  - Treatment should not be initiated.
  - Reassurance should be given that any hearing loss will usually return when the perforation heals, but a hearing test may be done in secondary care.

## 6. LEVEL 1: EVIDENCE BASED GUIDELINE

### **SIGN 66: Diagnosis and management of childhood otitis media in primary care, Issued: Feb 2003 (currently withdrawn as the evidence review is more than 10 years old)**

Healthcare professionals should have an increased awareness of the possibility of the presence of otitis media with effusion in asymptomatic children.

The following groups of children are at particular risk:

- those in day care
- those with older siblings
- those with parents who smoke
- those who present with hearing or behavioural problems. (SIGN evidence level B)

Children diagnosed with acute otitis media should not routinely be prescribed antibiotics as the initial treatment. (SIGN evidence level B)

Delayed antibiotic treatment (*antibiotic to be collected at parents' discretion after 72 hours if the child has not improved*) is an alternative approach which can be applied in general practice. (SIGN evidence level B)

If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary. (SIGN evidence level B)

Children with acute otitis media should not be prescribed decongestants or antihistamines. (SIGN evidence level A)

Parents should give paracetamol for analgesia but should be advised of the potential danger of overuse. (SIGN evidence level D)

Insertion of oils should not be prescribed for reducing pain in children with acute otitis media. (SIGN evidence level B)

Children with otitis media with effusion should not be treated with antibiotics. (SIGN evidence level D)

Decongestants, antihistamines or mucolytics should not be used in the management of otitis media with effusion. (SIGN evidence level B)

The use of either topical or systemic steroid therapy is not recommended in the management of children with otitis media with effusion. (SIGN evidence level B)

Autoinflation may be of benefit in the management of some children with otitis media with effusion. (SIGN evidence level D)

Children with frequent episodes (*more than four in six months*) of acute otitis media, or complications, should be referred to an otolaryngologist. (SIGN evidence level D)

Children under three years of age with persistent bilateral otitis media with effusion and hearing loss of  $\geq 25$  dB, but no speech and language, development or behavioural problems, can be safely managed with watchful waiting. If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss. (SIGN evidence level A)

Children with persistent bilateral otitis media with effusion who are over three years of age or who have speech and language, developmental or behavioural problems should be referred to an otolaryngologist. (SIGN evidence level B)

Parents of children with otitis media with effusion should be advised to refrain from smoking. (SIGN evidence level B)

Parents should be advised that breastfeeding may reduce the risk of their child developing otitis media with effusion. (SIGN evidence level C)

Grommet insertion is not a contraindication to swimming. (SIGN evidence level C)

(Soap reduces surface tension and may increase water ingress through grommets. In the absence of trial data on this issue, it is advisable to avoid immersion of the head in soapy water).

## 7. LEVEL 1: SYSTEMATIC REVIEW

**Cochrane Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children, Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ**

### ABSTRACT

**Background:** Otitis media with effusion (OME; 'glue ear') is common in childhood and surgical treatment with grommets (ventilation tubes) is widespread but controversial.

**Objectives:** To assess the effectiveness of grommet insertion compared with myringotomy or non-surgical treatment in children with OME.

**Search methods:** We searched the Cochrane ENT Disorders Group Trials Register, other electronic databases and additional sources for published and unpublished trials (most recent search: 22 March 2010).

**Selection criteria:** Randomised controlled trials evaluating the effect of grommets. Outcomes studied included hearing level, duration of middle ear effusion, language and speech development, cognitive development, behaviour and adverse effects.

**Data collection and analysis:** Data from studies were extracted by two authors and checked by the other authors.

**Main results:** We included 10 trials (1728 participants). Some trials randomised children (grommets versus no grommets), others ears (grommet one ear only). The severity of OME in children varied between trials. Only one 'by child' study (MRC: TARGET) had particularly stringent audiometric entry criteria. No trial was identified that used long-term grommets. Grommets were mainly beneficial in the first six months by which time natural resolution lead to improved hearing in the non-surgically treated children also. Only one high quality trial that randomised children (N = 211) reported results at three months; the mean hearing level was 12 dB better (95% CI 10 to 14 dB) in those treated with grommets as compared to the controls. Meta-analyses of three high quality trials (N = 523) showed a benefit of 4 dB (95% CI 2 to 6 dB) at six to nine months. At 12 and 18 months follow up no differences in mean hearing levels were found. Data from three trials that randomised ears (N = 230 ears) showed similar effects to the trials that randomised children. At four to six months mean hearing level was 10 dB better in the grommet ear (95% CI 5 to 16 dB), and at 7 to 12 months and 18 to 24 months was 6 dB (95% CI 2

to 10 dB) and 5 dB (95% CI 3 to 8 dB) dB better. No effect was found on language or speech development or for behaviour, cognitive or quality of life outcomes. Tympanosclerosis was seen in about a third of ears that received grommets. Otorrhoea was common in infants, but in older children (three to seven years) occurred in < 2% of grommet ears over two years of follow up.

**Authors' conclusions:** In children with OME the effect of grommets on hearing, as measured by standard tests, appears small and diminishes after six to nine months by which time natural resolution also leads to improved hearing in the non-surgically treated children. No effect was found on other child outcomes but data on these were sparse. No study has been performed in children with established speech, language, learning or developmental problems so no conclusions can be made regarding treatment of such children.

## 8. LEVEL 1: SYSTEMATIC REVIEW

**Cochrane Review: Adenoidectomy for otitis media in children, van den Aardweg MTA, Schilder AGM, Herkert E, Boonacker CWB, Rovers MM**

### ABSTRACT

**Background:** Adenoidectomy, surgical removal of the adenoids, is a common ENT operation worldwide in children with otitis media. A systematic review on the effectiveness of adenoidectomy in this specific group has not previously been performed.

**Objectives:** To assess the effectiveness of adenoidectomy versus non-surgical management or tympanostomy tubes in children with otitis media.

**Search methods:** We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; mRCT and additional sources for published and unpublished trials. The date of the most recent search was 30 March 2009.

**Selection criteria:** Randomised controlled trials comparing adenoidectomy, with or without tympanostomy tubes, versus non-surgical management or tympanostomy tubes only in children with otitis media. The primary outcome studied was the proportion of time with otitis media with effusion (OME). Secondary outcomes were mean number of episodes, mean number of days per episode and per year, and proportion of children with either acute otitis media (AOM) or otitis media with effusion (OME), as well as mean hearing level. Tertiary outcome measures included atrophy of the tympanic membrane, tympanosclerosis, retraction of the pars tensa and pars flaccid and cholesteatoma.

**Data collection and analysis:** Two authors assessed trial quality and extracted data independently.

**Main results:** Fourteen randomised controlled trials (2712 children) studying the effectiveness of adenoidectomy in children with otitis media were evaluated. Most of these trials were too heterogeneous to pool in a meta-analysis. Loss to follow up varied from 0% to 63% after two years. Adenoidectomy in combination with a unilateral tympanostomy tube has a beneficial effect on the resolution of OME (risk difference (RD) 22% (95% CI 12% to 32%) and 29% (95% CI 19% to 39%) for the non-operated ear at six and 12 months, respectively (n = 3 trials)) and a very small (< 5 dB) effect on hearing, compared to a unilateral tympanostomy tube only. The results of studies of adenoidectomy with or without myringotomy versus non-surgical treatment or myringotomy only, and those of adenoidectomy in combination with bilateral tympanostomy tubes versus bilateral tympanostomy tubes only, also showed a small beneficial effect of adenoidectomy on the resolution of the effusion. The latter results could not be pooled due to large heterogeneity of the trials. Regarding AOM, the results of none of the trials including this outcome indicate a significant beneficial effect of adenoidectomy. The trials were too heterogeneous to pool in a meta-analysis. The effects of adenoidectomy on changes of the tympanic membrane or cholesteatoma have not been studied.

**Authors' conclusions:** Our review shows 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 is small and the effects on changes in the tympanic membrane are unknown. The risks of operating should be weighed against these potential benefits. The absence of a significant benefit of adenoidectomy on AOM suggests that routine surgery for this indication is not warranted.

## 9. LEVEL 1: SYSTEMATIC REVIEW

**BMJ Evidence Review: Chronic suppurative otitis media, Peter Morris, Search date: May 2010**

### ABSTRACT

**Introduction:** Chronic suppurative otitis media (CSOM) is a common cause of hearing impairment and disability. Occasionally it can lead to fatal intracranial infections and acute mastoiditis, especially in developing countries.

**Methods and Outcomes:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of treatments for chronic suppurative otitis media in adults and in children? What are the effects of treatments for cholesteatoma in adults and in children? We searched: Medline, Embase, The Cochrane Library, and other important databases up to May 2010 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

**Results:** We found 51 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

**Conclusions:** In this systematic review, we present information relating to the effectiveness and safety of the following interventions: topical ear cleansing, surgery for cholesteatoma, systemic antibiotics, topical antibiotics, topical antibiotics plus topical corticosteroids, topical antiseptics, topical corticosteroids, tympanoplasty (with or without mastoidectomy).

### Key Points:

- Chronic suppurative otitis media (CSOM) causes recurrent or persistent discharge (otorrhoea) through a perforation in the tympanic membrane, and can lead to thickening of the middle-ear mucosa and mucosal polyps. It usually occurs as a complication of persistent acute otitis media with perforation in childhood.
  - CSOM is a common cause of hearing impairment, disability, and poor scholastic performance. Occasionally it can lead to fatal intracranial infections and acute mastoiditis, especially in developing countries.
- In children with CSOM, topical antibiotics may improve symptoms compared with antiseptics. The benefits of ear cleansing are unknown, although this treatment is usually recommended for children with ear discharge.
- We don't know whether topical antiseptics, topical or systemic antibiotics, or topical corticosteroids, alone or in combination with antibiotics, improve symptoms in children with CSOM compared with placebo or other treatments.
- In adults with CSOM, topical antibiotics either alone or in combination with topical corticosteroids may improve symptoms compared with placebo or either treatment alone, although we found few adequate studies. There is consensus that topical antibiotics should be combined with ear cleansing so that the antibiotics are able to reach the middle ear space.
  - We don't know whether topical antiseptics, topical corticosteroids, or systemic antibiotics are beneficial in reducing symptoms.
  - It is possible that antibiotics against gram-negative bacteria may reduce ear discharge more than other classes of antibiotics or placebo.
- We don't know whether tympanoplasty with or without mastoidectomy improves symptoms compared with no surgery or other treatments in adults or children with CSOM.
- Cholesteatoma is an abnormal accumulation of squamous epithelium usually found in the middle ear cavity and mastoid process of the temporal bone. Granulation tissue and ear discharge are often associated with secondary infection of the desquamating epithelium.
- Cholesteatoma can be either congenital (behind an intact tympanic membrane) or acquired. If untreated, it may progressively enlarge and erode the surrounding structures.
  - We don't know the beneficial effects of surgery, whether surgery can be delayed, or which surgical techniques are associated with the best outcomes in children or adults with cholesteatoma.

## 10. LEVEL 1: SYSTEMATIC REVIEW

**BMJ Evidence Review: Otitis media with effusion in children, Ian Williamson, Search date: March 2010**

### ABSTRACT

**Introduction:** Up to 80% of children have been affected by otitis media with effusion (OME) by the age of 4 years, but prevalence declines beyond 6 years of age. Non-purulent middle-ear infections can occur in children or adults after upper respiratory tract infection or acute otitis media. Half or more of cases resolve within 3 months and 95% within 1 year, but complications such as tympanic membrane perforation, tympanosclerosis, otorrhoea, and cholesteatoma can occur.

**Methods and Outcomes:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of interventions to prevent otitis media with effusion in children? What are the effects of pharmacological, mechanical, and surgical interventions to treat otitis media with effusion in children? We searched: Medline, Embase, The Cochrane Library, and other important databases up to March 2010 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

**Results:** We found one systematic review and one RCT that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

**Conclusions:** In this systematic review, we present information relating to the effectiveness and safety of the following interventions: adenoidectomy, antibiotics, antihistamines, autoinflation, bottle feeding, decongestants, exposure to other children, intranasal corticosteroids, mucolytics, oral corticosteroids, passive smoking, and ventilation tubes.

### Key Points:

- Otitis media with effusion (OME, glue ear) usually presents with concerns about the child's behaviour, performance at school, or language development.
  - Children usually only have mild hearing impairment and few other symptoms.
  - Up to 80% of children have been affected by the age of 4 years, but prevalence declines beyond 6 years of age.
  - Non-purulent middle-ear infections can occur in children or adults after upper respiratory tract infection or acute otitis media.
  - Half or more of cases resolve within 3 months and 95% within 1 year, but complications such as tympanic membrane perforation, tympanosclerosis, otorrhoea, and cholesteatoma can occur.
- Risk of OME is increased with passive smoking, bottle feeding, low socioeconomic group, and exposure to many other children.
  - However, there is no evidence to show whether interventions to modify these risk factors reduce the risk of OME.
- Autoinflation with purpose-manufactured devices may improve effusions over 2 weeks to 3 months, but long-term efficacy is unknown.
- We don't know whether non-purpose-manufactured devices are effective in treating otitis media with effusion. Children may find autoinflation difficult.
- Oral antibiotics, antihistamines plus oral decongestants, or mucolytics may be of no benefit in OME, and can cause adverse effects.
  - Antibiotics can cause adverse effects in up to one third of children with OME.
  - Antihistamines can cause behavioural changes, seizures, and blood pressure variability.
- Oral corticosteroids are unlikely to improve symptoms in OME, and can cause growth retardation.
  - Intranasal corticosteroids are unlikely to be of benefit in children with bilateral otitis media with effusion.

- Ventilation tubes may improve short-term outcomes, but the clinical effect size is small. They may also increase the risk of tympanic membrane abnormalities.
  - Ventilation tubes improve hearing for the first 2 years, but have no longer-term benefit, and may not improve cognition or language development.
  - Adenoidectomy may improve hearing when performed with tympanostomy, but the clinical relevance of the improvements is unclear.
- Combination treatment with ventilation tubes plus adenoidectomy may be more effective than adenoidectomy alone.

## 11. LEVEL 1: SYSTEMATIC REVIEW

**BMJ Evidence Review: Acute otitis media in children, Roderick P. Venekamp, Roger A.M.J. Damoiseaux, and Anne G.M. Schilder, Search date: October 2013**

### ABSTRACT

**Introduction:** Acute otitis media (AOM) is a common reason for primary care visits in children. Yet, there is considerable debate on the most effective treatment.

**Methods and Outcomes:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of treatments (analgesics, antibiotics, and myringotomy) in children with AOM? We searched: Medline, Embase, The Cochrane Library, and other important databases up to October 2013 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

**Results:** We found 17 studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

**Conclusions:** In this systematic review we present information relating to the effectiveness and safety of the following interventions: analgesics, antibiotics, delayed antibiotics, immediate antibiotics, longer courses of antibiotics, and myringotomy.

### Key Points:

- Acute otitis media (AOM) is characterised by the presence of middle-ear effusion together with an acute onset of signs and symptoms caused by middle-ear inflammation.
  - Middle-ear effusion without signs of an acute infection indicates otitis media with effusion (OME or 'glue ear'), while chronic suppurative otitis media (CSOM) is characterised by continuing (>3 months) middle-ear inflammation and ear discharge through tympanic membrane perforation or ventilation tubes (grommets). Interventions for these conditions are assessed in separate reviews in Clinical Evidence (see the reviews Otitis media with effusion in children and Chronic suppurative otitis media).
  - The most common pathogens in AOM are *Streptococcus pneumoniae*, non-typeable *Haemophilus influenzae*, and *Moraxella catarrhalis*. Local resistance patterns are important when choosing the type of antibiotic.
  - In the UK, antibiotics are prescribed for about 87% of AOM episodes in children's primary care visits.
  - Without antibiotics, the clinical symptoms of AOM resolve in about 80% of children within 3 days.
- Analgesics (paracetamol, non-steroidal anti-inflammatory drugs [NSAIDs], and topical anaesthetic drops) may reduce earache compared with placebo.
- Antibiotics seem to reduce pain at 2 to 7 days compared with placebo, but they increase the risks of vomiting, diarrhoea, or rash.
- We do not know whether any one antibiotic regimen should be used in preference to another, although amoxicillin may be more effective than macrolides and cephalosporin.
- Immediate antibiotic use seems most beneficial in children aged under 2 years with bilateral AOM and in children with AOM presenting with ear discharge.

- Immediate antibiotic treatment may provide short-term reduction for some symptoms of AOM, but it increases the risk of rash and diarrhoea compared with delayed treatment.
- Longer courses of antibiotics reduce short-term treatment failure but have no benefit in the longer term compared with shorter regimens (7 days or less).
- Myringotomy may be less effective than antibiotics at reducing symptoms, and we found no evidence that it was superior to no myringotomy.

## Appendix 2 – Diagnostic and Procedure Codes

### Surgical drainage of the middle ear (with or without the insertion of grommets) GM015

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

<b>GM015 - Surgical Drainage of the Middle Ear</b>	
Myringotomy with insertion of ventilation tube through tympanic membrane	D15.1
Suction clearance of middle ear	D15.2
Incision of ear drum NEC	D15.3
Other specified drainage of middle ear	D15.8
Unspecified drainage of middle ear	D15.9
With the following ICD-10 diagnosis code(s):	
Acute serous otitis media	H65.0
Other acute nonsuppurative otitis media	H65.1
Chronic serous otitis media	H65.2
Chronic mucoid otitis media	H65.3
Other chronic nonsuppurative otitis media	H65.4
Nonsuppurative otitis media, unspecified	H65.9
Acute suppurative otitis media	H66.0
Otitis media, unspecified	H66.9
Otitis media in bacterial diseases classified elsewhere	H67.0*
Otitis media in viral diseases classified elsewhere	H67.1*
Otitis media in other diseases classified elsewhere	H67.8*
Acute myringitis	H73.0
Chronic myringitis	H73.1
Other specified disorders of tympanic membrane	H73.8
Disorder of tympanic membrane, unspecified	H73.9
Policy Exceptions:	
Chronic tubotympanic suppurative otitis media	H66.1
Chronic atticoantral suppurative otitis media	H66.2
Other chronic suppurative otitis media	H66.3
Cholesteatoma of middle ear	H71.X
OPCS-4 code which might be used but policy states that adenoidectomy is not routinely commissioned:	
Total adenoidectomy	E20.1



## Appendix 3 – Version History

### Surgical drainage of the middle ear (with or without the insertion of grommets) GM015

The latest version of this policy can be found here [GM Surgical drainage of the middle ear policy](#)

Version	Date	Summary of Changes
0.1	04/09/2015	Initial draft
0.2	18/11/2015	<p>Changes made to policy following GM EUR Steering Group on the 18 November 2015:</p> <ul style="list-style-type: none"> <li>• Commissioning Recommendation and Funding Mechanism updated.</li> <li>• Commissioning criteria for surgical drainage of the middle ear reworded and the following paragraph added: <i>'If the above hearing test result is not available the result of an age / ability appropriate hearing test should be included with the request.'</i></li> <li>• Commissioning criteria for Concurrent Adenoidectomy: Following words added to second sentence: <i>'but prior approval via the IFR route is required. The request should include details of the indication for adenoidectomy as well as those for drainage of the middle ear.'</i></li> <li>• Suspected Cholesteatoma and Chronic Suppurative Otitis Media (CSOM) previously under Mandatory Criteria moved to the Policy Exclusion section.</li> <li>• Following 2 paragraphs added under the Policy Exclusion section: <i>'Locally commissioned treatment as part of a pathway of care within a contract or service level agreement is excluded from this policy.'</i> <i>'Treatment as part of previously agreed and externally funding trial is excluded from this policy.'</i></li> <li>• Funding Mechanism updated</li> </ul> <p>Subject to the above changes being made the GM EUR Steering Group agreed that the policy could be out for a period of clinical engagement.</p>
	15/03/2016	Report updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.
1.0	16/03/2016	<p>GM EUR Steering Group reviewed the draft policy on 16 March 2016 following feedback received during Clinical Engagement and the following changes were approved:</p> <ul style="list-style-type: none"> <li>• <b>Section 4: Criteria for Commissioning</b> <ul style="list-style-type: none"> <li>○ The second bullet point under Mandatory Criteria – Otitis Media with effusion (OME) amended to read: <i>"The child has had a developmentally appropriate hearing test confirming hearing loss and there are functional issues (including but not limited to speech and language development) *."</i> and the following added under the bullet point list: <i>"*This should be evidenced by the hearing test result and/ or a corroborating statement from the child's school / nursery etc.'</i></li> <li>○ The following added under Policy Exclusions: <i>"This policy applies to children under the age of 12 years (in line with NICE CG60) Adults with symptoms suggestive of OME should be referred for investigation. An IFR form with details of exceptionality is required for children over the age of 12 years.'</i></li> </ul> </li> <li>• Appendix 2 – Diagnostic and Procedure Codes added. Codes not added yet.</li> <li>• Wording for date of review amended to read <i>"One year from the date of approval by Greater Manchester Association Governing Group thereafter at</i></li> </ul>

1.1	<p>07/03/2017</p> <p>08/03/2017</p> <p>30/05/2017</p>	<p><i>a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)” on ‘Policy Statement’ and section ‘13. Date of Review’.</i></p> <p>Following the above changes the GM EUR Steering Group approved the policy to go through the governance process.</p> <p>Approved by Greater Manchester Association Governing Group</p> <p>Policy transferred to new template format.</p> <p><u>Commissioning Statement:</u> The wording: <i>’,provided the child meets the criteria for surgical drainage.’</i> added to the end of the <i>’NOTE’</i> under the heading <i>’Persistent bilateral OME with a hearing loss less than 25–30 dBHL’.</i></p>
2.0	21/03/2018	<p>Policy reviewed at GM EUR Steering Group where the following changes were made:</p> <ul style="list-style-type: none"> <li>• <u>Commissioning Statement:</u> <ul style="list-style-type: none"> <li>○ <i>’(Alternative commissioning arrangements apply)’</i> added after <i>’Policy Exclusions’</i> heading</li> <li>○ Policy Exclusions: <i>’Suspected Cholesteatoma’</i> section rewritten</li> <li>○ <i>’Fitness for Surgery’</i> section added</li> </ul> </li> <li>• <u>Date of Review:</u> Standard wording on next review added to state the policy will be reviewed <i>’Five years from the date of the last review, unless new evidence or technology is available sooner’</i></li> </ul> <p>The above changes were not considered to be material and therefore it was not necessary for the revised policy to go back through the governance process again.</p>