

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Otitis media with effusion in under 12s

This guideline will update the NICE guideline on otitis media with effusion in under 12s: surgery (CG60).

We plan to remove 'surgery' from the title of the guideline, because the proposed scope of the update covers other topics as well as surgery.

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

1 Why the guideline is needed

Otitis media with effusion (OME), also known as 'glue ear', is a common condition in early childhood. Up to 80% of children under 4 years are affected by it ([Williamson 2011](#)). OME is characterised by accumulation of fluid in the middle ear space, without associated signs of ear infection. In some cases this causes no symptoms, but OME is a common cause of persistent or fluctuating hearing loss, which is a central topic in this guideline. OME is usually diagnosed by taking a clinical history and doing a clinical examination including otoscopy, tympanometry and hearing testing.

OME will usually resolve on its own within a few weeks or months. However, the hearing loss can persist or fluctuate, and can affect one or both ears at different levels. This can cause:

- problems with the child's learning, language development and listening skills
- behavioural problems
- auditory deficits, affecting auditory processing and the structural integrity of the tympanic membrane

- wider consequences, such as difficulties with social relationships and confidence.

The first few years of a child's life (when OME is most prevalent) also cover a critical period in the development of auditory neuronal connections in the brain.

OME is particularly common in children with craniofacial anomalies, for example children with Down's syndrome or cleft palate. OME is also more common in children with mucosal problems such as allergic rhinitis or cystic fibrosis.

There is uncertainty in primary care on how to best diagnose and manage OME. When OME does not resolve on its own, it can be a recurring or persistent problem that has a significant impact on the day-to-day activities of the child. If this happens then further management will be needed, which could include:

- hearing support, for example hearing strategies or amplifiers
- pharmacological and other non-pharmacological interventions
- surgical interventions, such as placing grommets (small plastic ventilation tubes) in the eardrum.

Current practice for OME often focuses on when to refer children for surgery, but in many areas commissioners have set restrictions on who can have surgery. The approval process can take a long time, denying children the chance for a timely intervention for their hearing impairment. There can be an additional delay in getting grommets, because of surgical waiting lists. There are also communication problems between services, with paediatric audiology services often not aware of surgical delays. If paediatric audiology services know about delays they could provide a non-surgical solution. For some children a non-surgical treatment option, such as temporary hearing aids, may be a preferred first-line option. Advice can also be given to schools to help them support the needs of children with fluctuating or persistent hearing impairments caused by OME.

Persistent OME can have wide-ranging consequences. It is important to consider all the relevant needs of children with OME and provide the most suitable interventions.

2 Who the guideline is for

This guideline is for:

- all healthcare professionals involved in the care of children under 12 years
- healthcare commissioners
- children under 12 with suspected or confirmed otitis media with effusion (OME), their parents or carers and the public.

It may also be relevant for non-healthcare professionals working with children under 12 years of age with suspected or confirmed OME, such as:

- teachers
- social workers
- members of or people working in voluntary organisations and networks interested in OME in children.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#) and [Northern Ireland Executive](#).

Equality considerations

NICE has carried out an [equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to:

- children with complex needs, including learning disabilities
- children with sensory disorders and autistic children
- children of families of lower socioeconomic status

- children who do not speak English, or whose first language is not English
- children who are transient, for example travellers and refugees
- looked-after children.

3 What the guideline will cover

3.1 Who is the focus?

Groups that will be covered

All children under 12 years with suspected or confirmed otitis media with effusion (OME).

3.2 Settings

Settings that will be covered

All settings where NHS-commissioned care is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

- 1 Risk factors for OME.
- 2 Recognition of OME (to help identify when to refer for further investigation).
- 3 Natural history of OME (to help identify when intervention and follow-up is needed).
- 4 Interventions for children with OME.
- 5 Care during and after surgery.
- 6 Information for children, parents and carers.

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will

assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Areas that will not be covered in evidence reviews

- 1 Diagnosing or managing acute otitis media.
 - This is a different condition and is covered by the [NICE guideline on antimicrobial prescribing for acute otitis media](#).
- 2 Specific methods of assessing hearing in children.
 - This is not specific to OME.
- 3 Homeopathy, cranial osteopathy, acupuncture, diet changes, immunostimulants or massage.
 - In the 2008 guideline, these interventions were not found to be effective in managing OME and the guideline recommended against using them. We did not identify new evidence on these interventions when we checked in 2018. Therefore, we plan not to review the evidence on them as part of this update.

Related NICE guidance and other NICE publications

Published

- [Otitis media \(acute\): antimicrobial prescribing](#) (2018) NICE guideline NG91
- [Cystic fibrosis: diagnosis and management](#) (2017) NICE guideline NG78
- [Otovent nasal balloon for otitis media with effusion](#) (2016) medtech innovation briefing MIB59
- [Gastro-oesophageal reflux disease in children and young people: diagnosis and management](#) (2015) NICE guideline NG1
- [Suction diathermy adenoidectomy](#) (2009) NICE interventional procedure guidance IPG328

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to OME in children:

- [Babies, children and young people's experience of healthcare](#) (2021) NICE guideline NG204
- [Medicines optimisation](#) (2015) NICE guideline NG5

3.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services perspective, as appropriate.

3.5 Key issues and draft questions

While writing this scope, we have identified the following key issues and draft review questions related to them:

- 1 Risk factors for OME
 - 1.1 What are the modifiable risk factors for developing OME in children under 12 years?
- 2 Recognition of OME (to help identify when to refer for further investigation)
 - 2.1 What symptoms or signs are associated with OME in children under 12 years?
- 3 Natural history of OME (to help identify when intervention and follow-up is needed)
 - 3.1 What is the progression, resolution and recurrence (natural history) of OME without hearing loss at presentation in children under 12 years?
 - 3.2 What is the progression, resolution and recurrence (natural history) of OME with hearing loss at presentation in children under 12 years?

- 4 Interventions for children with OME
 - 4.1 What is the effectiveness of ventilation tubes for OME in children under 12 years?
 - 4.2 What is the effectiveness of adenoidectomy (with or without ventilation tubes) for OME in children under 12 years?
 - 4.3 What is the effectiveness of antibiotics for OME in children under 12 years?
 - 4.4 What is the effectiveness of non-antimicrobial pharmacological interventions (such as steroids, antihistamines, leukotriene inhibitors, mucolytics and decongestants) for OME in children under 12 years?
 - 4.5 What is the effectiveness of auto-inflation for OME in children under 12 years?
 - 4.6 What is the effectiveness of air conduction and bone conduction hearing aids for children with OME under 12 years?
- 5 Care during and after surgery
 - 5.1 What intraoperative or postoperative interventions are effective at preventing otorrhoea (ear discharge) after surgery for OME in children under 12 years?
 - 5.2 What interventions are effective for treating otorrhoea (ear discharge) after surgery for OME in children under 12 years?
 - 5.3 What should the follow-up strategy after surgical treatment be?
- 6 Information for children, parents and carers
 - 6.1 What information is valued by children under 12 years with suspected or confirmed OME and their parents and carers?

The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

3.6 Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

- hearing
- persistence or recurrence of OME
- listening skills
- receptive language skills and speech development
- psychosocial development
- educational attainment
- auditory processing development
- side effects of treatment
- quality of life
- integrity of the tympanic membrane.

4 Further information

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in December 2023.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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