NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline

Otitis media with effusion in under 12s

Draft for consultation, March 2023

This guideline covers This guideline covers treatment of children younger than 12 years who have otitis media with effusion, also known as 'glue ear'. It aims to improve hearing and quality of life in children with otitis media with effusion.

This guideline will update NICE guideline CG60 (published February 2008).

Who is it for?

- Healthcare professionals
- Commissioners and providers
- Children under 12 years old with otitis media, and their families and carers

What does it include?

- the recommendations
- recommendations for research
- rationale and impact sections that explain why the committee made the 2023 recommendations and how they might affect practice.
- the guideline context.

Information about how the guideline was developed is on the guideline's webpage. This includes the evidence reviews, the scope, details of the committee and any declarations of interest.

Contents

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

The recommendations in this guideline apply to otitis media with effusion, also known as 'glue ear', in under 12s. For guidance on antimicrobial prescribing strategy for acute otitis media (ear infection), see the NICE guideline on otitis media (acute): antimicrobial prescribing.

1.1 Information and advice

1.1.1 Ask children with suspected or confirmed otitis media with effusion (OME), and their parents and carers, about their concerns and the impact that OME is having on day-to-day living. Take this into account when agreeing a plan for investigation and treatment. **[2023]**

1.1.2 Give children with OME, and their parents and carers, the following information about the condition:

- what it is
- its cause
- its fluctuating nature
- its possible impact on the child's hearing, listening, language development, behaviour, and emotional and social wellbeing. **[2023]**

1.1.3 For children with OME without hearing loss, provide reassurance to them, their parents and carers that it will often get better on its own over time and explain that no treatment is necessary. **[2023]**

1.1.4 For children with OME without hearing loss, advise them and their parents and carers to seek medical help again if they have future concerns about hearing. **[2023]**

1.1.5 Discuss management options with children with confirmed OME and hearing loss, and their parents and carers. Use decision table 1 to guide and inform the conversation, and cover:

- the benefits, risks and practical considerations of each option [monitoring and support, hearing aids, grommets (ventilation tubes) and so on]
- supportive strategies, for example modifying the environment and listening strategies. **[2023]**

1.1.6 Give children with suspected or confirmed OME, and their parents and carers, information about OME that:

- is tailored to the individual needs and circumstances of the child and their parents and carers
- is age and developmentally appropriate for the child
- uses appropriate formats for the child (for example, face to face, in writing, digital, Easy Read, Braille, pictures, captioned videos, animations) and languages (including British Sign Language)
- uses simple terminology and avoids jargon.

Also see the section on communication and information in NICE's guideline on babies, children and young people's experience of healthcare. **[2023]**

1.1.7 Advise parents and carers about ways they can support their child with OME and hearing loss, including in educational settings, for example by:

- being close to and facing the child when speaking to them
- limiting background noise
- using visual aids

- informing their teacher that the child has OME, and asking if adjustments can be made in school to help (for example, taking the steps above, having the child sit near the front of class)
- preparing the child for interventions and ongoing management. **[2023]**

1.1.8 Give children with OME, and their parents and carers, a chance to ask questions at any stage where care or treatment options are being discussed. Allow time in discussions for this, and be willing to answer questions at later appointments after people have reviewed the information they have been given. **[2023]**

1.1.9 Ensure parents and carers are informed that management decisions may need to be reviewed, including the option of no active treatment, according to the changing needs of the child. **[2023]**

1.1.10 Advise parents and carers to avoid exposing their child to tobacco smoke because it may increase their risk of developing OME (see also recommendation 1.8.1 in the NICE guideline on tobacco: preventing uptake, promoting quitting and treating dependence). **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on information and advice.

Full details of the evidence and the committee's discussion are in evidence review N: information on suspected or confirmed OME and evidence review A: modifiable risk factors.

1.2 Recognition and assessment

1.2.1 Be aware that children with OME often present with any of the following features:

- hearing difficulties (for example, mishearing when not looking at who is speaking, difficulty in a group, asking for things to be repeated)
- indistinct speech (nasal, speaking through nose)
- delayed speech and language development

- frequent earache
- tinnitus. **[2023]**

1.2.2 Be aware that the following can also be associated with OME:

- behavioural problems (particularly lack of concentration or attention), being withdrawn, or irritability, or
- poor educational progress, or
- balance difficulties (for example, clumsiness). **[2023]**

1.2.3 Have a higher suspicion of OME if the child has any of the following features, but be aware the absence of these features does not rule out OME:

- a history of:
  - upper respiratory tract infections (URTIs)
  - acute otitis media (AOM)
- asthma
- wheezing
- dyspnoea
- eczema
- paroxysmal sneezing/ nasal itching
- urticaria
- deleterious sucking habits (for example finger or dummy sucking and bottle feeding, parafunctional sucking habits and mouth breathing)
- conjunctivitis
- snoring. **[2023]**

1.2.4 Be aware that OME is less likely if the child does not have any of the following features:

- nasal obstruction
- rhinorrhoea
- adenoid hypertrophy or history of adenoidectomy. **[2023]**

1.2.5 If OME is clinically suspected on the basis of the child's clinical history and assessment of the presenting features in recommendations 1.2.1 to 1.2.4, refer for formal assessment. **[2023]**

1.2.6 Formal assessment should include:

- 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. **[2008]**

1.2.7 Consider co-existing causes of hearing loss (for example, sensorineural, permanent conductive and non-organic causes) when assessing a child with OME and manage appropriately. **[2008]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on recognition and assessment.

Full details of the evidence and the committee's discussion are in evidence review B: recognising OME.

1.3 Reassessment

1.3.1 In children with OME-related hearing loss, advise on strategies to minimise the impact of hearing loss both at home and in educational settings (see recommendation 1.1.7). In bilateral OME (in both ears), reassess hearing after 3 months. Where the OME is unilateral (in one ear), consider reassessment of hearing after 3 months. **[2023]**

1.3.2 In children who are experiencing hearing difficulties that significantly affect day-to-day living, consider intervening earlier than the 3 month reassessment: see the sections on management of hearing loss, non-

surgical management of otitis media with effusion, and surgical management of otitis media with effusion. **[2023]**

1.3.3 At the 3-month audiology reassessment:

- If OME is present but hearing is normal, discharge. If future concerns about hearing develop, advise parents and carers to seek reassessment by the audiology service involved in their child's care.
- If there is unilateral hearing loss:
  - continue with the strategies in recommendation 1.3.1, and
  - consider reassessment of hearing after a further 3 months, or
  - if hearing is impacting daily living or communication, see the sections on management of hearing loss, non-surgical management of otitis media with effusion, and surgical management of otitis media with effusion.
- If there is bilateral hearing loss, see the sections on management of hearing loss, non-surgical management of otitis media with effusion, and surgical management of otitis media with effusion. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on reassessment.

Full details of the evidence and the committee's discussion are in evidence review C: natural history without hearing loss and evidence review D: natural history with hearing loss

1.4 Management of hearing loss

1.4.1 Consider air conduction hearing aids or bone conduction devices for children with OME-related hearing loss. **[2023]**

1.4.2 Consider air conduction hearing aids for children with OME-related hearing loss when:

- their hearing loss is stable, and

- this type of device would be better tolerated or is preferred, for example by avoiding the need for a headband as is used with bone conduction devices. **[2023]**

1.4.3 Consider bone conduction devices for children with OME-related hearing loss when:

- their hearing levels are known to fluctuate, or
- there are contraindications to using an air conduction hearing aid (such as a history of otorrhea, or anatomical issues such as narrow ear canals), and this type of device would be better tolerated or is preferred (for example, to avoid the choking risk from the small parts of an air conduction device). **[2023]**

1.4.4 Advise children, parents and carers about the risk of harm from coin/button batteries in hearing aids and other hearing devices. Also see the NHS National Patient Safety Alert on the risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on management of hearing loss.

Full details of the evidence and the committee's discussion are in evidence review J: hearing aids.

1.5 Non-surgical management of otitis media with effusion

Auto-inflation

1.5.1 Consider auto-inflation in children with OME if they are able to engage with the treatment. **[2023]**

For a short explanation of why the committee made this recommendation see the rationale and impact section on auto-inflation.

Full details of the evidence and the committee's discussion are in evidence review I: auto-inflation.

Antibiotics

1.5.2 Do not offer antibiotics to treat OME. **[2023]**

For a short explanation of why the committee made this recommendation see the rationale and impact section on antibiotics.

Full details of the evidence and the committee's discussion are in evidence review G: antibiotics.

Non-antimicrobial pharmacological interventions

1.5.3 Do not offer oral or nasal corticosteroids for OME or OME-related hearing loss. **[2023]**

1.5.4 Do not offer antihistamines, leukotriene receptor antagonists, mucolytics, proton pump inhibitors and anti-reflux medications, or decongestants for OME or OME-related hearing loss. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on non-antimicrobial pharmacological interventions.

Full details of the evidence and the committee's discussion are in evidence review H: non-antimicrobial pharmacological interventions.

Other non-surgical interventions

1.5.5 Do not use the following treatments for management of OME:

- homeopathy
- cranial osteopathy
- acupuncture
- dietary modification, including probiotics
- massage. **[2008, amended 2023]**

For a short explanation of why the committee made this recommendation see the rationale and impact section on other non-surgical interventions.

Full details of the committee's discussion are in evidence review G: antibiotics. The evidence relating to the 2008 recommendation is in supplement 3: evidence from 2008 guideline.

1.6 Surgical management of otitis media with effusion

Grommets

1.6.1 Consider grommets for the management of OME-related hearing loss in children. **[2023]**

1.6.2 Discuss the benefits and risks of grommets with the child and their parents and carers, and make a shared decision on their use. Cover that there is a risk of perforation of the eardrum, atelectasis, tympanosclerosis and infection associated with grommets. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on grommets.

Full details of the evidence and the committee's discussion are in evidence review E: ventilation tubes.

Adenoidectomy

1.6.3 When planning grommets for management of OME, consider adjuvant adenoidectomy unless there is an abnormality with the palate. **[2023]**

1.6.4 Discuss the benefits and risks of adenoidectomy with the child and their family or carers, and make a shared decision on whether to have the procedure. Include that there is a risk of haemorrhage, and velopharyngeal insufficiency. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on adenoidectomy.

Full details of the evidence and the committee's discussion are in evidence review F: adenoidectomy.

Prevention of otorrhoea

1.6.5 Consider a single dose of ciprofloxacin ear drops given intraoperatively during grommet insertion to prevent otorrhoea and tube blockage. **[2023]**

In March 2023, this was an off-label use of ciprofloxacin ear drops. See NICE's information on prescribing medicines.

1.6.6 Advise that water precautions should be taken to keep the ear dry (such as avoiding swimming, and taking care when bathing or washing hair) for 2 weeks after grommet surgery. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on prevention of otorrhoea.

Full details of the evidence and the committee's discussion are in evidence review K: preventing otorrhoea.

Treatment of infection after grommet insertion

1.6.7 If there is isolated postoperative otorrhoea (ear discharge) after grommet insertion, advise water precautions should be taken to keep the ear dry (such as avoiding swimming, and taking care when bathing or washing hair). **[2023]**

1.6.8 Advise children with recurrent otorrhoea after grommet surgery to use ear plugs or headbands if in contact with water. **[2023]**

1.6.9 Consider non-ototoxic topical antibiotic ear drops (such as ciprofloxacin) for 5 to 7 days for postoperative otorrhoea after grommet insertion. **[2023]**

In March 2023, this was an off-label use of non-ototoxic antibiotic-containing topical ear drops. See NICE's information on prescribing medicines.

1.6.10 For children with otorrhoea that is persistent and does not respond to topical antibiotics, consider removal of the grommets. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on treatment of infection after grommet insertion.

Full details of the evidence and the committee's discussion are in evidence review L: treating otorrhea.

Follow up after surgical treatment

1.6.11 Perform a postoperative hearing test 6 weeks after surgery for OME. **[2023]**

1.6.12 After surgery for OME, consider a routine 1-year follow up with a hearing test to pick up those children with hearing loss. **[2023]**

1.6.13 Consider an individualised follow-up plan if the child has an increased risk of unrecognised OME with hearing loss (for example, children with a learning disability). **[2023]**

1.6.14 Advise parents and carers to seek a reassessment by the audiology service involved in their child's care if they are concerned about a possible recurrence of hearing loss. **[2023]**

For a short explanation of why the committee made these recommendations see the rationale and impact section on follow up after surgical treatment.

Full details of the evidence and the committee's discussion are in evidence review M: follow-up after surgery.

Terms used in this guideline

This section defines terms that have been used in a particular way for this guideline.

Bone conduction devices

A collective term that covers bone conduction hearing aids as well as bone conduction hearing implants. Bone conduction devices transfer sound by bone vibration directly to the cochlea, bypassing the outer and the middle ear.

Grommets

Grommets are small plastic tubes which sit in a hole in the eardrum, and let air get in and out of the ear. Grommets are sometimes also called ventilation tubes.

Monitoring and support

Monitoring and support is a period during which time is allowed to pass before medical interventions or therapies are used. During this period, the person may undergo tests or have check-ups. The person may also receive other forms of support during this period. This period may also be known as active management or watchful waiting.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Hearing aids

What is the clinical and cost-effectiveness of air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years?

For a short explanation of why the committee made this recommendation see the rationale section on management of hearing loss.

Full details of the evidence and the committee's discussion are in evidence review J: hearing aids.

2 Grommets

What is the clinical and cost-effectiveness of grommets for hearing loss associated with OME in children under 12 years?

For a short explanation of why the committee made this recommendation see the rationale section on grommets.

Full details of the evidence and the committee's discussion are in evidence review E: ventilation tubes.

3 Natural history

What is the progression, resolution and recurrence of OME with and without hearing loss?

For a short explanation of why the committee made this recommendation see the rationale section on reassessment.

Full details of the evidence and the committee's discussion are in evidence review C: natural history without hearing loss and evidence review D: natural history with hearing loss.

4 Grommets

What is the effectiveness of grommets for managing OME with associated hearing loss for children with craniofacial abnormalities?

For a short explanation of why the committee made this recommendation see the rationale section on grommets.

Full details of the evidence and the committee's discussion are in evidence review E: ventilation tubes.

5 Prevention of otorrhoea

What water precautions are effective in preventing otorrhea after ventilation tube (grommet) surgery for hearing loss associated with OME in children under 12 years?

For a short explanation of why the committee made this recommendation see the rationale section on prevention of otorrhoea.

Full details of the evidence and the committee's discussion are in evidence review K: prevention of otorrhoea.

Other recommendations for research

Non-antimicrobial pharmacological interventions

What is the effectiveness of topical nasal steroids on the management of OME and OME related hearing loss in children under 12 years?

For a short explanation of why the committee made this recommendation see the rationale section on non-antimicrobial pharmacological interventions.

Full details of the evidence and the committee's discussion are in evidence review H: non-antimicrobial pharmacological interventions.

Non-antimicrobial pharmacological interventions

What is the effect of antihistamines, leukotriene receptor antagonists, mucolytics, proton pump inhibitors and decongestants on hearing in children with OME and chronic respiratory conditions?

For a short explanation of why the committee made this recommendation see the rationale section on non-antimicrobial pharmacological interventions.

Full details of the evidence and the committee's discussion are in evidence review H: non-antimicrobial pharmacological interventions.

Follow up after surgical treatment

What should the follow-up strategy be after surgical treatment for OME-related hearing loss in children under 12 years?

For a short explanation of why the committee made this recommendation see the rationale section on follow up after surgical treatment.

Full details of the evidence and the committee's discussion are in evidence review M: follow up after surgical treatment.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice.

Information and advice

Recommendations 1.1.1 to 1.1.10

Why the committee made the recommendations

There was high quality evidence showing that parents often felt their and their child's views about their child's illness were not taken into consideration by healthcare professionals, and they and their child were not given a choice about their child's treatment but felt coerced into decisions. The committee, based on their knowledge and experience, also agreed that the experience of OME is often different for each child, and therefore it is crucial that any treatment decisions be made in the context of the child's experience of OME and any associated impact or concerns, the parents' or carers' knowledge and experience of their child, and the family's circumstances. Therefore, they recommended that health professionals always ask the child, their parents or carers about their experiences to understand the impact of the illness on the child and the family.

There was a lack of consensus in the evidence on the information content that should be provided to parents and carers. However, the committee agreed, based on their knowledge and experience, that parents need to understand OME and its impact on a child's wellbeing, and that if they do not then they may not be receptive to potential management options. Therefore, they recommended children, parents and carers be provided with such information so they can make informed choices about care.

Children who have OME without hearing loss do not need treatment. However, the committee felt that it was important to clarify why it is not needed to these children and their parents when explaining this to them, as it may be a source of confusion or anxiety. It was also agreed that it would be helpful to remind children, parents and carers that they can always return for more advice if they have concerns about hearing loss in future.

The committee agreed, based on their knowledge and experience, that information should be shared with children, parents and carers as soon as OME is confirmed, and before any management decisions are made, to empower them to be involved in their care.

In the committee's experience, information is mostly provided verbally in face-to-face settings, but they agreed that having information that parents and carers could refer to later would be helpful in answering any questions that arise, as well as for explaining OME to other family members, schools and nurseries. There was low quality evidence on parents and carers' needs for detailed information in accessible formats. Therefore, the committee highlighted the most useful formats indicated by the evidence, along with formats they felt were beneficial from their experience.

The committee also considered low-quality evidence of parents reporting that they receive conflicting and confusing information from healthcare professionals, and low-quality evidence that information provided often included medical terms that were incomprehensible. Therefore, the committee agreed that information needs to be tailored to the children, parents or carers and should avoid medical terminology. The committee were aware that the 2021 NICE guideline on babies, children and young people's experience of healthcare includes more general recommendations about caring for children and young people and how to provide information to children, so included a cross reference to this guideline.

Based on their knowledge and experience, the committee agreed that parents and carers understanding the impact of OME is important for helping them understand the ways they can support their child while they are experiencing hearing loss. The committee listed some useful examples of interventions that could also be used in educational settings. The committee recognised that the biggest impact of hearing

loss on children is having limited receptivity to education, and agreed that support in educational settings should be thought of as part of the overall support given to children with OME.

In the committee's experience, parents and carers may change their minds about a chosen management decision, either because they want to try a different management option, or because they realise that a different option is better suited to their child. Therefore, they agreed giving opportunities to discuss and answer questions about treatment was important.

Because of the fluctuating nature of OME, management decisions may need to be reviewed or changed. Therefore, the committee agreed based on their knowledge and experience that healthcare professionals should inform the child, parents or carers about this, so that they are aware that it may happen and that it does not mean the previous treatment was the wrong choice.

There was some limited evidence that household smoking was not associated with development of OME. However, in the committee's experience, household smoking or passive smoking may increase the risk of developing OME. This is also mentioned in the NICE Clinical Knowledge Summary for OME (2021). Regardless of any risk associated with OME, it is widely accepted that passive smoking can cause a range of diseases and health conditions, so it is good practice to avoid exposing children to tobacco smoke.

How the recommendations might affect practice

The recommendations on information and advice are not expected to lead to a large change in current practice as they are consistent with existing NICE guidance (Babies, children and young people's experience of healthcare [NG204] and Tobacco: preventing uptake, promoting quitting and treating dependence [NG209]) and would promote treatment decisions that reflected the child's individual experience of OME.

Return to recommendations

Recognition and assessment

Recommendations 1.2.1 to 1.2.6

Why the committee made the recommendations

The committee were aware that all the evidence identified was on clinical features, and that there was a lack of evidence on signs and symptoms commonly reported by parents. They agreed, based on their knowledge and experience, that certain parent-reported factors may be associated with OME, and should be captured in the recommendations to help raise awareness of them. They also reviewed the advice from the 2008 NICE guideline on OME on clinical presentation, and from them agreed that hearing difficulty, earache, tinnitus and indistinct speech were important presenting features for OME frequently reported by parents. The committee also included delayed speech development as a potential presenting feature, in addition to delayed language development from the 2008 guideline, to capture delays in both receptive and expressive language and phonological elements.

The committee also agreed, based on knowledge and experience and backed up by the advice in the 2008 guideline, that in some children, OME could be indicated by behavioural problems, poor educational progress, or balance difficulties. However, these presenting features are not always an indication of OME. The committee therefore made a recommendation to raise awareness of these possible indicators of OME.

Based on the evidence, the committee agreed to make 2 recommendations listing presenting features: the first with features (history of URTIs or AOM, or other atopic symptoms) that would mean clinicians could have a higher suspicion of OME if they are present. However, the absence of these features also would not rule out OME.

For the second recommendation, the committee agreed that people with OME usually have nasal obstruction and rhinorrhoea, and this could help rule out OME in children who do not present with these symptoms. The committee also agreed that a history of adenoidectomy may be indicative for higher risk of OME. The evidence also showed that adenoid hypertrophy was potentially indicative of OME. However, the evidence also showed other diagnoses could not be ruled out just because of the presence of these symptoms.

The committee agreed, based on their knowledge and experience, that in a situation where the clinician suspected OME, the child should be referred for formal

audiological assessment to investigate whether there is any associated hearing loss. The committee agreed this would start children with suspected OME on the appropriate care pathway.

The committee reviewed the advice from the 2008 guideline on OME about formal assessment, and agreed the methods listed to assess OME are still used in current practice as the gold standard for diagnosis of OME.

The committee agreed, based on their knowledge and experience and backed up by the advice in the 2008 guideline, that co-existing causes of hearing loss can be missed. The recommendation on considering co-existing causes of hearing loss when assessing a child with OME was therefore brought forward from the 2008 guideline.

How the recommendations might affect practice

The committee agreed that the recommendations will reinforce current practice.

Most of the recommendations reflect current practice and therefore are not likely to have a significant resource impact. While there are costs associated with better and earlier recognition of OME there are also likely to be offsetting savings given the benefits of prompt recognition to expedite interventions and management that will improve health related quality of life and educational and developmental outcomes.

Return to recommendations

Reassessment

Recommendations 1.3.1 to 1.3.3

Why the committee made the recommendations

The committee felt that the available evidence on resolution of OME-related hearing loss was too varied and of too low quality to make a change to the standard watchful waiting period of 3 months. In the committee's experience, children with unilateral OME may not need reassessment after 3 months because they tend to hear well in a normal listening environment without excessive background noise, and there may not be a significant impact on the child's communication and development. However, the committee acknowledged that OME is a changing condition, and some children

may fluctuate between unilateral and bilateral OME. Therefore, the committee agreed to recommend that in children with bilateral OME hearing should be reassessed as standard after 3 months of watchful waiting, but be considered for those with unilateral OME. The committee also felt that it was important to highlight strategies for home and educational settings to reduce the impact of OME-related hearing loss, so cross-referenced advice elsewhere in the guidance on this.

Hearing loss may significantly affect day-to-day living for some children. In these cases the committee agreed, based on their knowledge and experience, that early intervention for hearing loss should be considered to avoid negatively impacting children's development and wellbeing. They therefore cross-referenced advice elsewhere in the guidance that covered relevant interventions.

In the committee's experience, children with OME do not need further assessment or interventions if there is no hearing loss. Therefore, the committee agreed that at the 3-month audiology reassessment children with OME and normal hearing should be discharged. However, as OME is often a fluctuating condition the committee felt parents should have the opportunity to re-contact audiology services to discuss the need for further hearing assessment for their child if they are concerned about recurrence of hearing loss. This may reduce delays in identifying recurrent hearing loss and therefore, appropriate interventions to address this and so avoid adverse consequences for the child.

Based on their knowledge and experience, the committee agreed that if hearing loss is unilateral at the 3-month audiology reassessment, strategies should be considered to minimise the impact of hearing loss both at home and in educational settings. They therefore cross-referenced advice elsewhere in the guidance on this. The committee also agreed that if hearing loss is unilateral at the 3-month audiology reassessment, a repeat assessment after a further 3 months should be considered. However, if there is concern about the impact of hearing loss on day-to-day living and communication, earlier intervention for hearing loss should be considered. Cross-references to advice elsewhere in the guidance covering relevant interventions were also added.

The committee agreed, based on their knowledge and experience, that if hearing loss is bilateral at the 3-month audiology reassessment interventions should be considered, as these children are at the greatest risk of negative effects on their development and quality of life. Cross-references to advice elsewhere in the guidance covering relevant interventions were also added.

It is not current practice to treat OME unless there is an associated loss of hearing. The committee agreed that the lack of evidence on the natural history of OME without hearing loss means that it is not possible to identify which children are most likely to go on to have OME with associated hearing loss. Therefore, they were unable to make any recommendations on treatment of OME without hearing loss to prevent progression to OME with hearing loss.

The committee made a recommendation for research on the progression, resolution and recurrence of OME with and without hearing loss to better inform future guideline development.

How the recommendations might affect practice

Most of the recommendations reflect current practice and are therefore not likely to have a significant resource impact. Earlier interventions could be cost effective for children who are experiencing hearing difficulties, as gains in health-related quality of life (HRQoL) would likely be seen and most additional costs would only be incurred in the event of spontaneous resolution of OME-associated hearing loss occurring in such children within the 3-month watchful waiting period.

Current practice may be affected by the recommendation that parents have the opportunity to re-contact audiology services when they are concerned about recurrence of hearing loss. There is variation in practice on this, and audiology services may or may not accept direct referrals. For audiology services who do not currently accept direct referrals the recommendation may have a resource impact on staff or training. However, this change may reduce delays in identifying recurrent hearing loss and, consequently, appropriate interventions to address this, avoiding adverse consequences for the child and the costs associated with this. The recommendation will give the flexibility for audiology services to accept direct referrals or to refer the child back to their GP if this is necessary.

Return to recommendations

Management of hearing loss

Recommendations 1.4.1 to 1.4.4

Why the committee made the recommendations

There was no available evidence on the effectiveness of air conduction hearing aids and bone conduction devices for OME-related hearing loss in children under 12 years. The committee agreed, based on their knowledge and experience, that bone conduction devices and air conduction hearing aids may improve development in terms of hearing, wellbeing, behaviour, speech and language. Because of a lack of evidence, the committee also made a recommendation for research on air conduction and bone conduction hearing aids/devices for hearing loss associated with OME in children under 12 years.

In the committee's experience it can be difficult to decide what types of hearing aids or devices are most appropriate for individual children: air conduction hearing aids are more suited to people with no fluctuation or change in hearing levels, and may be more acceptable to some children or their families as bone conduction devices tend to have a headband, and so are less discrete than air conduction hearing aids.

However, in children with history of recurrent or persistent otorrhoea air conduction hearing aids may not be suitable because otorrhoea can damage or occlude them, rendering them ineffective. Air conduction hearing aids may also not be suitable for children with anatomical issues such as narrow ear canals, because of difficulty in inserting the hearing aid.

The committee were aware that bone conduction hearing aids may be preferable to some children or their families as air conduction hearing aids may contain small parts which present a choking hazard. They also do not need adjustment when hearing levels change or fluctuate.

The committee agreed, based on their knowledge and experience, that young children and children with learning difficulties may put button batteries from hearing aids and hearing devices into their mouths that, if ingested, pose a significant risk of harm or death. Although the safety of hearing aids was outside the scope of the

guideline, the committee agreed it was important to raise awareness of the risk of button batteries in hearing aids and hearing devices so included reference to a NHS national patient safety alert.

How the recommendations might affect practice

The recommendations may lead to changes in practice over the provision of hearing aids or bone conduction devices. This has the potential both to increase costs and produce savings, but these are unlikely to be substantial changes. As more scope is given to provide hearing aids as an alternative to ventilation tubes, this may reduce inpatient stays and costs associated with surgery. Earlier intervention may also have a positive impact on development and behaviour, which then has the potential to reduce downstream costs.

The cost of a bone conduction device is considerably higher than for an air conduction device, but this would be offset to some extent by non-device costs which are higher for air conduction hearing aids. The number of children with narrow ear canals is small, however, and therefore any increased use of bone conduction devices in this group is unlikely to lead to a significant increase in costs.

Return to recommendations

Auto-inflation

Recommendation 1.5.1

Why the committee made the recommendation

There was low quality evidence that auto-inflation improved hearing in the very short-term (less than 6 weeks) compared with no treatment. The committee, based on their knowledge and experience, agreed that the critical period for hearing outcomes is in the short term, as reduced hearing levels, even for short periods of time, can significantly impact a child's development, and it is important to avoid this rather than wait for spontaneous resolution. Consequently, auto-inflation may reduce the need for further active interventions later. However, the committee were aware that some children, especially very young children, may not engage with or be able to use the device. They were also aware that school-age children may not have the opportunity to use auto-inflation devices 3 times a day as needed.

How the recommendation might affect practice

The recommendation is not likely to involve a significant change in practice or have a substantial resource impact, as it already reflects practice in some areas and is not an expensive intervention.

Return to recommendation

Antibiotics

Recommendation 1.5.2

Why the committee made the recommendation

The committee agreed, based on the evidence together with their knowledge and experience, that the potential benefits of antibiotics did not outweigh the risks associated with their use. There was low quality evidence that antibiotics might have a benefit in terms of hearing outcomes and persistence of OME when compared to no treatment, and less risk of ear-drum perforation when compared to placebo. However, the evidence indicated that the hearing improvement associated with the use of antibiotics is limited and would not reflect a clinically important difference in practice. Antibiotics also have a potential significant harm because they are associated with a higher risk of itching or rash, and diarrhoea.

Although only oral antibiotics were investigated, the committee agreed the findings could be extrapolated to topical antibiotics as well. Additionally, in the committee's experience, topical antibiotics tend to be weaker than oral antibiotics, so any effect on outcomes such as hearing or persistence of OME would likely be lower still.

The committee therefore agreed that neither oral nor topical antibiotics should be recommended for people with OME.

How the recommendation might affect practice

There may be some change in practice from stopping the use of antibiotics for the management of OME but this is likely to be cost saving.

Return to recommendation

Non-antimicrobial pharmacological interventions

Recommendations 1.5.3 to 1.5.4

Why the committee made the recommendations

There was some limited evidence that oral steroids might reduce persistence of OME in the very short term when compared to no treatment, and that nasal steroids might reduce persistence of OME in the short and very short term when compared to no treatment. There was also some evidence that nasal steroids had a benefit with regards to persistence of OME and generic health-related quality of life in the medium term. However, the evidence was all very low quality.

The committee, based on their knowledge and experience, were aware of the potential for children to experience systemic corticosteroid side effects. They were also aware of the potential harms of using nasal steroids and agreed that, although the risks of side effects was lower than for oral steroids, nasal steroids could be difficult to administer (in particular for very young children or children with learning difficulties or other disabilities). There was also no cost-effectiveness evidence that would support a recommendation to give steroids. As the evidence was not strong enough to outweigh the harms, the committee recommended that nasal and oral steroids should not be used to treat OME in children. The committee made a recommendation for research on the effectiveness of topical nasal steroids on the management of OME and OME related hearing loss in children under 12 years to better inform future guideline development.

Based on the evidence, the committee agreed that antihistamines, leukotriene receptor antagonists, mucolytics, and decongestants made little difference to relevant outcomes. Therefore, the committee agreed that these medications should not be used to treat OME in children under 12. The committee also agreed they could not make recommendations about proton pump inhibitors or other anti-reflux medications because of the lack of evidence regarding their effectiveness. The committee made a recommendation for research on the effect of antihistamines, leukotriene receptor antagonists, mucolytics, proton pump inhibitors, anti-reflux medications and decongestants on hearing in children with OME and chronic respiratory conditions to better inform future guideline development.

How the recommendations might affect practice

The recommendation not to use steroids, antihistamines and decongestants for OME or OME-related hearing loss reflects current practice. There may be some change in practice from stopping the use of leukotriene receptor antagonists, mucolytics, proton pump inhibitors and reflux medicines for OME or OME-related hearing loss but this is likely to be cost saving.

Return to recommendations

Other non-surgical interventions

Recommendation 1.5.5

Why the committee made the recommendation

The recommendation on interventions not to be used was brought forward from the 2008 guideline. An evidence review was not done for these interventions, as the review performed for the 2008 guideline did not find any evidence of effectiveness and no new applicable evidence has come to light since then. The committee agreed, based on their experience, that there is still variation in practice and so it was important to continue to advise against these interventions as there was a lack of evidence regarding their effectiveness in treating OME in children under 12.

How the recommendation might affect practice

The recommendation will reinforce current practice.

Return to recommendation

Grommets

Recommendations 1.6.1 to 1.6.2

Why the committee made the recommendations

The committee agreed, based on their experience, that reduced hearing levels even for only short periods of time can significantly impact a child's development. There was very low quality evidence that early grommet insertion led to improved final hearing thresholds in the short term when compared with monitoring and support. However, adverse events because of grommet insertion, such as ear drum

perforation and otorrhoea, could result in later complications such as impacting the child's development. Therefore, it is important to weigh up the potential benefits of grommet insertion against the risk of these events.

The committee agreed that in situations where OME is not having an impact on the child's hearing, there is no urgent need to consider surgery, regardless of whether the OME is persistent or transient, in light of the risks associated with grommet insertion. Therefore, grommet insertion for children without hearing loss was not recommended. The committee did however agree that grommet insertion should be considered for treatment of children with OME where the OME has resulted in hearing loss. Because of a lack of evidence, the committee also made two recommendations for research, one on the effectiveness of grommets for hearing loss associated with OME in children under 12 years and the other on the effectiveness of grommets for managing OME with associated hearing loss for children with craniofacial abnormalities.

An original economic evaluation was undertaken for the guideline to compliment the clinical evidence review. This analysis compared no intervention, hearing aids, grommet insertion alone and grommet insertion with adjuvant adenoidectomy. It found that grommet insertion was generally more cost-effective than no intervention, but that grommet insertion alone had comparable cost-effectiveness estimates and probability of being cost-effective relative to hearing aids and grommet insertion with adjuvant adenoidectomy. The committee concluded that this analysis supported their recommendation that grommet insertion should be considered for OME with hearing loss in children alongside other management options.

Currently, adverse events associated with grommet insertion are often not discussed with parents and carers before committing to treatment. In the committee's experience it is important that children, parents and carers should be informed of the benefits and risks of grommets when considering this intervention, to enable informed decision-making and ensure they are prepared if adverse events do occur.

How the recommendations might affect practice

The recommendation on grommets for the management of OME related hearing loss is not likely to involve a significant change in practice or have a substantial resource

impact. There was some limited clinical- and cost-effectiveness evidence to support a recommendation on grommets.

There may be a change in practice in discussing the benefits and risks of grommets with the child and their family or carers, as in current practice the risk of complications from grommet insertion may not be routinely discussed with parents and carers before committing to treatment. Doing so would enable informed decision-making and ensure they are prepared if adverse events do occur.

Return to recommendations

Adenoidectomy

Recommendations 1.6.3 to 1.6.4

Why the committee made the recommendations

Hearing is the most important outcome in children with OME for measuring the effectiveness of interventions. However, there was very limited, inconsistent and very low quality evidence for this outcome. There was some evidence that adenoidectomy with or without unilateral or bilateral grommets reduced the presence or persistence of OME. The committee agreed, based on their experience, that if adenoidectomy improves the OME, it may also have beneficial effects on hearing.

The committee noted that surgical approaches to adenoidectomy are safer now than when some of the studies in the evidence were done. Therefore, if someone is already having general anaesthesia for grommets, the added risk of doing adenoidectomy at the same time is likely to be very small. The committee agreed that the potential for improving OME, and in turn hearing, outweighed any additional risk. However, in the committee's experience adenoidectomy is likely to lead to velopharyngeal insufficiency or nasal regurgitation in children with an abnormality of the palate, so they agreed that it would not be appropriate for this group.

An original economic evaluation was undertaken for the guideline to compliment the clinical evidence review. This analysis compared no intervention, hearing aids, grommet insertion alone and grommet insertion with adjuvant adenoidectomy. Given the limitations of the analysis and inherent uncertainty in the model inputs, the committee concluded that there was not a single intervention that was clearly the

most cost-effective but considered there was sufficient evidence to support a recommendation to consider adjuvant adenoidectomy.

In the committee's experience the potential risks of adenoidectomy, such as haemorrhage and velopharyngeal insufficiency, are not routinely discussed with the child and their family. They agreed although the risks of these occurring are small, it is important that the child and their family are made aware of them.

How the recommendations might affect practice

The recommendation on adjuvant adenoidectomy would represent a change in practice. There was some limited clinical- and cost-effectiveness evidence to support a recommendation on adjuvant adenoidectomy. In addition, grommet insertion with adjuvant adenoidectomy may lead to reduced presence or persistence of OME and reduced time with effusion so could also lead to wider societal benefits.

Return to recommendations

Prevention of otorrhoea

Recommendations 1.6.5 to 1.6.6

Why the committee made the recommendations

There was moderate quality evidence that at 6 weeks follow-up intraoperative ciprofloxacin drops had a benefit in terms of presence of otorrhoea compared to no drops. There was also low quality evidence that intraoperative ciprofloxacin drops possibly had a benefit in terms of tube blockage. However, the committee noted there were inconsistencies in the evidence.

However, the committee agreed, based on their knowledge and experience, that otorrhoea was very painful for the child and could cause difficulties for families, and that a single dose of ciprofloxacin drops is unlikely to influence antibiotic resistance. Therefore, as the risk is minimal and benefits could include prevention of otorrhoea and tube blockage, a single application of ciprofloxacin drops intraoperatively should be considered.

The committee discussed that applying ear drops had a lower risk than injecting ciprofloxacin, which might result in complications such as dislodging the grommets. Therefore, the committee did not recommend injecting ciprofloxacin.

There was low quality evidence that intraoperative and postoperative ciprofloxacin drops had an important benefit in terms of tube blockage at 6 weeks follow-up compared to no drops. However the committee agreed that the evidence for this was unreliable, and that repeat applications of antibiotics would increase the risk for antibiotic resistance, so did not recommend postoperative ciprofloxacin drops.

Because of the uncertainty of the evidence, the committee agreed, based on knowledge and experience, to advise patients to keep the ear dry to prevent the risk of water permeating the lumen while the wound is still healing around the grommet. They also agreed that 2 weeks would usually be enough time for the wound to heal while not being impractical. The committee also made a recommendation for research on the effectiveness of water precautions in preventing otorrhea for hearing loss associated with OME in children under 12 years to better inform future guideline development.

How the recommendations might affect practice

Advice about water precautions are in line with current practice. Current practice around ear drops is varied, so the recommendation could represent a change in practice for some units. However, given the low cost of ear drops and the potential for some savings from reduced rates of otorrhoea the recommendation would not represent a significant resource impact to the NHS.

Return to recommendations

Treatment of infection after grommet insertion

Recommendations 1.6.7 to 1.6.10

Why the committee made the recommendations

There was no evidence available on the effectiveness of water precautions, however the committee agreed, based on their knowledge and experience, that it was

sensible to keep the ear dry in the event of postoperative otorrhoea after grommet insertion and that this should be advised.

For children who have otorrhoea repeatedly or for long periods of time, the committee acknowledged that being unable to swim can impact on the quality of life for children and their families. Therefore, based on their knowledge and experience, they recommended the use ear of plugs or head bands.

There was very low quality evidence showing hydrocortisone-bacitracin-colistin drops had an important benefit in terms of presence of otorrhoea at 2 weeks follow-up compared to an oral amoxicillin clavulanate suspension or to initial observation. However, these drops are not available in the UK so they could not be recommended.

The committee noted that non-ototoxic antibiotics, such as ciprofloxacin, were normally prescribed for otorrhoea. The committee reviewed whether the resolution of otorrhoea justified use of these antibiotics, given the potential for increasing antibiotic resistance, but noted that otorrhoea was very painful for the patient and could cause difficulties for families so should be treated if possible. In the committee's experience it is not standard practice to prescribe oral antibiotics for otorrhoea because they are usually used to treat underlying infection, whereas topical treatment should be sufficient to treat otorrhoea after grommet surgery because of the site of the infection. Systemic antibiotics are also associated with more side effects than topical antibiotics, so were agreed to be unsuitable. Therefore, the committee agreed that non-ototoxic drops, such as ciprofloxacin, should be considered as they can help clear otorrhoea and have a lower risk of damaging the ear.

Removal of grommets may be influenced by several factors, including the patient's discomfort, the frequency of and time between episodes, family concerns, and the weighing of risk of performing surgery dependant on the child's age and any comorbidities, versus the potential risks of repeat ear infections. There was a lack of evidence regarding how many recurrent episodes of otorrhoea would indicate the need for removal of grommets. However, based on their knowledge and experience, the committee felt that recurrent otorrhoea is of high concern because repeat infections have an ototoxic effect and the potential to damage the eardrum. They

therefore recommended grommet removal when otorrhoea was persistent and unresponsive to topical antibiotics.

How the recommendations might affect practice

Advice about water precautions are in line with current practice. Current practice around ear drops is varied, so the recommendation could represent a change in practice for some units. As non-ototoxic topical antibiotic-containing ear drops are an effective low-cost intervention, they would be likely to represent a cost-effective use of NHS resources.

Return to recommendations

Follow up after surgical treatment

Recommendations 1.6.11 to 1.6.14

Why the committee made the recommendations

The committee agreed, based on their knowledge and expertise, that postoperative hearing tests should be done 6 weeks after surgery. This allows sufficient time for postoperative bleeding to resolve, and is an opportunity to check if grommets have fallen out early. The committee acknowledged that it is important to detect potential complications of surgery as soon as possible, particularly hearing loss.

Children may still experience hearing loss after grommet interventions, as hearing loss can return when grommets fall out. In the committee's experience, grommets tend to fall out between 6 to 18 months after surgery, with most falling out about 6 months after surgery. However, children, parents and carers or teachers may not necessarily know when a grommet falls out, so children may be at risk of further unidentified hearing loss from about 6 months after surgery. In the committee's experience, hearing loss is not always identified by parents and schoolteachers. Therefore the committee agreed that it may be helpful to have a routine 1-year follow up with a hearing test (for example, audiogram) to pick up any children with hearing loss that may not be obvious. Having a routine 1-year follow-up for every child after grommet surgery is important for reducing the risk of inequality that may otherwise occur from relying on families to identify and raise concerns. It may also be an

opportunity to identify other potential complications after grommet surgery, such as perforation of the tympanic membrane.

Some children could be at increased risk of having unrecognised OME with hearing loss; for example, cognitive or communication difficulties may mean that hearing loss is not identified. The committee agreed that after surgery an individualised follow-up plan should be considered for these groups.

The committee recommended that parents and carers should have the opportunity to contact audiology services to discuss the need for further hearing assessment for their child if they are concerned about recurrence of hearing loss after surgery. This would remove potential barriers, such as needing to go through GP referral.

Because of a lack of evidence, the committee also made a recommendation for research on follow-up strategies after surgical treatment for OME-related hearing loss in children under 12 years.

How the recommendations might affect practice

Post-operative hearing tests at 6 weeks after surgery are current practice. The recommendation for routine 1-year follow-up would represent a change in practice. It would lead to an increase in resources in places that currently discharge children from follow-up once it has been established that their hearing is normal but a decrease in resources for areas that currently have a 3 to 6 month (or more regular) follow-up. There was no clinical- or cost-effectiveness evidence to support routine 1-year follow-up, and this was reflected in the strength of the recommendation.

The recommendation for a more regular and individualised follow-up plan would be for a relatively small population, and so would not have a significant resource impact.

Current practice may be affected by the recommendation that parents have the opportunity to contact audiology services to discuss the need for further hearing assessment for their child. There is variation in practice, and audiology services may or may not accept direct referrals. For audiology services who do not currently accept direct referrals the recommendation may have a resource impact on staff or training. However, this would only be a subset of the population having surgery and it is therefore not anticipated to be a large resource impact. This change may also

reduce delays in identifying recurrent hearing loss and, therefore, appropriate interventions to address this and so avoid adverse consequences for the child and associated costs. The recommendation will give the flexibility for audiology service to accept direct referrals or to refer the child back to their GP if this is necessary.

Return to recommendations

Context

Otitis media with effusion (OME), also known as 'glue ear', is a common condition in early childhood. 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 while the effusion (fluid) is present, 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, for some children, it can persist or fluctuate and result in a hearing loss in one or both ears hearing loss at different levels. The associated hearing loss 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.

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. 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 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 and more appropriate for the individual child's needs. Advice can also be given to schools to help them support the needs of children with fluctuating or persistent hearing impairments caused by OME.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE webpage on ear, nose and throat conditions.

For details of the guideline committee see the committee member list.

Update information

March 2023

This guideline is an update of NICE guideline CG60 (published February 2008) and will replace it.

Recommendations are marked **[2023]** if the evidence has been reviewed.

Recommendations that have been changed without an evidence review

Some recommendations ending **[2008]** have been carried over from the previous version of the guideline. We have not reviewed the evidence for these recommendations. In some cases minor changes have been made – for example, to update links, or bring the language and style up to date – without changing the intent of the recommendation.