Diagnosis and management of childhood otitis media in primary care

Section 1: Introduction

1.1 The need for a guideline

In terms of morbidity in children managed in general practice, middle ear conditions are probably the most important relating to the upper respiratory tract, with 75% of all cases of acute otitis media (AOM) occurring in children under the age of 10 years. One in four children will have an episode of AOM at some time during the first 10 years of life with a peak incidence of diagnosis occurring between the ages of three and six years.¹ North American studies have suggested that the incidence is higher in children in the first two years of life.²⁻⁵ The prevalence of otitis media with effusion (OME), commonly referred to as glue ear, is very high. In one study, around 80% of children had OME at least once before the age of four.⁶

1.2 Remit of the guideline

This guideline provides recommendations based on current evidence for best practice in the management of acute otitis media and otitis media with effusion. It provides evidence about detection, management, referral and follow up of children with these conditions.

It excludes discussion of surgical management such as the insertion of grommets and does not address issues beyond childhood years. In addition, the needs of children with genetic or facial abnormalities are not considered.

This guideline is likely to be of interest to general practitioners (GPs), practice nurses, audiologists, paediatricians, otolaryngologists, audiological physicians, health visitors, social workers, public health physicians, users of services and all other professions caring for children.

1.3 Statement of intent

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor, following discussion of the options with the patient, in light of the diagnostic and treatment choices available. However, it is advised, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient’s case notes at the time the relevant decision is taken.

1.4 Review and updating

This guideline was issued in 2003 and will be considered for review as new evidence becomes available. Any updates to the guideline in the interim period will be noted on the SIGN website: www.sign.ac.uk
2.1 Definitions

Otitis media is the generic term for middle ear inflammation which can exist in an acute and chronic state and can occur with or without symptoms. Different management strategies require that this disease be classified clinically as acute otitis media (AOM) or otitis media with effusion (OME). However, these should be considered as end points in a spectrum of conditions, the distinction between which is often difficult to determine.

There is no agreed universal definition of AOM. The working definition in this document is inflammation of the middle ear of rapid onset presenting most often with local symptoms (the two most common being earache and rubbing or tugging of the affected ear) and systemic signs (fever, irritability and poor sleep for example). There may be a preceding history of upper respiratory symptoms including cough and rhinorrhea (see section 2.4).

Otitis media with effusion is defined as inflammation of the middle ear, accompanied by the accumulation of fluid in the middle ear cleft without the symptoms and signs of acute inflammation. OME is often asymptomatic and earache is relatively uncommon (see section 2.4).

2.2 History taking

The history and clinical assessment of children with symptoms, which may be associated with otitis media, are used to differentiate between AOM, OME and non-otological pathology.

The symptoms most associated with acute otitis media are fever, earache, irritability, otorrhoea, lethargy, anorexia and vomiting. These lack sensitivity or specificity for diagnosis particularly in children under two in which group the symptoms of earache, conjunctival symptoms and rhinorrhea are associated with AOM.

In the case of OME, there may be no history to indicate the presence of the disease. A relevant element to be elicited in the history includes information about disability in terms of hearing difficulty, together with information on social interaction, behaviour, function in the educational setting and speech and language development. Clumsiness and poor balance may also be relevant.

A history alone is not sufficient to diagnose otitis media.

2.3 Examination techniques

The diagnosis of middle ear pathology and the ability to distinguish between AOM and OME, especially in children, can be difficult. In addition to appropriate training, otoscopy requires the use of a high quality, well illuminated otoscope. Disposable speculae for otoscopes are preferable, otherwise they should be sterilised appropriately. It has been suggested that the sensitivity of a skilled validated otoscopist in detecting the presence of middle ear fluid should be 90%, with a specificity of 80%.

Clearly this level of accuracy may be difficult to achieve in general non-specialist practice. The sensitivity of otoscopy in diagnosing middle ear pathology may be increased by the use of pneumo-otoscopy, which helps in the differentiation of a healthy middle ear from one containing fluid, but this technique is not widely used in UK clinical practice. The available literature suggests that
the sensitivity of pneumo-otoscopy when compared with the finding of fluid at myringotomy will range from 87%-99% with a mean of 93%. The mean specificity was 78%. These figures appear to be very similar amongst Otolaryngologists, Paediatricians and Paediatric Nurse Practitioners. If pneumo-otoscopy is to become part of routine practice in the UK, this will have to involve the training of practitioners.

2.4 Diagnosis

2.4.1 DIAGNOSIS OF AOM

Acute otitis media is a purulent middle ear process and, as such, otoscopic signs and symptoms consistent with a purulent middle ear effusion in association with systemic signs of illness are required. Ear related symptoms may include earache, tugging or rubbing of the ear, irritability, restless sleep and fever. Children may also have a history of cough and rhinorrhea, symptoms which are reported to increase the risk of AOM. Earache, however, is the single most important symptom. Evidence level 2+,3,4

Otoscopic appearances typical of AOM include bulging tympanic membrane with loss of the normal landmarks, change in colour, (typically red or yellow) and poor mobility. Evidence level 2+

Systemic signs of illness with a middle ear effusion are not sufficient to make the diagnosis, and similarly, neither is the finding of an incidental effusion in an otherwise well patient.

It should be borne in mind that the typical symptoms and signs (see Table 1) may have resolved by perforation of the tympanic membrane and discharge of pus. Additionally, AOM may leave a middle ear effusion for a variable period of time following resolution of the acute symptoms - the two forms of otitis media should be considered part of a disease continuum. Evidence level 1+,4

2.4.2 PRESENTATION PATTERNS FOR CHILDREN WITH OME

Most children have middle ear effusions at some time during childhood but these are transient in the majority and often asymptomatic. There is a minority in whom effusions persist over months or years causing hearing loss which in turn potentially impairs speech development and educational performance. Boys are more susceptible to OME than girls, as are children in day care and those with older siblings. Rates of bilateral OME are twice as high during winter than summer. Common cold and OME are the most frequent diseases of infancy, characterised by a multifactorial pathogenesis. There is an association between OME and respiratory infections and there is likely to be a causal relationship between parental smoking and both acute and chronic middle ear disease in children. Newborns in neonatal intensive care units have a high incidence of OME, which is also more prevalent in the first than second year of life.

Some case control studies have shown that balance problems are significantly worse in children with persistent OME than in healthy children. Other studies do not show these associations. 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.

Otitis media with effusion may lead to a variable group of behavioural symptoms including clumsiness, inattentive behaviour, and speech or language development difficulties.

The evidence shows that there is only a weak association between OME in early life and slowed speech and language development in children under four years of age. Similarly, only a weak association between early OME and delay in expressive language development has been demonstrated.\textsuperscript{32, 35} Evidence level 2++,2+

More research is needed to show whether persistent OME causes language delay and/or behavioural problems, and whether early intervention is indicated.

2.4.3 DIAGNOSIS OF OME

In many studies OME is diagnosed if there is middle ear effusion on pneumatic otoscopy with no signs of acute inflammation. In practice, pneumatic otoscopy is not used in primary care. No evidence based studies were identified concerning the most commonly used primary care diagnostic tool - otoscopy (with or without tuning fork testing).

Evidence of middle ear effusion consists of the presence of either:

- at least two tympanic membrane abnormalities (abnormal colour such as yellow, amber, or blue; opacification other than due to scarring; and decreased or absent mobility) and/or
- otoscopy typically showing a retracted/concave tympanic membrane with a colour change (typically yellow or amber). Air bubbles or an air/fluid level may be present and, while not typical, fullness or bulging may be visualised. Pneumo-otoscopy will demonstrate reduced or absent mobility.

The main symptom associated with OME is hearing loss (see Table 1). However this hearing loss is often not identified in infants and young children.\textsuperscript{7} Evidence level 4

<table>
<thead>
<tr>
<th>Table 1: Diagnostic features of AOM and OME</th>
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<tbody>
<tr>
<td>Earache</td>
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<tr>
<td>AOM</td>
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<tr>
<td>OME</td>
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In most situations, the GP will have to depend on history and otoscopy for diagnosing otitis media.

2.5 Audiological evaluation

2.5.1 AUDIOMETRY

Where audiometry is required for assessment of hearing thresholds and middle ear function (not screening) it should be carried out by suitably trained personnel, in quiet surroundings and with the correct equipment. This is a very specialised procedure and practices should adhere to specific criteria regarding staff training, room size and background noise levels to guarantee accuracy. If GPs wish to conduct audiological evaluation within the surgery setting, they should have the appropriate equipment and suitably trained staff. This can be expensive and time consuming, so such cases may be better referred to a local Community Audiology Clinic or to a local hospital otolaryngology (ENT) outpatient department.

2.5.2 TYMPANOMETRY

Tympanometry is a very useful tool for diagnosis but is rarely used in the primary care setting in the UK.

Children who require hearing loss assessment should be referred to an audiologist.

Diagnosis and management of childhood otitis media in primary care
Section 3: Medical treatment

3.1 Acute Otitis Media

3.1.1 ANTIBIOTIC TREATMENT

There is wide variation in the use of antibiotics between doctors in different countries, from as low as 31% of cases with AOM in the Netherlands to as high as 98% in Australia and the United States. Over a 30 year period the number of well conducted studies is small for such a common condition. There have only been eight trials of an acceptable standard and most of these trials suffer from a number of defects. The number of children entered into these trials ranged from 142 to 536. Evidence level 1++,1+,1-

In the general practice-based studies, the numbers of cases entered per doctor ranged between four and 14. A typical GP will see about 20 children with AOM every year, so a notable proportion of children have been excluded. No information is available about patients who were excluded from these trials. Low recruitment rates indicate that the type of children entered into trials may only be those with mild to moderate symptoms and signs. This raises the issue of how to interpret results when applied to all children with symptoms and sign of AOM. Evidence level 1++,1+,1-

Another problem in assessing the evidence from clinical trials is that entry criteria vary considerably. Some studies based clinical diagnosis of AOM largely on the presence of acute earache and at least one abnormal eardrum, but two studies excluded children with perforated tympanic membranes and it was not clear if all children with bulging red drums were considered suitable for inclusion. Interpretation of the results is further complicated by the fact that five of the trials excluded children under two years of age. Evidence level 1++,1+,1-
one trial has studied antibiotic treatment in children under two years of age, but even this study excluded infants who “needed antibiotics according to the doctor”.\textsuperscript{40} \textit{Evidence level 1++,1+,1-}

A meta-analysis of antibiotic versus placebo trials shows that antibiotics do not influence resolution of pain within 24 hours of presentation. At two to seven days after presentation, only 14% of children in control groups still have pain, although early use of antibiotics reduces the risk of pain by about 40%.\textsuperscript{41} Antibiotics also reduce contralateral AOM but seem to have little influence on subsequent attacks of otitis media or deafness. Antibiotics are associated with a near doubling of the risk of vomiting, diarrhoea or rashes.\textsuperscript{17} \textit{Evidence level 1++,1+,1-}

A study of predictors of poor outcome found that in children with AOM but without fever and vomiting, antibiotic treatment had little benefit.\textsuperscript{44} The lack of antibiotic did not lead to a poor outcome. The simplest method to target the minority of children at higher risk of poor outcome would be to select for antibiotic treatment those children with systemic features (ie either high temperature or vomiting). Another study has found that antibiotic treatment may benefit infants and younger children with severe AOM.\textsuperscript{45} \textit{Evidence level 1++,1+,1-}

About 17 children with AOM would need to be treated with a broad spectrum antibiotic rather than no antibiotic treatment to avoid a clinical failure.\textsuperscript{35} \textit{Evidence level 1++,1+,1-}

An alternative to antibiotics is recolonisation with a streptococci which significantly diminishes the recurrence rate of AOM in susceptible children, but this is not currently a practical proposition in primary care in the UK.\textsuperscript{41} \textit{Evidence level 1++,1+,1-}

Antibiotics in comparison to placebo and observational treatment may have a modest benefit on symptom resolution and failure rates, as variously defined, in children over the age of two years with AOM. The available evidence on natural history of AOM shows that in studies with close follow up, very few episodes of mastoiditis or other suppurative complications are reported in children with AOM not initially treated with antibiotics.

**Children diagnosed with acute otitis media should not routinely be prescribed antibiotics as the initial treatment.**

3.1.2 DELAYED ANTIBIOTIC TREATMENT

In a delayed treatment trial, 315 children aged six months to 10 years were allocated to one of two treatment strategies: immediate antibiotic or delayed antibiotic (antibiotic to be collected at parents’ discretion after 72 hours if the child has not improved).\textsuperscript{48} The outcome measures were symptom resolution, absence from nursery or school and paracetamol consumption. The main conclusions from this trial were that: \textit{Evidence level 1+}

- immediate antibiotics provided symptomatic benefit mainly after the first 24 hours, when symptoms were already resolving
- immediate antibiotics increased the incidence of diarrhoea by 10%
- only 24% of the parents in the delayed prescription group used antibiotics
- a “wait and see” approach in the management of AOM is feasible and acceptable to most parents and results in a 76% reduction in the use of antibiotic prescriptions. \textit{Evidence level 1+}
A large number of children with presumed AOM are seen by out-of-hours services. Given that follow up by the child’s own GP is unlikely to be delayed by more than a few hours, adequate analgesia plus a “wait and see” approach is reasonable as opposed to automatic recourse to antibiotic treatment.

**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.

### 3.1.3 CHOICE AND DURATION OF ANTIBIOTIC THERAPY

A large number of studies have established that, where organisms have been isolated from the middle ear, two organisms, *Streptococcus pneumoniae* and *Haemophilus influenzae*, are the principal aetiological agents in bacterial infection. Occasionally *Moraxella catarrhalis* can be isolated.

With *S. pneumoniae* and *H. influenzae*, broad spectrum antibiotics such as amoxicillin, or amoxicillin with clavulanic acid, are the drugs of choice if an antibiotic is to be used. Cefaclor, cotrimoxazole, trimethoprim and erythromycin can be effective, but are less safe than amoxicillin.

The optimal duration of treatment is not known and varies worldwide, with 50% of GPs prescribing a five day course in the UK, and the majority of doctors who treat AOM in the Netherlands using a six to seven days’ duration of antibiotic therapy. In North America the standard duration of treatment is recommended as 10 days.

A Cochrane review of duration of treatment found that five days of antibiotic is an effective treatment of uncomplicated ear infections in children. The optimum duration of treatment for infants and very young children and for children with severe AOM, has yet to be established. Some UK based general practice studies have shown that short course treatment (two to three days’ antibiotic) at conventional or high dose levels is as effective as the traditional five day course in children aged three or older, but in view of the small number of studies of two to three days’ treatment, the conventional five day course is recommended at dosage levels indicated in the British National Formulary. Evidence level 1+

**If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary.**

### 3.1.4 DECONGESTANTS, ANTIHISTAMINES AND MUCOLYTICS

A Cochrane review of the efficacy of decongestant and antihistamine therapy for AOM examined a total of 13 RCTs published between 1993 and 2000, involving 2,569 patients. A meta-analysis of these studies was performed. For the combined control groups, healing rates at two weeks were high, with rates of persistent AOM <23%. No additional benefit was demonstrated in intervention subgroups. Only the combined decongestant and antihistamine treatment group demonstrated statistically lower rates of persistent AOM at the two week period. No benefit was found for other outcomes including early or late cure rates, symptom resolution, prevention of surgery or other complications. There was an increased risk of medication side effects for those receiving an intervention, which reached statistical significance for the “any medication” and decongestant groupings. Evidence level 1++
Given the lack of benefit and increased risk of side effects, these data do not support the use of decongestant, antihistamine, or combined decongestant and antihistamine treatment in children with AOM. The small statistical benefit found in the combination medication group is of small clinical significance. No evidence to support the use of mucolytics for AOM was found.

**Children with acute otitis media should not be prescribed decongestants or antihistamines.**

3.1.5 ANALGESICS

One study of the efficacy of paracetamol for AOM has been identified. The original study was flawed and relied on a parental pain observation scale. Recalculation from the original figures showed a statistically significant benefit for the use of paracetamol. Although non-steroidal anti-inflammatory drugs are frequently used by parents, caution should be exercised because of the side effect profile. *Evidence level 1+*

**Parents should give paracetamol for analgesia but should be advised of the potential danger of overuse.**

3.1.6 OILS

Two RCTs have been identified and both show no benefit of inserting oils in reducing pain in AOM. *Evidence level 1+*

**Insertion of oils should not be prescribed for reducing pain in children with acute otitis media.**

3.1.7 HOMEOPATHY

There were no good quality trials identified in the treatment of AOM with homeopathy. One trial was identified as a randomised controlled study between antibiotic and homeopathic treatment. This study claimed marginal benefits for the homeopathically treated group but was poorly constructed with limited randomisation and very unequal group sizes. *Evidence level 1-

With a lack of robust evidence no recommendation can be made regarding the use of homeopathy in the treatment of AOM.

3.2 Otitis Media with effusion

3.2.1 ANTIBIOTIC TREATMENT

There is an extensive literature on the role of antibiotics in the management of OME but relatively few RCTs. Many of the available RCTs are comparison of one antibiotic with another rather than on the overall effectiveness of antibiotics on the condition. The evidence for the effectiveness of antibiotics is conflicting with some claiming substantial benefits and others not demonstrating benefit. Several meta-analyses of varying quality have been produced, again with conflicting conclusions.

On balance, the better conducted trials suggest short term benefit from antibiotics but this appears to be very short lived (two to four weeks). Two American systematic reviews
suggest benefit at one month but there is no evidence of benefit beyond this. A third meta-analysis of eight RCTs suggests no benefit from the particular antibiotic used. The particular antibiotic used does not seem material to this beneficial effect and the duration of treatment is also not relevant. The overall results suggest that there may be some benefit from antibiotics in the short term and the three reviews are not consistent. 

Evidence level 1-

This very common condition may be managed in a wide variety of ways ranging from observation to the prescription of relatively expensive antibiotics for long periods of time. The magnitude of the beneficial effect is small and the incidence of side effects including diarrhoea, skin rashes, allergy development, anaphylaxis and development of resistant strains of organism is considerable.

The short term benefits which appear to be scientifically demonstrable are not sufficient reason to recommend blanket prescription of antibiotics for this condition.

Children with otitis media with effusion should not be treated with antibiotics.

3.2.2 DECONGESTANTS, ANTIHISTAMINES AND MUCOLYTICS

One systematic review was identified which considered four RCTs dealing with antihistamines and decongestants but reporting on a heterogeneous patient group. A further RCT investigating the use of inhaled antihistamine in a Japanese population (age range: 5-38) was also examined. The studies considering intervention with antihistamines and/or decongestants showed no convincing benefits from the intervention on middle ear effusion clearance rate. Evidence level 1++,1+

With regard to mucolytic therapy, one systematic review comparing S-carboxymethylcysteine, its lysine salt or both versus placebo or no treatment was identified. This review included trials with many confounding variables and concluded that there is no significant positive benefit of treatment compared to placebo. A more recent RCT considered the role of S-carboxymethylcysteine versus placebo in reducing the need for surgery in patients with persistent OME. This study did not show sufficient evidence to promote the routine use of mucolytics. Evidence level 1+,1-

There is no evidence to support the routine use of antihistamines, decongestants or mucolytics in the management of OME, especially considering the potential adverse side effects.

Decongestants, antihistamines or mucolytics should not be used in the management of otitis media with effusion.

3.2.3 STEROIDS

One Cochrane review has been identified. Trials considered were heterogeneous, with initial diagnostic criteria, intervention and outcome measures being variable. Four comparisons were undertaken: Evidence level 1+

Oral steroids versus control (placebo or non-intervention control)

The review identified three RCTs and concluded that there is no significant difference in improvement between the groups after two weeks of treatment. Evidence level 1+
Oral steroids plus antibiotics versus control plus antibiotic

Steroids combined with an antibiotic lead to a quicker resolution of OME in the short term. However, there is no evidence for long term benefit from treating hearing loss associated with OME with either oral or topical nasal steroids. *Evidence level 1+*

Intranasal steroid versus control

One study was included in the review and showed no benefit. *Evidence level 1+*

Intranasal steroid plus antibiotic versus control plus antibiotic or antibiotic alone

One RCT studied the effects of intranasal steroids in combination with antibiotics. This demonstrated an effect in clearing middle ear effusions at four and eight weeks, with a less marked effect at 12 weeks although at this time there was remaining evidence of improved middle ear pressure in those treated with intranasal steroids and antibiotics compared with either antibiotics alone or placebo nasal spray. *Evidence level 1+*

This systematic review compared its results with two previous reviews.32, 66 Although varying improvement rates were reported, all three reviews have concluded that they could not recommend the use of steroids in OME. *Evidence level 1+*

**The use of either topical or systemic steroid therapy is not recommended in the management of children with otitis media with effusion.**

3.2.4 AUTOINFLATION

One review that considered six RCTs has been identified.67 The evidence from this review is conflicting, but does suggest that there may be some clinical benefit. However, young children may find autoinflation devices difficult to use and trials suggest that improvement is best if there is a high level of compliance. *Evidence level 1-

In addition, the evidence is of poor quality as different methods of inflation were used, assessors were not blinded to the treatment, study numbers were small and the follow up period was short. *Evidence level 1-

**Autoinflation may be of benefit in the management of some children with otitis media with effusion.**

3.2.5 HOMEOPATHY

There is very little high quality literature available on the role of homeopathy in the management of OME. One RCT comparing homeopathic and “standard care” for treatment of OME was identified.68 The study size was small and randomisation was not concealed. No conclusive effects were demonstrated. *Evidence level 1-

There is no evidence available to make any recommendations regarding the role of homeopathy in the management of OME.
4.1 Initial follow up

4.1.1 FOLLOW UP FOR AOM

The natural history of AOM is for spontaneous resolution in most cases. The possibility exists for incomplete resolution and the development of a longstanding effusion, or a chronic perforation with or without discharge. It is difficult to visualise the tympanic membrane of a discharging ear, so these patients should be re-examined after two weeks. If a perforated drum is visible at this stage further GP review is required. Patients with persisting problems should be referred to an otolaryngologist (see section 4.2.1).

4.1.2 FOLLOW UP FOR OME

As OME is a condition which is well recognised to relapse and remit during its natural history until resolution occurs, commonly around the age of seven to eight years, the observation that the effusion has cleared and the hearing has reverted to normal does not necessarily imply that the child will have no further problems. The strategy of watchful waiting has been developed before taking a decision about surgical intervention. Underpinning this is the concept that a single observation of the child does not permit an assessment of the severity of the condition which varies with time. A child diagnosed with OME should be observed for a period in order to assess severity and disability and evaluate the need for referral for an opinion within the secondary care services. This can be done in the primary care setting by regular review of history of symptoms from parents, teachers and speech and language therapist if appropriate. Otoscopy and, if facilities for accurate testing are available, audiometry and tympanometry, may be needed. A regular review within the primary care setting is advisable. Two or three monthly visits may be necessary before the picture becomes clear and the need for referral established.

4.2 Referral

4.2.1 REFERRAL FOR AOM PATIENTS

No studies were identified concerning when AOM patients should be referred. The pilot National Institute for Clinical Excellence (NICE) referral advice recommends referral for frequent episodes of AOM, which is defined as more than four episodes in six months. An American guideline recommends referral for more than three episodes in six months, or more than four episodes in 12 months. Neither the PRODIGY guideline (www.prodigy.nhs.uk) nor New Zealand Guideline Group (www.nzgg.org.nz) make any recommendation on referral for AOM. Evidence level 4

Given the absence of evidence better than expert opinion and the minor differences between previous guidelines, the NICE recommendation has been adopted.

Complications of AOM such as mastoiditis or facial nerve paresis require referral.

Children with frequent episodes (more than four in six months) of acute otitis media, or complications, should be referred to an otolaryngologist.
4.2.2 REFERRAL FOR OME PATIENTS

No studies on the referral of OME patients were identified. The evidence from three trials comparing early grommet insertion with delayed surgery/watchful waiting may be helpful in making referral decisions. *Evidence level 1++,1+

One American RCT (429 patients) of early versus delayed grommet insertion in children under three with mild to moderate hearing loss and OME showed that early surgery gave no benefit in terms of language development, speech sound production, cognition or behaviour.72 *Evidence level 1++,1+

Another RCT conducted in the Netherlands studied 182 children, under three years of age, who had failed a hearing test but were otherwise asymptomatic.73 Again no benefit with early surgery was demonstrated. *Evidence level 1++,1+

A UK study looking at behaviour and language development showed that early surgery gave marginally significant benefits in language development at nine months. Early surgical intervention significantly reduced behavioural problems by 17%. This difference was largely mediated by concurrent hearing loss. After 18 months, there was no longer a significant difference. However, the majority (85%) of the watchful waiting group had required surgery and 22% of all children still had behavioural problems.74,75 The conclusion was that there is some benefit from ventilation-tube insertion for expressive language and verbal comprehension but that the timing of surgery is not critical. *Evidence level 1++,1+

For children under three with OME and mild to moderate hearing loss (=<25 dB) and no other problems, there is consistent evidence that watchful waiting is as good as early surgery.72,73 It should be noted that the children in these trials all underwent audiometry to exclude a more serious degree of hearing loss.

The trial showing benefits from early surgery included children over three and those with behavioural or language problems.74,75 Accordingly, children with persistent OME over the age of three years, or with language, behavioural or developmental problems should be referred.

**A** Children under three years of age with persistent bilateral otitis media with effusion and hearing loss of =<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.

**B** 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.