



Diagnosis and management of childhood otitis media in primary care

A national clinical guideline

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KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

LEVELS OF EVIDENCE

1 ⁺⁺	High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1 ⁺	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 ⁻	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2 ⁺⁺	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2 ⁺	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 ⁻	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

GRADES OF RECOMMENDATION

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A	At least one meta-analysis, systematic review of RCTs, or RCT rated as 1 ⁺⁺ and directly applicable to the target population; <i>or</i> A body of evidence consisting principally of studies rated as 1 ⁺ , directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2 ⁺⁺ , directly applicable to the target population, and demonstrating overall consistency of results; <i>or</i> Extrapolated evidence from studies rated as 1 ⁺⁺ or 1 ⁺
C	A body of evidence including studies rated as 2 ⁺ , directly applicable to the target population and demonstrating overall consistency of results; <i>or</i> Extrapolated evidence from studies rated as 2 ⁺⁺
D	Evidence level 3 or 4; <i>or</i> Extrapolated evidence from studies rated as 2 ⁺

GOOD PRACTICE POINTS

<input checked="" type="checkbox"/>	Recommended best practice based on the clinical experience of the guideline development group
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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 Clinical assessment

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.⁷

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 rhinorrhoea (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).⁸

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 rhinorrhoea 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%.⁹ 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.¹⁰ 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.¹¹⁻¹⁶ 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.¹¹ Earache, however, is the single most important symptom.

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Otosopic appearances typical of AOM include bulging tympanic membrane with loss of the normal landmarks, change in colour, (typically red or yellow) and poor mobility.¹³

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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.¹⁶ 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.^{7,17,18}

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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.¹⁹ 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.^{20,21}

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Boys are more susceptible to OME than girls, as are children in day care and those with older siblings.²² Rates of bilateral OME are twice as high during winter than summer.²³ Common cold and OME are the most frequent diseases of infancy, characterised by a multifactorial pathogenesis.²⁴ There is an association between OME and respiratory infections²⁵ and there is likely to be a causal relationship between parental smoking and both acute and chronic middle ear disease in children.^{22,26,27} 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.²⁸

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Some case control studies have shown that balance problems are significantly worse in children with persistent OME than in healthy children.^{29,30} Other studies do not show these associations.³¹⁻³⁴

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B 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.^{32,35}

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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.⁷

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Table 1: Diagnostic features of AOM and OME

	Earache Fever Irritability	Middle ear effusion	Opaque drum	Bulging drum	Impaired drum mobility	Hearing loss
AOM	present	present	present	may be present	present	present
OME	usually absent	present	may be absent	usually absent	present	usually present

- 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.

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.¹⁴ 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.^{17,18,36-41} The number of children entered into these trials ranged from 142 to 536.

In the general practice-based studies, the numbers of cases entered per doctor ranged between four and 14.⁴² 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.

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.^{17,18,37,38,41} Only 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”.⁴⁰

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%.⁴³ 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.¹⁷

A study of predictors of poor outcome found that in children with AOM but without fever and vomiting, antibiotic treatment had little benefit.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.⁴⁵

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.⁴⁶

An alternative to antibiotics is recolonisation with α 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.⁴⁷

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.

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

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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).⁴⁸ The outcome measures were symptom resolution, absence from nursery or school and paracetamol consumption. The main conclusions from this trial were that:

- 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.

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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.

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

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.⁴⁹ 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.⁵⁰

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.⁵¹ 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,^{52,53} 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.⁵⁴

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B **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

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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.⁵⁵

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.

A 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.⁵⁶ 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.

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D 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.^{57,58}

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B 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.⁵⁹ This study claimed marginal benefits for the homeopathically treated group but was poorly constructed with limited randomisation and very unequal group sizes.

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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.^{32,60} A third meta-analysis of eight RCTs suggests no benefit from the particular antibiotic used.⁶¹ 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.

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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.

D 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.³² A further RCT investigating the use of inhaled antihistamine in a Japanese population (*age range: 5-38*) was also examined.⁶² The studies considering intervention with antihistamines and/or decongestants showed no convincing benefits from the intervention on middle ear effusion clearance rate.

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With regard to mucolytic therapy, one systematic review comparing S-carboxymethylcysteine, its lysine salt or both versus placebo or no treatment was identified.⁶³ 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.⁶⁴ This study did not show sufficient evidence to promote the routine use of mucolytics.

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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.

B 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.⁶⁵ Trials considered were heterogeneous, with initial diagnostic criteria, intervention and outcome measures being variable. Four comparisons were undertaken:

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.

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.

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Intranasal steroid versus control

One study was included in the review and showed no benefit.

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.

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.

B 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.

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.

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

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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.

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

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4 Follow up and referral

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.⁶⁹ 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.⁷⁰ An American guideline recommends referral for more than three episodes in six months, or more than four episodes in 12 months.⁷¹ Neither the PRODIGY guideline (www.prodigy.nhs.uk) nor New Zealand Guideline Group (www.nzgg.org.nz) make any recommendation on referral for AOM.

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.

D 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.

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

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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.

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.

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.

5 Implementation and audit

5.1 LOCAL IMPLEMENTATION

Implementation of national clinical guidelines is the responsibility of each NHS Board and is an essential part of clinical governance. It is acknowledged that every Trust cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

5.2 KEY POINTS FOR AUDIT

Management of acute otitis media:

- well defined practice policy about use of antibiotics and yearly review of antibiotic prescription rate for children with AOM are in place
- only proven treatments are used.

Referral criteria:

- criteria for referral for hearing and other assessments are available
- admission rates with reference to referral criteria are monitored
- follow up of children with hearing problems and those who have had operative intervention such as insertion of grommets is taking place.

6 Patient issues

6.1 INFORMATION FOR PARENTS, TEACHERS AND CARERS

Parents, teachers and carers should be aware that AOM and OME are particularly common in preschool children. In most cases they are transient episodes, however they can be recurrent and variable in presentation, and carers should be given clear information by primary care professionals of the circumstances requiring further attendances.

In cases where hearing loss is suspected or apparent, the following advice about basic communication is useful, making listening easier for the child and also reducing difficulties with adult interactions:

- Basic communication tips:
 - face the child when speaking
 - get the child's attention before starting to talk
 - background noise should be reduced as much as possible
 - speech should be clear with normal rhythm and volume.

Playgroup leaders, nursery or school teachers should be informed if a child has a hearing loss so that they can facilitate activities in class. This setting is often a difficult environment in terms of background noise and the child may be unwilling to highlight any difficulties in front of his or her peers.

The organisations listed in section 6.2 can provide patient information leaflets on otitis media and deaf awareness, either by post or on their websites.

6.1.1 ADVICE ON PARENTAL SMOKING

One large, rigorous cohort study,²² one small cohort study²⁷ and one meta-analysis²⁶ of 12 cohort and case control studies demonstrate an association between parental smoking and OME. The large cohort study showed a marked dose-dependent effect. The association persists after allowing for bias by social class.

2⁺⁺
2⁺

- B** Parents of children with otitis media with effusion should be advised to refrain from smoking.

6.1.2 ADVICE ON BREASTFEEDING

A large cohort study looked at the relationship between breastfeeding and OME.²² This one study on breastfeeding shows a protective effect. This is consistent with other proven anti-infective benefits of breastfeeding.

2⁺⁺

- C** Parents should be advised that breastfeeding may reduce the risk of their child developing otitis media with effusion.

6.1.3 ADVICE ON SWIMMING AND BATHING FOLLOWING GROMMET INSERTION

The effect of swimming on otorrhea after grommet surgery is more difficult to research and the only RCT identified was flawed in that 33% of patients randomised to 'non-swimming' chose to swim anyway.⁷⁶

1⁻

A later cohort study found no relationship between swimming and otorrhea.⁷⁷

2⁺

- C** Grommet insertion is not a contraindication to swimming.

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

6.2 LIST OF USEFUL CONTACT DETAILS

Defeating Deafness The Hearing Research Trust

330-332 Gray's Inn Road, London WC1X 8EE

Tel: 020 7833 1733 Text: 020 7915 1412 Fax: 020 7278 0404

Email: defeating.deafness@ucl.ac.uk

Defeating Deafness Information Service:

Freephone: 0808 808 2222

Website: www.defeatingdeafness.org

The National Deaf Children's Society

15 Dufferin Street, London EC1Y 8UR

Switchboard: 020 7490 8656 Information & Helpline: 020 7250 0123 Fax: 020 7251 5020

Website: www.ndcs.org.uk

The National Deaf Children's Society Scotland

293-295 Central Chambers, 93 Hope Street, Glasgow G2 6LD

Voice/Text: 0141 248 2429 Fax: 0141 248 2597

NHS 24

NHS 24 is a 24 hour nurse-led helpline providing confidential healthcare advice and information. This service will be available across Scotland in 2003.

Tel: 08454 24 24 24

Website: www.nhs24.com

Patient information sheets

Prepared by Mr Haytham Kubba using an evidence based technique have been awarded a Crystal Mark for clarity by the Plain English Campaign.

Website: www.orl-baohns.org/members/frameset.html

The Royal National Institute for Deaf People

19-23 Featherstone Street, London EC1Y 8SL

Tel: 0808 808 0123 Text: 0808 808 9000 Fax: 020 7296 8199

Website: www.rnid.org.uk

Royal College of Speech and Language Therapists

2 White Hart Yard, London SE1 1NX

Tel: 020 7378 3004 Fax: 020 7403 7254

Website: www.rcslt.org

British Association of Teachers of the Deaf

Website: www.batod.org.uk

7 Development of the guideline

7.1 INTRODUCTION

SIGN is a collaborative network of clinicians, other healthcare professionals, and patient organisations funded by the Scottish Executive Health Department. SIGN guidelines are developed by multidisciplinary groups of practising clinicians using a standard methodology based on a systematic review of the evidence. Further details about SIGN and the guideline development methodology are contained in "SIGN 50: A Guideline Developer's Handbook" available at www.sign.ac.uk

7.2 THE GUIDELINE DEVELOPMENT GROUP

Professor John Bain <i>Chairman</i>	<i>Professor of General Practice, Tayside Centre for General Practice, University of Dundee</i>
Dr Patricia Townsley <i>Secretary</i>	<i>Staff Grade in Community Paediatrics, Yorkhill NHS Trust, Glasgow</i>
Miss Karen Boyle	<i>Audiologist, Royal Hospital for Sick Children, Glasgow</i>
Mr John Dempster	<i>Consultant Otolaryngologist, Crosshouse Hospital, Kilmarnock</i>
Dr Ali El-Ghorr	<i>Programme Manager, SIGN</i>
Dr Peter Ewing	<i>General Practitioner, Crieff</i>
Mr Neil Geddes	<i>Consultant Otolaryngologist, Royal Hospital for Sick Children, Glasgow</i>
Dr Ann MacKinnon	<i>Senior Clinical Medical Officer (Paediatric Audiology), Tayside University Hospitals NHS Trust, Dundee</i>
Dr Adrian Margerison	<i>Community Paediatrician, Borders General Hospital, Roxburghshire</i>
Mr William McKerrow	<i>Consultant Otolaryngologist, Raigmore Hospital NHS Trust, Inverness</i>
Dr Neil Sabiston	<i>General Practitioner, Lossiemouth</i>
Dr Gavin Stark	<i>General Practitioner, Aberdeen</i>

The membership of the guideline development group was confirmed following consultation with the member organisations of SIGN. Declarations of interests were made by all members of the guideline development group. Further details are available from the SIGN Executive.

7.3 SYSTEMATIC LITERATURE REVIEW

A thorough literature search was undertaken in Medline, Embase, and Healthstar to obtain material from 1985 to 1999 inclusive. Internet searches on key websites were also conducted and passed on to the group. Additional references were identified by group members and peer reviewers. All material was assessed and evidence synthesised in accordance with SIGN methodology. Material not deemed to be of sufficient quality was discarded.

7.4 ACKNOWLEDGEMENTS

Ms Joanne Topalian	<i>Programme Manager, SIGN</i>
Mr Alex Haig	<i>Information Officer, Edinburgh</i>
Ms Ann Marie Newall	<i>Former member of the group and Ward Sister, Monklands Hospital, Lanarkshire</i>

7.5 CONSULTATION AND PEER REVIEW

7.5.1 NATIONAL OPEN MEETING

A national open meeting is the main consultative phase of SIGN guideline development, at which the guideline development group presents its draft recommendations for the first time. The national

open meeting for this guideline was held on 15 November 2001 and was attended by 80 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline. The comments received from the national open meeting were considered when the guideline was redrafted for peer review.

7.5.2 SPECIALIST REVIEWERS INVITED TO COMMENT ON THIS DRAFT

The guideline was also reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. SIGN is very grateful to all of these experts for their contribution to this guideline.

Dr Alan Begg	<i>General Practitioner, Montrose</i>
Professor George Browning	<i>MRC Institute of Hearing Research, Glasgow</i>
Professor Mark Haggard	<i>Director, MRC Institute of Hearing Research, Nottingham</i>
Mrs Susan Howden	<i>Speech and Language Therapy Centre for Child Health, Dundee</i>
Professor Paul Little	<i>Professor in Primary Care, Alderbrook Health Centre, Southampton</i>
Dr Richard Maw	<i>Consultant Otolaryngologist, Bristol Royal Hospital For Children</i>
Dr Allan Merry	<i>General Practitioner, Ardrossan</i>
Dr Robert Mills	<i>Consultant Otolaryngologist, University of Edinburgh</i>
Dr Paddy O'Neill	<i>General Practitioner, Norton Medical Centre, Stockton on Tees</i>
Dr Jack Paradise	<i>Department of Pediatrics, University of Pittsburgh School of Medicine, Pennsylvania</i>
Dr Ian Williamson	<i>Senior Lecturer in Primary Medical Care, Southampton University</i>

7.5.3 SIGN EDITORIAL GROUP

As a final quality control check, the guideline is reviewed by an Editorial Group comprising the relevant specialty representatives on SIGN Council to ensure that the peer reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. The Editorial Group for this guideline was as follows:

Dr David Alexander	<i>British Medical Association Scottish General Practice Committee</i>
Mrs Hilary Hood	<i>Speech and Language Therapy Department, Centre for Child Health, Dundee, representing Allied Health Care Professions</i>
Professor Gordon Lowe	<i>Chairman of SIGN; Co-Editor</i>
Dr Chris Kelnar	<i>Royal College of Paediatrics & Child Health</i>
Dr Lesley MacDonald	<i>Faculty of Public Health Medicine</i>
Dr Safia Qureshi	<i>SIGN Programme Director; Co-Editor</i>
Dr Sara Twaddle	<i>Director of SIGN; Co-Editor</i>
Dr Bernice West	<i>National Nursing Midwifery and Health Visiting Advisory Committee</i>

Each member of the guideline development group then approved the final guideline for publication.

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This Quick Reference Guide provides a summary of the main recommendations in the SIGN guideline on the diagnosis and management of childhood otitis media in primary care. The aim of this national guideline is to provide guidance about detection, management, referral and follow up of children with these conditions.

In terms of morbidity in children 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. The prevalence of otitis media with effusion (OME), commonly referred to as glue ear, is very high (around 80% of children are reported to have OME at least once before the age of four) and this condition has important implications for child development.

DEFINITIONS

AOM: 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 rhinorrhoea.

OME: 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.

CLINICAL ASSESSMENT

- In most situations, the GP will have to depend on history and otoscopy for diagnosing otitis media.
- Children who require hearing loss assessment should be referred to an audiologist.

Diagnostic features of AOM and OME

	Earache Fever Irritability	Middle ear effusion	Opaque drum	Bulging drum	Impaired drum mobility	Hearing loss
AOM	present	present	present	may be present	present	present
OME	usually absent	present	may be absent	usually absent	present	usually present

TREATMENT FOR AOM

In the majority of cases AOM is a self limiting condition.

Antibiotics for AOM

- B** Children diagnosed with acute otitis media should not routinely be prescribed antibiotics as the initial treatment.
- B** If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary.

Decongestants, antihistamines and mucolytics

- A** Children with AOM should not be prescribed decongestants or antihistamines.

Analgesics

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

Oils

- B** Insertion of oils should not be prescribed for reducing pain in children with AOM.

Homeopathy

There is insufficient evidence available to recommend homeopathy in the management of AOM (or OME).

REFERRAL FOR AOM PATIENTS

- D** Children with frequent episodes (*more than four in six months*) of AOM, or complications, should be referred to an otolaryngologist.

TREATMENT FOR OME

In the majority of cases OME is a self limiting condition.

Antibiotics for OME

- D** Children with otitis media with effusion should not be treated with antibiotics.

Decongestants, antihistamines and mucolytics

- B** Decongestants, antihistamines or mucolytics should not be used in the management of OME.

Steroids

- B** The use of either topical or systemic steroid therapy is not recommended in the management of children with OME.

Autoinflation

- D** Autoinflation may be of benefit in the management of some children with OME.

REFERRAL FOR OME PATIENTS

- A** Children under three years 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.

ACUTE OTITIS MEDIA

April 1998

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Purpose of the Guideline

Presented here are the guideline and the working papers used in its development. This effort originated as an educational exercise for a number of Hawkes Bay GPs and practice nurses in the latter part of 1997. Subsequently, there has been some feedback from Randall Morton, Bruce Arroll and Tim Kenealy. All of this material is presented.

Clearly, the guideline is unfinished – a number of discussions have emerged from it which, to resolve, would take almost as much effort as the original work. Life and its tasks, however, moves on and I am currently not resourced with time or funds to continue this journey at this time.

One of the important lessons about guideline development work, for me, is that a satisfactory conclusion needs to be properly resourced and the work involved is much greater than would initially appear. Indeed, the draft guideline is just a beginning. However, the material and the ensuing discussion is offered in the interests of stimulating debate and in the anticipation that others will build on it.

Stuart Foote

About the Guideline

Guideline Documentation

Clinical Topic:

Treatment of acute otitis media in general practice.

Population Addressed:

General practice patients aged 2 months to 15 years, otherwise healthy, living in Western "first world" communities.

Sponsoring Body:

Hawkes Bay Independent Practitioners Association, "Paradigm"

Date of Inception:

August 1997

Most Recent Update:

August 1997

Review Date:

August 2000 or earlier if necessary

Process of Development:

The guideline development team used an explicit evidence-based process to develop the guideline and to estimate the impact on health care outcomes for the Paradigm patient population

Measurement Plan:

No system of clinical data capture is currently in place to allow regular monitoring of the management of acute otitis media.

Team Composition:

Stuart Foote, Medical Director of Paradigm, guideline convener.

Bobi Munro, Nursing Director of Paradigm. *Practice Nurses GPs Paediatrician*

Marg Estcourt, PN; Stewart Drysdale, GP; Oliver Smales, Paediatrician; Joanne Watson, consumer;

Carol Pryce, PN; Gael Donald, GP; Dixie Reo, Maori consumer;

Cheryl Pierson, PN; Liz Whyte, GP; Bev Penny, consumer;

Joanne Roe, PN; Tim O'Donovan, GP; Carol Whatuira, Maori consumer;

Liz Dixon, GP; John Kerr, GP; Peter Stormer, GP; Tim Mason, GP; Paddy O'Brien, GP

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Guideline Information

Guideline

Early, empiric treatment of acute otitis media with antibiotics provides only modest benefit and causes a similar occurrence of antibiotic induced side effects.

It is recommended that parents of children with acute otitis media are given information about

- the benefits (NNT for less pain at 2-7 days = 17), and
- risks (NNT for vomiting, diarrhoea and rash = 17)

of antibiotic therapy. A shared decision-making approach to antibiotic therapy can then be followed.

The presence of other indications for antibiotic therapy should be taken into consideration in advising parents. Also, because of concerns about the generalisability of the evidence to Maori, Polynesian and poorer socio-economic groups, additional caution may be advised in withholding antibiotics from these groups.

If antibiotics are to be used, amoxicillin or cotrimoxazole are as effective as any other antibiotic, have a good safety profile and are cheaper. Of the two, amoxicillin may be marginally safer. Pain relief such as paracetamol or ibuprofen should be offered.

It is recommended that parents are advised to seek further advice if, after 48 hours, the child has persisting symptoms or is still unwell.

As otitis media with effusion (OME) is a consequence of and not a complication of acute otitis media, follow up in less than one month may lead to inappropriate therapy for OME. Therefore children with AOM should be reviewed in one month.

Evidence Summary

Definitions

Myringitis: Erythema of the tympanic membrane without MEE

Middle ear effusion (MEE)

- Fluid in the middle ear regardless of cause;
- Hearing loss;
- Diagnosis requires tympanometry or pneumatic otoscope

Acute otitis media (AOM): MEE with rapid onset symptoms

Recurrent otitis media (ROM): at least three episodes of AOM in past 6/12, or 4 in past 12/12.

Otitis Media with Effusion (OME): MEE without signs or symptoms of AOM

Incidence of AOM

- 1% of all patients attending NZ general practitioners include AOM as a reason for consultation.^[4]
- Extrapolation of consultation rates and incidence^[4] suggests 3071 presentations per year to Paradigm GPs.

Evidence of meta-analyses^[5,6]

- antibiotics did not influence resolution of pain at 24 hours.
- early use of antibiotics reduced the risk of pain at 2 - 7 days by 40%.
- only 14 % of all children still have pain at 2 - 7 days, therefore benefit is to 5.6% of all children with AOM (NNT* = 17) * NNT = numbers needed to treat to benefit/harm one.
- antibiotic use reduced contralateral AOM (NNT = 17).
- antibiotic used did not influence subsequent AOM or incidence of OME.
- antibiotics increased the incidence of vomiting, diarrhoea and rash in children - for every child benefitting from reduced pain, another will suffer antibiotic induced side effects.

- broad spectrum, b Lactamase covering antibiotics conferred no advantage over cheaper drugs such as amoxicillin or co-trimoxazole.
- aggressive use of b Lactamase drugs will cause bacterial resistance.
- antibiotics for less than 7 days has no impact on efficacy.
- these results do not apply to children with serious underlying disease, OME, concomitant illness other than viral URTI or co-existing disorders requiring antibiotic therapy.

Evidence from other sources

- combining an antibiotic with an oral steroid shows promising but unproven efficacy for OME but there is no evidence of benefit in AOM.^[7]
- both amoxicillin and co-trimoxazole are safe with co-trimoxazole perhaps having a marginally higher risk of serious side effects.^[1-3]

Balance Sheet

Assumptions

1. The numbers of cases (3071) likely to occur in HBIPA children (0-15) is based on an assumption of 100,000 patients, age/sex demographic patterns from CRHA statistics and the same consulting rate (3.04/year) and incidence (1%) derived from the Tilyard paper 4.
2. Following the guideline is likely to have various effects on consultation rates. Some will increase consumption (increased review at 48 hours), some will decrease (fewer patients seeking medical assistance with children with sore ears, fewer recalls at one week or so, fewer inappropriate prescriptions for OME due to early recall). As there is no reliable information on these effects, no account of possible changes is attempted in this balance sheet.
3. The intuitive assessment of the incidence of acute OM by GPs on the guideline panel was that the Tilyard paper seriously underestimated the incidence. Savings made may therefore be greater by as much as 100%.

For whole of HBIPA

Outcome	Current Practice	25% antibiotic reduction	50% antibiotic reduction
Number of cases treated with a/b.	3071	2303	1535
Reduced pain at 24 hours	0	0	0
Reduced pain at 2-7 days	180	135	90
Perforations prevented *	113	85*	56*
Deafness at 1 month*	1044		
Deafness at 3 months *	644		
Contralateral AOM prevented	180	135	90
Recurrent otitis media	663	663	663
Vomiting, Diarrhoea, Rash	506	424	342
Side effects inflicted	180	135	90
Antibiotic Cost **	\$24,489	\$18,366	\$12,244
Change mix to amoxil / cotrimox	\$20,391	\$15,293	\$10,195
Funds released for other services	\$4,098	\$9,196	\$14,294

* No statistically significant difference yet established.

** Based on surveyed use of antibiotics by HBIPA doctors for acute OM.

In summary

Reducing antibiotic prescribing for 3071 cases of AOM by 50% (the other 50% are assumed to have other indications for antibiotics, such as a sick child, purulent cough etc) will result in

- causing a small increase in total pain to 90 children
- possibly allowing 56 perforations to occur (not necessarily a bad thing)
- allowing 90 children to progress from unilateral to bilateral AOM
- avoiding inflicting vomiting, diarrhoea or rash on 90 children
- releasing \$14,000 to be used elsewhere in the health service

Other "hidden" benefits could include:

- encouraging an "evidence based approach" amongst professionals and patients
- encouraging self reliance
- reducing a dependence on the "magic bullet" approach to health care.

Meta-Analysis

Rosenfeld et al: *Clinical efficacy of antimicrobial drugs for AOM: Meta-analysis of 5400 children from 33 RCTs.*

Study type / grade Meta-analysis. (Grade I evidence if the meta analysis asks the same questions as ours.)

Only RCT of antibiotic vs placebo / no treatment / other antibiotic. (Therefore can potentially answer both our questions).

Studies were of empiric treatment (no bacterial identification made) of acute OM - (excluded ROM, OME, prophylaxis, etc).

Strong methodology of selection of the primary studies.

Outcomes *Primary:* clinical response to antibiotics.

C complete resolution of symptoms and signs within 7 - 14/7.

C anything other than this is a primary end point failure.

Secondary: OME.

C absence of OME at 30 days.

Design *Focus on discrete clinical question?* The absolute and comparative efficacy of antibiotics in AOM. (Exactly our two questions).

Explicit description of the literature search? Well described. Cochrane review says Arigorous in its methodology.

Methodological standards in primary studies: RCT where at least one group Rx'd antibiotics for AOM. NOT studies of bacterial pathogens; myringotomy; type of OM not clear; extraction of data for children (4/52 to 18 yrs) not possible; ROM; AOM failure management. Eligible studies weighted for quality.

Demographics of study populations: mainly white (75%) infants and preschoolers, mainly USA, Canada, UK.

Validity Study type (meta analysis) is appropriate for the questions.

Tested for homogeneity.

Publication bias discussed and concluded as unlikely.

Results For primary symptom control:
Any antibiotic relieved 14% more than no antibiotic. (13.7, 95% CI 8.2-19.2).

No advantage in broader spectrum antibiotics over simpler, cheaper drugs.

Therefore ARR = 14, NNT to relieve symptoms = 7.

Authors conclusions:

- Modest but significant efficacy antibiotics over placebo
- Amoxicillin & cotrimoxazole as effective as amox / clavunate, cephalosporins
- β -lactamase stable drugs of no advantage in efficacy, avoidance of mastoiditis and may increase bacterial drug resistance.
- Effectiveness of treatment in community may be lower than these studies as diagnostic certainty 58-73% only.
- Cannot detect the 1:7 that will benefit
- and cheaper
- efficacy studies based on 100% diagnostic certainty.

No difference between short course (<7/7) antibiotics or long course.

Concludes that decision whether or not antibiotic should be used rests as a negotiated decision with parents - their value judgement as to whether an NNT of 7 justifies the cost/risk. When an antibiotic is decided on, the safest/cheapest combination should be used.

Del Mar, Glasziou, Hayem: Are antibiotics indicated as initial treatment for children with acute otitis media? A meta-analysis.

Study type / grade

Meta-analysis. (Grade I evidence if the meta analysis asks the same questions as ours.)

- Only RCT of antibiotic vs placebo. (Therefore can potentially answer only the first of our questions).
- Studies were of empiric treatment (no bacterial identification made) of acute OM - (excluded ROM, OME, prophylaxis, etc).
- Strong methodology of selection of the primary studies.

Outcomes *Primary:* clinical response to antibiotics

C pain at 24 hrs, 2-7 days.

Secondary: perforation, deafness at 1/12 and 3/12, contralateral AOM, ROM.

C vomiting, diarrhoea, rash.

Design

Focus on discrete clinical question? The absolute efficacy of antibiotics in AOM. (Our first question).

Explicit description of the literature search? Well described and thorough

Methodological standards in primary studies: RCT where at least one group Rx'd antibiotics for AOM. NOT studies of bacterial pathogens; myringotomy; type of OM not clear; extraction of data for children (4/52 to 18 yrs) not possible; ROM; AOM failure management. Eligible studies weighted for quality.

Demographics of study populations: mainly European, USA, Canada. 7/12 to 15 yr age range. No description of race. Described consistency with developed world study and increased risks / poor outcomes in Third World. (Very low incidence mastoiditis in developed world, a lot higher in Third World.

Validity Study type (meta analysis) is appropriate for the question.

Tested for homogeneity.

Publication bias not discussed but unlikely as results consistent and in same direction.

Results

Outcome	Control (%)	Treatment (%)	Rate Reduction (%)	NNT
Pain at 24 hours	39.6	39	0	infinite
Pain at 2-7 days	14.3	9.7	4.6	21*
Perforation	7.3	3.7	3.6	27**
Deafness 1 month	34	35	not significant	
Deafness 3 months	26	21	not significant	
Contralateral AOM	16.6	10.6	6	17
Recurrent OM	21.6	21.6	0	
Vomiting, Diarrhoea, Rash	10.7	16.5	-5.8	17

* Worked out another way - 14.3% of children had pain persisting 2-7 days, antibiotics reduced this pain in 41%, giving an NNT of 17.

** not statistically significant.

Authors conclusions: Open discussion with parents giving them the information on which to balance a value judgement of benefits vs risks and costs.

Process Plan

Definitions

Middle ear effusion (MEE):

Fluid in the middle ear regardless of cause; hearing loss +/-; diagnosis requires tympanometry or pneumatic otoscope.

Myringitis:

Erythema of the tympanic membrane without MEE.

Acute otitis media (AOM):

MEE with rapid onset symptoms.

Recurrent otitis media (ROM):

at least three episodes of AOM in past 6/12, or 4 in past 12/12.

Otitis Media with Effusion (OME):

MEE without signs or symptoms of AOM.

What are we trying to do?

- Define options for care.
- What choices are there, and what are the consequences of those choices?
- Define outcomes of interest.
- Severity and duration of pain.
- Deafness (rate of OME after AOM).
- Adverse effects.
- Recurrent attacks (ROM).
- Cost of care

Define the Evidence

- Quantify the levels of benefit, harm and cost.

Incorporate Values

- Outcomes of importance to parents.
- Outcomes of importance to health professionals (eg antibiotic resistance)

Who should be involved?

Who are the key stakeholders?

- Children represented by parents.
- GPs, Practice Nurses.
- Specialists - paediatricians, ? ENT surgeons.
- IPA - quality and budgetary considerations.

Processes

Problem Identification

This problem already identified as an important problem where there is a gap between current knowledge and current practice. It is very common so is of high volume even if relatively low cost.

Suitability Screen

First level Screen

we do have doctor/nurse time, analytic resources, implementation capacity and administration support to be able to do this.

Second level Screen:

Owner: S Foote

Can we measure proposed change. No readily available internal data at this stage but it is possible to collect some and repeat in the future to measure change.

Literature search: Shows that there is little evidence to support widespread use of antibiotics as an initial treatment for AOM; the NNT for better pain control at 2/7 varies between 7 and 17; there is no advantage in pain control at 24/24; that antibiotic resistance is growing; risks of vomiting, diarrhoea and rash double with antibiotics; reduced contralateral AOM but little difference in ROM or OME. Also widespread variation in practice.

Is the size and importance of the gap worth the effort. Probably yes but need internal data to be sure of that.

Can we implement the change. Yes, using written material for professionals and parents, cellgroups, academic detailing, feedback.

Internal Data

We do not need this data to prove or disprove issues related to outcomes of use or non use of antibiotics in AOM - the external evidence provides that proof. Therefore, the data we need is to monitor change or compliance with the guideline - ie have the efforts of developing and implementing the guideline resulted in a change of practice.

Suggested data:

Outcome Category	Measurable Outcomes	Source of Data	Comments
Health status	Symptom control ROM OME Adverse effects	<ul style="list-style-type: none">• Surveys• Ultimately from a collective clinical information system	Monitoring outcomes of value for research and/or confirming that our results consistent with external evidence. Not necessary for this exercise
Patient satisfaction	Access to care Understanding of issues Satisfaction with process of care	<ul style="list-style-type: none">• Surveys• Sentinel groups	Need to discuss on 2/7/97 how to involve patient in this guideline development, implementation and evaluation
Provider satisfaction	Current practice attitudes	Survey	
Cost/utilisation	Consultation rates Antibiotic use or not Which antibiotics Dose/duration	<ul style="list-style-type: none">• Surveys• Chart pulls• External data	Need: number of AOM; a/b on initial Rx; a/b @ 48/24; which a/b, dose, duration; total cost/pt.

External Data or Evidence

Three recent meta-analyses are presented.

Reassess suitability and prepare balance sheet.

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4. Tilyard M, Dovey S, Walker S. *Otitis Media Treatment in NZ General Practice.* NZ Med J 1997; 110:143-5
5. Rosenfeld R, et al. *An Evidence-based approach to treating otitis media.* Paed Clinics North America. 43:6; December 1996
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