



## Otitis Media

### Otitis Media Guideline Team

#### Team leader

Heather L. Burrows, MD,  
PhD  
General Pediatrics

#### Team members

R. Alexander Blackwood,  
MD, PhD  
Pediatric Infectious  
Disease

James M. Cooke, MD  
Family Medicine

R. Van Harrison, PhD  
Medical Education

Kathryn M. Harmes, MD  
Family Medicine

Peter P Passamani, MD  
Pediatric Otolaryngology

#### Consultant

Kristin C Klein, PharmD  
UMH Pharmacy Services

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#### UMHS Guidelines Oversight Team

Grant Greenberg, MD, MA,  
MHSA  
R Van Harrison, PhD

#### Literature search service

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

**Patient population:** Pediatric patients (>2 months old) and adults

- Objectives:**
- (1) Limit acute symptoms and suppurative complications caused by acute otitis media.
  - (2) Maximize language development and minimize long term damage to middle ear structure associated with otitis media with effusion.
  - (3) Limit complications of antibiotic therapy including the development of antibiotic-resistant bacteria.

### Key points

#### Diagnosis

- Distinguish between acute otitis media (AOM) and otitis media with effusion (OME) (see Table 1). Symptoms of pain or fever, together with an inflammatory middle ear effusion, are required to make a diagnosis of AOM [I, D\*].
- The presence of middle ear effusion should be determined by the combined use of otoscopy, pneumatic otoscopy, and tympanometry when necessary [I, D\*].

#### Therapy of acute otitis media

- Recommend adequate analgesia for all children with AOM [I, D\*].
- Consider deferring antibiotic therapy for lower risk children with AOM [II, A\*].
- When antibiotic therapy is deferred, facilitate patient access to antibiotics if symptoms worsen (e.g., a "back-up" prescription given at visit or a convenient system for subsequent call-in) [I, C\*].
  - Amoxicillin is the first choice of antibiotic therapy for all cases of AOM.
    - Children:
      - Dosing: < 4 years, 80 mg/kg/day divided BID; ≥ 4 years, 40- 60 mg/kg/day [I, C\*].
      - Duration 5-10 days: 5 days is usually sufficient at lower cost and fewer side effects, although 10 days reduces clinical failure [A\*]. Consider 10-day course for children: with significant early URI symptoms and <2 years old, with possible sinusitis, and with possible strep throat [II, D\*].
      - Adults: either 875 mg BID x 10 days or 500 mg 2 tabs BID x 10 days [I, C\*].

In the event of allergy to amoxicillin, azithromycin (Zithromax) dosed at 30 mg/kg for one dose is the appropriate first line therapy.

- Treat AOM that is clinically unresponsive to amoxicillin after 72 hours of therapy with amoxicillin/clavulanate (Augmentin ES; amoxicillin component 80 mg/kg/day divided BID) for 10 days or with azithromycin (Zithromax) 20 mg/kg daily for 3 days [II, C\*].
- Patients with significant, persistent symptoms on high-dose amoxicillin/clavulanate (Augmentin ES) or azithromycin (Zithromax) may respond to IM ceftriaxone (Rocephin; 1-3 doses) [II, C\*]. The decision to use ceftriaxone (Rocephin) should take into account the negative impact it will have on local antibiotic resistance patterns.

#### Therapy of OME

- Children with middle ear effusions should be examined at 3 month intervals for clearance of the effusion [I, D\*].
- Children with evidence of mucoid effusions or anatomic damage to the middle ear should be referred to otolaryngology if effusion or abnormal physical findings persist for 3 months [I, D\*].
- Children with apparent serous effusions should be referred to otolaryngology if effusion persists for 6 months and there is evidence of hearing loss or language delay [I, D\*].
- Children with an asymptomatic middle ear effusion (no apparent developmental or behavioral problems) can be followed without referral [I, B\*].
- Parents of all children with OME should be informed about approaches to maximize language development in a child with a possible hearing loss [I, C\*].
- Decongestants and other nasal steroids have been shown not to decrease middle ear effusions [IIIA\*].

### Other Issues Addressed in the Text

#### Special Populations

- Otitis media in infants 0–8 weeks old
- Otitis media in children with chronic illnesses
- Otitis media in adults

#### Special Situations

- Primary care management of tympanostomy tubes
- Cerumen removal
- Care of otorrhea and acute otitis externa.

#### \* Strength of recommendation:

I = generally should be performed; II = may be reasonable to perform; III = generally should not be performed.

#### Level of evidence supporting a diagnostic method or an intervention:

A=randomized controlled trials; B=controlled trials, no randomization; C=observational trials; D=opinion of expert panel.

**Table 1. Diagnostic Definitions**

<p><b>Acute Otitis Media (AOM)</b> (ICD-9-CM code 382.9)</p> <ul style="list-style-type: none"> <li>Middle Ear Effusion (MEE) - demonstrated by pneumatic otoscopy, tympanometry, air fluid level, or a bulging tympanic membrane <i>plus</i></li> <li>Evidence of acute inflammation – opaque, white, yellow, or erythematous tympanic membrane or purulent effusion <i>plus</i></li> <li>Symptoms of otalgia, irritability, or fever</li> </ul> <p><b>Otitis Media with Effusion (OME)</b> (ICD-9-CM code 381.4) MEE without symptoms of AOM with or without evidence of inflammation</p>
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**Table 2. Treatment of Acute Otitis Media**

Presentation	Associated Treatment and Antibiotic Dose	Antibiotic Cost <sup>a</sup>	
		Generic	Brand
<b>Initial Presentation</b>			
Bulging or erythematous tympanic membrane with MEE and:			
<ul style="list-style-type: none"> <li>no symptoms (no fever, irritability, ear pain)</li> </ul>	See OME (Table 3)		
<ul style="list-style-type: none"> <li>minor symptoms (sleeping and acting well)               <ul style="list-style-type: none"> <li>&lt; 24 months &amp; unilateral AOM</li> <li>≥ 24 months &amp; unilateral or bilateral AOM</li> <li>&lt; 24 months &amp; bilateral AOM</li> </ul> </li> </ul>	Observation option; recommend ibuprofen Observation option; recommend ibuprofen Start ibuprofen + amoxicillin (see dosing below)		
<ul style="list-style-type: none"> <li>moderate symptoms (fever, significant pain, otalgia present &gt; 48 hours)</li> </ul>	Start ibuprofen + <u>amoxicillin</u> Pediatric: Age < 4: 80 mg/kg/day divided BID x 5-10 days Age ≥ 4: 40-60 mg/kg/day div BID x 5-10 days (max 1000 mg/dose) Adult: either 875 mg BID x 10 days or 500 mg 2 tabs BID x 10 days	\$11 \$28	NA NA
	If amoxicillin sensitivity <u>azithromycin (Zithromax)</u> <sup>c</sup>	\$8	NA
	Pediatric: 30 mg/kg x 1 dose (max 1500 mg) Adult: 500mg daily x 3 days	\$38 \$17	\$52 \$50
<ul style="list-style-type: none"> <li>severe symptoms (AOM with apparent systemic toxicity)</li> </ul>	Strongly consider laboratory testing to rule out serious coexistent disease. Consider other etiologies. <u>Ceftriaxone (Rocephin)</u> Pediatric: 50-75 mg/kg/day IM x 1-3 days (max 1000 mg/day) Adult: 1-2g IM/IV daily x 1-3 days	\$55-70 <sup>b</sup> \$70-102 <sup>b</sup>	\$113 <sup>b</sup> \$113-340 <sup>b</sup>
<b>Follow up</b>			
<ul style="list-style-type: none"> <li>If symptom relief</li> </ul>	Pediatrics: Follow up in 3 months. Adults: Follow up is not required if symptoms completely relieved.		
<ul style="list-style-type: none"> <li>If symptoms persist &gt; 3 days following initiation of treatment with amoxicillin, reevaluate. If middle ear findings persist:</li> </ul>	Either <u>amoxicillin/clavulanate (Augmentin ES)</u> Pediatric: 80 mg/kg div BID x 10 days (max 3 g) Adult: 875/125mg BID x 10 days or <u>azithromycin (Zithromax)</u> <sup>c</sup> Pediatric: 20 mg/kg daily for 3 days (max 1500 mg) Adult: 1 g daily for 3 days	\$59 \$26 \$48 \$32	\$130 \$214 \$52 \$149
<ul style="list-style-type: none"> <li>If significant symptoms continue to persist despite high dose amoxicillin/clavulanate or azithromycin, reevaluate and treat:</li> </ul>	Ceftriaxone (Rocephin; See “Severe Symptoms” above)		
<b>Recurrent AOM</b>			
AOM more than 14 days after finishing successful antibiotic treatment, assume that new AOM is unrelated to previous AOM.	See “Initial Presentation” above. (If antibiotic therapy is indicated: amoxicillin.)		
Follow up	See “Follow up” above		

Note: Evidence is limited for optimal drug, dosage, or duration of therapy for AOM in adults.

<sup>a</sup> Cost = Average wholesale price based -10% for brand products and Maximum Allowable Cost (MAC) + \$3 for generics on 30-day supply, *Amerisource Bergen item Catalog 5/12 & Blue Cross Blue Shield of Michigan Mac List, 5/12.*

<sup>b</sup> Cost also includes \$30 (charge at UM Health System) for performing each injection.

<sup>c</sup> The FDA issued a warning that azithromycin could cause potentially fatal irregular heart rhythm in some patients. At-risk patients include those with a slower-than-normal heartbeat, with potassium or magnesium deficiencies, and those using medications to treat existing heart arrhythmia.

**Table 3. Diagnosis and Treatment of Otitis Media with Effusion**

**Evaluate tympanic membranes** at every well child and sick child exam when feasible. Perform pneumatic otoscopy or tympanometry when possible. Record findings. If the tympanic membrane (TM) is occluded with cerumen, consider removal.

**If MEE, determine nature of effusion.** Attempt to distinguish between effusions that are likely to be transient, such as serous or purulent effusions and effusions likely to be persistent or associated with significant morbidity, such as mucoid effusions.

**For likely transient effusions, reevaluate at 3 month intervals**, including a screen for language delay. In the absence of anatomic damage or evidence for developmental or behavioral complications, continue to observe at 3 month intervals. If complications appear to arise, refer to otolaryngology.

**For apparent mucoid effusions or effusions that appear to be associated with anatomic damage**, such as adhesive otitis or retraction pockets, reevaluate in 4-6 weeks. If abnormality persists, refer to otolaryngology.

**No antibiotics** are indicated.

**Decongestants and nasal steroids are not indicated.**

If symptoms arise, see AOM (Table 2).

**Table 4. Risk factors for Developmental Difficulties**

- Hearing loss independent of OME
- Suspected or diagnosed speech and language delay
- Autism spectrum disorder
- Syndromes (i.e. Down Syndrome) or craniofacial abnormalities that include cognitive, speech, or language delays
- Blindness or uncorrectable visual impairment
- Cleft palate with or without an associated syndrome
- Developmental delay
- Known or suspected exposure to environmental disorganization, lack of linguistic stimulation, or neglect

## Clinical Background

### Clinical Problem and Current Dilemma

#### Incidence

Middle ear disease is among the most common issues faced by clinicians caring for children. Approximately 80% of children will experience at least one episode of acute otitis media (AOM) and 80-90% will experience at least one episode of otitis media with effusion (OME) before their third birthday. In 2006, these diagnoses were responsible for at least 8 million office visits and between 3 and 4 billion dollars in health care spending in the United States.

#### Variability in Diagnosis and Treatment

Despite the general familiarity with this common condition, a great deal of variability remains in diagnostic criteria, approaches to therapy, and follow-up. In 2004, the American Academy of Pediatrics and the American Academy of Family Physicians (AAP/AAFP) published a clinical practice guideline for AOM (National AOM-guideline), and the American Academy of Pediatrics and the American Academy of Otolaryngology-Head and Neck Surgery (AAP/AAOHN) published a guideline for the management of OME (National OME-guideline). These guidelines were intended to address this variability. The AAP published an updated guideline for the management of AOM in 2013.

**Diagnosis.** The National Guidelines emphasize the distinction between AOM and OME. The diagnosis of AOM is based on the presence of symptoms (ear pain, fever) in the context of an inflamed middle ear effusion. The diagnosis of OME is the presence of a middle ear effusion in the absence of symptoms. The effusion of OME can be serous, mucoid, or purulent.

**Use/overuse of antibiotics.** Clinicians have years of experience treating middle ear disease with antibiotics. The favorable natural history of these conditions and the marginal impact of antibiotic therapy on outcome are underappreciated by clinicians and by patients. Clinicians overestimate the extent to which clinical failure is due to antibiotic resistance, and overestimate the likelihood that second line medications will cover resistant organisms.

**Referral process.** Particularly for children, otolaryngology evaluation plays an important role in the management of recurrent AOM and persistent OME. However, the ability of the surgeon to reach the most appropriate decision for the management of a given patient may be limited by a lack of historical information including previous antibiotic therapy and an accurate time course of middle ear disease.

#### More Conservative Approach Recommended

In general, both of the 2004 national guidelines encouraged a more conservative approach to the care of these conditions than had been practiced previously. The 2013 AAP guideline clarified the use of this approach, incorporating the results of subsequent controlled trials of

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placebo vs. antibiotic therapy for young children, with more stringent diagnostic criteria for AOM than had been used in prior studies. This guideline is based upon the principles of these national guidelines.

Most clinical studies of AOM and OME have documented significant clinical uncertainty associated with the etiology and treatment of these conditions. Often the differences between therapies are statistically significant, but not clinically useful. Therefore, clinical recommendations in the UM guideline reflect the “number needed to treat” to improve the outcome for a single child rather than the statistical significance of randomized trials.

Recommendations presented here balance several factors, including speeding the resolution of short-term symptoms, preventing significant complications, reducing complications of therapy, minimizing cost and inconvenience, and maximizing patient satisfaction. Longer term and ecological considerations include the effects of middle ear disease on language development and the possible effects of antibiotic exposure on long term immunity and gut health. Ecological considerations include the effect of antibiotic prescriptions on antibiotic resistance in the community, with particular attention to penicillin resistant *Streptococcus pneumoniae* (PRSP), methicillin-resistant *Staphylococcus aureus* (MRSA), and multiple-resistant organisms relevant to immunocompromised patients. All of these factors must be considered in the context of the considerable variability and uncertainty surrounding the diagnosis and treatment of AOM.

## Rationale for Recommendations

### Etiology of AOM

**Pathogens.** AOM is usually a complication of eustachian tube dysfunction experienced during an acute viral upper respiratory infection. Some viruses, such as respiratory syncytial virus, adenovirus, and human metapneumovirus, are associated with higher rates of AOM. Bacteria are isolated from middle ear fluid cultures in 50-90% of cases of AOM and OME. *Streptococcus pneumoniae*, *Haemophilus influenzae* (non-typable), and *Moraxella catarrhalis* are the most common organisms isolated from middle ear fluid. *Haemophilus influenzae* and non-vaccine associated serotypes of *Strep. pneumoniae* have become the most prevalent organisms following the introduction of the pneumococcal heptavalent vaccine (PCV7). A variety of bacteria, including Group A strep and *Staphylococcal. aureus* are isolated from approximately 10% of ears. Approximately 5% of ears have multiple pathogens. Gram negative bacilli were identified in 10.5% of infants under 6 weeks of age in one recent study.

Physical exam findings are incompletely correlated with the etiology of AOM. Middle ear fluid is sterile in 25-50% of tympanocentesis specimens satisfying the above criteria for AOM, depending on the population examined. Furthermore, symptom scores do not distinguish bacterial from non-bacterial AOM nor among different bacterial etiologies. Persistent pathogenic bacteria can be cultured from asymptomatic ears and from approximately 20% of ears undergoing ventilation tube (VT) placement for chronic OME. These observations underscore the difficulty in equating AOM with bacterial infection.

### Risk Factors for AOM

**Age.** Age is a significant predictor of AOM frequency, severity, and responsiveness to treatment. Infants and toddlers are more severely affected, may take longer to respond to treatment, and can be more difficult to diagnose accurately. Consequently, clinicians should be cautious in extrapolating results from clinical trials involving older children to younger age groups.

**Additional risk factors.** Several specific risk factors for recurrent AOM and OME have been identified or are likely:

- Exposure to group day care with subsequent increase in respiratory infections.
- Exposure to environmental smoke or other respiratory irritants and allergens that interfere with Eustachian tube function.
- Lack of breast feeding.
- Supine feeding position.
- Use of pacifiers by toddlers and older children.
- Family history of recurrent AOM.
- Craniofacial abnormalities.
- Immune deficiency.
- Gastro-esophageal reflux.

### Diagnosis

**Distinguishing AOM and OME.** The distinction between AOM and OME does not refer to etiology or depend on whether pathogenic bacteria are present in the middle ear. No “gold standard” exists for the diagnosis of AOM. The National AOM-guideline defines AOM as a combination of (see Table 1):

- 1) middle ear effusion,
- 2) physical evidence of middle ear inflammation, and
- 3) the acute (< 48 hours) onset of signs and symptoms (i.e. ear pain, irritability, fever) referable to the middle ear.

Otitis media with effusion (OME) is defined as middle ear effusion (MEE) in the absence of acute symptoms.

### Techniques for identifying MEE.

The basic question facing a clinician evaluating a patient’s ears is whether or not MEE is present. If the presence or absence of MEE is not clear, all available techniques should be used. Techniques include otoscopy, pneumatic otoscopy, and tympanometry.

**Pneumatic otoscopy.** In the national guidelines, pneumatic otoscopy is recommended as an essential technique for the diagnosis of AOM and OME. In skilled hands with appropriate equipment this technique is 70-90% sensitive and specific for determining the presence of middle ear effusion. This can be compared to 60-70% accuracy with simple otoscopy. Pneumatic otoscopy is most helpful when cerumen is removed from the external auditory canal and the otoscopist uses equipment such as hard plastic reusable ear tips with rounded edges rather than disposable tips. Having a well-maintained, fully-charged otoscope is also important. Pneumatic otoscopy is also helpful in identifying middle ear pathology such as retraction pockets and tympanic membrane adhesion to the ossicles even in the absence on MEE.

**Tympanometry/acoustic reflectometry.** Tympanometry and acoustic reflectometry can be valuable adjuncts to, but not a substitute for, otoscopy and pneumatic otoscopy. Tympanometry provides an important confirmation of middle

ear fluid and is helpful for physicians honing their otoscopy skills. Tympanometry can also measure middle ear pressures and easily demonstrate the patency of myringotomy tubes by measuring increased external canal volumes. Tympanometry has a sensitivity and specificity of 70-90% for the detection of middle ear fluid, but depends on patient cooperation. Technical factors such as cerumen and probe position can lead to artifactual flattening of the tympanogram. The presence of a "normal" curve does not rule out the presence of air-fluid levels and effusion in the middle ear. However, together with normal otoscopy, a normal tympanogram is predictive of the lack of middle ear fluid. A "flat" tympanogram should be confirmed through repeated measurements, recording appropriate external canal volumes, and through correlation with pneumatic otoscopy. Acoustic reflectometry is also an appropriate approach for evaluating the presence of middle ear fluid, but, like tympanometry, it has imperfect sensitivity and specificity and must be correlated with the clinical exam.

For most clinical purposes, a tympanic membrane bulging with an apparent purulent effusion is a more useful sign of bacterial infection than isolated immobility on pneumatic otoscopy, and it is probably sufficient to make the diagnosis of AOM in association with typical symptoms. No symptoms directly correlate with the appearance of the tympanic membrane, so the clinician should not make the diagnosis of AOM based solely on the clinical history – the tympanic membrane should be directly visualized.

### Management of Acute Otitis Media (AOM)

Management recommendations for AOM are summarized in Table 2, including antibiotic choice, dosing, and cost. These recommendations emphasize flexibility and collaboration with parents to identify a mutually satisfying approach to deal with a specific episode of middle ear disease. Usually, this plan can be reduced to two specific questions: when to start antibiotic therapy and which antibiotic to choose. Basic management recommendations are:

- 1) Antibiotics should be started when they are likely to significantly reduce morbidity that cannot be better reduced through the use of analgesics.
- 2) High dose amoxicillin is the antibiotic of choice for every episode of AOM unless compelling reasons exist for choosing a different agent.

These fundamental management recommendations are based on the following principles.

- **Risk.** The risk of significant complications of middle ear disease should be minimized, including mastoiditis, meningitis, bacterial sepsis, intracranial abscess, prolonged symptoms of fever or irritability, and permanent hearing loss. These events are rare in children with AOM.
- **Resistance.** Selection of antibiotic-resistant pathogens due to antibiotic therapy should be avoided. The selection of antibiotic resistant bacteria in the community remains a major public health challenge.
- **Impact.** The impact of a course of antibiotic therapy on the outcome of an episode of AOM depends upon the age of the child and the severity of associated symptoms. Antibiotic therapy should be reserved for those situations in which it is likely to have a positive impact on outcome, i.e. situations not better treated with analgesics.

**Analgesics.** Analgesics are recommended for symptoms of ear pain, fever, and irritability. Analgesics are particularly important at bed time, since disrupted sleep is one of the most common symptoms motivating parents to seek care. Ibuprofen is preferred over acetaminophen, given its longer duration of action and its lower toxicity in the event of overdose. Additionally it has anti-inflammatory effects which may further potentiate its analgesic effect. Topical analgesics are likely not helpful except for short term pain management.

**Observation vs. initiating antibiotic therapy.** Although many children may show improvement on placebo, antibiotic therapy may be more beneficial than suggested by prior studies with less precise definitions of AOM. Two recent, randomized, placebo-controlled trials studied the treatment of AOM in children under 3 years old. Both studies used a strict definition of AOM, requiring a bulging TM with erythema. Patients were treated with amoxicillin/clavulanic acid. Both studies documented a significant difference in symptoms (fever and pain) in these young children when treated with antibiotics. In one of the studies, the rate of clinical failure at day 10 was 51% in children treated with placebo compared to 16% in children treated with antibiotics, for a number needed to treat of 3. The difference was more pronounced for children with bilateral AOM. A second study showed similar results.

A strategy for improving the care of AOM is to identify the subset of patients least likely to benefit from antibiotic therapy and consider deferring antibiotic therapy for those patients. This category would include children:

- > 2 years of age with relatively minor symptoms
- < 2 years of age with mild symptoms and unilateral disease.

Studies using observation options have shown that observation can be effective and safe, with no increases in rates of adverse outcomes, provided that good follow up occurs and access to "rescue" or "just in case" prescription therapy is provided. In most studies, about 1/3 of patients initially assigned to observation will request or require antibiotic treatment. However, this does not mean that the initial decision to defer antibiotics was mistaken, or even that the antibiotics were ultimately necessary. The observation option allows parents the flexibility of deciding for themselves when and if antibiotics are necessary, while substantially decreasing children's exposure to antibiotics.

The rate of antibiotic therapy can be significantly reduced through the provision of adequate parental education about the natural history of AOM. Specifically, parents should be informed at the outset that on average, not all children benefit from antibiotic therapy, that approximately 10% of children receiving antibiotics will have an untoward outcome such as diarrhea or rash. In addition, parents need to know that at many cases of AOM are caused by viruses, not bacteria, that no oral antibiotic eliminates more than 80% of the bacteria found in cases of AOM, and that oral analgesics, such as ibuprofen, are much more likely to speed resolution of symptoms than oral antibiotics. Finally, they need to know that 10-20% of children will continue to have symptoms no matter what therapy is given, and that apparent failure with the observation option does not mean that antibiotics will necessarily be needed in the future. These points are summarized in the patient education materials provided with this guideline.

A fairly extensive empirical data base supports these expectations. In the placebo controlled trials, the likelihood of prolonged symptoms leading to the eventual administration of antibiotics depended largely on the severity of symptoms at diagnosis, particularly fever. Therefore excluding such patients from the observation option is likely to increase clinician and parent confidence in this approach. The most important information derived from the four published trials of the observation option is that no significant complications occurred among more than 1,700 subjects followed without initial antibiotic therapy, despite the fact that approximately 50% of subjects had fever at enrollment. Thus, clinicians should feel comfortable that deferring antibiotics, even for moderately symptomatic patients, is unlikely to lead to untoward complications.

Any reduction in antibiotic usage is likely to be associated with decreased costs as well as decreased selective pressure for antibiotic resistant bacteria. Reduction in the use of first-line antibiotics would lead to a reduction in the need for second-line agents such as amoxicillin/clavulanate or cephalosporin. The use of beta-lactamase resistant antibiotics may promote colonization with resistant organisms.

“Back-up” options for prescriptions. In order for the observation to be acceptable for patients, clinicians must facilitate the subsequent access to antibiotics for patients whose symptoms worsen. One option is to provide parents with “back-up” prescriptions to be filled in the event of symptomatic persistence. Such prescriptions should be dated as needing to be filled within 3-4 days of diagnosis, to prevent parents from inappropriately treating future illnesses. Alternatively, a system by which parents can call to request antibiotic prescriptions without excessive inconvenience could be established. In one study, the use of a safety net prescription system reduced the number of courses of antibiotics given by 70%.

Antibiotic choice. The initial choice of antibiotic should almost always be high dose amoxicillin. The advantages of amoxicillin include cost, tolerability, safety, and efficacy. No antibiotic has been demonstrated to be superior to amoxicillin in clinical trials involving tympanocentesis before and after therapy. Oral cephalosporins are uniformly inferior to high-dose amoxicillin for pneumococcus, especially penicillin-resistant pneumococcus. Unless the patient is allergic to amoxicillin, in which case high-dose azithromycin (Zithromax) would be the first-line agent, no empirical basis exists for choosing any oral antibiotic besides amoxicillin for the treatment of AOM. This is true even if the patient has a past history of recurrent AOM or amoxicillin failure. Clinically ill children with AOM are much more likely to have pneumococcal infections, such as occult pneumonia, than beta-lactamase producing H. influenza (about 5-10% of all episodes of AOM). Since the mechanism of resistance for penicillin resistant pneumococcus is due to an altered penicillin binding protein (not secondary to a beta-lactamase) and the drug of choice for penicillin-resistant pneumococcus is high dose penicillin, we feel that the advantages of high dose amoxicillin outweigh the theoretical advantages of amoxicillin/clavulanic acid (Augmentin). If amoxicillin/clavulanic acid is used, suspensions meant for high dose amoxicillin dosing should be used (i.e., Augmentin ES) to decrease the rate of gastrointestinal upset.

Cephalosporins are only 70-80% effective in clearing middle ear bacteria in double tympanocentesis studies of AOM. In one study of cefdinir (Omnicef) efficacy, this antibiotic only cleared pathogenic bacteria from the middle ear space in 78% of patients including only 72% of ears with H. influenza. When used we recommend a 2<sup>nd</sup> generation cephalosporin, like cefuroxime (Ceftin), instead of a third generation cephalosporin, like cefdinir. Both are relatively equally effective against H. influenza and M. catarrhalis, but the 2<sup>nd</sup> generation cephalosporin will not drive secondary resistances to the same extent with streptococcus pneumoniae or enteric organisms.

Allergy to amoxicillin. If a patient has a significant amoxicillin allergy (e.g., urticaria, or airway hyper-reactivity), the recommended antibiotic is high-dose azithromycin (Zithromax). High dose azithromycin appears to be more effective than the commonly used 5 day course of this agent, and it appears to be clinically comparable to high dose amoxicillin in some studies. However, excessive use of azithromycin is associated with increasing rates of erythromycin resistance, particularly involving group A beta-hemolytic streptococci, and therefore its routine use should be discouraged. **Cefuroxime** (Ceftin) can also be used, although it is clinically inferior to amoxicillin. Third generation cephalosporins, such as cefdinir (Omnicef), are not more effective and carry with them an excessive risk of selection of resistant bacteria.

The use of ceftriaxone (Rocephin) should be reserved for episodes of clinical failure (see below) or for clinical situations in which the clinician suspects a serious bacterial infection as co-morbidity of the AOM. Strong consideration should be given to obtaining appropriate laboratory studies such as blood or urine cultures before administering ceftriaxone, as well as obtaining a white count with differential or C-reactive protein in order to confirm the severity of the illness. Follow up should be ensured, and alternative diagnoses, such as a viral illness or pneumonia, should be considered in the event of clinical failure. Although some children will likely benefit from IM ceftriaxone, the decision to prescribe this agent should not be made lightly, since the overuse of this agent is likely to significantly increase high level penicillin resistance in the community. Ceftriaxone can be administered for up to three days, but a single dose is often sufficient. Ceftriaxone might also be appropriate in situations where antibiotics are indicated but oral antibiotics are not tolerated, such as vomiting. Bicillin CR might also be a better overall option in that situation.

Amoxicillin dosing and duration. Given the risk of penicillin resistant pneumococcus, for children under 4 years amoxicillin should be dosed at 80 mg/kg per day divided twice a day for 5 to 10 days. Children 4 years and older can probably receive 40-60 mg/kg/day. Since the major impact of antibiotic therapy is to reduce symptoms at 48 - 72 hours, 5 days of therapy are usually sufficient. In one randomized trial of 5 vs. 10 days of amoxicillin, the 10 day course was associated with a significantly lower likelihood of clinical failure. However, in this study, “the number needed to treat” was 10 indicating that 10 children with AOM would need to be prescribed 10 days instead of five days of therapy, to improve the outcome for one. Since it is unclear how many parents continue to give amoxicillin consistently once the symptoms are resolved, it is possible that the increased cost and inconvenience of giving a ten day course might not be outweighed by the improvement in symptomatic outcome at 10 days. This would be particularly true in older children. Furthermore, illnesses,

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rashes, and diarrhea occur in all children at some time, and they will be more likely to occur while on antibiotics. Thus, consider reserving the use of a ten day course of antibiotics for children most likely to benefit, e.g. young children with significant early URI symptoms, children with possible sinusitis, and children with possible strep throats. In most other cases, one would expect the major symptoms to resolve in five days, even without treatment. If desired, a prescription could be given for ten days of amoxicillin with instructions to discontinue and discard the medication 2-3 days after resolution of symptoms.

Diarrhea and candidal infections are among the most common complications of antibiotic therapy. Therefore parents should be warned about this in advance. It is also appropriate to provide recommendations about diaper care and the application of clotrimazole (Lotrimin) cream in the event of diaper rash. Giving yogurt with active cultures might also be helpful.

**Probiotics.** Antibiotic administration in general, as well as for the management of AOM, is frequently associated with the onset of diarrhea (occurring in up to 40% of patients). Although the diarrhea is usually self-limited, it can become more worrisome when associated with *C. difficile*. A Cochrane meta-analysis of 10 randomized controlled trials in children from age 1 month to 15 years demonstrated that probiotics reduced the incidence of antibiotic associated diarrhea when given prior to the onset of diarrhea. Thus initiating a probiotic at the onset of antibiotic therapy can be considered in the management of AOM. *Lactobacillus GG* and *Saccharomyces boulardii* are frequently used strains, but commercially available preparations are not strictly regulated. Yogurt with active cultures and fermented milk are frequently used vehicles for the delivery of the desired probiotic.

**Persistent AOM.** Children experiencing persistent, significant AOM symptoms despite at least 48-72 hours of antibiotic therapy should be clinically reexamined to determine whether or not the persistent symptoms are associated with physical findings of AOM. In the event that a bulging, inflamed TM is observed, the child should be changed to a second line agent. For children initially on amoxicillin, high-dose amoxicillin/clavulanate is probably the best choice, although high dose azithromycin is comparable. For children with significant amoxicillin allergy (urticaria, systemic reactions, or erythema multiforme), who fail initially on azithromycin, cefuroxime is recommended. Oral ciprofloxacin is probably also an effective choice but is discouraged. Trimethoprim/sulfamethoxazole is no longer an effective agent for the treatment of AOM.

Recurrence of symptoms more than 2 weeks after the initial diagnosis of AOM should be assumed to be a new and unrelated episode of AOM caused by a new organism. Once again, high dose amoxicillin is the agent of choice. Also, consider the "Observation option". Clinicians should discourage the belief that "amoxicillin doesn't work" for a particular patient.

**Follow up of AOM.** The major rationale for the re-examination of children with AOM whose symptoms have resolved is to document the clearance of MEE. It is probably most appropriate to wait at least 3 months to perform this evaluation. In the event that MEE persists, the child should be entered into the algorithm for OME described below.

**Recurrent AOM.** Many children with AOM go on to have recurrent episodes and end up receiving multiple courses of antibiotics. Several strategies are likely helpful for this problem. First precisely define whether or not the child is suffering from recurrent AOM. Young children are frequently seen in the office with middle ear effusions and non-specific symptoms such as chronic sleep disturbances, nasal congestion, or fussiness. These children might not have AOM or they might have AOM mild enough to follow with watchful waiting. It is possible that unnecessary ear rechecks also contribute to excessive diagnoses of AOM.

For children with genuine recurrent AOM (3 or more episodes in 6 months), several strategies are likely to be helpful. Immunization with the pneumococcal conjugate vaccine and annual influenza vaccination have both been shown to have a small but statistically significant impact on the frequency of AOM, although the major benefit of each of these vaccines is in the prevention of systemic disease. Reduction in exposure to passive smoke and elimination of bottle propping and pacifiers are probably helpful. Xylitol gum or syrup use may also be helpful. Gastroesophageal reflux also appears to contribute to AOM, and it is possible that appropriate treatment of this condition could reduce middle ear disease. In some cases, undiagnosed food allergies probably contribute to GI disturbances, chronic rhinorrhea, and eczema. The chronic nasal congestion in turn contributes to AOM. For children in day care, recurrent rhinorrhea is the norm, and parents can be reassured that it will eventually resolve, particularly with the onset of summer. Particularly in infants evidence is growing that probiotics may reduce the incidence of infections, including otitis media, during the first year of life. While the evidence is not sufficient to support this practice, no detrimental effects have been described so the practice need not be discouraged.

In the event that recurrent AOM leads to intolerable symptoms, or is associated with significant complications or multiple, clinically significant antibiotic sensitivities, ventilation tube placement is a good option. In most cases, however, AOM is a benign, easily treatable condition that responds well to a combination of amoxicillin and analgesics. Furthermore, recurrent AOM has a favorable natural history, and in the only RCT of tympanostomy tubes vs. watchful waiting, tubes reduced the incidence of AOM and/or otorrhea by only one episode per year. On a positive note, ventilation tubes will turn what would otherwise be an episode of AOM into an episode of purulent ear drainage. Such drainage is likely to be less painful than the comparable episode of AOM and is effectively treated with ear irrigation ("otic toilet") and fluoroquinolone drops. Unfortunately, placement of ventilation tubes is also associated with an increased risk of long-term tympanic membrane abnormalities and reduced hearing compared to medical therapy. Thus, it is reasonable to reserve ventilation tube placement for those children with a more problematic clinical history.

Although it is tempting to place children on long term antibiotic therapy for the prophylaxis of recurrent AOM, long term therapy is not recommended in this era of increasing antibiotic resistance.

### Management of Otitis Media with Effusion (OME)

The diagnosis and treatment of OME are summarized in Table 3. Decongestants and nasal steroids are not recommended

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because multiple studies have shown them to be ineffective in hastening the clearance of middle ear fluid.

Approximately 80-90% of children will have at least one episode of OME by age 3 and 10-20% of well children will have OME detected at any given time. The significance of this observation is unclear, since most cases (80-90%) will resolve spontaneously in 3-4 months.

The two major complications of OME are:

- 1) a transient hearing loss, potentially associated with language development or behavioral problems, and
- 2) chronic anatomic injury to the tympanic membrane leading to the need for reconstructive surgery.

The likelihood of either of these outcomes depends on the persistence of the middle ear effusion and its association with chronic, negative middle ear pressures.

In order to address these complications of OME, it is worthwhile to distinguish between (a) transient serous or purulent effusions with neutral or positive pressure and (b) chronic mucoid effusions with negative pressure and anatomic changes to the TM.

In the absence of a significant hearing loss, evidence of damage to middle ear structures, or risk factors for poor outcome (see Table 4), we recommend clinical reevaluation for all children with OME at 3 month intervals until the effusion is cleared or complications are identified. Screening for speech delays should be undertaken at all regular well visits as well as at these clinical reevaluations. If developmental delay becomes apparent, the child should be referred to otolaryngology. In the event that the effusion appears mucoid or the tympanic membrane exhibits retraction pockets, tympanic membrane atelectasis, tympanic membrane adhesion to ossicles, or apparent cholesteatoma, the child should be reevaluated in 4 to 6 weeks to confirm the findings and then be referred to otolaryngology. Ideally, the routine use of pneumatic otoscopy will increase the rate of identification of such anatomic abnormalities even in the absence of MEE, particularly in children with benign abnormalities of the tympanic membrane such as tympanosclerosis.

Although it is often possible to rule out significant language delay using a routine screen for developmental milestones (such as the Ages and Stages screening tools), a referral to Early On (1-800-EARLY-ON) for a formal developmental evaluation is frequently appropriate. Early On is a state program mandated to provide developmental testing for children at risk of developmental delays. Such an evaluation would also provide parents with guidance in maximizing their child's development. This is particularly important since socioeconomic factors appear to have a substantial impact on language development and probably have more of an effect than the presence of OME with hearing loss. In many cases educational interventions may be as effective as surgical interventions. Interventions might include educating parents about effective strategies for optimizing the listening-learning environment for children with OME and hearing loss and providing appropriate books for parent/child reading (e.g., Reach Out and Read, which is a program providing books to the parents of young children at all well child visits).

## Communication between Primary Care and Specialty Clinicians

Optimal outcomes depend on communication between primary care and specialty clinicians. This communication could include a comprehensive timeline of middle ear disease, apparent resolution of MEE, and the use of antibiotic therapy and its subsequent complications. At a minimum, primary care clinicians should clearly indicate their reasons for referring the patient and their own clinical judgment about appropriate therapy. The specialist can then make a definitive decision about care that takes into account the perspectives of the individual primary care clinician. Such communication would likely increase trust between the otolaryngologist and the primary care clinician, decrease mixed messages heard by parents, and increase the confidence with which referrals are made.

## Special Circumstances

### Special Populations

**Otitis media in infants 0–8 weeks old.** The preceding guidelines specifically exclude the treatment of AOM in young infants. This population is at increased risk of a severe or atypical outcome from suppurative AOM. Middle ear pathogens found in young infants include the usual bacteria found in acute otitis media as well as Group B strep, gram negative enteric bacteria, and *Chlamydia trachomatis*. Febrile young neonates (<2 week old) with apparent AOM should undergo a full sepsis work up as would be otherwise indicated. Initiation of empiric amoxicillin is probably acceptable for infants over 2 weeks of age with URI and AOM who are otherwise well.

**Otitis media in adults.** Very little information has been published to guide recommendations for the management of middle ear disease in adults. In general one would expect that the principles discussed above would be expected to apply to the average patient with a long history of middle ear disease. However, the new onset of persistent middle ear disease in this population justifies a more thorough evaluation, specifically to rule out the possibility of a more serious underlying condition such as nasopharyngeal carcinoma.

Isolated AOM or transient OME may be due to a recent viral URI or superimposed Eustachian tube dysfunction. Patients with these conditions should be reevaluated at six weeks for resolution. Tympanometry or audiometry may be considered as part of this evaluation.

All adults with recurrent or persistent AOM or OME should probably be referred to otolaryngology for further evaluation, especially those without a lifelong history of middle ear disease. This includes adults with symptoms lasting more than six weeks, two or more episodes in a year, or persistent hearing loss.

### Special Situations

**Primary care follow-up and management of tympanostomy tubes.** Be familiar with the preferences of the surgeon to whom you refer patients, since he/she will likely be handling any complications of tube placement. Recommendations of the Division of Pediatric Otolaryngology at the University of Michigan Medical Center are summarized below.

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**Post-op irrigation.** After the tubes are placed in the operating room, antibiotic ear drops are placed in both ears to irrigate the tubes. The parent is given the bottle to administer the drops for the next 2 to 3 days.

**Ear drainage.** Ear drops combining a fluoroquinolone with a corticosteroid (i.e. Ciprodex) are the safest and most effective therapy for the draining ear. This includes ears draining through either a perforated ear drum or a patent tympanostomy tube. To be maximally effective, ensure that the drops can get to the site of infection. For this reason, clear the ear of purulent material prior to administration of antibiotic drops and introduce the antibiotic drops into the middle ear by pumping on the external ear canal with the tragus. Purulent debris can be easily cleared by warm water irrigation using 10 cc syringe topped with the luer from a cut off butterfly needle. The canal can then be dried using cotton or soft tissue paper.

In the presence of tympanic membrane perforations or ventilation tubes, do NOT use aminoglycoside containing ear drops since they are ototoxic. Do NOT use alcohol containing ear drops. An alternative would be to use a wash of white vinegar and water mixed 1:1.

Patients with significant systemic symptoms, such as fever, might benefit from systemic antibiotics.

**Management of tympanostomy tubes.** Most otolaryngologists no longer advise their patients to use ear plugs with swimming, bathing, or washing hair. In most cases the physical characteristics of the ventilation tubes prevent the entry of liquids into the middle ear space unless the child dives into deep water or pumps the liquid into the middle ear. In the event of subsequent otorrhea, infusion of fluoroquinolone drops is usually the only therapy necessary.

Patients with tubes should follow up with otolaryngology every six months and should be referred back to otolaryngology in the event of suspicion for ongoing middle ear disease. Tubes should be removed if they remain in place longer than 3 years.

**Cerumen removal.** The clinical justification for the removal of cerumen from asymptomatic patients is uncertain. Although this procedure has the potential to improve the visualization of the tympanic membrane, it also has the potential to cause significant morbidity, particularly pain, bleeding, and fear. The decision to remove cerumen should depend on the skill of the practitioner, the nature of the cerumen impaction, and the likely impact that examining the tympanic membrane will have on making therapeutic decisions.

If clinically indicated, the occasional diagnosis and treatment of AOM is appropriate even in the absence of full tympanic membrane visualization. A flexible approach is likely to result in an improved benefit/harm ratio. Tympanometry can sometimes demonstrate the clearance of MEE without the full visualization of the tympanic membrane.

In the event of hard packed cerumen, repeated irrigation with a warm mixture of hydrogen peroxide and warm tap water has the potential to loosen or remove the cerumen. Cerumenolytic drops such as carbamide peroxide (Debrox) or docusate sodium (Colace) can be helpful in softening the cerumen prior to removal. Proper restraint will also assist in atraumatic cerumen removal. In the absence of ear pain or apparent hearing loss, removal of cerumen does not provide additional benefit to the patient and is not necessary.

Children with cerumen impaction and tympanostomy tubes should be referred to otolaryngology for further management. It is also reasonable to refer young children with cerumen impactions to otolaryngology, since removal of such impactions is probably facilitated by access to an operating microscope and suction. Such children should have cerumenolytic drops instilled into the ears to soften the wax prior to the clinical encounter.

Ear candling, or auricular coning, is an "alternative medical procedure" that involves placing a cone shaped device in the ear and lighting it on fire, supposedly generating a vacuum to draw out wax. This practice is both ineffective and dangerous and can result in significant damage to the tympanic membrane and should be avoided.

**Acute otitis externa (AOE).** AOE is diagnosed by pushing on the tragus anterior to the external ear canal. If this procedure provokes severe pain, the diagnosis of AOE is likely. Although this diagnosis can generally be made on history alone, a clinical evaluation is usually indicated, since similar symptoms might be associated with aggressive disease. It is possible that the external auditory canal is so obstructed with purulence or debris that it is impossible to infuse antibiotic drops. In such a situation, the ear canal should be gently irrigated prior to infusion of antibiotic drops. Occasionally the walls of the canal are so swollen, that it might be necessary to place a wick, and an urgent referral to otolaryngology might be indicated.

The most recent literature review of AOE indicates that there is little clinical difference between the efficacy of topical antiseptics and that of topical antibiotics. Therefore, the instillation of dilute vinegar is probably sufficient in most cases. Persistent cases can be treated with a topical fluoroquinolone combined with a corticosteroid. Fluoroquinolone containing drops are also indicated in the event of a possible TM perforation. Analgesia, such as ibuprofen is always indicated for children with otitis externa. Given the severe pain sometimes associated with this condition, more potent pain medications such as codeine might be indicated.

**Bullous myringitis.** This is the development of blisters on the tympanic membrane in the context of AOM. The lesions can be singular or multiple and are generally associated with more severe symptoms of pain and fever. Bullous myringitis is noted with 1-16% of AOM episodes and has a slightly higher association with AOM in older children (>2 years old) and with recurrent AOM. A common misapprehension is that bullous myringitis is associated with *Mycoplasma pneumoniae* infection. In fact, several studies have demonstrated that bullous myringitis is seen in infections with the usual spectrum of bacterial pathogens- *H. influenzae*, *S. pneumoniae*, and *Moraxella catarrhalis*. Because of the more severe symptoms, it is reasonable to be more proactive in analgesia managements. These patients would not be good candidates for "watch and wait" antibiotic prescriptions and are likely to benefit from initial treatment with amoxicillin clavulanic acid.

**Spontaneous ear drum perforation.** This perforation occurs in approximately 6% of cases of AOM. In most cases it results in symptomatic relief of pressure from the middle ear. The resulting otorrhea however, can be disturbing to patients and their parents. As discussed above, ear drops containing fluoroquinolones (Ciprodex) can be an effective treatment in this situation.

In most cases, these ruptures will resolve spontaneously. Patients should be seen in follow up after 6 weeks to document healing. Referral to otolaryngology should occur if the perforation has not resolved in 12 months.

Patients can be allowed to swim with a perforated ear drum, but should be advised not to dive deeply.

**Mastoiditis.** Because mastoiditis can be a complication of AOM, some have raised concerns that the incidence of acute mastoiditis would increase with decreasing use of antibiotics. In a recent study looking at mastoiditis rates before and after the publications of the national AOM guidelines, no change in the rates of mastoiditis was identified.

### Strategy for Evidence Search

The guideline team had access to the literature searches performed for the initial version of this guideline (1997) and its updates (2002, 2006). For this update the literature search began with a review updated AHRQ Evidence Report on Management of Acute Otitis Media, which included a systematic review of literature through July 2010 (see annotated references). To supplement these searches with more recent findings, the team then conducted a prospective search of literature published on Medline from 7/1/10 to 9/30/12 (unless otherwise noted) using the major keywords of: human, English language, guidelines, controlled trials, and cohort studies. Eleven specific searches were performed using the following terms. Detailed search terms and strategy available upon request.

- (1) Otitis media with effusion or serous effusion: audiogram or oto acoustic emissions, diagnosis, treatment (since 6/1/06).
- (2) Recurrent otitis media, recurrent acute OM, or chronic or persistent OM: diagnosis, treatment.
- (3) Acute otitis media since (not recurrent, persistent, or chronic [addressed in #2]): etiology and natural history, diagnosis (signs and symptoms, hearing loss, delayed language development, otoscopy, pneumatic otoscopy, tympanometry, tympanocentesis, other diagnosis), treatment (antibiotic therapy [amoxicillin, cephalosporins, other antibiotics], adjunctive therapy (corticosteroid, antihistamines, decongestants, other), myringotomy or tympanostomy tubes, laser tympanostomy or laser miringotomy, complementary/alternative treatment (since 1/1/2001), other treatment.
- (4) Otitis media: infants 0–4 weeks (since 1/1/2001), diagnosis, treatment.
- (5) Otitis media: adults (since 1/1/2001), diagnosis, treatment.
- (6) Otitis media and mastoiditis.
- (7) Otitis media and screening for speech delay.
- (8) Otitis media not in #1–#7: diagnosis, treatment.
- (9) Cerumen impaction: treatment (since 6/1/06).
- (10) Otorrhea: treatment.
- (11) Probiotic bacteria after antibiotics (since 6/1/06).

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with recent clinical trials known to expert members of the panel, including subsequent minor revisions in 2014 based on evidence reported in the 2013 American Academy of Pediatrics guideline on the diagnosis and management of otitis media and other more recent clinical trials. Negative trials were specifically sought. The search was a single cycle. Conclusions were based on prospective randomized

controlled trials if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size. Expert consensus was used to formulate recommendations based on the available evidence.

### Related National Guidelines

This guideline generally conforms to:

- Management of Acute Otitis Media: Update. Evidence Report/Technology Assessment No. 198, Agency for Healthcare Research and Quality (2010)
- The Diagnosis and Management of Acute Otitis Media. Clinical Practice Guideline, American Academy of Pediatrics (2013).

### Measures of Clinical Performance

At this time no major national programs have clinical performance measures specifically for the diagnosis and treatment of otitis media.

### Disclosures

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member	Company	Relationship
R. Alexander Blackwood, MD, PhD	(none)	
Heather L Burrows, MD PhD	(none)	
James M. Cooke, MD	(none)	
Kathryn M. Harmes, MD	(none)	
Van Harrison, PhD	(none)	
Peter P Passamani, MD	(none)	
Kristin C Klein, PharmD	(none)	

### Review and Endorsement

Drafts of this guideline were reviewed in clinical conferences and by distribution for comment within departments and divisions of the University of Michigan Medical School to which the content is most relevant: Family Medicine, General Internal Medicine, General Pediatrics, Pediatric Infectious Disease, and Pediatric Otolaryngology. The guideline was approved by the UM C. M. Mott Children Hospital’s Pediatric Medical Surgical Joint Practice Committee and Executive Committee. The Executive Committee for Clinical Affairs of the University of Michigan Hospitals and Health Centers endorsed the final version.

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1997: Richard Linsk, MD, PhD, General Pediatrics, Alexander Blackwood, MD, PhD, Pediatric Infectious Disease, Steven Elgert, MD, Family Medicine, Van Harrison, PhD, Medical Education, H. Mark Hildebrandt, MD, General Pediatrics, Marci Lesperance, MD, Pediatric Otolaryngology.

2002: Richard Linsk, MD, PhD, General Pediatrics, Alexander Blackwood, MD, PhD, Pediatric Infectious Disease, James Cooke, MD, Family Medicine, Van Harrison, PhD, Medical Education, H. Mark Hildebrandt, MD, General Pediatrics, Marci Lesperance, MD, Pediatric Otolaryngology.

2007: Richard L. Linsk, MD, PhD, General Pediatrics, R. Alexander Blackwood, MD, PhD, Pediatric Infectious Disease, James M. Cooke, MD, Family Medicine, R. Van Harrison, PhD, Medical Education, Peter P Passamani, MD, Pediatric Otolaryngology.

## Annotated References

### Related national guidelines

Shekelle PG, Takata G, Newberry SJ, et al. Management of Acute Otitis Media: Update. Evidence Report/Technology Assessment No. 198. (Prepared by the Rand Evidence-Based Practice Center under Contract No. 290 2007 10056 I). Rockville, MD: Agency for Healthcare Research and Quality, November 2010.

Review of empirical evidence regarding treatments for acute otitis media.

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National OME guideline developed by representatives of the three specialty societies.

### Other annotated references

Coker, TM et al. (2010) Diagnosis, microbial epidemiology, and antimicrobial treatment of acute otitis media in children. *J Am Med Assn* 304:2161-2169

A systematic review of otitis media diagnosis and management taking into account the 2004 AAP guidelines and the widespread use of the pneumococcal conjugate vaccine.

Le Saux, N, et al. (2005) A randomized, double-blind, placebo-controlled noninferiority trial of amoxicillin for clinically diagnosed acute otitis media in children 6 months to 5 years of age. *Canadian Med. Assoc. J.* 172, 3: 335-341

Randomized, placebo controlled trial of 451 children of amoxicillin for moderate AOM. More pain at 3 days in placebo group. Clinical resolution at 14 days in 93% of amoxicillin treated subjects and 84% of subjects on placebo.

Marcetti, F et al. (2005) Delayed prescription may reduce the use of antibiotics for acute otitis media. *Arch Pediatr Adol Med* 159: 679-684

Observational trial of children with symptomatic AOM followed without antibiotics. Of the 933 initially followed with analgesics alone, only 24% ended up taking antibiotics. Clinical failure was associated with high fever and a red bulging ear drum. 50% of subjects had fever > 38 degrees at enrollment. Recurrent AOM and otorrhea were excluded.

Dagan, R, et al. (2000) Bacteriologic and clinical efficacy of amoxicillin/clavulanate vs. azithromycin in acute otitis media. *Pediatr Infect Dis J* 19:95-104

Double-tap study showing that antibiotics have a limited impact on clinical outcome and demonstrating that amoxicillin is significantly more effective in clearing middle-ear pathogens than conventional dose azithromycin.

Piglansky, L, et al. (2003) Bacteriologic and clinical efficacy of high dose amoxicillin for therapy of acute otitis media in children. *Pediatr Infect Dis J* 22:405-412

Double-tap study showing that high dose amoxicillin eliminated 62% of beta-lactamase positive H flu and 92% of pneumococcus indicating that it is superior to many second-line agents.

Leibovitz, E, et al. (2000) Bacteriologic and clinical efficacy of one day vs. three day intramuscular ceftriaxone for treatment of nonresponsive acute otitis media in children. *Pediatr Infect Dis J* 19:1040-5

Demonstrates the efficacy of IM ceftriaxone even in the case of patients with multiply resistant pneumococcus. Three doses of ceftriaxone are significantly more effective than a single dose.

Arguedas, A, et al. (2006) A multicenter, open label, double tympanocentesis study of highdose cefdinir in children with acute otitis media at high risk of persistent or recurrent infection. *Pediatr Infect Dis J* 25: 211-218

Double tap study of high dose cefdinir in untreated children with a history of previous AOM. 51% of 447 children enrolled had bacteria present at initiation of therapy. Repeat tympanocentesis was done 3-4 days after initiation of therapy. Cefdinir cleared only 72% of H flu and only 43% of resistant pneumococcus. Thus cefdinir does not provide the kind of in vivo bacteriologic success that most clinicians would attribute to an oral third generation cephalosporin. Similar patterns have been seen with all cephalosporins previously tested.

Arrieta, A et al. (2003) High dose azithromycin versus high-dose amoxicillin-clavulanate for the treatment of children with recurrent or persistent acute otitis media. *Antimicrobial Agents and Chemo* 47, 10: 3179-3186.

Randomized trial of 300 children with persistent or recurrent AOM. 63% had positive bacterial middle ear cultures. Azithromycin 20 mg/kg/day for 3 days was

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comparable or superior to high dose amoxicillin/clavulanate.

Paradise, JL, et al. (2005) Developmental outcomes after early or delayed insertion of tympanostomy tubes. *N Eng J Med* 353;6 : 576-586

Randomized trial of 429 children with persistent OME showing minimal effects of delaying VT placement on long term language development

Stenstrom, R, et al. (2005) Hearing thresholds and tympanic membrane sequelae in children managed medically or surgically for otitis media with effusion. *Arch Pediatr Adol Med* 159: 1151-1156

Follow up on randomized trial of VT placement vs. observation for 125 children with OME. 6-10 years later, subjects who received tubes were 4 times as likely to have pathologic abnormalities of the tympanic membrane including a 9 fold increase in perforations, atelectasis, and retraction pockets. Surgically treated subjects had hearing thresholds 2-8 dB higher than subjects managed medically.

Dohar, J, et al. (2006) Topical ciprofloxacin/dexamethasone superior to amoxicillin/clavulanic acid in acute otitis media with otorrhea through tympanostomy tubes. *Pediatrics* 118, 3: e561-9.

Randomized trial of 80 children demonstrating significantly more clinical cures (85% vs 59%) in children receiving topical vs. oral antibiotic therapy.

Turner, D et al. (2002) Acute otitis media in infants younger than two months of age: microbiology, clinical presentation and therapeutic approach. *Pediatr Infect Dis J* 21:669-674

Tympanocentesis and clinical course data was reviewed on 137 infants under 2 months. Typical pathogens for acute otitis media were identified. Acute otitis media did not affect the risk of a serious bacterial infection in these infants.