# Otitis Media: To Treat, To Refer, To Do Nothing: A Review for the Practitioner

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## Practice Gap

Acute otitis media is the most common bacterial illness in children and the most common medical condition for which antibiotics are recommended. A significant part of the financial burden resides in frequent antibiotic prescriptions, despite published evidence showing that antibiotics often are not indicated for treatment. This and other factors suggest the need for a review of the management of otitis media.

## Objectives

After completing the article, the reader should be able to:

1. Provide a review of the current recommendations for the recognition and treatment of acute otitis media.
2. Describe the current recommendations for the diagnosis and treatment of otitis media with effusion.
3. Delineate the complications related to chronic suppurative otitis media.

### INTRODUCTION AND EPIDEMIOLOGY

Otitis media (OM) is one of the most common clinical complaints in the pediatrician's office, accounting for more than 30 million clinic visits per year. (1) It is the second leading diagnosis in pediatric emergency department visits, comprising approximately 13% of all emergency department visits in any given year. Costs are estimated at more than $100 per episode of OM, with up to $5 billion spent in diagnosis and treatment annually. Most cases occur in children between 6 and 24 months of age, with a peak incidence between 9 and 15 months. In fact, as many as 62% of children have an episode of OM by the time they are 12 months old, and up to 83% of children are affected by their third birthday. (1) Acute OM (AOM) is uncommon in the first 6 postnatal months, and if identified, further evaluation is warranted. OM can be clinically identified as one of three entities: otitis media with effusion (OME), AOM, and chronic suppurative otitis media (CSOM).

**AUTHOR DISCLOSURE** Drs Rosa-Olivares, Porro, Rodriguez-Varela, Riefkohl, and Niroomand-Rad have disclosed no financial relationships relevant to this article. This commentary does not contain a discussion of an unapproved/investigative use of a commercial product/device.

## PATHOGENESIS OF ACUTE OTITIS MEDIA AND OTITIS MEDIA WITH EFFUSION

Eustachian tube dysfunction is usually triggered by a viral process. Such dysfunction is further complicated in early infancy by the horizontal anatomy of the tube, which makes middle ear fluid flow more challenging. Usually a viral upper respiratory tract infection precedes the onset of middle ear effusion (MEE). A viral process increases mucus production in the nasopharyngeal region, creating inflammation in the area. This eventually results in closure of the eustachian tube and buildup of fluid behind the tympanic membrane (TM). When OME develops, the middle ear fluid is sterile, but secretions from the nasopharyngeal area are not. Microorganisms present in the nasopharynx reflux into the middle ear space when the eustachian tube temporarily relaxes. This can result in bacterial adherence and colonization, which eventually can develop into the inflammatory process of AOM.

Eustachian tube function can be further compromised by factors such as bottle-feeding. Compared to breastfeeding infants, the child drinking from the bottle typically does not need to exert strong negative pressure to suck and swallow with breathing efforts. Because of pressure gradients and positioning during feeding, bottle-fed infants are more prone to develop milk pooling and pressure differentials between the middle ear and the nasopharynx, thereby reducing eustachian tube drainage. (2) Thus, exclusive breastfeeding for the first 6 months after birth protects against AOM and continues to be the recommendation of the American Academy of Pediatrics (AAP).

In addition to age and eustachian tube dysfunction, other factors contribute to the development of AOM and OME. The most common are listed in the Table.

Bacterial pathogens that most commonly trigger the inflammatory changes of AOM are *Streptococcus pneumoniae* (12%), nontypeable *Haemophilus influenzae* (56%), and *Moraxella catarrhalis* (22%). These bacteria are prevalent at all ages, including neonates. In addition, Gram-negative bacilli have been implicated in 10% of cases reported during the neonatal period. Of note, the incidence of *S pneumoniae*-related infections has significantly decreased since the implementation of universal vaccination with pneumococcal conjugate vaccine (PCV)7 and is projected to decrease further with the use of the PCV13 vaccine. Currently, nontypeable *H influenzae* strains are becoming the primary otopathogen in AOM, particularly in older children. During the first months after birth, diagnosing OM can be difficult due to limited examination and improper instrumentation. If AOM is diagnosed in the neonatal period, careful evaluation and follow-up is necessary because OM may be an isolated local infection or part of a septicemia. Depending on the presence or absence of fever, a partial or full sepsis evaluation and tympanocentesis for culture of the middle ear should be considered for the neonate.

TABLE. **Risk Factors for the Development of Acute Otitis Media and Otitis Media With Effusion**

| | |
|---|---|
| • Secondhand smoke | • Suboptimal breastfeeding rates |
| • Preterm birth | • Male gender |
| • Propped bottles/ supine feeding position | • Poor parental education |
| • Lack of pneumococcal vaccination | • Young age |
| • Siblings at home | • Day care participation |
| • Poor maternal health during pregnancy | • Allergic rhinitis |
| • Congenital facial or nasal anomalies | • Adenoid hypertrophy |
| • Family history of recurrent acute otitis media | • Obesity |
| • Gastroesophageal reflux | • Immunodeficiencies |
| • Pacifier use | • Ethnicity |
| • Fall and winter season | |

## CLINICAL MANIFESTATIONS OF ACUTE OTITIS MEDIA AND OTITIS MEDIA WITH EFFUSION

Patients with AOM often present with rapid onset of fever and ear pain as well as nonspecific signs, such as ear pulling/rubbing, irritability, decreased sleep, and other behavioral changes. Of these, ear pain is usually the most prominent symptom. Combinations of these clinical manifestations along with physical findings are key for diagnosing AOM. Differentiating between AOM and OME on physical examination depends on a combination of factors:

- Moderate-to-severe bulging of the TM (Fig 1) or new-onset otorrhea that is not related to otitis externa
- Mild bulging of the TM combined with sudden recent onset of ear pain or intense erythema of the TM

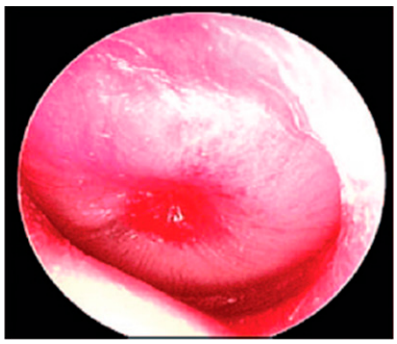

**Figure 1.** Acute otitis media. Reprinted with permission from Siegel RM, Bien JP. Acute otitis media in children: a continuing story. *Pediatr Rev*. 2004;25:187–193.

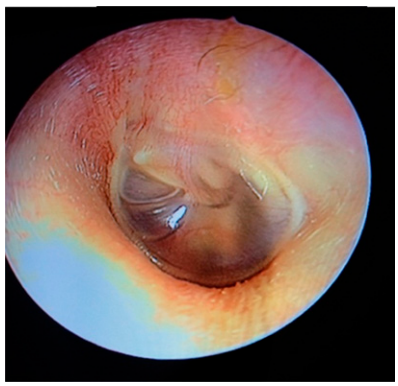

**Figure 2.** Otitis media with effusion. Courtesy of Yadiel A. Alameda, MD, Caribbean Sinus and Ear Institute, Puerto Rico.

- Presence of MEE

Bullous myringitis may occur in association with AOM in fewer than 10% of cases. In the past, *Mycoplasma* was believed to be the causative agent, but researchers have determined that the pathogens causing bullous myringitis and AOM are the same. Bullous myringitis is simply an extension of AOM and is not an indication for macrolide therapy.

OME is defined as the presence of middle ear fluid in the absence of acute symptoms such as TM bulging or erythema, otorrhea, pain, or fever. OME is the most prevalent ear disease in children. Between 80% and 90% of children have at least one confirmed episode of OME before school age and many develop recurrent (30%–40%) or persistent (5%–10%) effusion. Up to 50% of patients have OME 1 month after initial diagnosis of AOM, one third have OME 2 months after AOM, and 10% have OME 3 months after AOM. Tympanocentesis is the preferred method for detecting the presence of MEE, but it is rarely performed in the primary care setting. Otoscopy usually shows a translucent, gray or pink TM in a neutral or retracted position and visible fluid behind it (Fig 2). OME is the most common cause of conductive hearing loss in children. Children at high risk for language delay, learning problems, or evidence of significant hearing loss should be monitored at 3-month intervals to ensure resolution of the effusion. Intervention is necessary if hearing loss or structural abnormalities to the TM or middle ear are suspected. Pediatricians should consider otolaryngology (ENT) evaluation for patients whose OME persists longer than 3 months and is accompanied by speech delay and/or conductive hearing loss.

The AAP, American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery all agree that the best tool to differentiate AOM from OME is pneumatic otoscopy. Reduced mobility of the TM or response to negative pressure on pneumatic otoscopy is pathognomonic for OME. As an adjunct to otoscopy, tympanometry and acoustic reflectometry may be used to obtain a diagnosis. There is no evidence that these modalities are superior to pneumatic otoscopy. Tympanometry measures sound transmission by evaluating TM compliance, with more fluid in the middle ear creating less compliance of the membrane and less sound transmission. Acoustic reflectometry measures sound intensity when reflected back from the TM, with more fluid in the middle ear resulting in less mobility of the TM and, therefore, louder reflected sound captured by the instrument.

## MANAGEMENT OF ACUTE OTITIS MEDIA

When choosing a treatment plan for AOM, clinicians must consider both patient age and illness severity. The primary decision is whether observation without antibiotics (watchful waiting) is appropriate.

Observation with pain control (acetaminophen, ibuprofen, or topical anesthetics such as antipyrine-benzocaine drops) is a management option for children between 6 and 24 months of age who have unilateral nonsevere illness and for children older than 24 months who have unilateral or bilateral nonsevere disease. When feasible, observation without antibiotics is preferred because any reduction in antibiotic use is associated with decreased costs, fewer adverse effects, and diminished microbial resistance.

Pain with AOM may cause significant distress during the first few days of illness that often persists longer in younger children. Analgesics can provide pain relief within 24 hours, allowing some time for symptomatic alleviation

while the patient's natural immunity begins to respond. It is important to inform parents that symptomatic relief without the use of analgesics occurs 3 to 5 days into treatment for children who require antibiotic treatment. Follow-up should be arranged within 48 to 72 hours for reevaluation, whether in person or by phone, and if there is no improvement or symptoms have worsened, medical management should be instituted.

The justification for withholding antibiotic treatment from selected children with AOM is based upon analysis of numerous clinical trials conducted over the past 30 years. Review of these trials suggests most children with AOM do well without antimicrobial therapy. Observing children with AOM who are likely to improve on their own without initial antibiotic therapy reduces common adverse effects of antibiotics, such as diarrhea and diaper dermatitis. In two trials, antibiotic therapy significantly increased the absolute rates of diarrhea by 10% to 20% and of diaper rash or dermatitis by 6% to 16%. In addition, reduced antibiotic use decreases the prevalence of resistant bacterial pathogens. (3) Providing a good analgesic plan for parents, explaining what to expect in terms of pain control, and discussing the need for follow-up, especially if the signs and symptoms worsen, is an appropriate evidence-based approach.

Current guidelines from the AAP recommend immediate treatment for children younger than 6 months of age, those with severe illness, and children younger than 24 months of age with bilateral AOM. Once the decision is made to start antibiotic therapy, medication choice depends on when the child was treated last:

- If it has been more than 30 days from the last infection and the patient does not have purulent conjunctivitis (which can indicate infection by beta-lactam-resistant nontypeable *H influenzae*), amoxicillin is the antibiotic of choice dosed at 90 mg/kg per day divided in two doses. This higher dosing allows for better drug penetration into the middle ear as well as increased minimal inhibitory concentration. High-dose amoxicillin may also overcome the mechanism of penicillin resistance associated with PBP2x (penicillin-binding protein) in *S pneumoniae*.
- If it has been fewer than 30 days from the last infection or there is concomitant purulent conjunctivitis, amoxicillin plus clavulanate should be used, with the amoxicillin component at 90 mg/kg per day divided in two doses.

In cases of penicillin allergy, cefdinir, cefuroxime, cefpodoxime, and ceftriaxone are acceptable alternatives. If there is no improvement after treatment with amoxicillin for 48 to 72 hours, amoxicillin-clavulanate should be administered. Alternative drug choices for those with penicillin allergy in this situation are ceftriaxone and clindamycin. The length of treatment with oral antibiotics should be 10 days for children younger than 2 years of age, 7 days for children ages 2 to 5 years, and 5 to 7 days for children 6 years and older. If using ceftriaxone intramuscularly, the treatment duration is 3 days.

Close follow-up evaluation for patients with AOM is important because persistent treatment failure may necessitate further evaluation by an otolaryngologist or infectious disease specialist. In these cases, tympanocentesis or myringotomy tube placement may be indicated. This allows for culturing of the fluid specimen from the middle ear for bacteriologic diagnosis as well as drainage of the infection. Identifying the causative agent may also be necessary in immunocompromised patients and in those who are seriously ill or who have suppurative complications. The algorithm in Figure 3 describes the evaluation and management of AOM.

## MANAGEMENT OF OTITIS MEDIA WITH EFFUSION

The aim of treatment for OME is to prevent its two major complications: transient hearing loss potentially associated with language delay or behavioral problems and chronic anatomic injury to the TM that usually leads to surgery. As with AOM, the initial modality is watchful waiting. There is little harm in observing the child who is not at risk for speech, language, or learning difficulties compared to medical or surgical intervention. Parents should be informed that the child may have reduced hearing until the effusion resolves, but a short-lived effusion has minimal effect on the child's language development. About 70% to 90% of OME cases that result from AOM resolve spontaneously by 3 months. Documented bilateral OME of 3 months' duration or longer resolves spontaneously after 6 to 12 months in about 30% of children who are older than 2 years of age. In the absence of hearing loss, damage to the ossicular structure, or other middle ear pathology, all children with OME should be clinically reevaluated at 12-week intervals until the effusion clears or other complications are identified. As recommended by the AAP, screening for speech delays should be undertaken at all health supervision visits as well as at these clinical reevaluations. If speech delay is a concern, the child should be referred for further evaluation. On the other hand, if complications such as atelectasis of the TM, retraction pockets, persistent perforation with discharge, or cholesteatoma are identified, the

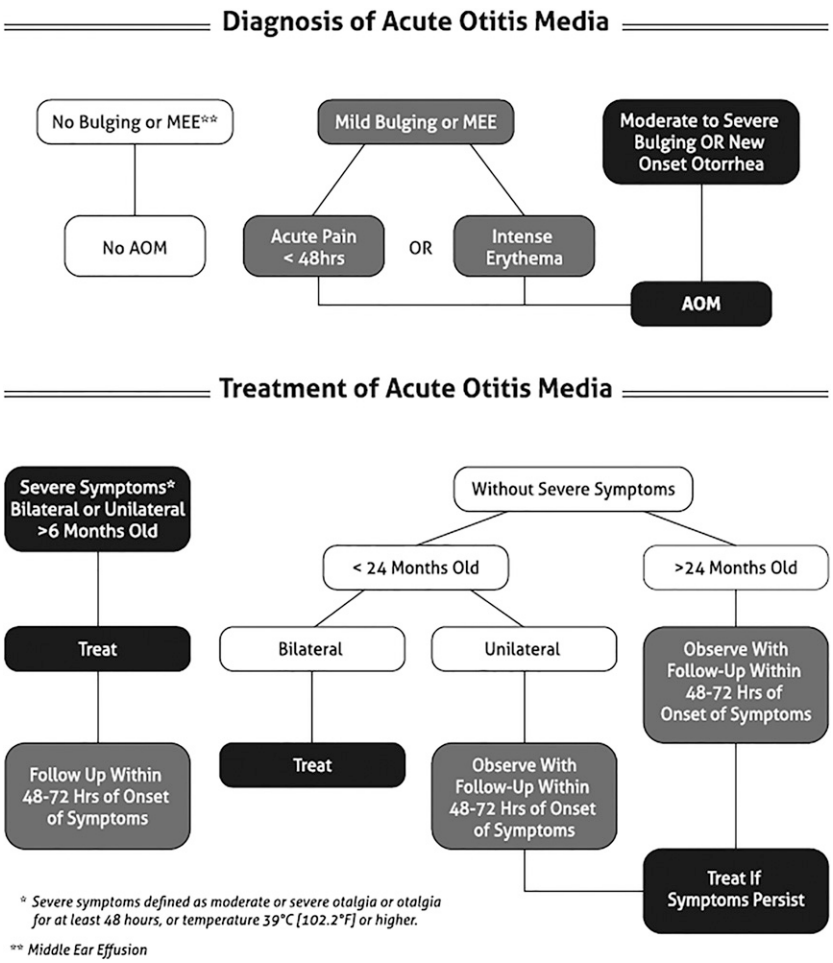


**Figure 3.** Algorithm created by Claudette Gonzales, MD, and Gabriela Saca, MD, based on information from: Lieberthal AS, et al. The diagnosis and management of acute otitis media. *Pediatrics*. 2013;131(3):e964–e999 and Leibovitz E, et al. Bacteriologic and clinical efficacy of one day vs. three day intramuscular ceftriaxone for treatment of nonresponsive acute otitis media in children. *Pediatr Infect Dis J*. 2000;19(11):1040–1045.

patient should be seen promptly (4 weeks or less) by the ENT specialist.

Medical treatment for OME is appropriate only if persistent and significant clinical benefits can be obtained clinically beyond spontaneous resolution. Studies in the past have shown a mild improvement following antibiotic therapy, but the benefits were only transient. New studies are focusing on the characteristics of the middle ear mucosa with chronic OME. A biofilm structure has been identified that could protect bacteria from medications and would argue against the benefit of antibiotic use in the management of OME. A biofilm is a complex community of microorganisms attached to a surface and protected by an extracellular polysaccharide matrix. Biofilms have been implicated in the failure of antimicrobials, reduction of their efficacy, and survival of residual organisms following drug therapy. Macrolides have known antibiofilm and anti-inflammatory properties and have been tested with promising results. Chen et al (4) showed that macrolides, specifically clarithromycin, can decrease recovery time for OME (effective rates 88.7%–92.5%, $P < 0.01$) if used in full doses for 1 week and then decreased to a low dose until after 1 week of documented resolution of MEE, typically for a total of 8 to 12 weeks. This research suggests that surgical intervention could be delayed or even avoided if macrolides clear the middle ear fluid, but further studies are needed to prove this hypothesis. Studies in which patients used antihistamines and decongestants, alone or in combination, found no benefit for any of the short- or long-term outcomes, including resolution of the fluid, hearing problems, or the necessity of additional referral to specialists. (5) Of interest, even children with allergic rhinitis and OME do not benefit from these medications. Therefore, antihistamines and decongestants are not recommended. Studies evaluating the efficacy of complementary and alternative medicine therapies have also failed to prove their efficacy in the treatment of AOM or OME.

ENT referral for evaluation of tympanostomy tubes is recommended if OME persists for more than 6 months

in one ear or 3 months in both ears in association with a 30-dB hearing loss in the speech range (500–2,000 Hz). Myringotomy alone is not recommended for OME treatment because 20% to 50% of children may relapse and need additional surgical intervention. Similarly, tonsillectomy and adenoidectomy are not routinely performed unless there are concomitant disease processes warranting such interventions. ENT evaluation is also encouraged in patients who have developed structural damage to the TM, such as retraction pockets, tympanosclerosis, and cholesteatoma (the latter usually is associated with dizziness, facial nerve weakness, or visible keratin debris in the ear canal). Children with craniofacial abnormalities and immunodeficiencies warrant an earlier evaluation by ENT to avoid further complications.

## CHRONIC SUPPURATIVE OTITIS MEDIA PATHOGENESIS AND CLINICAL DESCRIPTION

CSOM is the most severe form of OM, and despite well-designed longitudinal studies, it is the type of OM most likely to persist if untreated. CSOM is characterized by a perforated TM, with persistent drainage from the middle ear lasting more than 6 weeks. A large central perforation of the TM is most common (Fig 4).

The pathogenesis of CSOM is multifactorial. Children with immunodeficiencies, structural anomalies/malformations, and some living in native (indigenous) areas are at increased risk compared to the general population. The range of bacterial pathogens associated with CSOM is considerably broader when compared with AOM. Presently, methicillin-resistant *Staphylococcus aureus* (MRSA) is most common isolate. Methicillin-sensitive *S aureus* (MSSA), *Pseudomonas*, *Proteus*, anaerobes such as *Peptostreptococcus* and *Fusobacterium*, and fungi also have been reported. The diagnosis is based upon consistent clinical findings; cultures are reserved for unresponsive disease. Chronic suppuration can occur with or without cholesteatoma, and the clinical history of both conditions can be similar. Dizziness, facial nerve weakness, or keratin debris should prompt consideration of cholesteatoma. CSOM should be distinguished from chronic OME, in which no perforation or active infection is present. CSOM is uncommon in the developed world, but in the developing world, it has up to a 45% prevalence rate.

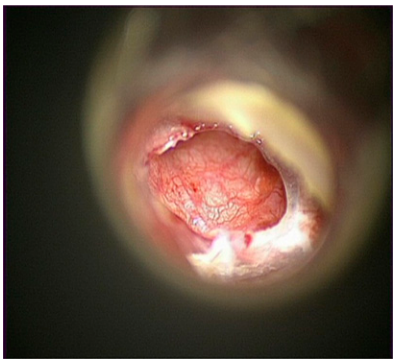

**Figure 4.** Large perforation in chronic suppurative otitis media. Courtesy of Yadiel A. Alameda, MD, Caribbean Sinus and Ear Institute, Puerto Rico.

Risk factors for the development of CSOM are similar to those for the development of AOM and OME. CSOM most often occurs in the first 5 years after birth. A recent risk factor study found that most cases of CSOM in the developed world now occur as a complication of tympanostomy tube insertion. (6) Early diagnosis is key to minimizing complications such as facial paralysis, subperiosteal abscess, mastoiditis, labyrinthitis, meningitis, cerebral abscess, lateral sinus thrombosis, extradural abscess, hydrocephalus, and encephalitis. The overall mortality rate is 7% to 15%. The incidence of CSOM complications is higher in the pediatric population.

## CHRONIC SUPPURATIVE OTITIS MEDIA COMPLICATIONS AND TREATMENT PLAN

The most common sequela of CSOM is conductive or sensorineural hearing loss. Normal hearing is in the range of 0 to 25 dB. Chronic infection of the middle ear that causes lining inflammation and discharge, TM perforation, and ossicular chain disruption can result in conductive hearing loss in the 30- to 60-dB range. This level of hearing loss is mild to moderate and would make hearing soft-to-moderate speech in a noisy background difficult. The site of perforation corresponds to the degree of hearing loss. Typically, posterior perforations result in greater decibel loss compared to other locations. Hearing assessment evaluation by audiology is necessary for any child in whom hearing loss is suspected. When identified, amplification devices are recommended for those children with long-term conductive hearing loss or bilateral sensorineural hearing loss. Children with permanent hearing loss using amplification devices should be managed by a multidisciplinary team.

Although the literature on CSOM has shortcomings, reasonable evidence supports the efficacy of topical quinolones over systemic antibiotics. Use of ofloxacin or ciprofloxacin otic solution for 2 weeks is recommended. If treatment fails,

culture-directed antibiotics should be the next option, leaving the use of parenteral antibiotics as the last alternative. Some choices for intravenous therapy include piperacillin, ceftazidime, and the quinolones. If ear discharge does not respond to 21 days of therapy, other complications or diagnoses need to be entertained. When perforations fail to heal, surgical repair may be indicated. Computed tomography scan is recommended before surgical intervention to evaluate inflammatory diseases of the temporal bone. Magnetic resonance imaging is better for locating otogenic intracranial complications. When cholesteatoma is present, mastoidectomy with tympanoplasty is typically required.

## Summary

- On the basis of research evidence, a recommended strategy for improving the care of middle ear infections is to identify the subset of patients least likely to benefit from antibiotic therapy. They include children ages 6 months to 23 months with unilateral disease without severe signs and symptoms (moderate or severe otalgia, otalgia lasting more than 48 hours, or temperature of 39°C [102.2°F]), and those older than 2 years of age with unilateral or bilateral disease who have mild signs and symptoms.(9)
- On the basis of research evidence, the initial treatment of otitis media with effusion is watchful observation. There is little harm in observing a child who is not at risk for speech, language, or learning difficulties compared to medical or surgical intervention.(4)
- On the basis of research evidence, administration of the annual influenza vaccine and the conjugated pneumococcal vaccination has been shown to have a small but statistically significant impact on the frequency of middle ear disease. (7)(8)
- On the basis of expert opinion, optimal outcomes depend on communication between clinicians and parents. At a minimum, primary care clinicians should state their reasons for their own clinical judgment about appropriate management and for referral to otolaryngology if necessary.

*CME quiz and references for this article are at http://pedsinreview.aappublications.org/content/36/11/480.full.*

## Parent Resources from the AAP at HealthyChildren.org

- English: https://www.healthychildren.org/English/health-issues/conditions/ear-nose-throat/Pages/Ear-Infection-Information.aspx
- Spanish: https://www.healthychildren.org/spanish/health-issues/conditions/ear-nose-throat/paginas/ear-infection-information.aspx
- English: https://www.healthychildren.org/English/health-issues/conditions/ear-nose-throat/Pages/Your-Child-and-Ear-Infections.aspx
- Spanish: https://www.healthychildren.org/spanish/health-issues/conditions/ear-nose-throat/paginas/your-child-and-ear-infections.aspx

# PIR Quiz

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1. In which of the following scenarios would you choose observation with pain control without the use of antibiotics?
    A. A 4-month-old with unilateral purulent effusion, decreased tympanic membrane mobility with pneumatic otoscopy, minimal pain, no fever, and no other generalized symptoms.
    B. A 15-month-old with bilateral purulent effusion, decreased tympanic membrane mobility with pneumatic otoscopy, minimal pain, no fever, and no other generalized symptoms.
    C. A 20-month-old with unilateral purulent effusion, decreased tympanic membrane mobility with pneumatic otoscopy, fever (temperature of 39.3°C [102.8°F]), and otalgia.
    D. A 30-month-old with unilateral purulent effusion, decreased tympanic membrane mobility with pneumatic otoscopy, fever (temperature of 39.4°C [103.0°F]), and otalgia.
    E. A 3-year-old with a unilateral purulent effusion, decreased tympanic membrane mobility with pneumatic otoscopy, minimal pain, no fever, and no other generalized symptoms.
2. A 15-month-old girl presents with a 3-day history of cough, congestion, and rhinorrhea and a 1-day history of temperature to 38.3°C (101°F) and right-sided "pink eye." On physical examination, she has right conjunctival injection and a right tympanic membrane that is erythematous and bulging, with minimal mobility with pneumatic otoscopy. Which of the following is the treatment of choice in this patient?
    A. Observation without the use of antibiotics.
    B. Oral amoxicillin.
    C. Oral amoxicillin-clavulanate.
    D. Topical ofloxacin ophthalmic drops.
    E. Topical trimethoprim with polymyxin B ophthalmic drops.
3. A 2-year-old girl is being seen today for a health maintenance visit. Her mother states her daughter is feeling well today, but 3 months ago, while on vacation, she was treated for a left acute otitis media with amoxicillin. The patient is fully immunized and has normal growth and development. Her physical examination findings are normal except for her left tympanic membrane, which is gray-blue. Air fluid levels are present and there is decreased tympanic membrane mobility with pneumatic otoscopy. What is the next step in the management of this patient?
    A. Oral amoxicillin-clavulanate.
    B. Oral cetirizine.
    C. Oral phenylephrine.
    D. Parenteral ceftriaxone.
    E. Reassessment in 8 to 12 weeks.
4. You see the same 2-year-old girl described in the previous question in your office 12 weeks later. She has the same physical examination findings but is still without symptoms. Her parents note that she seems to say "What?" frequently when they are talking to her. What is your next step in the management of this patient?
    A. Oral prednisone.
    B. Reassessment in 8 to 12 weeks.
    C. Referral to audiology.
    D. Referral to otolaryngology.
    E. Referral to speech pathology.

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This journal-based CME activity is available through Dec. 31, 2017, however, credit will be recorded in the year in which the learner completes the quiz.

5. A 2-year-old boy presents with an 8-week history of persistent drainage from his left ear. His mother recently lost her job and insurance and has not sought medical care for her son during this time. On physical examination, you note purulent yellow material in the right external auditory canal and a large central perforation of the tympanic membrane. Of the following, the most common pathogen causing this condition is:

   A. Methicillin-resistant *Staphylococcus aureus.*
   B. *Moraxella catarrhalis.*
   C. Nontypeable *Haemophilus influenzae.*
   D. *Pseudomonas aeruginosa.*
   E. *Streptococcus pneumoniae.*

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