

Pediatric otitis media: To treat or not to treat with antibiotics

Research shows more than 80% of cases resolve spontaneously without treatment.

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A BACTERIAL OR VIRAL infection of the middle ear, acute otitis media (AOM) is the most common childhood infection in the United States for which antibiotics are prescribed. It's also the leading reason for pediatric healthcare visits, accounting for nearly 30 million outpatient visits. Many children experience recurrent AOM.

Infants and children are prone to AOM because their short, broad, horizontal Eustachian tubes allow pathogens to spread easily from the nasopharynx to the middle ear. This permits fluid from the upper respiratory tract to travel to the middle ear, causing inflammation. The fluid accumulates microorganisms that foster infection, causing a virus or bacteria to spread.

AOM incidence starts between ages 0 and 12 months and peaks at age 2. By 12 months, 62% of infants have had at least one episode; by age 3, about 85% have had at least one episode. Incidence decreases to about 2% by age 8.

Practitioners' dilemma

Many pediatric providers aren't sure whether to prescribe antibiotics for children with presumptive AOM or to observe instead, waiting to see if the infection resolves on its own. Antibiotics are prescribed for AOM more often than for any other childhood illness, despite literature showing a positive response to watchful waiting. In fact, recent research indicates more than 80% of



AOM cases resolve spontaneously without treatment. (See *Reviewing the evidence*.) What's more, inappropriate antibiotic therapy contributes to unnecessary antibiotic use, increases bacterial resistance, reduces antibiotic efficacy, and ultimately contributes to the growing problem of bacterial resistance.



LEARNING OBJECTIVES

1. State how pediatric acute otitis media (AOM) is diagnosed.
2. Discuss the treatment of pediatric AOM.
3. Describe the educational needs of parents whose children have AOM.

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Diagnosis

Diagnostic criteria for AOM include:

- acute symptom onset
- signs and symptoms of middle ear inflammation
- bulging tympanic membrane (TM)
- decreased TM mobility
- middle-ear effusion (MEE).

In some cases, clinicians mistakenly diagnose AOM when the child doesn't meet the criteria, or when the child actually has otitis media with effusion, not AOM. Some have doubts about following AOM diagnosis and treatment guidelines. They may prescribe antibiotics simply because they don't want parents to feel they've left the office empty-handed.

Diagnosis

AOM can be diagnosed in several ways. The quickest, most common, and least uncomfortable method is otoscopic TM examination, which provides an enlarged and illuminated view of the outer and middle ear.

Guidelines recommend pneumatic otoscopy as the gold standard for providing greater diagnostic precision. With this method, a simple otoscope is adapted with an insufflator bulb; then a puff of air is released into the patient's ear to assess TM mobility. Normally, the TM fluctuates with the puff of air, whereas a bulging TM with fluid behind it doesn't move. This tool is 70% to 90% sensitive and specific in finding evidence of MEE—an im-

Reviewing the evidence

Many researchers have investigated optimal treatment of pediatric acute otitis media (AOM). Some of the published studies address the same clinical aspect of AOM, but their findings aren't in total agreement. Nonetheless, evidence from meta-analyses, systematic reviews, and randomized controlled trials show AOM resolves spontaneously in most cases. Therefore, clinical management should focus on limiting antibiotic use while providing adequate analgesia to improve the child's comfort level.

A 2009 systematic review (Sanders et al) compared an observational (watch-and-wait) approach with immediate antibiotics in children with AOM. It showed antibiotics had no early impact and modest overall impact on the course of AOM. It also found antibiotics didn't reduce tympanic membrane perforation or AOM recurrence.

Confirming these findings, a 2012 systematic review (Cheong and Hussain) discovered that 88% of AOM cases resolved spontaneously within 4 to 7 days of symptom onset in children ages 2 and older. This review also found that immediate antimicrobial therapy decreased otalgia (ear pain) by treatment day 4 and that prophylactic antibiotics were more effective in reducing AOM recurrences than adenoidectomy and tympanostomy tube placement. However, a 2013 evidence-based clinical practice guideline (Lieberthal et al) states that practitioners should not prescribe prophylactic antibiotics to reduce the frequency of ear infections in children with recurrent AOM.

Those findings were confirmed by a 2015 meta-analysis (Venekamp et al), which concluded antibiotics didn't significantly relieve otalgia. Twenty-four hours after diagnosis, otalgia resolved spontaneously in 60% of children whether or not they received antibiotics. Even 3 to 7 days after diagnosis, patients under observational monitoring had little difference in pain level than those receiving antibiotics. On the other hand, analgesics (not antibiotics) can relieve otalgia in the first 24 hours after symptom onset. Pain control is an important consideration in AOM treatment and should be provided when otalgia first develops, whether or not the child has started antibiotics. Eardrops also provide effective analgesia in some

children and can ease parents' anxiety over their child's pain.

A 2010 landmark systematic review (Kozyrskyi et al) studied the duration of antibiotic therapy for AOM with the goal of determining optimal length of therapy. It concluded a 5-day antibiotic regimen should be recommended only for uncomplicated AOM. Shorter antibiotic therapy reduces costs, improves compliance, and decreases antibiotic resistance. However, this review also found that in complicated AOM, reducing antibiotic therapy from 10 days to 5 days increased the likelihood of worsening signs and symptoms, as well as AOM relapses or recurrences. Therefore, clinicians should consider AOM severity when determining antibiotic duration.

Why treatment may fail

A 2014 meta-analysis of AOM treatment failures (Gisselsson-Solen) found that for 4,500 subjects, the observation-only approach led to more failures than antibiotic treatment. Observation may not be the best choice if the child's family has a history of poor adherence to medical or nursing guidance or if the child attends a daycare facility. Children younger than 6 months who attend daycare outside the home are at high risk for treatment failure with the observational approach and probably should receive antibiotics immediately. Conversely, if the risk of treatment failure is low, observation is a realistic approach.

A 2011 placebo-controlled trial (Tahtinen et al) compared outcomes in children ages 6 to 35 months who received amoxicillin-clavulanate with those who received placebo. The first group had 62% fewer treatment failures and were 81% less likely to need rescue treatment than the placebo group. (Treatment failure was defined as continuing or recurrent AOM signs and symptoms within 30 days of initial treatment.) These findings suggest infants and young toddlers can benefit initially from antibiotic treatment.

Overall, the evidence indicates that when determining the best way to treat AOM, clinicians should consider the child's age, AOM severity, the family's past compliance with healthcare recommendations, and whether the child is cared for at home or in a daycare facility.

portant factor in deciding whether to treat AOM or observe the patient instead.

Acoustic reflectometry measures pressure within the ear canal. The procedure is relatively inexpensive and safe and doesn't require a seal for pressurization. Available over the counter, it provides a useful way to detect fluid behind the TM. However, it shouldn't be the only tool used to diagnose AOM.

In many cases, clinicians have difficulty distinguishing viral AOM from bacterial AOM without a cul-

ture of middle-ear fluid, which typically isn't done in the primary care setting. As a result, clinicians may refer patients to an ear, nose, and throat (ENT) specialist for tympanocentesis to determine if the infection is viral or bacterial (especially if the child has recurrent ear infections). For this test, the patient must stay still while the clinician removes fluid from behind the TM with a needle and syringe; the fluid is sent for culturing. Tympanocentesis requires expensive special equipment and extra staff or nursing personnel.

What's more, this invasive procedure involves a needle, which can cause pain and trauma in the child. It's usually done only in resistant AOM cases by an ENT specialist.

Treatment

Because the evidence indicates AOM usually resolves spontaneously, practitioners should focus on providing adequate analgesia and limiting antibiotic use. Also, before prescribing antibiotics, they must strongly suspect bacteria are prevalent in the middle ear.

Treating vs. observing AOM

This table summarizes current recommendations on when to treat acute otitis media (AOM) and when to observe the patient for symptom resolution.

Treat AOM if:

- the child is younger than 6 months
- the child is 6 months or older with severe signs and symptoms
- the child is younger than age 2 with bilateral AOM, even without severe signs and symptoms
- the child has craniofacial abnormalities, immunosuppression, Down syndrome, or cochlear implants
- patient monitoring can't be guaranteed for the first 3 days.

Observe if:

- close patient monitoring is available at home and the parent (or other home caregiver) has a trusting relationship with the clinician
- the child is age 6 to 23 months with unilateral AOM without severe signs or symptoms or fever
- the child is age 2 or older with bilateral or unilateral AOM without severe signs or symptoms.

Clinical practice guidelines

Current clinical practice guidelines on AOM management recommend observation and close follow-up for children ages 6 to 23 months with nonsevere unilateral AOM. (Nonsevere AOM is defined as mild ear pain with symptoms present for less than 48 hours and a body temperature below 102.2° F [39° C]). The guidelines also recommend observing children ages 24 months and older with nonsevere unilateral or bilateral AOM. (See *Treating vs. observing AOM*).

On the other hand, clinicians should consider prescribing immediate antibiotics for patients who:

- are younger than age 6 months
- have risk factors (such as underlying illness, craniofacial abnormalities, immunosuppression, Down syndrome, or cochlear implants)
- have persistent purulent drainage from the ear (otorrhea)
- have moderate to severe otalgia (ear pain)
- have a temperature above 102.2° F (39° C).

Antibiotics also are recommended if patient monitoring within the first 3 days can't be guaranteed.

If symptoms don't improve or if they worsen within 48 to 72 hours after either antibiotic initiation or the start of observation, clinicians should consider other treatment options, after reassessing the patient in a clinical setting and excluding other differential diagnoses. They must weigh the potential benefits of therapy against potential harm. Studies show 1 in 14 children who receives antibiotics experiences an adverse effect, such as diarrhea, vomiting, or rash. Observing the child instead of prescribing antibiotics can avoid these adverse effects.

Antibiotic therapy

When antibiotics are indicated, high-dose amoxicillin is recommended as the first-line treatment

because it's effective against the most common bacteria found in AOM, including *Streptococcus pneumoniae* (the most common gram-positive bacterium) and the gram-negative bacteria *Haemophilus influenzae* and *Moraxella catarrhalis*. Amoxicillin in liquid form is palatable, safe, and cheap, with a narrow microbiologic spectrum. Recommended duration of therapy is 10 days for children ages 2 and younger with moderate to severe AOM; 7 days for children ages 2 to 6; and 5 to 7 days for those ages 7 and older.

Amoxicillin-clavulanate is indicated for children who:

- have received amoxicillin in the past 30 days
 - have AOM with concurrent conjunctivitis
 - require beta-lactamase coverage.
- Treatment of recurrences depends partly on whether AOM recurs within 30 days of the patient's last antibiotic course, or later than that.
- If AOM recurs *within* 30 days of the patient's last antibiotic course, the most likely cause is either a pathogen that has become resistant or one that wasn't susceptible to that antibiotic. Other antibiotic options may include oral cephalosporins. For instance, ceftriaxone I.M. can be

used as a second-line treatment at the provider's discretion. Levofloxacin is used off-label only by infectious disease specialists to treat severely resistant AOM after tympanocentesis in children. Other second-line antibiotics that may be used if amoxicillin fails include amoxicillin-clavulanate and oral cephalosporins (cefdinir, cefuroxime, and cefpodoxime). If the second-line antibiotic fails, options may include clindamycin plus a third-generation cephalosporin, along with an ENT consult. Erythromycin and azithromycin can be used if the child is allergic to both penicillin and cephalosporins; however, these drugs don't provide broad-spectrum coverage for the bacteria typically found in AOM. (See *Treating children with penicillin allergies*.)

- If AOM recurs more than 30 days after an antibiotic course, the most likely cause is a different bacterial or viral pathogen or one that's not susceptible to that antibiotic. In the latter case, treatment should include amoxicillin-clavulanate as initial therapy, even if the patient received this antibiotic for the previous episode. If clinical improvement doesn't occur within 48 to 72 hours after starting the antibiotic,

Treating children with penicillin allergies

For children with known penicillin allergies, practitioners should prescribe a cephalosporin (such as cefdinir, cefuroxime, or ceftriaxone) instead of amoxicillin (a form of penicillin) for acute otitis media. However, guidelines caution against prescribing cephalosporins for patients who've had severe anaphylactic reactions to penicillin.

For patients with true penicillin allergy, macrolide antibiotics (such as erythromycin and azithromycin) can be given. However, both drugs have poor efficacy against *Haemophilus influenzae* and *Streptococcus pneumoniae*. Clindamycin is useful in some cases of penicillin-resistant *S. pneumoniae* but lacks efficacy against *H. influenzae*.

the clinician should consider antibiotic treatment a failure.

Observation

Most studies have found no increase in complications, such as mastoiditis or cholesteatoma, when children were selected properly for observational management of AOM, as long as follow-up was ensured and rescue antibiotics were available for persistent or worsening symptoms. However, the decision to observe the child rather than prescribe immediate antibiotic therapy must be made jointly between clinicians and parents. Clinicians who choose observation must ensure adequate patient follow-up and instruct parents to contact them if symptoms worsen or don't improve in the next 48 to 72 hours.

Some clinicians give parents a written antibiotic prescription with specific instructions not to fill it unless the child's symptoms get worse over the next 2 or 3 days. Others insist parents call them to request an antibiotic prescription.

Parent education

Providing adequate parent (or other home caregiver) education is essential. Teach parents that the child should show clinical improvement in 48 to 72 hours after starting antibiotics—for instance, a temperature decrease if the child has a fever, reduced irritability and fussiness, and resumption of normal eating and drinking patterns. If no improvement occurs within that time, advise them to call the pri-

mary care provider for evaluation for possible antibiotic resistance or a coexisting viral infection.

Teaching parents about antibiotics

Parental demands are a leading reason why some clinicians immediately prescribe antibiotics for children with AOM. Many parents (and even some healthcare providers) are misinformed about current practice guidelines and need to be educated on why antibiotics shouldn't always be given initially. Some can't accept that a condition that has always been treated with antibiotics may resolve on its own.

Be sure to explain the nature of AOM, emphasizing that antibiotics aren't always the best solution and shouldn't always be given at initial symptom onset. Discuss current AOM treatment guidelines. Tell parents the condition usually is self-limiting and doesn't require antibiotics. Emphasize that antibiotics aren't harmless and frequently cause side effects. Reassure them that if their child's symptoms persist, the clinician may prescribe antibiotics with careful follow-up and reassessment.

Helping parents prevent AOM

To help prevent recurrences or new AOM infections, teach parents about factors that can increase their child's AOM risk. (See *Risk factors for AOM*.)

Be sure to cover the following points:

- Eliminate exposure to second-hand tobacco smoke.

- Avoid supine bottle feeding.
- Eliminate pacifier use after age 6 months because it can cause backflow of nasal and pharyngeal secretions to the middle ear, promoting bacterial growth.
- Breastfeed the child for at least the first 6 months, if possible. Bottlefed infants have reversed secretion flow into the middle ear, which can promote infection.
- If possible, limit or avoid day care outside the home, which exposes children to many contagious illnesses.
- Use analgesics for pain control, if recommended.
- Keep the child adequately hydrated.
- If the clinician has prescribed antibiotics, review possible adverse drug effects and tell parents when to report adverse effects to the primary provider.

Take advantage of well-child visits

The well-child visit is an important opportunity to discuss how to prevent AOM and evaluate the child's immunization schedule with parents. Strongly encourage an annual influenza vaccine for children older than 6 months as well as the pneumococcal conjugate vaccine, according to current immunization guidelines. Both vaccines drastically decrease AOM incidence and thus the possible need for antibiotics. Office visits for AOM have declined 40% since introduction of the pneumococcal conjugate vaccine. The influenza vaccine has a 30% to 55% efficacy rate in children who have AOM with coexisting upper respiratory illness.

Team approach

Sound clinical skills and judgment can play a role in the proper treatment of pediatric patients with AOM. In addition, studies indicate a team approach to treating AOM significantly reduces unnecessary antibiotic prescriptions. If you work in a healthcare provider group, advo-

cate that the group adopt a practice guideline and reach a consensus to establish an antibiotic policy. ★

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Risk factors for AOM

Risk factors for acute otitis media (AOM) in children include:

- exposure to secondhand tobacco smoke
- preschool or daycare attendance
- bottle feeding
- pacifier use
- allergies
- esophageal reflux
- siblings with recurrent ear infections
- congenital or acquired autoimmune diseases
- chromosomal abnormalities
- craniofacial abnormalities (such as cleft palate or Down syndrome), which may involve oral-palate and Eustachian tube defects that can interfere with normal tube ventilation
- lower socioeconomic status. AOM risk may be related to unhealthy diets, poor housing conditions, and limited access to medical care.

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Please mark the correct answer online.

Manuel, 5 months old, is brought to his primary care provider (PCP) by his parents. They report he has been crying more often, is tugging at his ear, and seems more irritable. Neither his 2-year-old sister nor his 4-year-old brother has had a serious illness recently.

1. Which of the following is not a risk factor for pediatric AOM?

- Exposure to secondhand tobacco smoke
- Allergies
- Pacifier use
- Being cared for at home during the day

2. Which anatomic feature puts Manuel and other children at higher risk for AOM?

- A long, narrow, horizontal Eustachian tube
- A short, narrow, vertical Eustachian tube
- A long, broad, vertical Eustachian tube
- A short, broad, horizontal Eustachian tube

3. Which of the following would lead the PCP to suspect Manuel has AOM?

- Normal tympanic membrane (TM)
- Inner-ear effusion
- Decreased TM mobility
- Symptom onset of 4 days ago

4. Manuel's PCP performs pneumatic otoscopy to determine the presence of AOM. Which statement about this test is accurate?

- A simple otoscope is adapted with an insufflator bulb.
- Guidelines recommend using it only as a secondary diagnostic tool.
- The test is about 50% to 60% sensitive and specific.
- A puff of air is used to determine inner ear effusion.

5. Manuel's parents tell the PCP they checked his ear with acoustic reflectometry. Which statement about this technique is correct?

- It is relatively expensive.
- It is associated with adverse effects.
- It measures pressure within the ear canal.
- The user must establish a pressure seal.

6. Manuel's PCP decides not to perform a tympanocentesis. This procedure:

- helps determine if the infection is viral or bacterial.
- typically is performed in the primary care setting.
- requires no special equipment or additional staff.
- does not require the child to remain still during the test.

7. Manuel's PCP diagnoses him with moderate AOM. Which of the following findings leads the PCP to prescribe an antibiotic?

- The parents can monitor Manuel closely at home.
- Manuel is 5 months old.
- His temperature is 99.5° F (37.5° C).
- He has a minimal amount of effusion.

8. Which of the following might have led Manuel's PCP to take a wait-and-watch approach instead of prescribing antibiotics?

- Age of 1 with bilateral AOM and no severe signs or symptoms
- Presence of Down syndrome
- Age of 3 with unilateral AOM and no severe signs or symptoms
- Presence of craniofacial abnormalities

9. Nonsevere AOM is defined as mild ear pain with:

- symptoms present for less than 48 hours and a temperature below 102.2° F (39° C)
- mild ear pain with symptoms present for less than 72 hours
- temperature below 103.8° F (39.8° C)
- temperature below 103.5° F (39.7° C)

10. The PCP instructs Manuel's parents to continue giving him amoxicillin for:

- 5 days.
- 7 days.
- 10 days.
- 14 days.

11. Education for parents of children with AOM should include which of the following?

- The child should show clinical improvement 12 to 48 hours after starting the antibiotic.
- The child should show clinical improvement 72 to 96 hours after starting the antibiotic.
- If the child isn't receiving antibiotics, antibiotics aren't harmless and frequently cause side effects.
- If the child isn't receiving antibiotics, future AOM episodes will require antibiotic treatment.

12. Which action can Manuel's parents take to reduce the risk of future AOM episodes?

- Use supine bottle feeding.
- Encourage pacifier use.
- Avoid giving him fluids.
- Breastfeed him for the first 6 months.

13. Despite his parent's best efforts, Manuel's AOM recurs 90 days after he finishes antibiotic therapy. Which would be an appropriate antibiotic for the PCP to prescribe now?

- Erythromycin
- Cefpodoxime
- Azithromycin
- Amoxicillin-clavulanate