Updated Guidelines For The Diagnosis And Management Of Acute Otitis Media

This issue of EM Practice Guidelines Update reviews the 2013 update of the guideline on the diagnosis and management of acute otitis media (AOM) for healthy children aged 6 months to 12 years. Published by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), the guideline authors emphasize the use of a "specific, stringent definition of AOM" to limit unnecessary treatment with antibiotics in patients without a certain diagnosis. The management recommendations outline which children should be treated with antibiotics immediately and which children can be offered a "watch and wait" approach. This review focuses on the recommendations most relevant to pediatric emergency medicine practice.

Practice Guideline Impact

- Emergency clinicians should make the diagnosis of AOM in children who present with: (1) moderate to severe bulging of the tympanic membrane (TM) or new-onset otorrhea not due to acute otitis externa; or (2) mild bulging of the TM and recent (< 48 h) onset of ear pain or intense erythema of the TM.
- The management of AOM should include assessment and treatment of pain.
- Emergency clinicians should prescribe immediate antibiotic treatment for AOM for children with otorrhea, children with severe symptoms, and children aged 6 months to 2 years with bilateral AOM.
- Emergency clinicians can either start immediate antibiotic treatment or offer observation (if there is good follow-up) for children aged 6 to 23 months with nonsevere unilateral AOM and children aged ≥ 24 months with nonsevere unilateral or bilateral AOM.
Introduction To The Guidelines: Acute Otitis Media

This issue of *EM Practice Guidelines Update* reviews the guideline entitled “The Diagnosis and Management of Acute Otitis Media,” published in *Pediatrics* in March 2013, available at: http://pediatrics.aappublications.org/content/131/3/e964.long

AOM remains the leading condition for which antibiotics are prescribed for children in the United States.\(^1,2\) It accounts for 13% of all emergency department (ED) visits and 30 million clinic visits by children, making it the second most common diagnosis in the pediatric ED after upper respiratory infections.\(^3\) In May 2004, the AAP and AAFP published the “Clinical Practice Guideline: Diagnosis and Management of Acute Otitis Media.”\(^4\) This earlier guideline used a less-stringent definition of AOM that could have led to the misdiagnosis of children having otitis media with effusion (OME) as having AOM. The 2004 guideline also provided management recommendations for children with an “uncertain” diagnosis. The updated guidelines removed this category, emphasizing the importance of good visualization of the TM and excellent otoscopic skills for accurate diagnosis to guide management.

The 2004 guideline was notable for recommending observation without the use of antibiotics in select patients. Despite awareness and significant publicity of these 2004 recommendations, evidence has shown that clinicians are hesitant to change their practice.\(^5\) Management of AOM with “watchful waiting” rather than prescription of antibiotics did not increase after the 2004 guideline publication.\(^6\) A 2007 study reported that up to 91% of ED patients received an antibiotic prescription for AOM.\(^7\)

The recommendations in the 2004 guideline to observe rather than to treat with antibiotics were based on studies that used nonspecific inclusion criteria that did not represent a patient population with highly certain AOM. Furthermore, older studies tended to exclude very young children with severe disease and those with recent antibiotic treatment or recent diagnosis of AOM. Thus, the studies were not reflective of the full spectrum of patients covered by these guidelines.\(^8\) The 2013 update relied upon studies with stringent diagnostic criteria to ensure that the patients, indeed, had AOM, and, based on these stronger data, actually expand the recommendations for which patients can be observed without antibiotic treatment.

The guideline authors acknowledge that the adherence to the 2004 guidelines was quite poor, and they comment that this, unfortunately, parallels the impact of practice guidelines across specialties. They highlight the need for increased dissemination of guideline content.

-- Kimberly Kahne, MD
Assessment Of The Guideline Methodology

To create this guideline, the AAP and AAFP partnered with the Agency for Healthcare Research and Quality and the Southern California Evidence-Based Practice Center. Using an evidence report created by these agencies, a multidisciplinary writing committee used BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor) software to aid in crafting action-oriented recommendations and in determining the strength of the evidence. The relationship between the strength of the evidence and the recommendation is shown in Table 1.

The author of this issue of EM Practice Guidelines Update, Kimberly Kahne, MD, as well as the Editor-in-Chief, Sigrid Hahn, MD, MPH, graded these guidelines using the Appraisal of Guidelines for Research and Education (AGREE) II instrument (available at http://www.agreetrust.org/). This instrument is a checklist that allows users to grade a guideline on 23 items in 6 domains, reflecting the degree to which the guideline developers used unbiased, best-practice methodology in developing the guideline and writing the recommendations. The results of the AGREE assessment are presented in Figure 1, with a percentile calculated for each domain (maximum of 100%). The score for relevance to emergency medicine is not part of the AGREE instrument, but reflects the judgment of the author and editor of this issue.

—Kimberly Kahne, MD; and Sigrid Hahn, MD, MPH

Table 1. Definition Of Evidence Quality Used In American Academy of Pediatrics Recommendations

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
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<tbody>
<tr>
<td>A. Well designed RCTs or diagnostic studies on relevant population</td>
<td>Strong Recommendation</td>
<td>Option</td>
</tr>
<tr>
<td>B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies</td>
<td>Recommendation</td>
<td>Option</td>
</tr>
<tr>
<td>C. Observational studies (case-control and cohort design)</td>
<td>Option</td>
<td>No Rec</td>
</tr>
<tr>
<td>D. Expert opinion, case reports, reasoning from first principles</td>
<td>Strong Recommendation</td>
<td>Recommendation</td>
</tr>
<tr>
<td>X. Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit or harm</td>
<td></td>
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</tr>
</tbody>
</table>

Figure 1. AGREE Criteria For Acute Otitis Media Guidelines

Abbreviation: AGREE, Appraisal of Guidelines for Research and Education.
The recommendations excerpted here are presented as they appear in the original guidelines, including the strength of recommendation and the level of evidence. This review does not include all recommendations provided in the original documents published by the AAP and the AAFP. Instead, it includes those recommendations most pertinent to emergency clinicians.

**Diagnosis Of Acute Otitis Media**

- **Key Action Statement 1A:** Clinicians should diagnose AOM in children who present with moderate to severe bulging of the TM or new onset of otorrhea not due to acute otitis externa. (Evidence Quality: Grade B, Strength: Recommendation)

- **Key Action Statement 1B:** Clinicians should diagnose AOM in children who present with mild bulging of the TM and recent (< 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. (Evidence Quality: Grade C, Strength: Recommendation)

- **Key Action Statement 1C:** Clinicians should not diagnose AOM in children who do not have middle ear effusion (based on pneumatic otoscopy and/or tympanometry). (Evidence Quality: Grade B, Strength: Recommendation)

**Editorial Comment: Kimberly Kahne, MD**

The challenging feature of these diagnostic criteria for many clinicians will be that they rely upon pneumatic otoscopy, and the guideline authors call this the “standard” tool for diagnosis. Although they acknowledge that many clinicians lack experience in removing cerumen adequately or performing pneumatic otoscopy, an incomplete examination is no longer considered acceptable.

The guideline recommends the tools to help develop the appropriate skills, including the following video:
http://www2.aap.org/sections/infectdis/video.cfm

These revised criteria were developed in reaction to criticisms of the 2004 definition, which lacked precision, and the fact that the guidelines had a category of recommendations for patients with an “uncertain diagnosis,” which many felt tacitly endorsed incomplete visualization of the TM and poor otoscopic skills. The 2013 criteria were chosen to achieve higher specificity while recognizing that the decreased sensitivity may exclude less severe presentations of AOM.

**Pain Management For Acute Otitis Media**

- **Key Action Statement 2:** The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. (Evidence Quality: Grade B, Strength: Strong Recommendation)

**Editorial Comment: Kimberly Kahne, MD**

Although many episodes of AOM are associated with pain, clinicians often view it as a secondary complaint that may not require direct attention. Pain associated with AOM can be substantial and can last longer in young children. Acetaminophen and ibuprofen are considered the mainstay of pain management for AOM.
Antibiotic Treatment Or Observation For Management For Acute Otitis Media

- **Key Action Statement 3A: Severe AOM** – The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children aged > 6 months with severe signs or symptoms (ie, moderate or severe otalgia or otalgia for at least 48 hours, or temperature 39°C [102.2°F] or higher). (Evidence Quality: Grade B, Strength: Strong Recommendation)

- **Key Action Statement 3B: Nonsevere bilateral AOM in young children** – The clinician should prescribe antibiotic therapy for bilateral AOM in children aged < 24 months without severe signs or symptoms (ie, mild otalgia for < 48 hours, temperature < 39°C [102.2°F]). (Evidence Quality: Grade B, Strength: Recommendation)

- **Key Action Statement 3C: Nonsevere unilateral AOM in young children** – The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children aged 6 months to 23 months without severe signs or symptoms (ie, mild otalgia for < 48 hours, temperature < 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Strength: Recommendation)

- **Key Action Statement 3D: Nonsevere AOM in older children** – The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children aged ≥ 24 months without severe signs or symptoms (ie, mild otalgia for < 48 hours, temperature < 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Strength: Recommendation)

**Editorial Comment: Kimberly Kahne, MD**

Since the 2004 guideline, substantial research has been published on the initial management of AOM, including randomized controlled trials on antibiotic therapy versus placebo or no therapy. The evidence-based recommendations are summarized in Table 2.

**Table 2. Recommendations For Initial Management For Uncomplicated Acute Otitis Media**

<table>
<thead>
<tr>
<th>Age</th>
<th>Otorrhea with AOM*</th>
<th>Unilateral or bilateral AOM* with severe symptoms†</th>
<th>Bilateral AOM* without otorrhea</th>
<th>Unilateral AOM* without otorrhea</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mo - 2 y</td>
<td>Antibiotic therapy</td>
<td>Antibiotic therapy</td>
<td>Antibiotic therapy</td>
<td>Antibiotic therapy or additional observation‡</td>
</tr>
<tr>
<td>≥ 2 y</td>
<td>Antibiotic therapy</td>
<td>Antibiotic therapy</td>
<td>Antibiotic therapy or additional observation‡</td>
<td>Antibiotic therapy or additional observation‡</td>
</tr>
</tbody>
</table>

*Applies only to children with well-documented AOM with high certainty of diagnosis.
†A toxic-appearing child, persistent otalgia more than 48 h, temperature ≥ 39°C (102.2°F) in the past 48 h, or if there is uncertain access to follow-up after the visit.
‡This plan of initial management provides an opportunity for shared decision-making with the child’s family for those categories appropriate for additional observation. If observation is offered, a mechanism must be in place to ensure follow-up and the initiation of antibiotics if the child worsens or fails to improve within 48 to 72 h of AOM onset.

Abbreviation: AOM, acute otitis media.

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These recommendations contrast with the 2004 guideline, which recommended antibiotic therapy for all children aged 6 months to 2 years with a “certain” diagnosis. Evidence has supported the safety of observation or delayed antibiotic usage in young children and is an appropriate management option when there is shared decision-making with the parent.
Choice Of Antibiotics For Acute Otitis Media

- **Key Action Statement 4A:** Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made and the child has not received amoxicillin in the past 30 days or the child does not have concurrent purulent conjunctivitis or the child is not allergic to penicillin. (Evidence Quality: Grade B. Strength: Recommendation)

- **Key Action Statement 4B:** Clinicians should prescribe an antibiotic with additional beta-lactamase coverage for AOM when a decision to treat with antibiotics has been made, and the child has received amoxicillin in the last 30 days or has concurrent purulent conjunctivitis, or has a history of recurrent AOM unresponsive to amoxicillin. (Evidence Quality: Grade C. Strength: Recommendation)

- **Key Action Statement 4C:** Clinicians should reassess the patient if the caregiver reports that the child’s symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. (Evidence Quality: Grade B. Strength: Recommendation)

Editorial Comment: Kimberly Kahne, MD

Once the decision has been made to start antibiotics, the emergency clinician must choose an antibiotic that will have a high likelihood of being effective against the most likely bacterial pathogen, taking into account cost, taste, convenience, and adverse effects.

There have been no changes to the recommendation for first-line antibiotic choice since the 2004 guideline, despite new data on the effects of 7-valent pneumococcal conjugate vaccine (PCV7, Prevnar®) and the awareness of an increase in multidrug-resistant strains of pneumococci. High-dose amoxicillin (80-90 mg/kg per day in 2 divided doses) yields middle ear fluid levels that exceed the minimum inhibitory concentrations of all intermediate (and many highly resistant) strains of *Streptococcus pneumoniae*. The 3 most common bacterial pathogens in AOM remain *S pneumoniae*, nontypeable *Haemophilus influenzae*, and *Moraxella catarrhalis*. Since the introduction of PCV7, there has been a shift towards *H influenzae* and non-PCV7 serotypes of *S pneumoniae*. The antibiotic susceptibility pattern for *S pneumoniae* is expected to continue to evolve with the use of 7-valent pneumococcal conjugate vaccine (PCV13, Prevnar 13®).

**Tables 3 and 4 (page 7)** show a number of medications that are clinically effective; however, amoxicillin remains first-line due to its effectiveness in combination with low cost, safety, acceptable taste, and narrow microbiologic spectrum. Patients who have taken amoxicillin in the previous 30 days, patients with concurrent conjunctivitis, or patients for whom coverage for beta-lactamase-positive *H influenza* and *M catarrhalis* is desired should be started on amoxicillin-clavulanate (Augmentin®) at a dose of 90 mg/kg/day of amoxicillin with 6.4 mg/kg/day of clavulanate. Alternative antibiotics vary in their efficacy against AOM pathogens.

For children aged < 2 years and children with severe symptoms, a standard 10-day course is recommended. A 7-day course may be recommended for children aged 2 through 5 years with mild or moderate AOM. For children aged ≥ 6 years with mild to moderate symptoms, a 5- to 7-day course is adequate.
### Table 3. Recommended Antibiotics For (Initial Or Delayed) Treatment Of Pediatric Acute Otitis Media

<table>
<thead>
<tr>
<th>Recommended First-line Treatment</th>
<th>Alternative Treatment (If Penicillin Allergy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin (80-90 mg/kg/day in 2 divided doses)</td>
<td>Cefdinir‡ (14 mg/kg/day in 1 or 2 doses)</td>
</tr>
<tr>
<td>Amoxicillin-clavulanate* (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day of clavulanate [amoxicillin-to-clavulanate ratio, 14:1] in 2 divided doses)</td>
<td>Cefuroxime‡ (30 mg/kg/day in 2 divided doses)</td>
</tr>
<tr>
<td>Amoxicillin-clavulanate* (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day of clavulanate [amoxicillin-to-clavulanate ratio, 14:1] in 2 divided doses)</td>
<td>Cefpodoxime‡ (10 mg/kg/day in 2 divided doses)</td>
</tr>
<tr>
<td>Amoxicillin-clavulanate* (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day of clavulanate [amoxicillin-to-clavulanate ratio, 14:1] in 2 divided doses)</td>
<td>Ceftriaxone‡ (50 mg IM or IV per day for 1 or 3 days)</td>
</tr>
</tbody>
</table>

*May be considered in patients who have received amoxicillin in the previous 30 days or who have the otitis-conjunctivitis syndrome.

‡Cefdinir, cefuroxime (Ceftin®, Zinacef®), cefpodoxime, and ceftriaxone (Rocephin®) are highly unlikely to be associated with cross-reactivity with penicillin allergy, on the basis of their distinct chemical structures.

Abbreviations: IM, intramuscular; IV, intravenous

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### Table 4. Recommended Antibiotics After 48-72 Hours Of Failure Of Initial Antibiotic Treatment For Pediatric Acute Otitis Media

<table>
<thead>
<tr>
<th>Recommended First-line Treatment</th>
<th>Alternative Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin-clavulanate* (90 mg/kg/day of amoxicillin with 6.4 mg/kg/day of clavulanate in 2 divided doses)</td>
<td>Ceftriaxone,‡ 3 days</td>
</tr>
<tr>
<td>Amoxicillin-clavulanate* (90 mg/kg/day of amoxicillin with 6.4 mg/kg/day of clavulanate in 2 divided doses)</td>
<td>Clindamycin (Cleocin®), 30-40 mg/kg/day in 3 divided doses, with or without a third-generation cephalosporin</td>
</tr>
<tr>
<td>Ceftriaxone (50 mg IM or IV for 3 days)</td>
<td>Failure of second antibiotic</td>
</tr>
<tr>
<td>Clindamycin (30-40 mg/kg/day in 3 divided doses) plus third-generation cephalosporin</td>
<td>Typanocentesis†</td>
</tr>
<tr>
<td>Tympanocentesis†</td>
<td>Consult specialist†</td>
</tr>
</tbody>
</table>

*May be considered in patients who have received amoxicillin in the previous 30 days or who have the otitis-conjunctivitis syndrome.

†Perform tympanocentesis/drainage if skilled in the procedure, or seek a consultation from an otolaryngologist for tympanocentesis/drainage. If the tympanocentesis reveals multidrug-resistant bacteria, seek an infectious disease specialist consultation.

‡Cefdinir, cefuroxime, cefpodoxime, and ceftriaxone are highly unlikely to be associated with cross-reactivity with penicillin allergy on the basis of their distinct chemical structures.

Abbreviations: IM, intramuscular; IV, intravenous

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References


CME Questions

To take the CME test, visit: www.ebmedicine.net/G0514 or scan the QR code below with a smartphone:

1. Which of the following patients meets criteria for the diagnosis of AOM?
   a. A 3-year-old girl with otorrhea and evidence of acute otitis externa on examination
   b. A 3-year-old girl with mild bulging of the TM and complaints of ear pain for the past 24 hours
   c. A 3-year-old girl with moderate erythema of the TM and complaints of ear pain for the past 24 hours
   d. A 3-year-old girl with upper respiratory infection symptoms and complaints of right-sided otalgia

2. Which of the following patients meets criteria for the diagnosis of AOM?
   a. A 6-month-old boy with mild bulging of the TM and ear-pulling for 2 weeks
   b. A 6-month-old boy with mild bulging of the TM
   c. A 6-year-old boy with severe bulging of the TM
   d. None of the above

3. Which antibiotic should be initiated in a 15-month-old girl diagnosed with uncomplicated bilateral AOM?
   a. Amoxicillin 45 mg/kg/day divided into 2 doses
   b. Amoxicillin 80-90 mg/kg/day divided into 2 doses
   c. Ceftriaxone 50 mg/kg intramuscular injection x 1
   d. Clindamycin 30-40 mg/kg/day in divided into 3 doses

4. In which patient is observation an inappropriate form of management?
   a. A 3-year-old with unilateral AOM and severe otalgia for 48 hours
   b. A 10-month-old with unilateral AOM and fever to 38.5°C for 48 hours
   c. A 10-month-old with bilateral AOM and fever to 38.5°C for 48 hours
   d. A and B
   e. A and C
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Objectives: Upon completion of this article, you should be able to: (1) apply knowledge of criteria for diagnosing AOM and recognize differences between AOM and other ear infections, such as OME; (2) identify patients that can be observed for a period versus prescribing immediate antibiotics; and (3) assess patient history and local susceptibility to prescribe the most appropriate medication.

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## Updated Guidelines For Diagnosis And Management Of Acute Otitis Media

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<td>Guidelines For The Evaluation And Management Of Upper Gastrointestinal Bleeding</td>
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<td>Guidelines For The Evaluation And Management Of Acute Cerebrovascular Syndrome Part I: Diagnosis And Evaluation Of Transient Ischemic Attack (Stroke CME)</td>
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