

ACUTE OTITIS MEDIA

EXECUTIVE SUMMARY

PHYSICIAN OWNER: DR. DAVID TOLO



Primary Objective

Develop a pathway for treating acute otitis media (AOM) in Children's Physicians and Urgent Care clinics that standardizes first and second line antibiotic selection according to published literature taking into account local antibiotic resistance patterns

Recommendations

Exclusion Criteria:

- Toxic appearing
- Children < 6 months or > 12 years of age
- Tympanostomy tubes
- Anatomic abnormalities
- Cleft palate
- Genetic conditions with craniofacial abnormalities such as Down Syndrome
- Immune deficiencies
- Cochlear implants
- Children with otitis media with effusion without acute otitis media

Symptoms:

- Older children with AOM usually present with a history of rapid onset of ear pain.
- Young pre-verbal children with AOM usually present with a history of rapid onset of signs and symptoms such as otalgia, (suggested by pulling/tugging/rubbing/holding) of the ear, irritability, excessive crying, otorrhea, fever, or changes in the child's sleep or behavior pattern as noted by the child's caregiver(s). These findings other than otorrhea are nonspecific and frequently overlap those of an uncomplicated viral upper respiratory infection (URI). Other symptoms of a viral URI, such as cough and nasal discharge or stuffiness, often precede or accompany AOM and are nonspecific also. Accordingly, clinical history alone is poorly predictive of the presence of AOM, especially in younger children.^{1,3}

Distinguishing AOM from Otitis Media with Effusion (OME):

- OME may occur either as the aftermath of an episode of AOM or as a consequence of Eustachian tube dysfunction attributable to URI. It may also precede or predispose to the development of AOM.³
- OME does not represent an acute infectious process that benefits from antibiotics.³

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Examination of the Tympanic Membrane (TM):

- Visualization of the tympanic membrane with identification of a middle ear effusion (MEE) and inflammatory changes is necessary to establish the diagnosis of AOM with certainty. Fullness or bulging of the tympanic membrane on otoscopy has the highest predictive value for the presence of MEE.¹
- The normal TM is translucent, pearly gray and has a ground glass appearance. The normal TM should move inward on positive pressure in the external canal and outward on negative pressure, especially in the superior posterior quadrant.³ • The pneumatic otoscope is the standard tool used in diagnosing OM.³
- If the TM does not move perceptibly with applications of gentle positive or negative pressure, middle ear effusion (MEE) is likely.³
- When compared with color and mobility, bulging is also the best predictor of AOM.¹
- Opacification or cloudiness, other than that caused by scarring, is also a consistent finding and caused by edema of the TM.¹
- Redness of the tympanic membrane caused by inflammation may be present and must be distinguished from the pink erythematous flush evoked by crying or high fever, which is usually less intense and remits as the child quiets down.¹

Presentation and Clinical Management:

- 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.³
- AOM should also be diagnosed in children who present with mild bulging of the TM and recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM.³
- For cases of severe AOM; the clinician should prescribe antibiotic therapy for children greater than 6 months old.³
- For cases of non-severe AOM; the clinician should prescribe antibiotic therapy for children 6 months through 23 months of age. For children 24 months of age and older; clinician should either offer antibiotic therapy or in shared decision making with child's caregiver, offer observation. When observation is selected; a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48-72 hours.³
- Observation as initial management for AOM in properly selected children does not increase suppurative complications, provided that follow-up is ensured and a rescue antibiotic is given for persistent or worsening symptoms.³

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- In numerous studies, only approximately one-third of children initially observed received a rescue antibiotic for persistent or worsening AOM, suggesting that antibiotic use could be reduced by 65% in eligible children. Given the high incidence of AOM, this reduction could help substantially in curtailing antibiotic related adverse events.³
- Initial observation of AOM should be part of a larger management strategy that includes analgesics, caregiver information that includes education about the self-limited nature of most episodes of AOM, and provisions for a rescue antibiotic.³

Antimicrobial Therapy: First Line Antibiotics:

First Line Antibiotics:

- **Amoxicillin (high dose)** 90 mg/kg/day PO in two divided doses (usual adult dose 4000 mg/day divided two times a day)
 - o If a decision is made to treat with an antibacterial agent, the clinician should prescribe high dose amoxicillin for most children if they have not been prescribed amoxicillin in the last 30 days. The justification to use high dose amoxicillin as first line therapy in most patients with AOM relates to its general effectiveness against susceptible and intermediate resistant pneumococci as well as its safety, low cost, acceptable taste, and narrow microbiologic spectrum.^{1,3} The Omaha area does have a high prevalence of non-susceptible *S. Pneumoniae* > 10%.
- **Amoxicillin Clavulanate (high dose)** 90 mg/kg/day in two divided doses (usual adult dose 3500 mg/day divided two times a day; dosing based on Amoxicillin component)
 - o In patients who have had amoxicillin in the last 30 days, have severe illness (moderate to severe otalgia or fever of 39°C or higher and in those whom additional coverage for β -lactamase–positive *Haemophilus influenzae* and *Moraxella catarrhalis* is desired high dose amoxicillin clavulanate therapy should be initiated. This dose has sufficient potassium clavulanate to inhibit β -lactamase-producing *H. influenzae* and *M. catarrhalis*.¹
 - o Risk factors for the presence of bacterial species likely to be resistant to amoxicillin include attendance at child care, recent receipt (less than 30 days) of antibacterial treatment, and age younger than 2 years.^{1,3}
- **Ceftriaxone** 50 mg/kg/dose IM (max single dose of 1000 milligrams)
 - o For children who are vomiting, unable to tolerate oral medication, or unlikely to be adherent to the initial doses of antibiotic. If clinical improvement is observed at 24 hours, an oral antibiotic can be substituted to complete the course of therapy.

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- o Children who are still significantly febrile or symptomatic at 24 hours may require additional parenteral doses before switching to oral therapy.

First Line Antibiotics for Patients Allergic to Penicillin:

- **Cefdinir** 14 mg/kg/day PO in one dose (usual adult dose 600 mg/day given once daily)
- [Penicillin Allergy Facts](#)

For Patients that Clinically Worsen After 72 Hours or Fail to Improve After 3-5 Days of Amoxicillin (high dose) Antimicrobial Therapy:

- **Amoxicillin Clavulanate (high dose)** 90 mg/kg/day PO in two divided doses (usual adult dose 4000 mg/day divided two times a day; dosing based on Amoxicillin component)
 - o In children with persistent, severe symptoms of AOM and unimproved otologic findings after initial treatment, the clinician may consider changing the antibiotic. If the child was initially treated with amoxicillin and failed to improve, amoxicillin clavulanate should be used.³

Second Line Antibiotic Therapy in Patients with or without Penicillin Allergies:

- **Cefdinir** 14 mg/kg/day PO in one dose (usual adult dose 600 mg/day given once daily) AND Clindamycin 30-40 mg/kg day PO in three divided doses (usual adult dose 1350 mg/day divided three times a day)
- **Cefixime** 8 mg/kg/day PO in one dose (usual adult dose 400 mg/day given once a day) AND Clindamycin 30-40 mg/kg day PO in three divided doses (usual adult dose 1350 mg/day divided three times a day)
- **Ceftriaxone** 50 mg/kg/dose IM (max single dose of 1000 milligrams) AND Clindamycin 30-40 mg/kg/day PO in three divided doses (usual adult dose 1350 mg/day divided three times a day)
- **Doxycycline** 2-4 mg/kg/day PO in one dose (usual adult dose 200 milligrams given once daily) for patients > 8 years of age
 - o For Patients that are < 8 years of age and cephalosporin allergic, providers should contact Infectious Disease

Notes About Antimicrobial Therapy:

- Although dual therapy with third generation cephalosporins and clindamycin is suggested for first line therapy with allergies to penicillin; this is not currently an accepted practice in our local community. The

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efficacy of monotherapy with Cefdinir as first line treatment of AOM will be followed and studied through the collection of data from this pathway's 3rd metric.

- Second and third-generation oral cephalosporins are no longer recommended for empiric monotherapy due to variable rates of resistance among *S. pneumoniae*. Combination therapy with a third-generation oral cephalosporin plus clindamycin is recommended to cover penicillin-resistant *S. Pneumoniae*.
- The dosing for clindamycin varies between conditions because of the tissue being treated. Children's infectious disease physicians recommend a higher dose of clindamycin to treat sinusitis and otitis media due to the need to penetrate biofilm. Additionally the organisms associated with acute bacterial sinusitis infections and otitis media are generally not as susceptible as those of Group A Streptococcus.
- Placebo-controlled trials of AOM over the past 30 years have shown consistently that most children do well, without adverse sequela, even without antibacterial therapy. Deferring antibiotic treatment for 48-72 hours should be reserved for otherwise healthy children 2 years of age and older without severe symptoms or with an uncertain diagnosis.¹
- Macrolides (clarithromycin & azithromycin) are not recommended for empiric therapy due to high rates of resistance of *S. pneumoniae* (~30%). "The prevalence of macrolide-resistant *S. pneumoniae* in the United States has escalated dramatically since the 1990's. Studies reveal that whereas only 5% of *S. pneumoniae* clinical isolates in the United States were resistant to macrolides in 1993, >30% had become resistant by 2006. During 2005-2007, 43% of invasive *S. pneumoniae* isolates were macrolide-resistant." ⁴
- Trimethoprim-sulfamethoxazole (TMP/SMX) is not recommended for empiric therapy because of high rates of resistance among both *S. pneumoniae* and *Haemophilus influenzae* (~30-40%). "Surveillance of recent respiratory isolates in the United States indicates a variable, but significant increase in penicillin–intermediate and macrolide or TMP/SMX-resistant *S. pneumoniae* and β -lactamase-producing *H. influenzae*. Accordingly, antimicrobial agents previously recommended as an alternative to amoxicillin or amoxicillin-clavulanate, such as macrolides, TMP/SMX, or secondor third-generation oral cephalosporins, can no longer be recommended because of increasing resistance among *S. pneumoniae* and/or *H. influenzae*." ⁴
- Prophylactic antibiotics should not be prescribed to reduce the frequency of AOM in children with recurrent AOM (defined as the occurrence of 3 or more episodes of AOM in a 6 month period of time or the occurrence of 4 or more episodes of AOM in a 12 month period that includes at least 1 episode in the preceding 6 months).³

Duration of Therapy:

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- The optimal duration of therapy for patients with AOM is uncertain; the usual 10 day course of therapy was derived from the duration of treatment of streptococcal pharyngotonsillitis.³
- For children younger than 2 years the standard 10 day course of antibiotics is favored based on several studies and younger children may take longer to improve clinically than older children. The longer 10 day course of antibiotics is also recommended for children with severe symptoms. A 7 day course of oral antibiotics appears to be equally effective in children 2 years of age and older with mild or moderate AOM.³

Referrals to Consider:

- The use of tympanostomy tubes for treatment of ear disease in general, and for AOM in particular, has been controversial and the literature on surgery for recurrent AOM is scant. However, tympanostomy tubes remain widely used in clinical practice for both OME and recurrent OM. AOM remains a common indication for referral to an otolaryngologist.³
- Adenoidectomy, without myringotomy and/or tympanostomy tubes, has not been shown to reduce the number of episodes of AOM.³

Pain Management Therapy:

- The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain.³
- During the 24 hours after the diagnosis of AOM, the child's symptoms may worsen slightly. In the next 24 hours, the patient's symptoms should begin to improve. If initially febrile, the temperature should decline within 48 to 72 hours. Irritability/fussiness should lessen or disappear, and sleeping and drinking patterns should normalize.³
- The management of pain, especially during the first 24 hours of an episode of AOM, should be addressed regardless of the use of antibacterial agents. While various treatments for otalgia have been used, none have been studied. Treatment of pain should be selected based on consideration of benefits and risks in partnership with child's caregiver.¹
- Analgesics are recommended by the American Academy of Pediatrics (AAP) for pain management regardless if antibiotics are prescribed and should continue as long as pain persists.

Prevention:

- Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP and AAFP. Pneumococcal conjugate vaccines have proven effective in preventing OM caused by pneumococcal serotypes contained in the vaccines.³

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Influenza Vaccine:

- Clinicians should recommend annual influenza vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP and AAFP. Most cases of AOM follow upper respiratory tract infections caused by viruses, including influenza viruses. As many as two thirds of children with influenza may have AOM.³

Lifestyle Changes:

- Eliminating passive exposure to tobacco smoke has been postulated to reduce the incidence of AOM in infancy.³
- Avoiding supine bottle feeding and reducing or eliminating pacifier use in the second 6 months of life may reduce the incidence of AOM.³

RATIONALE

- **Safety:** Shall be improved by selecting the appropriate antibiotics to treat acute otitis media.
- **Quality:** Will be improved by instituting consistent antibiotic selection, dosing and care between providers. • **Cost:** Will be improved by decreasing the cost associated with doing unnecessary testing and prescribing unnecessary or inappropriate antibiotics.
- **Delivery:**
 - o Providing appropriate antibiotic therapy for acute otitis media should reduce complications associated with the infection.
 - o Providing appropriate therapy to patients with acute otitis media will help reduce antibiotic resistance.
- **Engagement:** Is created and supported by the involvement of a multidisciplinary team in the development and maintenance of the pathway.
- **Patient/Family Satisfaction:** Shall be improved by providing the highest quality care based on established guidelines and the latest evidence available in the literature. For children with non-severe symptoms who are older than 24 months, there is also an opportunity for shared decision making regarding the initiation of antibiotic therapy versus further observation between provider and care givers in the treatment of acute otitis media.

IMPLEMENTATION ITEMS

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- Algorithm
- Sinusitis SmartSet and SmartText

METRICS PLAN

1. Decrease the number of prescriptions written for azithromycin, clarithromycin, and trimethoprim-sulfamethoxazole (TMP/SMX) for the treatment of acute otitis media by 90%. A total of 15,053 prescriptions were given out for the treatment of acute otitis media in 2015 by Children's Physicians providers. Of those approximately 4% were for azithromycin, clarithromycin, or trimethoprim-sulfamethoxazole (TMP/SMX).
2. Increase the percentage of patients who are not penicillin allergic that receive either high dose amoxicillin or high dose Amoxicillin Clavulanate as first line treatment for acute otitis media.
3. Monitor monotherapy use with cephalosporins and associated response rates.

SUPPORTING DOCUMENTS (Pathway, inclusion/exclusion criteria, definitions, algorithm)

- Algorithm
- Severe AOM – moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C (102.2°F) or higher³
- Non-severe AOM – mild otalgia for less than 48 hours and temperature less than 39°C (102.2°F)³

TEAM MEMBERS

Dr. Nancy Knowles, Dr. Debra Tomek, Dr. Christopher Youngman, Jen Zwiener PharmD, Dr. Andrea Green-Hines

EVIDENCE

1. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics. 2013; 131(3): e964-e999
2. Children's Hospital of Philadelphia Clinical Pathway for Evaluation /Treatment of Acute Otitis Media in Children 2 months to 12 Years Old. Revised January 2020. Author: Joffe M. MD

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3. Lieberthal A, Carroll A, Chonmaitree T, et al. The diagnosis and management of acute otitis media. *Pediatrics* 2013;131:e964; originally published online February 25, 2013; DOI: 10.1542/peds.2012-3488
4. American Academy of Pediatrics. Pneumococcal Infections. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book. 2018 Report of the committee on infectious diseases*. American Academy of Pediatrics; 2018;639-651.

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