

## Management of acute otitis media – a summary

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The present position statement updates a previous document released in 1998 (1). It does not address infections among children with craniofacial abnormalities, immunocompromising conditions or complicated acute otitis media (AOM), or newborns younger than eight weeks of age.

For the complete version of the present position statement and references, please visit [www.cps.ca/English/publications/InfectiousDiseases.htm](http://www.cps.ca/English/publications/InfectiousDiseases.htm).

### ARE CERTAIN CHILDREN AT HIGHER RISK FOR AOM?

The major risk factors for AOM are young age and daycare attendance. Other risk factors include orofacial abnormalities, household crowding, exposure to cigarette smoke, premature birth, not being breastfed, immunodeficiency and a positive family history of otitis media. Children of First Nations or Inuit ethnicity are also at higher risk for AOM.

### HOW SHOULD ONE DIAGNOSE AOM?

It is rare to have AOM in the absence of an upper respiratory tract infection. On examination, one should look for pus under pressure behind the tympanic membrane (Table 1).

### If AOM is diagnosed based on the criteria in Table 1, is antimicrobial treatment indicated?

Viruses play an important role in the pathogenesis of AOM and may be a direct cause of spontaneously resolving AOM (2). However, studies (3-5) using tympanocentesis show bacteria such as *Streptococcus pneumoniae*, *Haemophilus influenzae* or *Moraxella catarrhalis* are present most of the time.

Symptoms of AOM will resolve more quickly if antimicrobials are prescribed (6). However, the treatment effect is small – approximately 15 children have to be treated for one child to have resolution of symptoms (clinical cure) by 48 h. There have been criticisms of the studies that led to this conclusion, including the use of clinical diagnostic criteria, use of clinical as opposed to bacteriological cure, and inconsistent use of placebo in the control groups (7). Despite these criticisms, it is clear that spontaneous resolution occurs in most cases. Not all children with AOM should receive immediate treatment with antimicrobial agents, and a watchful waiting approach with analgesia can be used in many cases.

### WHEN IS IT APPROPRIATE TO ADOPT A WATCHFUL WAITING APPROACH?

If the child is older than six months of age, with mild signs and symptoms, observation without the use of antimicrobials for 48 h to 72 h may be an option if follow-up can be assured (Table 2) (8). The family should be advised about analgesia and either instructed to return if there is no improvement or provided with a prescription for antimicrobials that can be filled at the parents' discretion (deferred prescription). Although symptom resolution may take slightly longer with this approach, parents are generally satisfied, and only approximately one-third of those children eventually receive antimicrobials (9,10).

This watchful waiting option is not appropriate for children who have severe symptoms (appear toxic, have severe otalgia and/or high fever [greater than 39°C, orally]) (11). Aboriginal children have been found to have a high incidence of chronic suppurative otitis media, but it is not known whether a watchful waiting approach in these children increases the risk of this complication. Nonetheless, it would seem prudent to prescribe antimicrobials sooner to Aboriginal children.

### WHAT ARE THE RISKS OF COMPLICATIONS IF ANTIMICROBIALS ARE DEFERRED OR NOT PRESCRIBED FOR AOM?

In the Netherlands, where 30% of children with AOM receive an antimicrobial prescription, the incidence of mastoiditis was double the incidence in countries where prescription rates were greater than 90% (12). However, given the rarity of mastoiditis, at least 2500 prescriptions would have to be filled to prevent one case. Furthermore, only one-quarter of mastoiditis cases require a mastoidectomy, and one-half of children with mastoiditis develop this complication despite previously taking antimicrobials for AOM (13). There are no comparable studies for other severe suppurative complications of AOM, but again, it seems likely that thousands of children would have to be treated to prevent one complication.

There are also risks associated with the use of antimicrobials, including diarrhea, Stevens-Johnson syndrome or anaphylaxis. Additionally, antibiotic resistance is primarily driven by the over-use of antibiotics.

**TABLE 1**  
The signs or symptoms that must be present to make a diagnosis of acute otitis media

**Signs of a middle ear effusion:**

- An immobile tympanic membrane (as demonstrated by pneumatic insufflation, tympanogram or acoustic reflectometry) or presence of liquid in the external ear canal as a result of tympanic membrane rupture (acute otorrhea)
- +/- Opacification of the tympanic membrane (not secondary to scarring)
- +/- Loss of the bony landmarks behind the tympanic membrane (specifically loss of the short or lateral process of the malleus)
- +/- A visible air fluid level behind the tympanic membrane

**Signs of middle ear inflammation:**

- Bulging tympanic membrane with marked discolouration (hemorrhagic, red, gray or yellow)

**Acute onset of symptoms:**

- Rapid onset of ear pain (otalgia), or unexplained irritability in a preverbal child

Data are adapted from references 37 to 43

**TABLE 2**  
Watchful waiting approach

Observation for 48 h to 72 h without antimicrobial agents is appropriate in the following instances:

- The child is older than six months of age
- The child does not have immunodeficiency, chronic cardiac or pulmonary disease, anatomical abnormalities of the head or neck, a history of complicated otitis media (otitis media accompanied by suppurative complications or chronic perforation), or Down syndrome
- The illness is not severe – otalgia appears to be mild and fever is lower than 39°C in the absence of antipyretics
- Parents are capable of recognizing signs of worsening illness and can readily access medical care if the child does not improve

If the child's status worsens or does not improve during the observation period, and the primary diagnosis still appears to be acute otitis media, antimicrobial therapy must be started

## WHAT IS THE FIRST-CHOICE ANTIMICROBIAL AGENT FOR AOM?

Amoxicillin remains the drug of choice because it is inexpensive and well tolerated, and can achieve high levels in the middle ear (Table 3). Beta-lactamase-producing *M catarrhalis* and *H influenzae* may not respond to amoxicillin, but spontaneous resolution of AOM is common with these organisms.

## IF SYMPTOMS DO NOT RESOLVE, SHOULD THE ANTIMICROBIAL BE CHANGED?

Symptoms should improve within one to two days and resolve within two to three days of starting antimicrobials. If symptoms have not improved after two days, the antimicrobial should be changed to one that targets both penicillin-resistant *S pneumoniae* and beta-lactamase-producing organisms – two choices are amoxicillin/clavulanate (Table 4) or parenteral ceftriaxone (14). Middle ear effusions, on the other hand, may persist for months, despite clinical and bacteriological resolution. Therefore, the presence of middle ear effusion does not necessitate a change in antimicrobials.

**TABLE 3**  
Antimicrobial agents for acute otitis media (AOM)\*

**First-line treatment (no penicillin allergy):**

- Amoxicillin – 75 mg/kg/day to 90 mg/kg/day divided twice per day<sup>†</sup>

**Second-line treatment:**

- Cefprozil – 30 mg/kg/day divided twice per day
- Cefuroxime axetil – 30 mg/kg/day divided twice per day
- Ceftriaxone – 50 mg/kg intramuscularly (or intravenously) x 1 dose
- Azithromycin – 10 mg/kg once per day x 1 dose, then 5 mg/kg once per day x 4 doses
- Clarithromycin – 15 mg/kg/day divided twice per day

**If initial therapy fails (ie, no symptomatic improvement after two to three days):**

- Amoxicillin-clavulanate – 90 mg/kg/day amoxicillin, 6.4 mg/kg/day clavulanate divided twice per day for 10 days<sup>†‡</sup>
- If AOM-related symptoms do not resolve with amoxicillin/clavulanate, a course of ceftriaxone 50 mg/kg/day intramuscularly (or intravenously) once per day x 3 doses could be considered. Alternatively, a referral to otolaryngology for tympanocentesis may be considered to determine the etiological agent and to guide therapy

\*See text for comments on duration. Adult dose should never be exceeded;

<sup>†</sup>This is a higher dose than usual, chosen to increase the likelihood of eradicating penicillin-resistant pneumococci. If lower doses are used, traditional three times daily dosing is more appropriate. Some experts also recommend three times daily dosing for the higher dose range; <sup>‡</sup>See Table 4 for amoxicillin plus amoxicillin-clavulanate dosing options

**TABLE 4**  
Dosing table for amoxicillin-clavulanate plus amoxicillin to achieve 90 mg/kg/day of the amoxicillin component and 6.4 mg/kg/day of the clavulanate component for acute otitis media that failed initial antimicrobial therapy\*

Drug	Dose of amoxicillin from amoxicillin-clavulanate	Dose of amoxicillin to add
Clavulin-125F suspension, Clavulin-250F suspension, Apo-Amoxi Clav 125 mg suspension, Apo-Amoxi Clav 250 mg suspension, Clavulin-500F tablets or Apo-Amoxi Clav 500 mg tablets (4:1 formulations)	25 mg/kg/day	65 mg/kg/day
Clavulin 200 suspension or Clavulin 400 suspension, Clavulin 875 mg tablet or Apo-Amoxi Clav 875 mg tablet (7:1 formulations)	45 mg/kg/day	45 mg/kg/day
Clavulin 250 tablet or Apo-Amoxi Clav 250 mg tablet (2:1 formulations)	12.5 mg/kg/day	77.5 mg/kg/day
14:1 formulations (not yet licensed in Canada)	90 mg/kg/day	None

\*Maximum total dose of amoxicillin is 4 g (which will apply to children 45 kg or heavier)

## WHAT IS AN APPROPRIATE DURATION OF ANTIMICROBIAL THERAPY FOR AOM?

Five days of antimicrobial treatment with amoxicillin or second-generation cephalosporins are at least as effective as 10 days of therapy in children older than two years of age with uncomplicated AOM (15,16).

### DO SOME CHILDREN WARRANT A 10-DAY COURSE OF THERAPY FOR AOM?

Yes – children younger than two years of age, children with frequent, recurrent AOM or otitis media with perforated tympanic membrane, and children who failed their initial antimicrobial warrant a 10-day course of therapy because these children are at increased risk of treatment failure (exceptions to this rule are azithromycin for which a five-day course is the maximum, and ceftriaxone for which one dose is usually given for uncomplicated cases and three doses for cases that failed initial therapy) (17).

### WHAT CAN PARENTS DO TO REDUCE THEIR CHILD'S RISK OF DEVELOPING AOM?

Parents can reduce their child's risk for AOM by implementing practices that reduce the chances of contracting viral respiratory tract infections or by preventing other factors that promote inflammation of the eustachian tube:

- excellent hand hygiene (18);
- exclusive breastfeeding until at least three months of age (19-21);
- if bottle feeding cannot be avoided, do not prop the bottle and use fully ventilated bottles (22);
- pacifier use in children younger than three years of age increases the risk for recurrent otitis media by up to 25%. The risk appears to be related to the frequency of use (23,24);
- limiting daycare exposure for very young children decreases the risk of upper respiratory tract infection and therefore AOM (25);
- encourage childcare providers to develop and implement procedures for hand hygiene, as well as toy and environmental cleaning (26); and
- not smoking (27).

### WHICH VACCINES WILL OFFER PROTECTION AGAINST AOM?

The influenza vaccine is highly encouraged for healthy children older than six months of age and for their caregivers (28). Influenza plays a role in the pathogenesis of AOM, and the killed influenza vaccine has been shown to provide some protection against AOM in toddlers (29-31). Although not yet available in Canada, the live attenuated intranasal vaccine showed high efficacy (94% to 98%) in preventing influenza-associated AOM in children 15 to 71 months of age (32,33). The pneumococcal conjugate vaccine is part of the routine schedule for all Canadian children. This vaccine has limited efficacy against AOM because only seven pneumococcal serotypes are contained in the current vaccine. However, newer vaccines with more serotypes and other bacterial components are showing a greater effect against AOM (34,35).

### RECOMMENDATIONS (36)

The levels of evidence reported in the recommendations have been described using the evaluation of evidence criteria outlined by the Canadian Task Force on Preventive Health Care (36).

- To properly diagnose AOM, there must be signs of a middle ear effusion, middle ear inflammation and an acute onset of symptoms. Signs of a middle ear effusion may include a tympanic membrane that is immobile with or without opacification, loss of bony landmarks or a tympanic membrane that has ruptured with fluid in the external ear canal. Signs of middle ear inflammation include a tympanic membrane that is bulging and discoloured. Symptoms of AOM include rapid onset of ear pain or unexplained irritability in a preverbal child (AII-2).
- For otherwise healthy children older than six months of age with no craniofacial abnormalities, with mild clinical signs and symptoms, a watchful waiting approach for 48 h to 72 h is an option if follow-up can be assured (BI). Advice regarding analgesics must be provided. It is recommended to either have the family return if the child does not improve or provide a prescription for antimicrobials that they can fill at their own discretion (deferred prescription).
- If a decision is made to treat with antimicrobials, high-dose amoxicillin (75 mg/kg/day to 90 mg/kg/day) is the first choice for AOM therapy (AI/AII). A five-day course is appropriate for most children older than two years of age, with a 10-day course being reserved for younger children (AI) or those with complicated or frequently recurrent AOM (AIII).
- Parents should be educated about the factors that may increase the risk of AOM in their children (BII-III).
- The influenza vaccine (AII) and pneumococcal conjugate vaccine (AI) should be offered to all children of appropriate age.

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