

Health Policy & Clinical Effectiveness Program

Evidence Based Clinical Practice Guideline For medical management of

Acute Otitis Media

in children 2 months to 13 years of age

<u>A literature review was conducted in August, 2006</u> which found no new studies that would require changes to the recommendations; see Development Process section for method and results.

Target Population

Inclusion: Intended primarily for use in:

• Children age 2 months up to 13 years of age who present with signs and symptoms of acute otitis media.

Exclusion:

- Children with comorbid conditions increasing the risk or severity of acute otitis media, including immunodeficiencies, craniofacial or neurologic abnormalities, or sensory deficits.
- Children with pressure equalization (PE) tubes in place.

Target Users

Includes but is not limited to (in alphabetical order):

- Attending physicians
- Community physicians and practitioners
- Emergency department physicians
- Otolaryngologists^a
- Patient / family
- Patient care staff
- Residents

Introduction References in parentheses () Evidence strengths in [] (See last page for definitions)

Acute otitis media describes a viral or bacterial infection of the middle ear space, concurrent with effusion, and characterized by rapid onset; see Table 2. See Table 1 for definitions and abbreviations of otitis media used in this guideline, and Appendix 1 for a drawing of the middle ear and definitions and common names useful for patient / family education purposes.

Otitis media (OM) is one of the most common reasons for visits to the primary care physician, particularly for the young child, though decreasing trends for visit rates have been observed through the 1990s (*McCaig 2002 [O]*). Decreasing rates of antibiotic prescription have also been documented, though acute otitis media (AOM) remains the most common reason for antibiotic use in children in the U.S. and accounted for over 13 million prescriptions in 2000 (*AAP 2004 [S]*, *Finkelstein 2003 [O]*, *McCaig 2002 [O]*). History of AOM has been reported at 48% of children by age 6 months, 79% by age 1 year and 90% by age 2 years (*Paradise 1997 [C]*). The result is an annual U.S. total cost of \$2.98 billion for all direct and indirect AOM health services (*AAP 2004 [S]*).

The challenges presented in the management of AOM involve the ability to reach diagnostic certainty and a lack of strong evidence regarding antibiotic efficacy to improve outcomes in a condition that demonstrates a high natural resolution against a backdrop of increasing bacterial resistance. Yet, medical outcomes related to risk of serious bacterial infections must be considered.

Although the greatest risk for medical complications from AOM occurs in children under two years, hearing outcomes are important to monitor in the older child with recurrent AOM or with a history of <u>otitis media</u> <u>with effusion (OME)</u>. Thus, children up to the age of 13 years have been included in this guideline.

The increased use in recent years of immunizations in young children against *S. pneumoniae* and influenza has begun to have an impact on the incidence of AOM, its bacteriology (*Casey 2004 [C]*) and its sequelae. Though the effectiveness of influenza vaccination in preventing AOM remains unclear (*Hoberman 2003 [A], Belshe 2000 [A]*), the heptavalent conjugated pneumococcal vaccine (PCV7, Prevnar[®]) effectively reduces the incidence of OM by at least 6-8% and significantly decreases subsequent PE tube placement (*Straetemans 2003 [M], Fireman 2003 [A], Eskola 2001 [A], Black 2000 [A], Black 2004 [C], Whitney 2003 [D]*).

In the target population, the objectives of this guideline are to:

- improve the use of appropriate diagnostic criteria,
- improve the use of appropriate antibiotic therapy,
- improve symptom relief,
- avoid medical complications, and
- improve parental involvement in decision-making around the management of AOM

Revision Publication Date: October 29, 2004 Original Publication Date: March, 1999

^a Otolaryngologist = ENT, ear/nose/throat

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Otitis Type	Definition	Comment
MEE (middle ear effusion)	Any fluid in middle ear space regardless of cause.	Assess presence by pneumatic otoscopy or tympanometry.
Myringitis	Erythema of tympanic membrane (TM) without MEE (may be mimicked by crying).	Most often viral. Does not respond to antibiotics. May be seen in early AOM or during resolution.
AOM (acute otitis media)	MEE with rapid onset of one or more of the following: otalgia, ear pulling, otorrhea, fever, irritability, anorexia, vomiting, or other symptoms.	Most frequent diagnosis by pediatricians: 48% of children by age 6 months, 79% by age 1 year and 90% by age 2 years (<i>Paradise 1997 [C]</i>).
Sporadic AOM	AOM occurring more than 3 months after a prior episode of AOM.	Compare to recurrent AOM.
Recurrent AOM (otitis-prone condition)	History of 6 episodes over a 12 month period, taking into account the severity of episodes, clustering of episodes, and persistence of otitis media with effusion.	Affects about 15-30% of children.
OME (otitis media with effusion)	MEE without signs or symptoms of infection.	Childhood prevalence of about 15%. Often follows AOM.
Chronic OME	OME with duration more than 3 months.	

 Table 1 Abbreviations and Definitions of Types of Otitis

Etiology

Common bacterial causes of OM are *S. pneumoniae*, *H. influenzae* and *M. catarrhalis* (AAP 2004 [S]). Viral infections are also a common cause of OM and are present in 41% of AOM cases, with RSV (respiratory syncytial virus), parainfluenza viruses and influenza viruses comprising as much as 81% of the viral pathogens (*Heikkinen 1999 [C], Pitkaranta 1998 [C]*). Viral and bacterial interaction in the middle ear may contribute to delayed resolution of inflammation and of bacterial clearance (*Chonmaitree 2000 [S]*). With the introduction of the vaccine against serotypes of *S. pneumoniae* (PCV7) in 2000, the prevalence of *S. pneumoniae* in OM may change (*Eskola 2001 [A], Black 2004 [C], Casey 2004 [C], Block 2004 [D], Klein 1994 [S]*).

Risk factors for AOM include age less than 2 years, exposure to family members with respiratory infections, parental smoking, daycare attendance, excessive pacifier use, breastfeeding duration less than 3 months and genetic predisposition (*Uhari 1996 [M], Niemela 2000 [A], Bradley 2003 [C], Casselbrant 1999 [C]).*

Guideline Recommendations

Assessment and Diagnosis

General

Signs and symptoms of AOM are often non-specific and overlap with those of upper respiratory infections.

Clinical diagnosis is especially less reliable in the child under 2 years of age. This contributes to difficulty in accurately diagnosing AOM and in evaluating results of clinical trials (*Dagan 2002 [S]*, *Froom 1990 [O]*, *Wald 2003 [E]*).

Note: In a chart review, only 38% of pediatricians' diagnoses of AOM met CDC criteria for the diagnosis (*Garbutt 2003 [O]*). Inter-rater agreement for AOM diagnosis has been measured at 64% (*Blomgren 2003 [C]*).

History and Physical Examination

1. It is recommended that the components to assess for AOM in the history and physical include history of acute onset of symptoms, presence of middle ear effusion (MEE), and signs and symptoms of middle ear inflammation (*AAP 2004 [S]*). See Table 2.

Note 1: Accurate diagnosis of AOM, critical to the management decision, is a competency that may be improved with specific training (*Rosenfeld 2002 [O], Steinbach 2002 [O], Pichichero 2001* [*O*]). See CD-rom available in Pratt Library (*Wald 2002 [E]*) and an interactive case module on-line with the AAP^b.

Note 2: A bulging, cloudy, immobile and distinctly red TM is most helpful in the diagnosis of AOM (*Rothman 2003 [M], Leibovitz 2003b [C], Karma 1989 [D]*). See Table 3. Note 3: A parental report of AOM symptoms is somewhat reliable (sensitivity 71%, specificity

^b AAP = American Academy of Pediatrics <u>http://www.aap.org/otitismedia/www/</u>

Table 2 Requirements for Diagnosis of AOM

. history of acute onset of signs and symptoms
2. presence of MEE
indicated by one of the following:
 bulging tympanic membrane (ear drum)
 decreased mobility of tympanic membrane
 o discharge from the ear (otorrhea)
signs and symptoms of ME inflammation
indicated by either:
 red tympanic membrane or
 discomfort affecting normal activity and/or sleep
(earache otalgia)

(AAP 2004 [S])

Table 3 Likelihood Ratios (LR) for Clinical Signs^c

Sign of tympanic membrane	Positive LR (95% CI) ^d
Bulging	51 (36-73)
Cloudy	34 (28-42)
Distinctly impaired mobility	31 (26-37)
Distinctly red	8.4 (6.7-11)
Normal color	0.2 (0.19-0.21)
Normal mobility	0.2 (0.19-0.21)
(Rothman 2003 [M], Karma 1989 [[D])

80%, positive predictive value 51%, likelihood ratio [LR] 3.55) (*Kontiokari 1998 [C]*).

Note 4: Non-specific symptoms include cough, rhinitis, poor appetite and vomiting and have likelihood ratios (LR) near 1.0 (*Heikkinen 1995 [C]*, *Niemela 1994 [C]*).

2. It is recommended that pneumatic otoscopy and /or tympanometry be used to enhance accuracy when diagnosing AOM (*Spiro 2004 [A], Karma 1989 [D], Brookhouser 1998 [S], Pelton 1998 [S], Jones 2003 [O], Pichichero 2002 [O], Pichichero 2001 [O]).*

Note 1: Pneumatic otoscopy and tympanometry measure the degree of mobility of the tympanic membrane as an indication of the presence of middle ear effusion (*Jerger 1970 [C], Jones 2003 [O], Pichichero 2002 [O]*). A large, randomized controlled trial demonstrated that the appropriate use of tympanometry would reduce OM diagnoses by 14%-40% (*Spiro 2004 [A]*). **Note 2:** Acoustic reflectometry is not often used nor readily available in the Cincinnati area, though the procedure is acceptable for determining the presence of MEE (*Block 1999 [C]*, *Barnett 1998 [C], Block 1998 [C], Kimball 1998 [S]*).

- 3. It is recommended that ear pain (otalgia) be assessed, as determined by discomfort affecting normal activity and/or sleep (*Kontiokari 1998 [C], AAP 2001 [S]*).
- 4. It is recommended that, for patients with recurrent AOM, additional attention be paid to parental concerns about hearing loss, speech delay or language delay (*Roberts 2004 [M]*).

Management

General

AOM is a disease with a high spontaneous resolution rate (78-80% resolve within 7-14 days), and routine antibiotic therapy of all children with suspected AOM results in the treatment of many children in whom there may be either modest benefit and/or modest adverse outcomes from antibiotic therapy (*Glasziou 2003 [M], Marcy 2001 [M], Rosenfeld 1994 [M], Dowell 1998b [S]*). Moreover, the decision to use antibiotics and the specific choice of antibiotics must take into account the increasing emergence of bacterial resistance (*Doern 1998 [C], Jacobs 2003 [O], Mason 2003 [O]*).

Note: AOM may have potentially serious complications including mastoiditis, meningitis, and intracranial abscess formation. There is an increased incidence of mastoiditis in some countries which limit use of antibiotics for AOM, but a causal relationship is not fully supported by these data. Prevalence of mastoiditis in the U.S. is 0.4%, and 2,500 cases of AOM would need to be treated with antibiotics to prevent one case of mastoiditis (number needed to treat [NNT] = 2,500) (*Van Zuijlen* 2001 [O]).

Treatment

1. It is recommended that all children with AOM who have a positive assessment for pain be treated with an appropriate analgesic (*AAP 2004 [S]*, *AAP 2001 [S]*).

Note 1: Ear pain in AOM is self-limiting and time is the greatest factor in pain reduction (*Sarrell 2003 [A]*). Therefore, the immediate availability of a safe and effective analgesic is more important than which agent is used. These include oral agents (acetaminophen or

^c Likelihood ratios quantify the <u>change</u> in probability of AOM when a given sign or symptom is present in a specific clinical case and depend upon a starting estimate of probability. For more information, see Appendix 2 for definition and use of LR.

^d 95%CI: 95% Confidence Interval expresses the uncertainty (precision) of a measured value; it is the range of values within which we can be 95% sure that the true value lies. A study with a larger sample size will generate more precise measurements, resulting in a narrower confidence interval.

ibuprofen) or topical ear drops (anesthetic or Naturopathic Herbal Extract Ear Drops) (*Perrott* 2004 [*M*], Sarrell 2003 [*A*], Sarrell 2001 [*A*], Bertin 1996 [*A*], Hoberman 1997 [*B*], AAP 2001 [*S*]). **Note 2:** In patients with a perforated eardrum and/or discharge from the ear, avoid topical analgesic ear drops as their use will likely result in severe dizziness and vomiting.

2. It is recommended that treatment with a 10-day course of antibiotics be given to children less than 2 years of age with AOM (*Cohen 2000 [A], Cohen 1998 [A], AAP 2004 [S]*).

Amoxicillin, in the dose range of 80-90 mg/kg/day is effective in the treatment of a first episode of AOM or for a recurrence more than 1 month since recovery from a prior episode of AOM (*Rosenfeld 1994* [*M*], *Piglansky 2003* [*C*], *AAP 2004* [*S*]). See Table 4 for doses for this first-line therapy. In cases when the clinician has a high suspicion for concurrent conjunctivitis-otitis media syndrome, commonly caused by a beta-lactamase producing organism, it is reasonable to consider a second-line antibiotic (*Wald 1997* [*S*]).

For children with allergies to penicillin, or other reasons to consider alternative antibiotics, consider a second-line antibiotic. In a child less than 1 year of age with a history of a penicillin allergy, a careful review of the reported reaction is prudent. See extended list of antibiotic options, doses and preparations in Appendix 3 (*Rosenfeld 1994 [M]*).

Note: While it is suggested in general that children under two years of age with AOM be treated with antibiotics, it is recognized that in certain situations observation without antibiotics or with a safety-net antibiotic prescription (SNAP) may be reasonable. See Table 5 for SNAP definition. Local data suggest that the relapse/recurrence rate (defined in the study as a new case of AOM occurring between 7-60 days from initial episode) is about 3 times higher in children less than 2 years of age (34% compared to 10%) (Siegel 2004 [C]). If observation or SNAP is utilized, both the clinician and the parents are advised to be aware of the higher relapse/recurrence rate in this age group and close follow-up must be assured (Siegel 2003 [C]).

Table 4 First line antibiotic medication and doses

Antibiotic	Dose and frequency	Max Daily Dose
amoxicillin	80-90 mg/kg per day, divided • 40-45 mg/kg BID or • 25-30 mg/kg TID	2 gm/day

Table 5 Safety-net antibiotic prescription (SNAP) definition and management

- SNAP is a prescription for an appropriate antibiotic, as determined by the practitioner, <u>written to be filled only within 5 days of the office visit.</u>
 Instruct the parent not to fill SNAP unless symptoms worsen at any time or unless symptoms do not improve during a waiting period of 48 72 hours.
 Instruct the parent that a well-appearing child diagnosed with AOM may quickly progress to a more severe case, and to call and/or follow-up with practitioner if this occurs.
 (*Siegel 2003 [C]*)
- 3. It is recommended that in children over age 2 years with AOM and who are well-appearing, that the treatment options be discussed with the family and that the family be involved in the decision-making. The options include:
 - treatment with a safety-net antibiotic prescription (SNAP) to be filled after 48 72 hours if symptoms do not resolve with observation. See Table 5 for SNAP definition and management.
 - treatment with a 5 day course of antibiotics (see treatment recommendation 2 and Table 4 for discussion of antibiotic selection and doses). Note 1: There is inadequate evidence to say that antibiotic therapy is or is not beneficial to most children with AOM (Wald 2003 [E]). Note 2: No antibiotic prescription, with followup within 48 - 72 hours, is also an option in the specific case when a practitioner would like to control the observation option more closely. Note 3: An observation option information sheet for parents is available for use through the CCHMC Health Topics website (New York Regional Otitis Project 2002 [X], Rosenfeld 2001 [X]). Note 4: Parental involvement in the decision to use antibiotic therapy and the use of SNAP with pain control are effective in reducing the use of antibiotics (Pshetizky 2003 [B], Siegel 2003 [C]). Note 5: In a Cincinnati office-based study, the relapse/recurrence rate for all ages (new case of AOM occurring between 7-60 days from initial episode) was 24% in those that filled the SNAP, compared to 11% in those that did not fill the SNAP, *p* < 0.025 (Siegel 2004 [C]).

Table 6 Factors to consider for AOM treatment

- temperature > 38.6° C (101.5° F) in the past 48 hr
- symptoms suggestive of AOM for > 48 hr
- toxic appearance
- tympanic membrane of the infected ear not intact
- another episode of AOM within past 3 mo
- signs of impending perforation in the infected ear as judged by the examining clinician
- a coexisting bacterial infection
- concerns of clinician that the family would be unable to seek medical care if the child's clinical status were to worsen
- concerns of caregiver or clinician that the caregiver could not gain an acceptable understanding of the therapeutic plan
- 4. It is recommended that children over age 2 years with AOM and with severe illness (see Table 6) be treated with a 5 day course of antibiotics (see treatment recommendation 2 and Table 4 for discussion of antibiotic selection and doses) (*Kozyrskyj 2000 [M]*, *Kozyrskyj 1998 [M]*).
- 5. It is recommended, for a child with a recurrence of AOM in less than 1 month from completion of antibiotic therapy from a prior episode of AOM, or for a child who has recently been on antibiotics for other reasons, that antibiotic choices other than amoxicillin be considered (*Leibovitz 2003a [C], Carlin 1987 [C], Dowell 1998a [S], Klein 1998 [S])*. For extended list of antibiotic options, doses and preparations see Appendix 3.

Note: There is no strong evidence to support prolonged or prophylactic antibiotic therapy in recurring AOM (*Williams 1993 [M]*, *Koivunen 2004 [A]*). Persistent MEE is common and parents may be counseled to expect fluid to take several weeks to months to clear (*Rosenfeld 2003 [M]*, *AAP 2004 [S]*).

6. It is **not** recommended that other therapies be used in the treatment of AOM (*AAP 2004 [S]*).

Note 1: Steroids, antihistamines, decongestants, and complementary or alternative treatments have not been documented to be efficacious in the treatment of AOM (*Butler 2002 [M], Flynn 2002 [M], Barnett 2000 [C], AAP 2004 [S]*). Antihistamines may prolong the duration of MEE. **Note 2:** Median duration of MEE was 73 days for patients on antihistamine compared to 25 days for patients on placebo (p = 0.04) in a randomized controlled study (*Chonmaitree 2003 [A]*).

Note 3: It is recognized that use of complementary and alternative medicine (CAM) is common and its use is often not

reported to the primary care physician (PCP) (*Eisenberg 1998 [O], Spigelblatt 1994 [O]*). The PCP may take the AOM visit as an opportunity to begin a respectful discussion regarding the safety and efficacy of CAM with families who report its use^e.

Follow-up: to Treatment and Observation Options

7. It is recommended, for the first or a sporadic episode of AOM, that when the initial management approach fails, the clinician reevaluate the antibiotic decision.

If symptoms worsen at any time or if symptoms do not improve during a waiting period of 48 - 72 hours of initial presentation with AOM, and reexamination continues to suggest that AOM is the appropriate diagnosis, then start amoxicillin if not already initiated or change to an alternative antibiotic if the child is already on a first line drug.

Note: Options for alternative antibiotics include:

- amoxicillin/clavulanate; efficacy has been shown for AOM and may be used when resistance is likely (*Hoberman 1997 [A], Dagan* 2001 [C])
- ceftriaxone IM; 3 consecutive daily doses is efficacious in non-responsive AOM for children with vomiting or otherwise unable to tolerate oral dosing (*Leibovitz 2000 [A]*).
 For children with allergies to penicillin, or other reasons to consider another antibiotic choice, see extended list of antibiotic options, doses and preparations in Appendix 3.
- 8. It is recommended that the clinician reevaluate the patient in 4-8 weeks after diagnosis, depending on existing risk factors, to document resolution or persistence of effusion (*AAP 2004 [S], Local Expert Consensus [E]*).

Consults and Referrals

1. It is recommended that a practitioner have a low threshold for referral for an audiologic evaluation by a pediatric audiologist if concerns around hearing, speech, or language are raised by parents, clinician or other caregivers because of recurrent AOM (*Mandel 1991 [A], Hsu 1998 [C], Teele 1990 [C], Bachmann 1998 [S]).*

^e CCHMC Health Topic on <u>Alternative Therapy</u> : http://www.cincinnatichildrens.org/svc/prog/specialneeds/resources/alternative.htm

- 2. It is recommended that a child be referred for an otolaryngological evaluation for:
 - recurrent acute otitis media, (history of 6 episodes over a 12 month period taking into account the severity of episodes, clustering of episodes, and persistence of otitis media with effusion)
 - persistent otorrhea
 - concerns about mastoiditis, or other complications of acute otitis media
 - perceived need for tympanocentesis and/or myringotomy (e.g. acute episode not responsive to medical therapy)

• abnormal audiologic evaluation (*Froom 1993 [C]*).

Education

- 1. It is recommended that the family be educated regarding the natural history of AOM, signs and symptoms of clinical deterioration, and appropriate follow-up.
- 2. It is recommended that the practitioner discuss with the parent that persistent MEE is common and parents may expect fluid to take several weeks to months to clear (*Rosenfeld 2003 [M*], AAP 2004 [S]).
- 3. It is recommended that the family be educated about preventable risk factors. These include:
 - exposure to others (especially family members) with upper respiratory infections (*Uhari 1996 [M*]);
 - parental smoking or other sources of second-hand smoke (*Uhari 1996 [M], Ilicali 1999 [C]*);
 - daycare attendance (*Uhari 1996 [M], Bradley 2003 [C]*); Note: Though daycare attendance may not be preventable, options to reduce risk of AOM include delaying daycare, selecting a setting with fewer children, and/or verifying the daycare facility's handwashing policies, actual handwashing practices, and availability of sinks.
 - excessive pacifier use, limiting use to when the child is falling asleep (*Uhari 1996 [M], Niemela 2000 [A]*);
 - breastfeeding duration less than 3 months (*Uhari 1996* [*M*]);
 - bottlefeeding with the child on his/her back; assure that infants are offered bottle feedings while sitting in upright positions (*Tully 1995 [B]*).

Parents may also benefit by understanding nonpreventable risk factors or common misconceptions.

- anatomy of the eustachian tube in young children
- it is not always known why a child gets AOM
- allergies do not cause AOM.

Health Topics on CCHMC's website^f:

- Ear Infections and Acute Otitis Media
- Types of Hearing Tests
- <u>Managing Ear Infections (Acute Otitis Media)</u>

See Appendix 1 for a drawing of the middle ear and definitions and common names useful for patient / family education purposes.

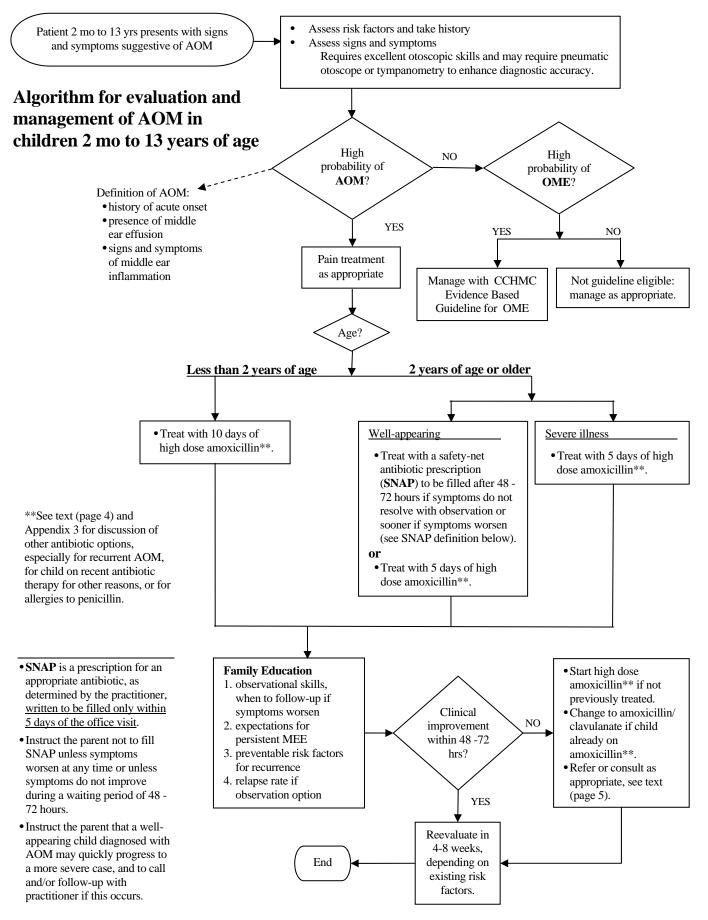
A parent information brochure, <u>Acute Ear Infections and</u> <u>Your Child</u>, is available for bulk purchase from the AAP^g.

^f CCHMC Health Topic website:

www.cincinnatichildrens.org/health/info

^g AAP = American Academy of Pediatrics <u>www.aap.org</u>

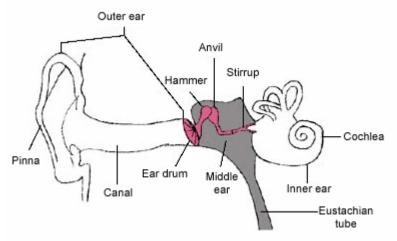
Evidence Based Clinical Practice Guideline for medical management of Acute Otitis Media



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Appendix 1: Resources for patient / family education purposes

Drawing of the middle ear



Definitions and common names useful to non-clinicians

TERM	Common name or definition		
adenoidectomy	removal of the adenoids (tissue in the back of the throat near the tonsils)		
anvil	the middle bone of the 3 bones of the middle ear; also called incus		
canal, external auditory	the passage leading from the opening of the external ear to the eardrum		
cerumen	earwax		
cochlea	a part of the inner ear, in the shape of a snail shell, which is the sensory organ of hearing		
effusion	fluid in the middle ear		
erythema	redness (of the eardrum)		
eustachian tube	a tube connecting the middle ear to the back of the throat; responsible for equalizing pressure in the middle ear		
hammer	the outermost bone of the 3 bones of the middle ear; shaped like a hammer; also called malleus		
insufflation	blowing air into the ear to determine mobility of the eardrum, an indication of the presence or absence of fluid		
mastoiditis	infection of the bone behind the middle ear		
myringotomy	a surgical cut in the eardrum to drain fluid		
otalgia	earache, pain in the middle ear		
otitis media	inflammation of the middle ear		
otolaryngolog-	referring to ENT, ear/nose/throat specialty		
otorrhea	discharge from the ear		
otoscopy	looking in the ear with an otoscope		
pinna	the part of the outer ear projecting from the head		
pneumatic otoscopy	observing eardrum movement when air is blown into the ear; to determine mobility of the eardrum, an indication of the presence or absence of fluid		
rhinitis	runny nose		
stirrup	the innermost bone of the 3 bones of the middle ear; also called stapes		
tympanic membrane	eardrum, also abbreviated TM		
tympanocentesis	obtaining a sample of fluid from the middle ear to determine the presence of bacteria or virus		
tympanometry	a measurement of the mobility of the eardrum to determine the presence of fluid		
tympanogram	the graph from a tympanometry test		
tympanostomy tubes	tubes surgically placed in the eardrum to re-establish ventilation to the middle ear, also called:		
	ventilation tubes		
	• PE tubes (pressure equalization tubes)		
	• grommets		

Appendix 2 Definition of LIKELIHOOD RATIOS (LR) in the context of evaluating signs and symptoms for the diagnosis of Acute Otitis Media

A likelihood ratio (LR) is:

the likelihood of the presence of the sign or symptom in the child WITH AOM, divided by the likelihood of the presence of the sign or symptom in the child WITHOUT AOM.

An **LR value**:

- greater than 10 is very helpful in increasing diagnostic certainty the presence of sign or symptom is 10 times more likely to be present in a child with AOM than in a child without AOM
- of 1 is not helpful the presence of sign or symptom is just as likely to be present in child with AOM as in a child without AOM
- less than 0.2 is very helpful in ruling out the condition the presence of sign or symptom is one-fifth as likely to be present in a child with AOM as in a child without AOM

For more information on LRs see: http://www.cebm.utoronto.ca/glossary/lrs.htm#top

Probability worksh	eet for your own use	0.1	1	- 99
1. Based on	(Prior Factors Considered),	Long Color		
my estimate of the this child has AOM	pre-test probability is <u>%</u> that	0.2		98
		0.5	10000	+ 95
2. The sign or sympto	m I found,, has an		2000-	
LR of		1	1000 + 500+	- 90
3. Using the nomogra	m, I calculate that the post-test	2-	200 100	- 80
probability is	% that this child has AOM.	5-	50-	- 70 - 60
4. Repeat steps 1-3, as	desired, for each additional sign or		20— 10—	- 50
symptom observed	(shortcut: multiply LRs before starting).	10 —	5-	- 40
5. The final post-test	probability is% that this child	20 -	2 -	- 30
has AOM.		30 —	+05	+ 20
Probability Worksheet	EXAMPLE	40 +	-02	
	age, daycare exposure, the current community	50 —	-0.1	+ 10
	the chief complaint for this visit, my	60	+ 0.05	
uncalculated, but prof	essional estimate of the pre-test probability is	70	+ 0.02	- 5
50% that this child ha	as AOM, before I have had a chance to examine		+0.01	Con.
the child.		80 +	+ 0.005	+ 2
2. The sign or symptom an LR of 51 .	I found, a bulging tympanic membrane, has	90 —	-0.002	- 1
	I calculate that the post-test probability is as AOM.	95 —	- 0.0005	- 05
(shortcut: multiply LI	or each additional sign or symptom observed Rs before starting), I find a normally colored	98 —		- 02
TM which has a likelihoth signs together).	hood ratio of 0.2 (51 X $0.2 = 10 = LR$ for	ее		⊥ 0.1
6 6 ,	ant findings, the final post-test probability is as AOM.	Pre-Test Probability (%)	Likelihood Ratio	Post-Test Probability (%)

Probability Worksheet for your own use

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Appendix 3 Expanded Table of Antibiotic Options, Doses and Preparations						
Antibiotic	Dose, Frequency & Max Daily Dose				Middle Ear Penetration	Comments
First Line Thera	ру					
Amoxicillin	80 - 90 mg / kg / day Max daily dose 2 gm taken as: 40 - 45 mg / kg BID or 25 - 30 mg / kg TID	Suspension (per 5mL): 125, 200, 250 or 400 mg	OK	Low	Excellent; Can exceed MICs of intermediate and resistant <i>S.</i> <i>pneumoniae</i> with higher doses (<i>Canafax</i> 1998 [<i>C</i>], Seikel 1997 [<i>C</i>], Lister 1997 [<i>F</i>]).	Recommended as first line therapy.
Second Line The	rapy					
Penicillin						
Amoxicillin/ clavulanate (Augmentin®)	(amoxicillin) 40 - 45 mg / kg / day Max daily dose: 2 gm taken as: 20 - 22 mg / kg BID	Suspension (per 5mL) amoxicillin component: 125, 200, 250, 400, 600 mg	ОК	High	Excellent (Seikel 1997 [C])	For use in a patient with persistent or recurrent disease or with known or suspected beta-lactamase producing organisms, such as in conjunctivitis- otitis media syndrome. May add 40 - 45 mg / kg / day of <u>amoxicillin</u> to yield 80 - 90 mg / kg / day of amoxicillin component. Maximum dose of <u>clavulanate</u> not to exceed 6.4 mg / kg / day, to minimize diarrhea.
Cephalos	porins					
Cefdinir (Omnicef®)	14 mg / kg / day Max daily dose: 600 mg taken as: 7 mg / kg BID or 14 mg / kg once a day	Suspension (per 5 mL): 125 mg	Very Good	High	Excellent	(Klein 2000 [S])
Cefprozil (Cefzil)	30 mg / kg / day Max daily dose: 1 gm taken as: 15 mg / kg BID	Suspension (per 5mL): 125 or 250 mg	Un- pleasant	High	Good (Shyu 1994 [C])	Similar efficacy to amoxicillin/ clavulanate with less GI side effects (Arguedas 1991 [A], Gupta 2004 [C]).
Cefuroxime (Ceftin®)	30 mg / kg / day Max daily dose: 1 gm taken as: 15 mg / kg BID	Suspension (per 5 mL): 125 or 250 mg	Un- pleasant	High	Good	(Gooch 1996 [A])
Ceftriaxone (Rocephin®)	50 mg / kg Max daily dose: 1 gm taken as: one dose IM or 3 daily doses IM for treatment failure (<i>Leibovitz 2000 [A]</i>)	N/A	N/A	High	Good (Gudnason 1998 [C])	Reserve for children with vomiting or otherwise unable to tolerate oral dosing. Has been shown to be efficacious (Barnett 1997 [A], Green 1993 [A], Chamberlain 1994 [B]).
Macrolides / Azilides						
Azithromycin (Zithromax®)	day 1 = 10 mg / kg day 2 - 5 = 5 mg / kg Max daily dose: 250mg taken: once a day or 20 mg / kg once daily for 3 days Max daily dose: 500 mg	Suspension (per 5 mL): 100 or 200 mg	OK	High	Unknown	One study showed efficacy and safety with a high dose (20 mg/ kg) 3-day regimen with success in children with recurrent or persistent AOM (<i>Arrieta</i> 2003 [A]).
Clarithromycin (Biaxin®)	15 mg / kg / day Max daily dose: 1gm taken as: 7.5 mg / kg BID	Suspension (per 5 mL): 125 or 250 mg	Un- pleasant	High	Good	Middle ear fluid penetration is excellent after multiple doses (<i>Guay</i> 1993 [S]).

Appendix 3	Expanded Table of Antibiotic Op	tions, Doses and Preparations
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Acute Otitis Media Team Members 2004

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All Team Members and Clinical Effectiveness support staff listed above have signed a conflict of interest declaration.

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Kim Collins (Medical Education)

*Member of previous Otitis Media guideline development Team

Development Process

The process by which this guideline was developed is documented in the <u>Guideline Development Process Manual</u>; a Team Binder maintains minutes and other relevant development materials. The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using the grading scale that follows, and examined current local clinical practices.

CCHMC Evidence Grading Scale				
М	Meta-analysis Systematic Review		Basic laboratory research	
А	Randomized controlled trial: large sample	S	Review article	
В	Randomized controlled trial: small sample	Q	Decision analysis	
С	Prospective trial or large case series	L	Legal requirement	
D	Retrospective analysis	0	Other evidence	
Е	E Expert opinion or consensus		No evidence	

To select evidence for critical appraisal by the group, the citations in the AAP Clinical Practice Guideline for Acute Otitis Media were reviewed. Additionally, the Medline, EmBase and the Cochrane databases were searched for dates of January, 2003 through June, 2004 to generate an unrefined, "combined evidence" database using a search strategy focused on answering clinical questions relevant to OM and employing a combination of Boolean searching on humanindexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. The citations were reduced by: eliminating duplicates, review articles, non-English articles, and adult articles. The resulting abstracts were reviewed by a methodologist to eliminate low quality and irrelevant citations. During the course of the guideline development, additional clinical questions were generated and subjected to the search process, and some relevant review articles were identified. December, 2002 was the last date for which literature was reviewed for the previous version of this guideline. The details of previous review strategies are not documented. However, all original citations were reviewed for appropriateness to this revision.

A search using the above criteria was conducted for dates of July, 2004 through August, 2006. Sixty-five relevant articles were selected as potential future citations for the guideline. However, none of these references were determined to require changes to the 2004 version of the recommendations.

Appropriate companion documents have been developed to assist in the effective dissemination and implementation of the guideline. Experience with implementation of the original publication of this guideline has provided learnings which have been incorporated into this revision.

Once the guideline has been in place for three years, the development team reconvenes to explore the continued validity of the guideline. This phase can be initiated at any point that evidence indicates a critical change is needed.

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference and clinical expertise. During formulation of these guidelines, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

The guideline has been reviewed and approved by clinical experts not involved in the development process, and other individuals as appropriate to their intended purposes.

The guideline was developed without external funding. All Team Members and Clinical Effectiveness support staff listed have declared whether they have any conflict of interest and none were identified.

Copies of this Evidence-Based Care Guideline (EBCG) are available online and may be distributed by any organization for the global purpose of improving child health outcomes. Website address: <u>http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/evbased/default.htm</u> Examples of approved uses of the EBCG include the following:

- copies may be provided to anyone involved in the organization's process for developing and implementing evidence-based care guidelines;
- hyperlinks to the CCHMC website may be placed on the organization's website;
- the EBCG may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at <u>HPCEInfo@cchmc.org</u> for any EBCG adopted, adapted, implemented or hyperlinked by the organization is appreciated.

NOTE: These recommendations result from review of literature and practices current at the time of their formulations. This guideline does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this guideline is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

For more information about these guidelines, their supporting evidences and the guideline development process, contact the Health Policy & Clinical Effectiveness office at: 513-636-2501 or HPCEInfo@cchmc.org.

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Evidence Based Clinical Practice Guideline for medical management of Acute Otitis Media

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