NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

ACUTE OTITIS MEDIA

Guidelines

1. **American Academy of Pediatrics, American Academy of Family Physicians (AAP/AAFP)**. Diagnosis and management of acute otitis media. Pediatrics 2004; 113(5):1451-65. [135 references]
2. **Cincinnati Children's Hospital Medical Center**. Evidence based clinical practice guideline for medical management of acute otitis media in children 2 months to 13 years of age. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Oct. 16 p. [113 references]
3. **Scottish Intercollegiate Guidelines Network (SIGN)**. Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 18 p. (SIGN publication; no.66). [77 references]
4. **University of Michigan Health System (UMHS)**. Otitis media. Ann Arbor (MI): University of Michigan Health System (UMHS); 2007 July. 12 p. [13 references]

INTRODUCTION

A direct comparison of American Academy of Pediatrics, American Academy of Family Physicians (AAP/AAFP), Cincinnati Children's Hospital Medical Center (CCHMC), Scottish Intercollegiate Guidelines Network (SIGN) and University of Michigan Health System (UMHS) recommendations for diagnosing and managing acute otitis media (AOM) in pediatric patients is provided in the tables, below.

The comparison focuses on the appropriate diagnosis and initial treatment of a child presenting with AOM; however, the scope of the guidelines and the populations they consider vary. For example, the AAP/AAFP and CCHMC guidelines address AOM only, while SIGN and UMHS also address otitis media with effusion (OME). The topic of OME is addressed in separate guidelines by AAP/AAFP and CCHMC, and in another synthesis available on the National Guideline Clearinghouse (NGC) Web site.

All four guidelines included in this synthesis focus on the pediatric population. The AAP/AAFP, CCHMC guidelines apply to children age 2 months and older, while SIGN does not specify an age range, targeting children in general. The UMHS guideline targets children age 2 months and older as well as adults with suspected or confirmed otitis media. AAP/AAFP, CCHMC and SIGN note that recommendations concerning children with underlying conditions that increase the risk for AOM or alter its natural course (such as cleft palate, Down syndrome, and immunodeficiencies) are beyond the guidelines' scope. Two guidelines also explicitly exclude from consideration additional patient subgroups: AAP/AAFP

excludes children with a clinical recurrence of AOM within 30 days, while CCHMC excludes children with pressure equalization (PE) tubes in place. The UMHS guideline addresses special populations including infants 0 to 8 weeks old, children with chronic illnesses and adults. These recommendations, however, are beyond the scope of this guideline. In developing their recommendations, CCHMC and UMHS considered the conclusions of AAP/AAFP.

- Table 1 provides a quick-view glance at the primary interventions considered by each group.
- Table 2 provides a comparison of the overall scope of the guidelines.
- Table 3 provides a more detailed comparison of the specific recommendations offered by each group for the topics under consideration in this synthesis, including:
    - Definition of AOM
    - Diagnosis
    - Observation Without Treatment
    - Use of Analgesics
    - Antimicrobial Therapy
    - Education and Preventive Counseling
    - Recommendations For Referral
    - Use of Complementary and Alternative Medicine
- Table 4 lists the potential benefits and harms associated with the implementation of each guideline as stated in the original guidelines.
- Table 5 presents the rating schemes used by the guideline groups to rate the level of evidence and/or the strength of the recommendations.

A summary discussion of the areas of agreement and areas of differences among the guidelines is presented following the content comparison.

Abbreviations used in the text and table:

- AAFP, American Academy of Family Physicians
- AAP, American Academy of Pediatrics
- AOM, acute otitis media
- CCHMC, Cincinnati Children's Hospital Medical Center
- MEE, middle ear effusion
- OM, otitis media
- OME, otitis media with effusion
- PE, pressure equalization
- SIGN, Scottish Intercollegiate Guidelines Network
- SNAP, safety-net antibiotic prescription
- UMHS, University of Michigan Health System

TABLE 1: COMPARISON OF INTERVENTIONS AND PRACTICES CONSIDERED
("✓" indicates topic is addressed)

	AAP/AAFP (2004)	CCHMC (2004)	SIGN (2003)	UMHS (2007)

Definition Of AOM	✓	✓	✓	✓
Diagnosis	✓	✓	✓	✓
Observation Without Treatment	✓	✓	✓	✓
Use Of Analgesics	✓	✓	✓	✓
Antimicrobial Therapy	✓	✓	✓	✓
Education and Preventive Counseling	✓	✓		✓
Recommendations For Referral		✓	✓	✓
Use Of Complementary And Alternative Medicine	✓	✓	✓	✓

TABLE 2: COMPARISON OF GUIDELINE SCOPE	
Objectives	
AAP/AAFP (2004)	To provide recommendations to primary care clinicians for the management of children from 2 months through 12 years of age with uncomplicated AOM
CCHMC (2004)	• To improve the use of appropriate diagnostic criteria • To improve the use of appropriate antibiotic therapy • To improve symptom relief • To avoid medical complications • To improve parental involvement in decision-making around the management of AOM
SIGN (2003)	• To provide recommendations based on current evidence for best practice in the management of AOM and OME • To provide evidence about detection, management, referral, and follow-up of children with AOM and OME **Notes:** • This guideline excludes discussion of surgical management such as the insertion of grommets and does not address issues beyond childhood years. In addition, the needs of children with genetic or facial abnormalities are not considered. • Recommendations regarding OME are considered in a separate

	synthesis.
UMHS (2007)	• To limit acute symptoms and suppurative complications caused by acute otitis media • To limit complications of antibiotic therapy including the development of antibiotic-resistant bacteria
Target Population	
AAP/AAFP (2004)	• United States • Children from 2 months through 12 years of age with AOM seen in primary care settings
CCHMC (2004)	• United States • Children age 2 months up to 13 years of age who present with signs and symptoms of AOM **Note:** Children with comorbid conditions increasing the risk or severity of otitis media, including immunodeficiencies, craniofacial or neurologic abnormalities, or sensory deficits, are excluded. Children with pressure equalization (PE) tubes in place are also excluded.
SIGN (2003)	• Scotland • Children with AOM or OME **Note:** The needs of children with genetic or facial abnormalities are not considered.
UMHS (2007)	• United states • Pediatric patients greater than two months old and adults with suspected or confirmed otitis media (acute otitis media or otitis media with effusion)
Intended Users	
AAP/AAFP (2004)	Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians

CCHMC (2004)	Advanced Practice Nurses Allied Health Personnel Health Care Providers Nurses Patients Physician Assistants Physicians
SIGN (2003)	Advanced Practice Nurses Nurses Patients Physician Assistants Physicians Public Health Departments Social Workers Speech-Language Pathologists
UMHS (2007)	Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians

TABLE 3: COMPARISON OF RECOMMENDATIONS FOR THE DIAGNOSIS, MANAGEMENT, AND PREVENTION OF AOM IN PEDIATRIC PATIENTS
Definition of AOM

AAP/AAFP (2004)	A diagnosis of AOM requires 1) a history of acute onset of signs and symptoms, 2) the presence of MEE, and 3) signs and symptoms of middle-ear inflammation. Elements of the definition of AOM are all of the following: 1. Recent, usually abrupt, onset of signs and symptoms of middle-ear inflammation and MEE 2. The presence of MEE that is indicated by any of the following: a. Bulging of the tympanic membrane b. Limited or absent mobility of the tympanic membrane c. Air-fluid level behind the tympanic membrane d. Otorrhea 3. Signs or symptoms of middle-ear inflammation as indicated by either: a. Distinct erythema of the tympanic membrane, or b. Distinct otalgia (discomfort clearly referable to the ear[s] that results in interference with or precludes normal activity or sleep)
CCHMC (2004)	**Definitions used in this guideline:** • AOM: MEE with rapid onset of one or more of the following: otalgia, ear pulling, otorrhea, fever, irritability, anorexia, vomiting, or other symptoms • Sporadic AOM: AOM occurring more than 3 months after a prior episode of 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 OME **Requirements for diagnosis of AOM:** 1. History of acute onset of signs and symptoms 2. Presence of MEE indicated by one of the following: • Bulging tympanic membrane • Decreased mobility of tympanic membrane (ear drum) • Discharge from the ear (otorrhea) 3. Signs and symptoms of ME inflammation indicated by either: • Red tympanic membrane, or • Discomfort affecting normal activity and/or sleep (earache, otalgia)
SIGN	The working definition of AOM in this Guideline is inflammation

(2003)	of the middle ear of rapid onset presenting most often with local symptoms (the two most common being earache and rubbing or tugging of the affected ear) and systemic signs (fever, irritability, and poor sleep, for example). There may be a preceding history of upper respiratory symptoms including cough and rhinorrhea.
UMHS (2007)	**<u>Diagnostic Definitions</u>** **Acute Otitis Media (AOM)** • MEE - demonstrated by pneumatic otoscopy, tympanometry, air fluid level, or a bulging tympanic membrane ***plus*** • Evidence of acute inflammation - opaque, white, yellow, or erythematous tympanic membrane or purulent effusion ***plus*** • Symptoms of otalgia, irritability, or fever
Diagnosis of AOM	
AAP/AAFP (2004)	• To diagnose AOM, the clinician should confirm a history of acute onset, identify signs of MEE, and evaluate for the presence of signs and symptoms of middle-ear inflammation. **(Recommendation)** • *Children with AOM usually present with a history of rapid onset of signs and symptoms such as otalgia (or pulling of the ear in an infant), irritability in an infant or toddler, otorrhea, and/or fever. These findings, other than otorrhea, are nonspecific and frequently overlap those of an uncomplicated viral upper respiratory infection. Other symptoms of a viral upper respiratory infection, 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.* • *The presence of MEE is commonly confirmed with the use of pneumatic otoscopy but can be supplemented by tympanometry and/or acoustic reflectometry. MEE also can be demonstrated directly by tympanocentesis or the presence of fluid in the external auditory canal as a result of tympanic membrane perforation.* • If the patient fails to respond to the initial management option within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. **(Recommendation)**

CCHMC (2004)	**General** • Signs and symptoms of AOM are often nonspecific 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 & McCracken, 2002 [S]; Froom et al., 1990 [O]; Wald, 2003 [E]). **History and Physical Examination** • It is recommended that the components to assess for AOM in the history and physical include history of acute onset of symptoms, presence of MEE, and signs and symptoms of middle ear inflammation (American Academy of Pediatrics [AAP] Subcommittee, 2004 [S]). (See table titled "Requirements for Diagnosis of AOM" under "Definition of Acute Otitis Media (AOM)," above.) • It is recommended that pneumatic otoscopy and/or tympanometry be used to enhance accuracy when diagnosing AOM (Spiro et al., 2004 [A]; Karma et al., 1989 [D]; Brookhouser, 1998 [S]; Pelton, 1998 [S]; Jones & Kaleida, 2003 [O]; Pichichero, 2002 [O]; Pichichero & Poole, 2001 [O]). • **Note**: 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 et al., 1999 [C]; Barnett et al., 1998 [C]; Block et al., 1998 [C]; Kimball, 1998 [S]). • It is recommended that ear pain (otalgia) be assessed, as determined by discomfort affecting normal activity and/or sleep (Kontiokari et al., 1998 [C]; "The assessment and management," 2001 [S]). • 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, Rosenfeld, & Zeisel, 2004 [M]).
SIGN (2003)	• AOM is a purulent middle ear process and, as such, otoscopic signs and symptoms consistent with a purulent MEE in association with systemic signs of illness are required. Ear related symptoms may include earache, tugging or rubbing of the ear, irritability, restless sleep, and fever. Children may also have a history of cough and rhinorrhea, symptoms which are reported to increase the risk of AOM. Earache, however, is the single most important

	symptom. *(Evidence level 2+,3,4)* • Otoscopic appearances typical of AOM include bulging tympanic membrane with loss of the normal landmarks, change in colour (typically red or yellow), and poor mobility. *(Evidence level 2+)* • Systemic signs of illness with a MEE are not sufficient to make the diagnosis, and similarly neither is the finding of an incidental effusion in an otherwise well patient. • It should be borne in mind that the typical symptoms and signs (see Table 1 in the original guideline document) may have resolved by perforation of the tympanic membrane and discharge of pus. Additionally, AOM may leave a MEE for a variable period of time following resolution of the acute symptoms - the two forms of otitis media should be considered part of a disease continuum. *(Evidence level 1+,4)*
UMHS (2007)	**Diagnosis** • Distinguish between AOM and OME (see Table 1 in the original guideline document). • Symptoms of pain or fever, together with an inflammatory middle ear effusion, are required to make a diagnosis of AOM *[D*]*. • The presence of middle ear effusion should be determined by the combined use of otoscopy, pneumatic otoscopy, and tympanometry when necessary *[D*]*. **Rationale for Recommendations** **Diagnosis** **Distinguishing AOM and OME.** The distinction between AOM and OME does not refer to etiology or depend on whether pathogenic bacteria are present in the middle ear. No "gold standard" exists for the diagnosis of AOM. The National AOM-guideline defines AOM as a combination of (see Table 1 in the original guideline document): 1. Middle ear effusion 2. Physical evidence of middle ear inflammation 3. The acute onset of signs and symptoms (i.e., ear pain, irritability, fever) referable to the middle ear OME is defined as MEE in the absence of acute symptoms. **Techniques for identifying MEE** The basic question facing a clinician evaluating a patient's ears is

	whether or not MEE is present. If the presence or absence of MEE is not clear, all available techniques should be used. Techniques include otoscopy, pneumatic otoscopy, and tympanometry. Pneumatic otoscopy. In the national guidelines, pneumatic otoscopy is recommended as an essential hands with appropriate equipment this technique is 70 to 90% sensitive and specific for determining the presence of middle ear effusion. This can be compared to 60 to 70% accuracy with simple otoscopy. Pneumatic otoscopy is most helpful when cerumen is removed from the external auditory canal and the otoscopist uses equipment such as hard plastic reusable ear tips with rounded edges rather than disposable tips. Having a well-maintained, fully-charged otoscope is also important. Pneumatic otoscopy is also helpful in identifying middle ear pathology such as retraction pockets and tympanic membrane adhesion to the ossicles even in the absence on MEE. Tympanometry/acoustic reflectometry. Tympanometry and acoustic reflectometry can be valuable adjuncts to, but not a substitute for, otoscopy and pneumatic otoscopy. Tympanometry provides an important confirmation of middle ear fluid and is helpful for physicians honing their otoscopy skills. Tympanometry can also measure middle ear pressures and easily demonstrate the patency of myringotomy tubes by measuring increased external canal volumes. Tympanometry has a sensitivity and specificity of 70 to 90% for the detection of middle ear fluid, but depends on patient cooperation. Technical factors such as cerumen and probe position can lead to artifactual flattening of the tympanogram. The presence of a "normal" curve does not rule out the presence of air-fluid levels and effusion in the middle ear. However, together with normal otoscopy, a normal tympanogram is predictive of the lack of middle ear fluid. A "flat" tympanogram should be confirmed through repeated measurements, recording appropriate external canal volumes, and through correlation with pneumatic otoscopy. Acoustic reflectometry is also an appropriate approach for evaluating the presence of middle ear fluid, but, like tympanometry, it has imperfect sensitivity and specificity and must be correlated with the clinical exam. For most clinical purposes, a tympanic membrane bulging with an apparent purulent effusion is a more useful sign of bacterial infection than isolated immobility on pneumatic otoscopy, and it is probably sufficient to make the diagnosis of AOM in association with typical symptoms. The clinician should feel comfortable diagnosing AOM based on the clinical history, even if a cerumen impaction prevents pneumatic otoscopy and adequate visualization of the tympanic membrane, if the clinician feels that AOM is likely. Conversely, the clinician should not diagnose AOM

	without the presence of symptoms no matter what physical findings are observed.
Observation Without Treatment In Patients With AOM	
AAP/AAFP (2004)	• Observation without use of antibacterial agents in a child with uncomplicated AOM is an option for selected children based on diagnostic certainty, age, illness severity, and assurance of follow-up. **(Option)** • If the patient fails to respond to the initial management options within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. If AOM is confirmed in the patient initially managed with observation, the clinician should begin antibacterial therapy. **(Recommendation)**

CCHMC (2004)	AOM is a disease with a high spontaneous resolution rate (78 to 80% resolve within 7 to 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 et al., 2003 [M]; Marcy et al., 2001 [M]; Rosenfeld et al., 1994 [M]; Dowell et al., "Otitis media," 1998 [S]). Moreover, the decision to use antibiotics and the specific choice of antibiotics must take into account the increasing emergence of bacterial resistance (Doern et al., 1998 [C]; Jacobs et al., 2003 [O]; Mason et al., 2003 [O]).
	
	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 in original guideline.) 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 et al., 2003 [C]).
	
	• It is recommended that in children over age 2 years with AOM and who are well-appearing the treatment options be discussed with the family and that the family be involved in the decision making. The options include:
	  • Treatment with a SNAP to be filled after 48 to 72 hours if symptoms do not resolve with observation
	  • Treatment with a 5-day course of antibiotics (see treatment recommendation #2 and Table 4 in the original guideline document 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 follow-up within 48 to 72 hours, is also an option in the specific case when a practitioner would like to control the observation option more closely.
SIGN (2003)	• Children diagnosed with AOM should not routinely be prescribed antibiotics as the initial treatment. **(Grade B)** • Delayed antibiotic treatment (antibiotic to be collected at parents' discretion after 72 hours if the child has not improved) is an alternative approach which can be applied in general practice. **(Grade B)**
UMHS (2007)	**Therapy of Acute Otitis Media** • Consider deferring antibiotic therapy for lower risk children with AOM *[A*]*. • When antibiotic therapy is deferred, facilitate patient access to antibiotics if symptoms worsen (e.g., a "back-up" prescription given at visit or a convenient system for subsequent call-in) *[D*]*. **Observation vs. Initiating Antibiotic Therapy** Amoxicillin therapy provides a small increase in the likelihood of short term resolution of AOM symptoms. A strategy for improving the care of AOM is to identify the subset of patients least likely to benefit from antibiotic therapy and consider deferring antibiotic therapy for those patients. This category would likely include children over 2 years of age or children without fever or with relatively minor symptoms. The rate of antibiotic therapy can be significantly reduced through the provision of adequate parental education about the natural history of AOM. Specifically, parents should be informed at the outset that on average, only one in ten children benefit from antibiotic therapy, that approximately 10% of children receiving antibiotics will have an untoward outcome such as diarrhea or rash, and that occasionally children on antibiotics acquire more aggressive and antibiotic resistant bacteria leading to invasive bacterial infections requiring hospital admission and IV antibiotics. In addition, parents need to know that at least a third of cases of AOM are caused by viruses, not bacteria, that

	no oral antibiotic eliminates more than 80% of the bacteria found in cases of AOM, and that oral analgesics, such as ibuprofen, are much more likely to speed resolution of symptoms than oral antibiotics. Finally, they need to know that 10 to 20% of children will continue to have symptoms no matter what therapy is given, and that apparent failure with the observation option does not mean that antibiotics will necessarily be needed in the future. These points are summarized in the patient education materials provided with this guideline. "Back-up" options for prescriptions. In order for the observation to be acceptable for patients, clinicians must facilitate the subsequent access to antibiotics for patients whose symptoms worsen. One option is to provide parents with "back-up" prescriptions to be filled in the event of symptomatic persistence. Such prescriptions should be dated as needing to be filled within 3 to 4 days of diagnosis, to prevent parents from inappropriately treating future illnesses. Alternatively, a system by which parents can call to request antibiotic prescriptions without excessive inconvenience could be established. In one study, the use of a safety net prescription system reduced the number of courses of antibiotics given by 70%.
Use of Analgesics in Patients with AOM	

AAP/AAFP (2004)	• The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. **(Strong Recommendation)**
	• The clinician should select a treatment based on a consideration of benefits and risks and, when possible, incorporate parent or caregiver and patient preference:
	  • Acetaminophen, ibuprofen
	  • Effective analgesia for mild to moderate pain. Readily available. Mainstay of pain management for AOM.
	  • Home remedies (distraction, external application of heat or cold, oil)
	  • No controlled studies that directly address effectiveness
	  • May have limited effectiveness
	  • Topical agents (benzocaine [Auralgan®, Americaine Otic®] and naturopathic agents [Otikon Otic Solution®])
	  • Additional, but brief, benefit over acetaminophen in patients older than 5 years
	  • Comparable to ametocaine/phenazone drops (Anaesthetic®) in patients older than 6 years
	  • Homeopathic agents
	  • No controlled studies that directly address pain.
	  • Narcotic analgesia with codeine or analogs

	• Effective for moderate or severe pain. Requires prescription, risk of respiratory depression, altered mental status, gastrointestinal upset, and constipation. • Tympanostomy/myringotomy • Requires skill and entails potential risk
CCHMC (2004)	• It is recommended that all children with AOM who have a positive assessment for pain be treated with an appropriate analgesic (AAP Subcommittee, 2004 [S]; "The assessment and management," 2001 [S]). **Note 1**: Ear pain in AOM is self-limiting and time is the greatest factor in pain reduction (Sarrell, Cohen, & Kahan, 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 ibuprofen) or topical ear drops (anesthetic or Naturopathic Herbal Extract Ear Drops) (Perrott et al., 2004 [M]; Sarrell, Cohen, & Kahan, 2003 [A]; Sarrell, Mandelberg, & Cohen, 2001 [A]; Bertin et al., 1996 [A]; Hoberman et al., "Efficacy of Auralgan," 1997 [B]; "The assessment and management," 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.
SIGN (2003)	• Parents should give paracetamol for analgesia but should be advised of the potential danger of overuse. **(Grade D)** • Insertion of oils should not be prescribed for reducing pain in children with AOM. **(Grade B)**
UMHS (2007)	Therapy of acute otitis media • Recommend adequate analgesia for all children with AOM *[D*]*. **Analgesics**. Analgesics are recommended for symptoms of ear pain, fever, and irritability. Analgesics are particularly important at bed time, since disrupted sleep is one of the most common symptoms motivating parents to seek care. Ibuprofen is preferred over acetaminophen, given its longer duration of action and its lower toxicity in the event of overdose. Topical analgesics can also be helpful.
Antimicrobial Therapy In Patients With AOM	

AAP/AAFP (2004)	• If a decision is made to treat with an antibacterial agent, the clinician should prescribe amoxicillin for most children. **(Recommendation)** • When amoxicillin is used, the dose should be 80 to 90 mg/kg/day. **(Option)** • If the patient fails to respond to the initial management option within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. If AOM is confirmed in the patient initially managed with observation, the clinician should begin antibacterial therapy. If the patient was initially managed with an antibacterial agent(s), the clinician should change the antibacterial agent(s). **(Recommendation)** See Table 6 in the original guideline document for recommended antibacterial agents for patients who are being treated initially with antimicrobial agents or have failed 48 to 72 hours of observation or initial management with antimicrobial agents.
CCHMC (2004)	• 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 et al., 2000 [A], 1998 [A]; AAP Subcommittee, 2004 [S]). Amoxicillin, in the dose range of 80 to 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 et al., 1994 [M]; Piglansky et al., 2003 [C]; AAP Subcommittee, 2004 [S]). (See Table 4 in original guideline document for recommended doses for 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 (Rosenfeld et al., 1994 [M]). [NGC note: see extended list of antibiotic options, dosages, and preparations in Appendix 3 of original guideline]. 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 SNAP may be reasonable. (See Table 5 in original guideline document concerning SNAP definition and management.) 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 et al., 2003 [C]).

- It is recommended that in children over age 2 years with AOM and who are well-appearing, that the treatment options are discussed with the family and that the family be involved in the decision making. The options include:
    - Treatment with a SNAP to be filled after 48 to 72 hours if symptoms do not resolve with observation.
    - Treatment with a 5-day course of antibiotics (See treatment recommendation 2 and Table 4 in the original guideline document 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 follow-up within 48 to 72 hours, is also an option in the specific case when a practitioner would like to control the observation option more closely.

- It is recommended that children over age 2 years with AOM and with severe illness (see Table 6 in original guideline document) be treated with a 5-day course of antibiotics (See treatment recommendation 2 and Table 4 in the original guideline document for discussion of antibiotic selection and doses) (Kozyrskyj et al., 2000 [M], 1998 [M]).
- 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 et al., 2003 [C]; Carlin et al., 1987 [C]; Dowell et al., "Principles of judicious use," 1998 [S]; Klein, 1998 [S]). (For an extended list of antibiotic options, doses, and preparations, see Appendix 3 of the original guideline document.)

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

- 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 to 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 et al., "Equivalent efficacy," 1997 [A]; Dagan et al., 2001 [C]). • Ceftriaxone intramuscularly (IM): 3 consecutive daily doses is efficacious in nonresponsive AOM for children with vomiting or otherwise unable to tolerate oral dosing (Leibovitz et al., 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 of the original guideline document.
SIGN (2003)	• If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary. **(Grade B)** With *Streptococcus pneumoniae and Haemophilus influenzae*, broad spectrum antibiotics such as amoxicillin, or amoxicillin with clavulanic acid, are the drugs of choice if an antibiotic is to be used. Cefaclor, cotrimoxazole, trimethoprim and erythromycin can be effective, but are less safe than amoxicillin.
UMHS (2007)	**Therapy of AOM** • Amoxicillin is the first choice of antibiotic therapy for all cases of AOM. For children under 4 years of age, amoxicillin should be dosed at 80 mg/kg/day divided BID for 5 to 10 days. Children 4 years of age or older can probably be treated at 40 to 60 mg/kg/day *[C*]*. In the event of allergy to amoxicillin, azithromycin dosed at 30 mg/kg for one dose is the appropriate first line therapy. • Treat AOM that is clinically unresponsive to amoxicillin after 72 hours of therapy with amoxicillin/clavulanate (amoxicillin component 80 mg/kg/day divided BID) for 10 days or with azithromycin 20 mg/kg daily for 3 days *[C*]*. • Patients with significant, persistent symptoms on high-dose amoxicillin/clavulanate or Azithromycin should receive 1 to 3 doses of IM ceftriaxone *[C*]*. The decision to use ceftriaxone should take into account the possible impact of this

antibiotic on patterns of antibiotic resistance.

Basic management recommendations are:

1. Antibiotics should be started when they are likely to significantly reduce morbidity that cannot be better reduced through the use of analgesics.
2. High dose amoxicillin is the antibiotic of choice for every episode of AOM unless compelling reasons exist for choosing a different agent.

Antibiotic choice. The choice of antibiotic should almost always be high dose amoxicillin. The advantages of amoxicillin include cost, tolerability, safety, and efficacy. No antibiotic has been demonstrated to be superior to amoxicillin in clinical trials involving tympanocentesis before and after therapy. Oral cephalosporins are uniformly inferior to high-dose amoxicillin for pneumococcus, especially penicillin-resistant pneumococcus. Unless the patient is allergic to amoxicillin, in which case high-dose azithromycin would be the first-line agent, no empirical oxicillin in some studies. However, excessive use of azithromycin is associated with increasing rates of erythromycin resistance, particularly involving group A beta-hemolytic streptococci, and therefore its routine use should be discouraged. Cefdinir can also be used, although it is clinically inferior to amoxicillin and carries with it an excessive risk of selection of resistant bacteria.

The use of ceftriaxone should be reserved for episodes of clinical failure (see below) or for clinical situations in which the clinician suspects a serious bacterial infection as a comorbidity of the AOM. Consideration should be given to obtaining appropriate laboratory studies such as blood or urine cultures before administering ceftriaxone, and it is reasonable to obtain a white count with differential or C reactive protein in order to confirm the severity of the illness. Follow up should be ensured, and alternative diagnoses, such as a viral illness or Kawasaki disease, should be considered in the event of clinical failure. Although some children will likely benefit from IM ceftriaxone, the decision to prescribe this agent should not be made lightly, since the overuse of this agent is likely to significantly increase high level penicillin resistance in this population. Ceftriaxone can be administered for up to three days, but a single dose is often sufficient. Ceftriaxone might also be appropriate in situations where antibiotics are indicated but oral antibiotics are not tolerated, such as vomiting or medication refusal. Bicillin CR might also be an option in that situation.

Amoxicillin dosing and duration. Given the risk of penicillin resistant pneumococcus, for children under 4 years amoxicillin should be dosed at 80 mg/kg per day divided twice a day for 5 to 10 days. Children 4 years and older are at lower risk of

	resistant pneumococcus and therefore can probably receive 40 to 60 mg/kg/day. Since the major impact of antibiotic therapy is to reduce symptoms at 48 to 72 hours, 5 days of therapy are usually sufficient. Since it is unclear how many parents continue to give amoxicillin consistently once the symptoms are resolved, and since inconsistent antibiotic dosing would be predicted to select more effectively for antibiotic resistant bacteria, it is possible that the increased cost and inconvenience of giving a ten day course might not be outweighed by the improvement in symptomatic outcome at 10 days. This would be particularly true in older children. Furthermore, illnesses, rashes, and diarrhea occur in all children at some time, and they will be more likely to occur while on antibiotics. Thus, we recommend reserving the use of a ten day course of antibiotics for children most likely to benefit, e.g., young children with significant early URI symptoms, children with possible sinusitis, and children with possible strep throats. In most other cases, one would expect the major symptoms to resolve in five days, even without treatment. If desired, a prescription could be given for ten days of amoxicillin with instructions to discontinue and discard the medication 2 to 3 days after resolution of symptoms. Diarrhea and candidal infections are among the most common complications of antibiotic therapy. Therefore parents should be warned about this in advance. It is also appropriate to provide recommendations about diaper care and the application of clotrimazole cream in the event of diaper rash. Giving yogurt with active cultures might also be helpful.
Education and Preventive Counseling	
AAP/AAFP (2004)	• Clinicians should encourage the prevention of AOM through reduction of risk factors. **(Recommendation)** During infancy and early childhood, reducing the incidence of respiratory tract infections by altering child care center attendance patterns can reduce the incidence of recurrent AOM significantly. The implementation of breastfeeding for at least the first 6 months also seems to be helpful against the development of early episodes of AOM. Avoiding supine bottle feeding ("bottle propping"), reducing or eliminating pacifier use in the second 6 months of life, and eliminating exposure to passive tobacco smoke have been postulated to reduce the incidence of AOM in infancy; however, the utility of these interventions is unclear.
CCHMC (2004)	• It is recommended that the family be educated regarding the natural history of AOM, signs and symptoms of clinical deterioration, and appropriate follow-up.

	• 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 & Kay, 2003 [M]; AAP Subcommittee, 2004 [S]).
	• It is recommended that the family be educated about preventable risk factors. These include:
	  • Exposure to others (especially family members) with upper respiratory tract infections (Uhari, Mantysaari, & Niemela, 1996 [M])
	  • Parental smoking or other sources of second-hand smoke (Uhari, Mantysaari, & Niemela, 1996 [M]; Ilicali et al., 1999 [C])
	  • Daycare attendance (Uhari, Mantysaari, & Niemela, 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 hand washing practices and availability of sinks.
	  • Excessive pacifier use, limiting use to when the child is falling asleep (Uhari, Mantysaari, & Niemela, 1996 [M]; Niemela et al., 2000 [A])
	  • Breastfeeding duration less than 3 months (Uhari, Mantysaari, & Niemela, 1996 [M])
	  • Bottlefeeding with the child on his/her back: assure that infants are offered bottle feedings while sitting in upright positions (Tully, Bar-Haim, & Bradley, 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.

SIGN (2003)	No specific recommendations are given for patient education or preventive counseling for AOM.
UMHS (2007)	**Risk Factors for AOM** **Age**. Age is a significant predictor of AOM frequency, severity, and responsiveness to treatment. Infants and toddlers are more severely affected, and appear to be less responsive to therapy than older children. Consequently, clinicians should be cautious in extrapolating results from clinical trials involving older children to younger age groups.

Additional risk factors. Several specific risk factors for recurrent AOM and OME have been identified or are likely:

- Exposure to group day care with subsequent increase in respiratory infections.
- Exposure to environmental smoke or other respiratory irritants and allergens that interfere with Eustachian tube function.
- Lack of breast feeding.
- Supine feeding position.
- Use of pacifiers.
- Family history of recurrent AOM.
- Craniofacial abnormalities.
- Immune deficiency.
- Gastro-esophageal reflux.

Observation vs. Initiating Antibiotic Therapy

The rate of antibiotic therapy can be significantly reduced through the provision of adequate parental education about the natural history of AOM. Specifically, parents should be informed at the outset that on average, only one in ten children benefit from antibiotic therapy, that approximately 10% of children receiving antibiotics will have an untoward outcome such as diarrhea or rash, and that occasionally children on antibiotics acquire more aggressive and antibiotic resistant bacteria leading to invasive bacterial infections requiring hospital admission and intravenous (IV) antibiotics. In addition, parents need to know that at least a third of cases of AOM are caused by viruses, not bacteria, that no oral antibiotic eliminates more than 80% of the bacteria found in cases of AOM, and that oral analgesics, such as ibuprofen, are much more likely to speed resolution of symptoms than oral antibiotics. Finally, they need to know that 10 to 20% of children will continue to have symptoms no matter what therapy is given, and that apparent failure with the observation option does not mean that antibiotics will necessarily be needed in the future. These points are summarized in the patient education materials provided with this guideline.

Recurrent AOM

For children with genuine recurrent AOM (3 or more episodes in 6 months), several strategies are likely to be helpful. Immunization with the pneumococcal conjugate vaccine and annual influenza vaccination have both been shown to have a small but statistically significant impact on the frequency of AOM, although the major benefit of each of these vaccines is in the prevention of systemic disease. Reduction in exposure to passive smoke and elimination of bottle propping and pacifiers are probably helpful. Gastroesophageal reflux also appears to contribute to AOM, and it is possible that appropriate treatment

	of this condition could reduce middle ear disease. In some cases, undiagnosed food allergies probably contribute to gastrointestinal (GI) disturbances, chronic rhinorrhea, and eczema. The chronic nasal congestion in turn contributes to AOM. A trial of a soy formula might be helpful. For children in day care, recurrent rhinorrhea is the norm, and parents can be reassured that it will eventually resolve, particularly with the onset of summer. In the event that recurrent AOM leads to intolerable symptoms, or is associated with significant complications or multiple, clinically significant antibiotic sensitivities, ventilation tube placement is a good option. In most cases, however, AOM is a benign, easily treatable condition that responds well to a combination of amoxicillin and analgesics. Furthermore, recurrent AOM has a favorable natural history, and in the only RCT of tympanostomy tubes vs. watchful waiting, tubes reduced the incidence of AOM and/or otorrhea by only one episode per year. On a positive note, ventilation tubes will turn what would otherwise be an episode of AOM into an episode of purulent ear drainage. Such drainage is likely to be less painful than the comparable episode of AOM and is effectively treated with ear irrigation ("otic toilet") and fluoroquinolone drops. Unfortunately, placement of ventilation tubes is also associated with an increased risk of long-term tympanic membrane abnormalities and reduced hearing compared to medical therapy. Thus, it is reasonable to reserve ventilation tube placement for those children with a more problematic clinical history. Although it is tempting to place children on long term antibiotic therapy for the prophylaxis of recurrent AOM, long term therapy is not recommended in this era of increasing antibiotic resistance.
Recommendations For Referral	
AAP/AAFP (2004)	No recommendations offered
CCHMC (2004)	• 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 et al., 1991 [A]; Hsu, Levine, & Giebink, 1998 [C]; Teele et al., 1990 [C]; Bachmann & Arvedson 1998 [S]). • It is recommended that a child be referred for an otolaryngological evaluation for: • Recurrent AOM (history of 6 episodes over a 12-month period taking into account the severity of episodes, clustering of episodes, and persistence of

	OME) • Persistent otorrhea • Concerns about mastoiditis, or other complications of AOM • Perceived need for tympanocentesis and/or myringotomy (e.g., acute episode not responsive to medical therapy) • Abnormal audiologic evaluation (Froom et al., 1993 [C])
SIGN (2003)	• Children who require hearing loss assessment should be referred to an audiologist **(Good practice point)**. • Children with frequent episodes (more than four in six months) of AOM, or complications, should be referred to an otolaryngologist **(Grade D)**. • Complications of AOM such as mastoiditis or facial nerve paresis require referral
UMHS (2007)	**Referral process.** Otolaryngology evaluation plays an important role in the management of recurrent AOM and persistent OME. However, the ability of the surgeon to reach the most appropriate decision for the management of a given patient may be limited by a lack of historical information including previous antibiotic therapy and an accurate time course of middle ear disease. **Special Situations** **Primary care follow-up and management of tympanostomy tubes.** Be familiar with the preferences of the surgeon to whom you refer patients, since he/she will likely be handling any complications of tube placement. Patients with tubes should follow up with otolaryngology every six months and should be referred back to otolaryngology in the event of suspicion for ongoing middle ear disease. Tubes should be removed if they remain in place longer than 3 years. **Cerumen Removal** Children with cerumen impaction and tympanostomy tubes should be referred to otolaryngology for further management. It is also reasonable to refer young children with cerumen impactions to otolaryngology, since removal of such impactions is probably facilitated by access to an operating microscope and suction.
Use of Complementary and Alternative Medicine For AOM	

AAP/AAFP (2004)	There is insufficient evidence to make a recommendation regarding the use of complementary and alternative medicine for AOM. **(No Recommendation)**
CCHMC (2004)	It is **not** recommended that other therapies be used in the treatment of AOM (AAP 2004 [S]). **Note**: Steroids, antihistamines, decongestants, and complementary or alternative treatments have not been documented to be efficacious in the treatment of AOM (Butler & Van Der Voort, 2002 [M]; Flynn, Griffin, & Tudiver, 2002 [M]; Barnett et al., 2000 [C]; AAP Subcommittee, 2004 [S]. Antihistamines may prolong the duration of MEE. **Note**: 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 et al., 1998 [O], Spigelblatt et al., 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.
SIGN (2003)	While homeopathy was considered, due to lack of evidence, no recommendation can be made at this time.
UMHS (2007)	No recommendations offered.

TABLE 4: BENEFITS AND HARMS	
Benefits	
AAP/AAFP (2004)	• Appropriate diagnosis and initial treatment of a child presenting with AOM • Improved adherence to a consistent definition of AOM • Appropriate use of antibacterial agent(s) including improved decision making when an alternative to amoxicillin is indicated
CCHMC (2004)	• Effective medical management of AOM in children 2 months to 13 years of age • Improved use of appropriate diagnostic criteria • Improved use of appropriate antibiotic therapy • Improved symptom relief • Avoidance of medical complications • Improved parental involvement in decision-making around the

	management of AOM
SIGN (2003)	• Antibiotics in comparison to placebo and observational treatment may have a modest benefit on symptom resolution and failure rates, as variously defined, in children over the age of two years with AOM. The available evidence on natural history of AOM shows that in studies with close follow up, very few episodes of mastoiditis or other suppurative complications are reported in children with AOM not initially treated with antibiotics.
UMHS (2007)	Accurate diagnosis and effective treatment and management of otitis media
Harms	
AAP/AAFP (2004)	**General Antibiotic Therapy** • Antibacterial agent treatment might mask mastoiditis signs and symptoms, producing a subtle presentation that can delay diagnosis. • Antibiotics may lead to diarrhea, rash, anaphylaxis, and symptoms of hematologic, cardiovascular, central nervous, renal, hepatic, and respiratory systems. • Antimicrobial drug resistance may increase with increased use of antibiotics. **Analgesic Therapy** • Narcotic analgesia with codeine or analogs has a risk of respiratory depression, altered mental status, gastrointestinal upset, and constipation
CCHMC (2004)	None stated
SIGN (2003)	**Analgesic Therapy** • Although non-steroidal anti-inflammatory drugs (NSAIDs) are frequently used by parents, caution should be exercised because of the side effect profile.
UMHS (2007)	• Common side effects of antibiotics are diarrhea, rash, and candidal infections. Occasionally, children on antibiotics acquire more aggressive and antibiotic resistant bacteria leading to

	invasive bacterial infections requiring hospital admission and intravenous antibiotics. • Excessive use of azithromycin is associated with increasing rates of erythromycin resistance, particularly involving group A beta-hemolytic streptococci, and therefore its routine use should be discouraged. • Cefdinir carries with it an excessive risk of selection of resistant bacteria. • The overuse of ceftriaxone is likely to significantly increase high level penicillin resistance in this population. • Placement of ventilation tubes is also associated with an increased risk of long-term tympanic membrane abnormalities and reduced hearing compared to medical therapy.

TABLE 5: EVIDENCE RATING SCHEMES	
AAP/AAFP (2004)	**Recommendations Rating Scheme:** **Strong Recommendation** - A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present. **Recommendation** - A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms. Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences. **Option** - Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another. Clinicians should consider the option in their decision making, and patient preference may have a substantial role. **No Recommendation** - No recommendation indicates that there is

	a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear. Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.
CCHMC (2004)	The type of evidence is identified and classified for each recommendation using the following scheme: **Evidence Based Grading Scale** A: Randomized controlled trial: large sample B: Randomized controlled trial: small sample C: Prospective trial or large case series D: Retrospective analysis E: Expert opinion or consensus F: Basic laboratory research S: Review article M: Metal analysis Q: Decision analysis L: Legal requirement O: Other evidence X: No evidence **References Supporting the Recommendations** • American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics 2004 May;113(5):1451-65. PubMed • Bachmann KR, Arvedson JC. Early identification and intervention for children who are hearing impaired. Pediatr Rev 1998 May;19(5):155-65. [7 references] PubMed • Barnett ED, Klein JO, Hawkins KA, Cabral HJ, Kenna M, Healy G. Comparison of spectral gradient acoustic reflectometry and other diagnostic techniques for detection of middle ear effusion in children with middle ear disease. Pediatr Infect Dis J 1998 Jun;17(6):556-9; discussion 580. PubMed • Barnett ED, Levatin JL, Chapman EH, Floyd LA, Eisenberg D, Kaptchuk TJ, Klein JO. Challenges of evaluating homeopathic treatment of acute otitis media. Pediatr Infect Dis J 2000 Apr;19(4):273-5. PubMed • Bertin L, Pons G, d'Athis P, Duhamel JF, Maudelonde C, Lasfargues G, Guillot M, Marsac A, Debregeas B, Olive G. A randomized, double-blind, multicentre controlled trial of ibuprofen versus acetaminophen and placebo for symptoms of acute otitis media in children. Fundam Clin Pharmacol 1996;10(4):387-92. PubMed • Block SL, Mandel E, McLinn S, Pichichero ME, Bernstein S, Kimball S, Kozikowski J. Spectral gradient acoustic reflectometry for the detection of middle ear effusion by pediatricians and parents. Pediatr Infect Dis J 1998 Jun;17(6):560-4; discussion 580. PubMed

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SIGN (2003)	**Grades of Recommendations** **A** - At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or randomised controlled trial rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results **B** - A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+ **C** - A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++ **D** - Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+ **Levels of Evidence** **1++** - High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias **1+** - Well-conducted meta-analyses, systematic reviews of RCTs, or

	RCTs with a low risk of bias **1-** - Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias **2++** - High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal **2+** - Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal **2-** - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal **3** - Non-analytic studies, e.g., case reports, case series **4** - Expert opinion
UMHS (2007)	**Levels of Evidence** A. Randomized controlled trials B. Controlled trials, no randomization C. Observational trials D. Opinion of expert panel

GUIDELINE CONTENT COMPARISON

The American Academy of Pediatrics/American Academy of Family Physicians (AAP/AAFP), Cincinnati Children's Hospital Medical Center (CCHMC), Scottish Intercollegiate Guidelines Network (SIGN), and University of Michigan Health System (UMHS) present recommendations for the diagnosis and management of acute otitis media (AOM) in pediatric patients based on evidence available at the time of each report and provide explicit reasoning behind their judgments, ranking the level of evidence for each major recommendation. CCHMC also offers literature citations to support its major recommendations.

Each guideline develops a working definition for AOM, but the focus of the guidelines and their respective target populations vary. For example, the AAP/AAFP and CCHMC guidelines are limited to a discussion of recommendations for the diagnosis and treatment of uncomplicated AOM, with both groups presenting recommendations for OME in separate guidelines. The SIGN and UMHS guidelines consider the diagnosis and treatment of both AOM and OME.

Areas of Agreement

Diagnosis of AOM

There is overall general agreement regarding the definition and requirements for diagnosing AOM. All of the groups agree that the diagnosis of AOM should be based on an acute onset of signs and symptoms (e.g., earache, tugging of the ears, irritability, fever), evidence of middle ear effusion (MEE) (e.g., bulging of the tympanic membrane, limited or absent mobility of the tympanic membrane), and evidence of acute inflammation (e.g., bulging tympanic membrane with loss of normal landmarks, change in color, and poor mobility). Furthermore, both AAP/AAFP and SIGN agree that systemic signs of illness with a MEE or clinical history alone are not sufficient to make a diagnosis of AOM.

Comparison of Recommendations for the Use of Analgesics in Patients with AOM

All four groups recommend analgesic use in AOM, particularly acetaminophen and ibuprofen. UMHS notes that ibuprofen is preferred over acetaminophen, given its longer duration of action and its lower toxicity in the event of overdose. The SIGN guideline warns that although NSAIDs are frequently used by parents, caution should be used because of their side effect profile. AAP/AAFP notes that topical agents such as benzocaine and naturopathic agents may provide additional, but brief, benefit over acetaminophen in patients older than 5 years. They add that narcotic analgesia with codeine or analogs is effective for moderate or severe pain. In addition to acetaminophen and ibuprofen, CCHMC also recommends topical ear drops (anesthetic or naturopathic herbal extract), but cautions against their use in patients with a perforated eardrum and/or discharge from the ear, as their use will likely result in severe dizziness and vomiting. UMHS also notes that topical analgesics can be helpful.

Comparison of Recommendations for Antimicrobial Therapy in Patients with AOM

Amoxicillin as First-Line Therapy. All four guidelines recommend amoxicillin for first-line therapy (when the use of antibiotics is warranted). SIGN also recommends amoxicillin/clavulanate for first-line therapy.

Duration of Therapy. In spite of uncertainty concerning the optimal duration of therapy, the guidelines are in general agreement that a course ranging from 5 to 10 days is appropriate. In addition, AAP/AAFP and CCHMC are in agreement that children younger than 2 years should receive a 10-day course of therapy. See "Areas of Differences" below, for a discussion of differences in the recommendations concerning duration of therapy.

Amoxicillin Alternatives. Three guidelines, AAP/AAFP, CCHMC and UMHS, address alternative antimicrobials in the event of clinical failure (see below paragraph) or intolerance/allergy to amoxicillin. In the event of allergy to amoxicillin, UMHS recommends azithromycin as the appropriate first line therapy. In this instance AAP/AAFP and CCHMC recommend cephalosporins (e.g., cefdinir, cefuroxime, ceftriaxone) and macrolides/azalides (azithromycin, clarithromycin) as alternatives. SIGN does not specifically address the issue of allergy to amoxicillin, but states that cefaclor, cotrimoxazole, trimethoprim, and erythromycin can be effective, but are less safe than amoxicillin.

Clinical Failure. For patients initially treated with amoxicillin as first-line therapy who have not improved within 72 hours, AAP/AAFP and CCHMC agree that amoxicillin/clavulanate is the preferred second-line therapy. UMHS recommends that clinical unresponsiveness to amoxicillin should be treated with either amoxicillin clavulanate or azithromycin. AAP/AAFP and CCHMC also agree that patients with beta-lactamase producing organisms should be treated with high-dose amoxicillin-clavulanate. SIGN does not specifically address the issue of treatment failure.

Comparison of the Use of Patient Education and Preventive Counseling in AOM

The SIGN guideline makes recommendations concerning prevention of OME, but not of AOM. In contrast, the AAP/AAFP. CCHMC and UMHS guidelines encourage clinicians to counsel parents concerning preventable risk factors for AOM.

AAP/AAFP, CCHMC and UMHS agree that day care attendance, pacifier use, and exposure to tobacco smoke significantly increase the risk of AOM. AAP/AAFP states that, during infancy and early childhood, reducing the incidence of respiratory tract infections by altering child care center attendance patterns can significantly reduce the incidence of AOM. AAP/AAFP, CCHMC and UMHS include short duration of breastfeeding and bottlefeeding with the child on his/her back as additional preventable risk factors.

AAP/AAFP, CCHMC and UMHS agree that administration of the pneumococcal conjugate vaccines reduces the risk of ear infections slightly (UMHS reserves this option for children with recurrent AOM [3 or more episodes in 6 months]). AAP/AAFP and UMHS also suggest the influenza vaccine may be useful for the prevention of AOM. AAP/AAFP states that pneumococcal conjugate vaccines have proven effective in preventing vaccine-serotype pneumococcal otitis media, but their overall benefit is small, with only a 6% reduction in the incidence of AOM. CCHMC agrees that the effectiveness of influenza vaccination in preventing AOM remains unclear. UMHS notes that the pneumococcal conjugate vaccine and annual influenza vaccination have both been shown to have a small but statistically significant impact on the frequency of AOM, although the major benefit of each of these vaccines is in the prevention of systemic disease.

Comparison of Recommendations for Referral

Concerning referral to an audiologist, CCHMC recommends that the practitioner have a low threshold for referral for an audiologic evaluation if concerns around hearing, speech, or language are raised by parents, clinicians, or other caregivers because of recurrent AOM. SIGN recommends referral to an audiologist when audiometry is required for assessment of hearing thresholds and middle ear function. AAP/AAFP makes no recommendation concerning the need for an audiology referral for AOM patients.

CCHMC and SIGN recommend referral to an otolaryngologist in cases of complicated or persistent AOM. CCHMC recommends referral for recurrent AOM, persistent otorrhea, concerns about mastoiditis or other complications, evaluation for surgery, and an abnormal audiologic evaluation. SIGN identified no studies concerning when AOM patients should be referred and therefore adopts the recommendation of the National Institute for Clinical Excellence (NICE) that

children with frequent episodes of AOM (more than four in six months) should be referred to an otolaryngologist. SIGN also recommends referral for complications of AOM such as mastoiditis or facial nerve paresis.

UMHS makes more recommendations for referral for OME than for AOM patients. They acknowledge that otolaryngology evaluation plays an important role in the management of recurrent AOM and persistent OME. They add, however, the ability of the surgeon to reach the most appropriate decision for the management of a given patient may be limited by a lack of historical information including previous antibiotic therapy and an accurate time course of middle ear disease. UMHS also provides referral recommendations for special circumstances, including management of tympanostomy tubes and cerumen removal. AAP/AAFP makes no recommendations concerning referrals to an otolaryngologist.

Comparison of Recommendations for the Use of Complementary and Alternative Medicine (CAM) for AOM

Both AAP/AAFP and SIGN agree that no recommendations can be made due to an absence of evidence of effectiveness in the literature. CCHMC specifically recommends against CAM and certain other therapies to treat AOM. Recognizing that use of CAM is common, however, CCHMC encourages providers to respectfully discuss its safety and efficacy with families who report its use. UMHS does not address this topic.

Areas of Differences

Observation of AOM without Treatment

Although all four guidelines provide a delayed treatment option in which antibacterial treatment of selected children is deferred for 48 to 72 hours, they differ concerning the patient groups to which this option applies. AAP/AAFP, CCHMC and UMHS use age and/or symptom criteria to determine if observation without treatment is appropriate, while SIGN does not limit the option based on either age or symptoms.

AAP/AAFP recommends that deferred treatment should be limited to otherwise healthy children aged 6 months to 2 years with non-severe illness at presentation and an uncertain diagnosis, as well as to children age 2 years and older without severe symptoms at presentation or with or an uncertain diagnosis.

While CCHMC generally recommends that children under two years of age be treated with antibiotics, they do note that in certain situations observation without antibiotics or with a SNAP may be reasonable. For children over age 2 years who are well-appearing, CCHMC recommend that treatment options be discussed with the family. These options include SNAP or a 5-day course of antibiotics.

UMHS notes that deferring antibiotic therapy for lower risk children should be considered. They add that this category would likely include children over 2 years of age or children without fever or with relatively minor symptoms. Should symptoms worsen, UMHS recommends that patient access to antibiotics should be

facilitated, e.g. a "back-up" prescription given at the visit or a convenient system for subsequent call-in.

SIGN recommends that in general antibiotics should not be prescribed for the initial management of AOM. Delayed antibiotic treatment (antibiotic to be collected at parents' discretion after 72 hours if child has not improved) is recommended as an alternative approach.

Comparison of Recommendations for the Use of Antimicrobial Therapy in Patients with AOM

Amoxicillin Dose. Recommendations concerning amoxicillin dosing differ slightly among the guideline groups. AAP/AAFP and CCHMC recommend 80 to 90 mg/kg/day. UMHS similarly recommends 80 mg/kg/day for children under 4 years of age, but for children 4 years of age or older, however, they note that this population can probably be treated at 40 to 60 mg/kg/day. The SIGN guidelines do not provide amoxicillin doses, but refer the reader to the British National Formulary.

Duration of Therapy. Recommendations differ regarding the recommended duration of initial amoxicillin therapy. As noted above under "Areas of Agreement," AAP/AAFP and CCHMC generally agree that an initial 10 day course of antibiotics is preferred in children under 2 years of age. For children 2 years of age and older, however, CCHMC recommends they receive a 5-day course of therapy, while AAP/AAFP recommends that only children age 6 years and older with mild to moderate disease receive a 5- to 7-day course of therapy; younger children and/or those with severe disease are recommended to receive the standard 10-day course. In contrast to both AAP/AAFP and CCHMC, UMHS recommends that children under 4 years of age should receive a 5 to 10 day course of therapy, and that in children 4 years of age or older 5 days of therapy are usually sufficient. They add that they recommend reserving the use of a ten day course of antibiotics for children most likely to benefit, e.g., young children with significant early URI symptoms, children with possible sinusitis, and children with possible strep throats. SIGN differs from the three other groups in recommending the conventional five day course, regardless of patient age.

This Synthesis was prepared by ECRI on November 4, 2005. The information was verified by AAP on April 6, 2006; by CCHMC on May 1, 2006; by SIGN on April 5, 2006; and by UMHS on April 28, 2006. This synthesis was revised on December 6, 2007 to remove recommendations from UMHS and on April 14, 2008 to update UMHS recommendations.

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