NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

OTITIS MEDIA WITH EFFUSION

Guidelines

1. **American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics (AAFP/AAOHNS/AAP)**. Otitis media with effusion. Pediatrics 2004 May;113(5):1412-29. [172 references]
2. **Cincinnati Children's Hospital Medical Center (CCHMC)**. Evidence based clinical practice guideline for medical management of otitis media with effusion in children 2 months to 13 years of age. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Oct.; 11 p. [67 references]
3. **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 the American Academy of Family Physicians/American Academy of Otolaryngology-Head and Neck Surgery/American Academy of Pediatrics (AAFP/AAOHNS/AAP), Cincinnati Children's Hospital Medical Center (CCHMC), and University of Michigan Health System (UMHS) recommendations for the diagnosis and management of otitis media with effusion (OME) is provided in the tables below.

The guidelines differ somewhat in scope. The UMHS guideline addresses diagnosis and management of both acute otitis media (AOM) and OME; recommendations for AOM are addressed in a separate synthesis. All of the guidelines focus on the pediatric population, targeting children 2 months and older. The UMHS guideline also addresses adults. AAFP/AAOHNS/AAP also addresses research needs related to OME. In formulating their recommendations, CCHMC and UMHS reviewed the conclusions drawn by AAFP/AAOHNS/AAP.

- 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 OME
  - Diagnosis and Evaluation
  - Children at Risk for Speech, Language or Learning Problems
  - Non-Surgical Management
  - Hearing Testing

    - Referral To Subspecialists
    - Tympanostomy (PE) Tube Placement
- 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 tables.

Abbreviations used in the text and table:

- AAFP, American Academy of Family Physicians
- AAOHNS, American Academy of Otolaryngology-Head and Neck Surgery
- AAP, American Academy of Pediatrics
- AOM, acute otitis media
- CAM, complementary and alternative medicine
- CCHMC, Cincinnati Children's Hospital Medical Center
- GP, general practitioner
- MEE, middle ear effusion
- OM, otitis media
- OME, otitis media with effusion
- PE, pressure equalizing, pressure equalization
- UMHS, University of Michigan Health System

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

	AAFP/AAOHNS/AAP (2004)	CCHMC (2004)	UMHS (2007)
Definition of OME	✓	✓	✓
Diagnosis and Evaluation	✓	✓	✓
Children at Risk for Speech, Language or Learning Problems	✓	✓	✓
Non-Surgical Management	✓	✓	✓
Hearing Testing	✓	✓	✓
Referral To Subspecialists	✓	✓	✓
Tympanostomy (PE) Tube Placement	✓	✓	✓

TABLE 2: COMPARISON OF GUIDELINE SCOPE	
Objectives	
AAFP/AAOHNS/AAP (2004)	To inform clinicians of evidence-based methods to identify, monitor, and manage OME in children aged 2 months through 12 years
CCHMC (2004)	• To improve the identification of the at-risk child • To improve the use of appropriate referral criteria • To improve parental involvement in decision-making around the management of OME
UMHS (2007)	• To maximize language development and minimize long term damage to middle ear structure associated with otitis media with effusion • To limit complications of antibiotic therapy including the development of antibiotic-resistant bacteria
Target Population	
AAFP/AAOHNS/AAP (2004)	• United States • Children aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae **Note**: The guideline may not apply to children more than 12 years old, because OME is uncommon and the natural history is likely to differ from younger children who experience rapid developmental change.
CCHMC (2004)	• United States • Children age 2 months up to 13 years of age who present with signs and symptoms of OME **Note**: Children with functioning pressure equalization (PE) tubes in place are excluded.
UMHS (2007)	• United states • Pediatric patients greater than two months old and adults with suspected or confirmed otitis media (AOM or OME)
Intended Users	

AAFP/AAOHNS/AAP (2004)	Advanced Practice Nurses Nurses Physician Assistants Physicians Speech-Language Pathologists
CCHMC (2004)	Advanced Practice Nurses Allied Health Personnel Health Care Providers Nurses Patients Physician Assistants Physicians Speech-Language Pathologists
UMHS (2007)	Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians

TABLE 3: COMPARISON OF RECOMMENDATIONS FOR DIAGNOSIS AND MANAGEMENT OF OME	
Definition Of OME	
AAFP/AAOHNS/AAP (2004)	OME is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection.
CCHMC (2004)	OME is defined as the presence of fluid in the middle ear without signs or symptoms of acute otitis media. More specifically: • OME: MEE without signs or symptoms of infection • Chronic OME: OME with duration more than 3 months
UMHS (2007)	**Diagnostic Definitions** **OME** (ICD-9-CM code 381.4) MEE without symptoms of AOM with or without evidence of inflammation
Diagnosis and Evaluation	

AAFP/AAOHNS/AAP (2004)	• **Pneumatic Otoscopy**: Clinicians should use pneumatic otoscopy as the primary diagnostic method for OME, and OME should be distinguished from AOM. (This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm). *Aggregate evidence quality: **A**, diagnostic studies in relevant populations* *Policy level: **strong recommendation*** Non-pneumatic otoscopy is not advised for primary diagnosis. • **Tympanometry**: Tympanometry can be used to confirm the diagnosis of OME. (This option is based on cohort studies and a balance of benefit and harm.) *Aggregate evidence quality: **B**, diagnostic studies with minor limitations* *Policy level: **option*** • **Documentation**: Clinicians should document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME. (This recommendation is based on observational studies and strong preponderance of benefit over harm.) *Aggregate evidence quality: **C**, observational studies* *Policy level: **recommendation***
CCHMC (2004)	**General** Signs and symptoms of OME are often only identified upon follow-up to AOM or at an unrelated office visit. **History and Physical Examination** • It is recommended that a focused history and physical of the child with OME includes assessment and documentation of:

	• Intermittent ear pain, fullness, or popping • Hearing/speech concerns (Roberts, Rosenfeld, & Zeisel, 2004 [M]) • Balance (Golz, Angel-Yeger, & Parush, 1998 [C]; Casselbrant et al., 1995 [C]) • Bilaterality • Duration of effusion • Recurrent AOM • Presence of any craniofacial anomalies (AAFP/AAOHNS/AAP, 2004 [S]) • It is recommended that OME be diagnosed by the presence of MEE, as assessed by pneumatic otoscopy, without signs and symptoms of acute inflammation (AAFP/AAOHNS/AAP, 2004 [S]). **Note**: Adequate illumination for OME diagnosis requires appropriate maintenance of pneumatic otoscopes in the office, including changing the light bulb and battery (Barriga, Schwartz, & Hayden, 1986 [O]). • It is recommended that tympanometry may be used to enhance accuracy when diagnosing OME (Karma et al., 1989 [D]; Shekelle et al., 2003 [S]; Brookhouser, 1998 [S]; Jones and 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]).
UMHS (2007)	**Diagnosis** • Distinguish between AOM and OME in making therapeutic decisions. Symptoms of pain or fever, together with an inflammatory middle ear effusion, are required to make a diagnosis of AOM. (Refer to Table 1 in original guideline document for details.) *[D]* • The presence of middle ear effusion should be determined by the combined use of otoscopy, pneumatic otoscopy, and tympanometry when necessary *[D]*. **Diagnosis and Treatment of Otitis Media with**

	Effusion **Evaluate tympanic membranes** at every well child and sick child exam when feasible. Perform pneumatic otoscopy or tympanometry when possible. Record findings. If the tympanic membrane (TM) is occluded with cerumen, consider removal. **If MEE, determine nature of effusion.** Attempt to distinguish between effusions that are likely to be transient, such as serous or purulent effusions and effusions likely to be persistent or associated with significant morbidity, such as mucoid effusions. **Rationale for Recommendations** **Diagnosis** **Distinguishing AOM and OME.** 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 technique for the diagnosis of AOM and OME. In skilled 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.
Children At Risk For Speech, Language, Or Learning Problems	
AAFP/AAOHNS/AAP (2004)	**Child at Risk**: Clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and should evaluate hearing, speech, language, and need for intervention more promptly. (This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.) *Aggregate evidence quality: **C**, observational studies of children at risk; **D**, expert opinion on the ability of prompt assessment and management to alter outcomes* *Policy level: **recommendation***
CCHMC (2004)	It is recommended that the child with OME who is at risk for developmental difficulties be identified early. These children include those with sensory, physical, cognitive, or behavioral factors listed below

	(AAFP/AAOHNS/AAP, 2004 [S]). **Note**: Children with Down syndrome (Shott, Joseph, & Heithaus, 2001 [C]; Whiteman, Simpson, & Compton, 1986 [C]), cranial facial dysostosis (Corey, Caldarelli, & Gould, 1987 [C]), cleft palate (Paradise & Bluestone, 1974 [C]), and autism (Rosenhall et al., 1999 [C]) have been shown to be at higher risk for OME and/or its associated outcomes of developmental delay in hearing, speech, or language. **Risk Factors for Developmental Difficulties** (AAFP/AAOHNS/AAP, 2004 [S]) • Permanent hearing loss independent of OME • Suspected or diagnosed speech and language delay or disorder • Autism-spectrum disorder and other pervasive developmental disorders • Syndromes (e.g., Down) or craniofacial disorders that include cognitive, speech, and language delays • Blindness or uncorrectable visual impairment • Cleft palate with or without associated syndrome • Developmental delay
UMHS (2007)	**Therapy of OME** • Parents of all children with OME should be informed about approaches to maximize language development in a child with a possible hearing loss *[C]*. **Risk Factors for Developmental Disabilities** • Hearing loss independent of OME • Suspected or diagnosed speech and language delay • Autism spectrum disorder • Syndromes (i.e., Down Syndrome) or craniofacial abnormalities that include cognitive, speech, or language delays • Blindness or uncorrectable visual impairment • Cleft palate with or without an associated syndrome • Developmental delay • Known or suspected exposure to environmental disorganization, lack of linguistic stimulation, or

	neglect **Management of OME** Although it is often possible to rule out significant language delay using a routine screen for developmental milestones, a referral to Early On (1-800-EARLY-ON) for a formal developmental evaluation is frequently appropriate. Early On is a state program mandated to provide developmental testing for children at risk of developmental delays. Such an evaluation would also provide parents with guidance in maximizing their child's development. This is particularly important since socioeconomic factors appear to have a substantial impact on language development and probably have more of an effect than the presence of OME with hearing loss. In many cases educational interventions may be as effective as surgical interventions. Interventions might include educating parents about effective strategies for optimizing the listening-learning environment for children with OME and hearing loss and providing appropriate books for parent/child reading (e.g., Reach Out and Read, which is program providing books to the parents of young children at all well child visits).
Non-Surgical Management	
AAFP/AAOHNS/AAP (2004)	• **Watchful Waiting**: Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown). (This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.) *Aggregate evidence quality: **B**, systematic review of cohort studies* *Policy level: **recommendation*** • **Medication**: Antihistamines and decongestants are ineffective for OME and are not recommended for treatment; antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management. (This recommendation is based on systematic review of randomized, controlled trials and the

	preponderance of harm over benefit.) *Aggregate evidence quality: **A**, systematic review of well-designed, randomized, controlled trials* *Policy level: **recommendation against*** • **Surveillance**: Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. (This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.) *Aggregate evidence quality: **C**, observational studies and some randomized trials* *Policy level: **recommendation*** • **Complimentary and alternative medicine (CAM)**: No recommendation is made regarding CAM as a treatment for OME. (There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.) *Aggregate evidence quality: **D**, case series without controls* *Policy level: **no recommendation*** • **Allergy Management**: No recommendation is made regarding allergy management as a treatment for OME. (There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.) *Aggregate evidence quality: **D**, case series without controls* *Policy level: **no recommendation***
CCHMC (2004)	The foundation of OME management is follow-up and monitoring of the presence or resolution of effusion. This monitoring is clinically important for the early identification of the child at risk for developmental difficulties and for the appropriate timing for referral of the child with persistent OME. • It is recommended that observation without

	antibiotics be the first line management option for at least 3 months for the child with OME (AAFP/AAOHNS/AAP, 2004 [S]).
	• It is recommended that all children with OME who have a positive assessment for pain be treated with an appropriate analgesic, though ear pain in OME is not common (AAP Subcommittee on Management of Acute Otitis Media, 2004 [S]; The assessment and management of acute pain, 2001 [S]).
	• It is recommended, for the otherwise healthy child with persistent OME, that no medication be given (Williamson, 2002 [S]).
	• It is recommended that the child with OME who is at risk for developmental difficulties (see table Risk Factors for Developmental Difficulties above) be aggressively managed as appropriate to his/her condition. This individualized management may include:
	  • Earlier referral for audiologic evaluation (Friel-Patti & Finitzo, 1990 [C]; Carney & Moeller, 1998 [S])
	  • Shorter intervals between visits
	  • Antibiotic therapy
	  • Referral for speech/language assessment
	  • Referral for PE tubes, and/or
	  • Referral for other otolaryngological evaluation
	
	Note: Preventive strategies may be helpful to children from special populations, from poor socioeconomic environments, or with development delays who are at risk for language and learning delay and who are experiencing hearing loss due to OME (Roberts et al., 2003 [M], 1998 [C], 1995 [C]; Roberts, Burchinel, & Zeisel, 2002 [C]). See Table 3 in the original guideline document.
	
	• It is recommended that the otherwise healthy child with OME be evaluated at 1 to 2 months after diagnosis and then again at 3 months after diagnosis, or until either spontaneous, medical, or surgical resolution of the effusion is achieved or until basis for a referral is identified (Paradise et al., "Otitis media," 2003 [A], "Early versus delayed insertion," 2003 [A], 2001 [A]; AAFP/AAOHNS/AAP, 2004 [S]; Paradise, 2002 [X]).
	• It is **not** recommended that other therapies be

	used in the treatment of OME. Systemic steroids, antihistamines, decongestants, and complementary or alternative treatments have not been documented to be efficacious in the treatment of OME, and some herbal preparations may have harmful side effects (Ernst, 2003 [M]; Mandel et al., 1987 [A]; Harrison, Fixsen, & Vickers, 1999 [B]; Fallon, 1997 [C]; Williamson, 2002 [S]; Miller et al., 2000 [S]). **Note** It is recognized that use of CAM is common and its use is often not reported to the primary care physician (Eisenberg et al., 1998 [O]; Spigelblatt et al., 1994 [O]). The physician may take the OME visit as an opportunity to begin a respectful discussion regarding the safety and efficacy of CAM with families who report its use.
UMHS (2007)	**Therapy of Otitis Media with Effusion** • Children with middle ear effusions should be examined at 3 month intervals for clearance of the effusion *[D]*. • Children with evidence of mucoid effusions or anatomic damage to the middle ear should be referred to otolaryngology if effusion or abnormal physical findings persist for 3 months *[D]*. • Children with apparent serous effusions should be referred to otolaryngology if effusion persists for 6 months and there is evidence of hearing loss or language delay *[D]*. • Children with an asymptomatic middle ear effusion (no apparent developmental or behavioral problems) can be followed without referral *[D]*. • Parents of all children with otitis media with effusion should be informed about approaches to maximize language development in a child with a possible hearing loss *[C]*. **Diagnosis and Treatment of Otitis Media with Effusion** **For likely transient effusions, reevaluate at 3 month intervals,** including a screen for language delay. In the absence of anatomic damage or evidence for developmental or behavioral complications, continue to observe at 3 month intervals. If complications appear to arise, refer to

	otolaryngology. **For apparent mucoid effusions or effusions that appear to be associated with anatomic damage,** such as adhesive otitis or retraction pockets, reevaluate in 3 months. If abnormality persists, refer to otolaryngology. **No antibiotics** are indicated. If symptoms arise, see AOM (Table 2 in the original guideline document). **Rationale for Recommendations** <u>Management of OME</u> The diagnosis and treatment of OME is summarized in Table 3 of the original guideline document. In the absence of a significant hearing loss, evidence of damage to middle ear structures, or risk factors for poor outcome (see Table 4 in the original guideline document), we recommend clinical reevaluation for all children with OME at 3 month intervals until the effusion is cleared or complications are identified. If developmental delay becomes apparent, the child should be referred to otolaryngology. In the event that the effusion appears mucoid or the tympanic membrane exhibits retraction pockets, tympanic membrane atelectasis, tympanic membrane adhesion to ossicles, or apparent cholesteatoma, the child should be revaluated in 3 months to confirm the findings and then be referred to otolaryngology.
Hearing Testing	
AAFP/AAOHNS/AAP (2004)	• **Hearing and Language**: Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME; language testing should be conducted for children with hearing loss. (This recommendation is based on cohort studies and the preponderance of benefit over risk.) *Aggregate evidence quality: **B**, diagnostic studies with minor limitations; **C**, observational studies* *Policy level: **recommendation***

CCHMC (2004)	It is recommended that a child be referred for audiologic evaluation (see Table 4 in the original guideline document): • If OME persists for at least 3 months • If concerns are noted for hearing, speech, or language by parents, teachers, or healthcare providers • 3 months after a prior audiologic evaluation in a child being observed with OME (Johnston et al., 2004 [A]; Brody et al., 1999 [C]; Rosenfeld, Goldsmith, & Madell, 1998 [C]; AAFP/AAOHNS/AAP, 2004 [S]; Local Expert Consensus [E])
UMHS (2007)	No specific recommendations offered. Refer to "Referral to Subspecialists" section of this synthesis for recommendations pertaining to referral to otolaryngology.
Referral To Subspecialists	
AAFP/AAOHNS/AAP (2004)	• **Referral**: When children with OME are referred by the primary care clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of AOM and developmental status of the child. (This option is based on panel consensus and a preponderance of benefit over harm.) *Aggregate evidence quality: **C**, observational studies* *Policy level: **option*** See the original guideline document for additional detail about the minimum information that should be conveyed when making a referral.

CCHMC (2004)	• It is recommended that a child be referred for audiologic evaluation (see Table 4 in the original guideline document):
	  • If OME persists for at least 3 months
	  • If concerns are noted for hearing, speech, or language by parents, teachers, or

	healthcare providers, or • 3 months after a prior audiologic evaluation in a child being observed with OME (Johnston et al., 2004 [A]; Brody et al., 1999 [C]; Rosenfeld, Goldsmith, & Madell, 1998 [C]; AAFP/AAOHNS/AAP, 2004 [S]; Local Expert Consensus [E]) • It is recommended that a child with MEE of at least 3 months duration be referred for evaluation for PE tube insertion 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) • Moderate hearing loss (see Table 4 in the original guideline document) • Anatomic changes developing secondary to OME or AOM • Clinical symptoms of severe retraction pockets in the tympanic membrane; otalgia; tinnitus; or if neurologic problems related to balance are evident • Complications from AOM or chronic OME (such as mastoiditis, facial nerve paralysis, disturbance in balance, or meningitis) (Paradise et al., 2001 [A]; Engel-Yeger, Golz, & Parush, 2004 [C]; Paradise, 2002 [X]). • It is recommended that a child with MEE for at least 3 months duration with mild hearing loss (see Table 4 in the original guideline document) be considered for evaluation for PE tube insertion based upon risk factors (Teele, Klein, & Rosner, 1989 [C]) which may include: • Developmental disorders (Shott, Joseph, & Heithaus, 2001 [C]) • Previous PE tubes • Sibling history of ear infection • Male gender • Fall and winter season (Gordon, Grunstein, & Burton, 2004 [C]) **Note**: The decision to refer earlier or later for evaluation for PE tube insertion rests on the advantages of avoiding surgery due to resolution of OME during the period of delay versus the added advantage the surgery provides by being performed sooner rather than later in the cases

	which do not resolve. The value placed on these uncertain variables by clinicians, combined with the patient biology and family preferences may result in different decisions for different patient:clinician dyads. • It is recommended that a child with signs of speech delay be referred for a speech and language evaluation (AAFP/AAOHNS/AAP, 2004 [S]). • It is recommended that appropriate and complete documentation, including what is expected from the specialist, accompany referrals to otolaryngologist, audiologist, or speech pathologist (Kuyvenhoven & De Melker, 1990 [D]; AAP Subcommittee on Management of Acute Otitis Media, 2004 [S]).
UMHS (2007)	• Children with evidence of mucoid effusions or anatomic damage to the middle ear should be referred to otolaryngology if effusion or abnormal physical findings persist for 3 months *[D]*. • Children with apparent serous effusions should be referred to otolaryngology if effusion persists for 6 months and there is evidence of hearing loss or language delay *[D]*.
Tympanostomy (PE) Tube Placement	
AAFP/AAOHNS/AAP (2004)	• When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis). Repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME. Surgical candidacy for OME largely depends on hearing status, associated symptoms, the child's developmental risk (see Table 3 in the original guideline document), and the anticipated chance of timely spontaneous resolution of the effusion. Candidates for surgery include children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of

	hearing status, and OME and structural damage to the tympanic membrane or middle ear. Ultimately, the recommendation for surgery must be individualized based on consensus between the primary care physician, otolaryngologist, and parent or caregiver that a particular child would benefit from intervention. Children with OME of any duration who are at risk are candidates for surgery.

CCHMC (2004)	Evaluation for placement of PE tubes is the most common reason children with OME are referred to an otolaryngologist. The discussion of alternatives, risks, benefits, and expected outcomes associated with tube placement begins with the primary care clinician and is continued with the otolaryngologist if the patient is referred.
	
	• It is recommended that the child with OME who is at risk for developmental difficulties (see table Risk Factors for Developmental Difficulties above) be aggressively managed as appropriate to his/her condition. This individualized management may include:
	  • Earlier referral for audiologic evaluation (Friel-Patti & Finitzo, 1990 [C]; Carney & Moeller, 1998 [S])
	  • Shorter intervals between visits
	  • Antibiotic therapy
	  • Referral for speech/language assessment
	  • Referral for PE tubes, and/or
	  • Referral for other otolaryngological evaluation
	• It is recommended that an introduction and a discussion be initiated by the primary care clinician with the parents of children with documented OME of the procedure, alternatives, risks, benefits, and expected outcomes of PE tube insertion being considered for otolaryngological referral (Local Expert Consensus [E]).
	
	Note: It has been shown that insertion of tympanostomy tubes will reduce the total amount of time with effusions that a child will experience, but has not been shown to affect important speech/language development, behavior, or cognitive outcomes up to 4 years of age. Furthermore, prompt insertion of PE tubes (compared to delaying insertion 6 to 9 months) in otherwise healthy children with persistent (>3 months) OME in the first 3 years of life results in increased tympanic membrane (TM)

abnormalities compared to children selectively managed; however, this finding is of questionable clinical significance (Johnston et al., 2004 [A]; Paradise et al, 2001 [A]).

- It is recommended that a child with MEE of at least 3 months duration be referred for evaluation for PE tube insertion 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)
    - Moderate hearing loss (see Table 4 in the original guideline document)
    - Anatomic changes developing secondary to OME or AOM
    - Clinical symptoms of severe retraction pockets in the tympanic membrane; otalgia; tinnitus; or if neurologic problems related to balance are evident
    - Complications from AOM or chronic OME (such as mastoiditis, facial nerve paralysis, disturbance in balance, or meningitis) (Paradise et al., 2001 [A]; Engel-Yeger, Golz, & Parush, 2004 [C]; Paradise, 2002 [X]).
- It is recommended that a child with MEE for at least 3 months duration with mild hearing loss (see table entitled "Hearing Loss Definitions and Expected Auditory Behaviors in Children with OME" in original guideline) be considered for evaluation for PE tube insertion based upon risk factors (Teele, Klein, & Rosner, 1989 [C]) which may include:
    - Developmental disorders (Shott, Joseph, & Heithaus, 2001 [C])
    - Previous PE tubes
    - Sibling history of ear infection
    - Male gender
    - Fall and winter season (Gordon, Grunstein, & Burton, 2004 [C])

Note: The decision to refer earlier or later for evaluation for PE tube insertion rests on the advantages of avoiding surgery due to resolution of OME during the period of delay versus the added advantage the surgery provides by being performed sooner rather than later in the cases which do not resolve. The value placed on these uncertain variables by clinicians, combined with the patient biology and family preferences may

	result in different decisions for different patient:clinician dyads.
UMHS (2007)	**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. Recommendations of the Division of Pediatric Otolaryngology at the University of Michigan Medical Center are summarized below. Post-op irrigation. After the tubes are placed in the operating room, antibiotic ear drops are placed in both ears to irrigate the tubes. The parent is given the bottle to administer the drops for the next 2 to 3 days. Ear drainage. Ear drops combining a fluoroquinolone with a corticosteroid are the safest and most effective therapy for the draining ear. This includes ears draining either through a perforated ear drum or through a patent tympanostomy tube. To be maximally effective, ensure that the drops can get to the site of infection. For this reason, clear the ear of purulent material prior to administration of antibiotic drops and introduce the antibiotic drops into the middle ear by pumping on the external ear canal with the tragus. Purulent debris can be easily cleared by warm water irrigation using 10 cc syringe topped with the luer from a cut off butterfly needle. The canal can then be dried using cotton or soft tissue paper. Aminoglycoside containing ear drops, such as gentimicin, tobramycin, and neomycin (Cortisporin) should not be used in the presence or tympanic membrane perforations or ventilation tubes since they are ototoxic. Patients with significant systemic symptoms, such as fever, might benefit from systemic antibiotics. Management of tympanostomy tubes. Most otolaryngologists no longer advise their patients to use ear plugs with swimming, bathing, or washing hair. In most cases physical characteristics of ventilation tubes prevent the entry of liquids into the middle ear space unless the child dives into deep water or pumps the liquid into the middle ear. In the event of subsequent otorrhea, infusion of fluoroquinolone drops is usually the only therapy

	necessary. 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.

TABLE 4: BENEFITS AND HARMS	
Benefits	
AAFP/AAOHNS/AAP (2004)	• Pneumatic Otoscopy: improved diagnostic accuracy; inexpensive equipment • Tympanometry: increased diagnostic accuracy beyond pneumatic otoscopy; documentation • Screening: potentially improved developmental outcomes, which have not been demonstrated in the best current evidence • Documentation: defines severity, duration has prognostic value, facilitates future communication with other clinicians, supports appropriate timing of intervention, and, if consistently unilateral, may identify a problem with specific ear other than OME (e.g., retraction pocket or cholesteatoma). • Child at Risk: optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; avoiding limitations on the benefits of educational interventions because of hearing problems from OME. • Watchful Waiting: avoid unnecessary interventions, take advantage of favorable natural history, and avoid unnecessary referrals and evaluations • Medication: avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse • Hearing and Language: to detect hearing loss and language delay and identify strategies or interventions to improve developmental outcomes • Surveillance: avoiding interventions that do not improve outcomes. • Referrals: better communication and improved decision-making • Surgery: improved hearing, reduced prevalence of OME, reduced incidence of AOM, and less need for additional tube insertion (after adenoidectomy) • Complementary and Alternative Medicine (CAM): not

	established • Allergy Management: not established
CCHMC (2004)	• Effective medical management of OME in children 2 months to 13 years of age • Improved identification of the at-risk child • Improved use of appropriate referral criteria • Improved parental involvement in decision-making around the management of OME
UMHS (2007)	Accurate diagnosis and effective treatment and management of otitis media
Harms	
AAFP/AAOHNS/AAP (2004)	• Pneumatic Otoscopy: cost of training clinicians in pneumatic otoscopy • Tympanometry: acquisition cost, administrative burden, and recalibration • Screening: inaccurate diagnosis (false-positive or false-negative), overtreating self-limited disease, parental anxiety, cost of screening, and/or unnecessary treatment • Documentation: administrative burden • Child at Risk: cost, time, and specific risks of medications or surgery • Watchful Waiting: delays in therapy for OME that will not resolve with observation; prolongation of hearing loss • Medication: adverse effects of specific medications: side effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood-pressure variability; side effects of antimicrobials may include rashes, vomiting, diarrhea, allergic reactions, alteration of the child's nasopharyngeal flora, societal impact of antimicrobial therapy on bacterial resistance and transmission of resistant pathogens, and cost; oral steroids can produce behavioral changes, increased appetite, weight gain, adrenal suppression, fatal varicella infection, and avascular necrosis of the femoral head • Hearing and Language: parental anxiety, direct and indirect costs of assessment, and/or false-positive results • Surveillance: allowing structural abnormalities to develop in the tympanic membrane, underestimating the impact of hearing loss on a child, and/or failing to detect significant signs or

	symptoms that require intervention • Referrals: confidentiality concerns, administrative burden, and/or increased parent or caregiver anxiety • Surgery: risks of anesthesia and specific surgical procedures; sequelae of tympanostomy tubes • CAM: potentially significant depending on the intervention • Allergy Management: adverse effects and cost of medication, physician evaluation, elimination diets, and desensitization
CCHMC (2004)	None stated
UMHS (2007)	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	
AAFP/AAOHNS/AAP (2004)	**RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE** **Evidence Quality for Grades of Evidence** **Grade A**: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population **Grade B**: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies **Grade C**: Observational studies (case-control and cohort design) **Grade D**: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies) **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS** **Guideline Definitions for Evidence-Based**

	Statements **Strong Recommendation**: A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication:* Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present. **Recommendation**: A recommendation means that the subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication:* Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences. **Option**: An option means that either the quality of evidence that exists is suspect (grade D) or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another. *Implication:* Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set boundaries on alternatives; patient preference should have a substantial influencing role. **No Recommendation**: No recommendation means that there is both a lack of pertinent evidence (grade D) and an unclear balance between benefits and harms. *Implication:* Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.
CCHMC (2004)	**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: Meta-analysis
Q: Decision analysis
L: Legal requirement
O: Other evidence
X: No evidence

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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 Family Physicians/American Academy of Otolaryngology-Head and Neck Surgery/American Academy of Pediatrics (AAFP/AAOHNS/AAP), Cincinnati Children's Hospital Medical Center (CCHMC), and University of Michigan Health System (UMHS) present recommendations for diagnosis and management of otitis media with effusion (OME). All of the guidelines 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.

The guidelines differ somewhat in scope. The UMHS guideline addresses diagnosis and management of AOM and OME. While the AAFP/AAOHNS/AAP and CCHMC guidelines address otitis media (OM) in children only, the UMHS guideline targets adults as well. Within the pediatric population, all of the guidelines target children 2 months and older. All of the groups address the consideration of PE tubes. AAFP/AAOHNS/AAP also addresses research needs related to OME.

Areas of Agreement

Diagnosis

Diagnostic Otoscopy

The guidelines agree that otoscopy should be used to determine if MEE is present and they are in general agreement that pneumatic otoscopy is preferable to simple otoscopy. All of the groups cite research showing that pneumatic otoscopy has higher diagnostic sensitivity and specificity than simple otoscopy.

Adjunctive Diagnostic Techniques

All of the guidelines agree that tympanometry is a useful adjunct to otoscopy for diagnosing OME.

AAFP/AAOHNS/AAP and CCMHC further agree that acoustic reflectometry can be a useful adjunctive technique, although CCMHC observes that it is not often used nor readily available in the Cincinnati area. UMHS notes that acoustic reflectometry, like tympanometry, has imperfect sensitivity and specificity and must be correlated with the clinical exam.

Management

Watchful Waiting

There is general agreement among the guidelines that the majority of OME cases resolve spontaneously within a few weeks. All of the groups explicitly recommend that the child with OME who is not at risk be managed by watchful waiting for 3 months.

Medication

Antibiotics. The guidelines are in agreement that antibiotics should not be used to treat most cases of OME. While all of the groups recommend against the use of antibiotics for OME in otherwise healthy children, CCHMC does include antibiotic therapy as an option for aggressive individual management of children with OME who are at risk for developmental difficulties.

Other Medications. AAFP/AAOHNS/AAP and CCHMC are in agreement that decongestants and antihistamines should not be used in the management of OME, with AAFP/AAOHNS/AAP noting they have not been shown to be beneficial and are associated with potential adverse side effects. These guidelines recommend against the use of systemic steroids, citing lack of evidence of long-term benefit. Additionally, AAFP/AAOHNS/AAP observes there is no evidence that nasal steroids are associated with improved outcomes. UMHS does not address these therapies.

Children at Risk

There is agreement among the guidelines that children at risk for hearing, speech and language, and/or developmental problems should be identified early and managed aggressively, including early referral for hearing, speech, and language assessment and evaluation by an otolaryngologist.

Hearing Testing

The guidelines generally agree in their recommendations concerning the need for hearing testing. For uncomplicated OME, AAFP/AAOHNS/AAP and CCHMC recommend hearing testing when OME persists for 3 months or longer; CCHMC further recommends hearing testing 3 months following initial audiologic evaluation in the child being observed with OME.

UMHS does not make specific recommendations for hearing testing, but recommends referral to otolaryngology if effusion or abnormal physical findings persist for 3 months.

All of the guidelines recommend prompt hearing testing when language delay, learning problems, and/or a significant hearing loss is suspected in a child with OME, regardless of the duration of OME.

PE Tube Insertion

The guidelines agree that early referral to an otolaryngologist is warranted for children at risk for hearing, speech and language, or developmental delays; children with anatomical abnormalities (such as cleft palate, bifid uvula, and Down syndrome); and children with clinical complications of OME. They also agree that PE tube insertion is the surgical intervention of choice, though AAFP/AAOHNS/AAP also considers adenoidectomy. Further, AAFP/AAOHNS/AAP and CCHMC generally recommend surgical evaluation for children with OME lasting 3 or 4 months with hearing loss or other complications. UMHS' recommendations regarding the decision to undergo PE tube placement are primarily targeted at AOM, not OME patients. They also include recommendations regarding primary care follow-up and management of tympanostomy tubes.

Areas of Differences

As discussed above, while all of the guidelines recommend against the routine use of antibiotics for OME, CCHMC includes exceptions for which antibiotic use may be warranted, such as for aggressive individualized management of the child with OME who is at risk for developmental difficulties.

This synthesis was prepared by ECRI on February 13, 2006. The information was verified by AAP on March 6, 2006, and by CCHMC and UMHS on March 20, 2006. This synthesis was updated on December 6, 2007 to remove recommendations from UMHS and on April 18, 2008 to update UMHS recommendations. This synthesis was updated in December 2008 to remove recommendations from SIGN.

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