Clinical Practice Guideline: Otitis Media with Effusion (Update)

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Abstract

Objective: This update of a 2004 guideline from the American Academy of Otolaryngology – Head and Neck Surgery Foundation provides evidence-based recommendations to manage otitis media with effusion (OME), defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection. Changes from the prior guideline include consumer advocates added to the update group, evidence from 4 new clinical practice guidelines, 20 new systematic reviews, and 49 randomized control trials, enhanced emphasis on patient education and shared-decision making, a new algorithm to clarify action statement relationships, and new and expanded recommendations for the diagnosis and management of OME.

Purpose: The purpose of this multidisciplinary guideline is to identify quality improvement opportunities in managing OME and to create explicit and actionable recommendations to implement these opportunities in clinical practice. Specifically, the goals are to improve diagnostic accuracy, identify children who are most susceptible to

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developmental sequelae from OME, and to educate clinicians and patients regarding the favorable natural history of most OME and the lack of efficacy for medical therapy (e.g., steroids, antihistamines, decongestants). Additional goals relate to OME surveillance, evaluating hearing and language, and managing OME detected by newborn screening. The target patient for the guideline is a child aged 2 months through 12 years with OME, with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The guideline is intended for all clinicians who are likely to diagnose and manage children with OME, and applies to any setting in which OME would be identified, monitored, or managed. This guideline, however, does not apply to patients under age 2 months or over age 12 years.

Action Statements: The update group made *strong recommendations* that clinicians (1) should document the presence of middle-ear effusion with pneumatic otoscopy when diagnosing OME in a child; (2) should perform pneumatic otoscopy to assess for OME in a child with otalgia, hearing losss, or both ; (3) should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy; (4) should manage the child with otitis media with effusion OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or 3 months from the date of diagnosis (if onset is unknown); and (5) should recommend *against* using intranasal or systemic steroids for treating OME; (6) should recommend *against* using systemic antibiotics for treating OME; and (7) should recommend *against* using antihistamines, decongestants, or both for treating OME. The update group made *recommendations* that clinicians (1) should document in the medical record counseling of parents of infants with OME who fail a newborn screening regarding the importance of

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follow-up to ensure that hearing is normal when OME resolves and to exclude an underlying sensorineural hearing loss (SNHL); (2) should determine if a child with OME is at increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors; (3) should evaluate at-risk children for OME at the time of diagnosis of an at-risk condition and at 12 to 18 months of age (if diagnosed as being at-risk prior to this time); (4) should *not* routinely screen children for OME who are not at-risk and do not have symptoms that may be attributable to OME, such as hearing difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort (5) should educate children with OME and their families regarding the natural history of OME, need for follow-up, and the possible sequelae; (6) should obtain an age-appropriate hearing test if OME persists for 3 months or longer OR for OME of any duration in an at-risk child; (7) should counsel families of children with bilateral OME and documented hearing loss about the potential impact on speech and language development; (8) should reevaluate, at 3- to 6-month intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected; (9) should recommend tympanostomy tubes when surgery is performed for OME in a *child under age 4 years*; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis); (10) should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed OME in a *child aged 4 years or older; and (11)* should document resolution of OME, improved hearing, or improved quality of life when managing a child with OME.

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Keywords

Otitis media with effusion, middle ear effusion, tympanostomy tubes, adenoidectomy, clinical practice guideline

Differences from Prior Guideline

This clinical practice guideline is an update, and replacement, for an earlier guideline published in 2004 by the American Academy of Otolaryngology – Head and Neck Surgery Foundation. (Rosenfeld, et al, 2004) An update was necessitated by new primary studies and systematic reviews that might suggest a need for modifying clinically important recommendations. Changes in content and methodology from the prior guideline include:

- Addition of consumer advocates to the guideline development group
- New evidence from 4 clinical practice guidelines, 20 systematic reviews, and 49 randomized controlled trials
- Emphasis on patient education and shared decision-making with an option grid for surgery and new tables of counseling opportunities and frequently asked questions
- Expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion
- Enhanced external review process to include public comment and journal peer review
- Additional information on pneumatic otoscopy and tympanometry to improve diagnostic certainty for otitis media with effusion (OME)

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- Expanded information on speech and language assessment for children with OME
- New recommendations for managing OME in children who fail a newborn hearing screen, evaluating at-risk children for OME, and educating and counseling parents
- A new recommendation against using topical intranasal steroids for treating OME
- A new recommendation against adenoidectomy for a primary indication of OMEin children under age 4 years, including those with prior tympanostomy tubes, unless a distinct indication exists (nasal obstruction, chronic adenoiditis).
- A new recommendation for assessing OME outcomes by documenting OME resolution, improved hearing, or improved quality of life (QOL)
- New algorithm to clarify decision-making and action statement relationships

Introduction

Otitis media with effusion (OME) is defined as the presence of fluid in the middle ear (Figure 1, Table 1) without signs or symptoms of acute ear infection (Stool 1994, Berkman 2013). The condition is common enough to be called an "occupational hazard of early childhood" (Rosenfeld 2005) because about 90% of children have OME before school age (Tos 1984) and develop 4 episodes of OME every year (Mandel 2008). Synonyms for OME include ear fluid and serous, secretory, or nonsuppurative otitis media.

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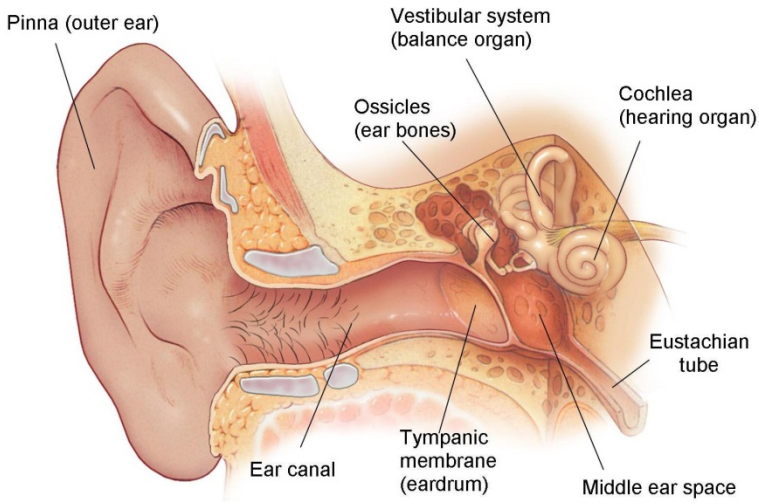

Figure 1. Location of the middle ear space. OMEoccurs when fluid builds up in the middle ear space, which normally is air filled and lies just behind the eardrum. With permission (Rosenfeld 2005).

Table 1. Abbreviations and definitions of common terms

Term	Definition
Otitis media with effusion (OME)	The presence of fluid in the middle ear without signs or symptoms of acute ear infection (AOM).
Chronic OME	OME persisting for 3 months or longer from the date of onset (if known) or from the date of diagnosis (if onset is unknown).
Acute otitis media (AOM)	The rapid onset of signs and symptoms of inflammation of the middle ear.
Middle ear effusion (MEE)	Fluid in the middle ear from any cause, but most often from OME and during, or after, an episode of AOM.

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Hearing assessment	A means of gathering information about a child's hearing status, which may include caregiver report, audiologic assessment by an audiologist, or hearing testing by a physician or allied health professional using screening or standard equipment, which may be automated or manual. Does not include use of noisemakers or other non-standardized methods.
Pneumatic otoscopy	A method of examining the middle ear by using an otoscope with an attached rubber bulb to change the pressure in the ear canal and see how the eardrum reacts. A normal eardrum moves briskly with applied pressure but when there is fluid in the middle ear the movement is minimal or sluggish.
Tympanogram	An objective measure of how easily the tympanic membrane vibrates and at what pressure it does so most easily (pressure-admittance function). If the middle ear is filled with fluid (e.g., OME), vibration is impaired and the result is a flat, or nearly flat, tracing; if the middle ear is filled with air, but at a higher or lower pressure than the surrounding atmosphere, the peak on the graph will be shifted in position based on the pressure (to the left if negative, to the right if positive).
Conductive hearing loss (CHL)	Hearing loss from abnormal or impaired sound transmission to the inner ear, which is often associated with effusion in the middle ear, but can be caused by other middle ear abnormalities as TM perforation, or ossicle abnormalities
Sensorineural hearing loss (SNHL)	Hearing loss that results from abnormal transmission of sound from the sensory cells of the inner ear to the brain.

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About 2.2 million diagnosed episodes of OME occur annually in the United States at a cost of $4.0 billion (Shekelle 2003). The indirect costs are likely much higher since

OME is largely asymptomatic and many episodes are therefore undetected, including those episodes in children with hearing difficulties or school performance issues. In contrast, acute otitis media (AOM) is the rapid onset of signs and symptoms of inflammation in the middle ear (Lieberthal 2013), most often with ear pain and a bulging eardrum. In lay terms, OME is often called "ear fluid" and AOM "ear infection" (Figure 2). The lay language in Table 2 can help parents and families better understand OME, why it occurs, and how it differs from ear infections.

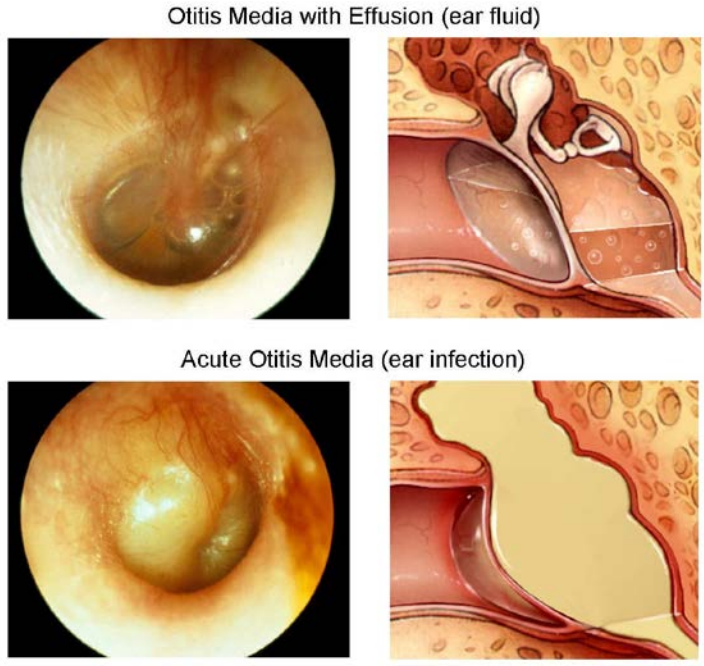

Figure 2. Comparison of OME (top) with AOM (bottom). The left images show the appearance of the eardrum on otoscopy and the right images depict the middle ear space. For OME, the middle ear space is filled with mucus or liquid (top right). For AOM, the middle ear space is filled with pus and the pressure causes the eardrum to bulge outward (bottom right). With permission (Rosenfeld 2005).

Table 2. Frequently asked questions: Understanding ear fluid

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Question	Answer
What is ear fluid and how common is it?	Ear fluid, also called otitis media with effusion (OME), is a build-up of mucus or liquid behind the eardrum, without symptoms of an ear infection. Nearly all children get ear fluid at least once by school age.
How does ear fluid differ from an ear infection?	Ear infections (AOM) occur when germs (bacteria and/or viruses) enter the middle ear and cause fever, ear pain, and active (acute) inflammation. Both AOM and OME have fluid in the middle ear, but with OME the fluid is not actively infected and pain may be absent or minimal.
If my child gets ear fluid, how can I tell?	You might not be able to tell. Some children with OME have obvious hearing problems, but other children may have no symptoms at all or more subtle findings (e.g., ear rubbing, clumsiness, selective hearing, disturbed sleep). Your doctor can detect ear fluid by looking in the ear canal (otoscopy) or by measuring the movement of the eardrum (tympanometry or pneumatic otoscopy).
What causes ear fluid?	OME may be caused by a cold, an ear infection (AOM), or by the normal congestion (negative pressure) that many young children have in their middle ear. Often OME is detected during a routine doctor's visit and the exact cause is unknown.
Should I worry if my child has ear	Most fluid goes away on its own in weeks or months, especially if it was caused by a cold or an ear infection. OME is of more concern if it lasts more than 3 months or when your child has other problems that could be

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fluid?	made worse by persistent ear fluid (e.g., delays in speech, language, learning, or development). Your doctor should check the ears periodically until the fluid is gone.
What is the best way to manage ear fluid?	There are many opinions about managing OME, but the best advice can be found in clinical practice guidelines, which make recommendations based on best available evidence and by considering the potential benefits and harms of different strategies.

AOM, acute otitis media; MEE, middle earmiddle ear effusion; OME, otitis media with effusion

OME may occur during an upper respiratory infection, spontaneously because of poor eustachian tube function (Figure 3), or as an inflammatory response following AOM, most often between ages 6 months and 4 years (Paradise 1997). In the first year of life, more than 50% of children will experience OME, increasing to more than 60% by age 2 years (Casselbrant 2003). When children aged 5 to 6 years in primary school are screened for OME, about 1 in 8 are found to have fluid in one or both ears (Martines 2010). The prevalence of OME in children with Down syndrome or cleft palate, however, is much higher, ranging from 60 to 85% (Flynn 2009; Maris 2014).

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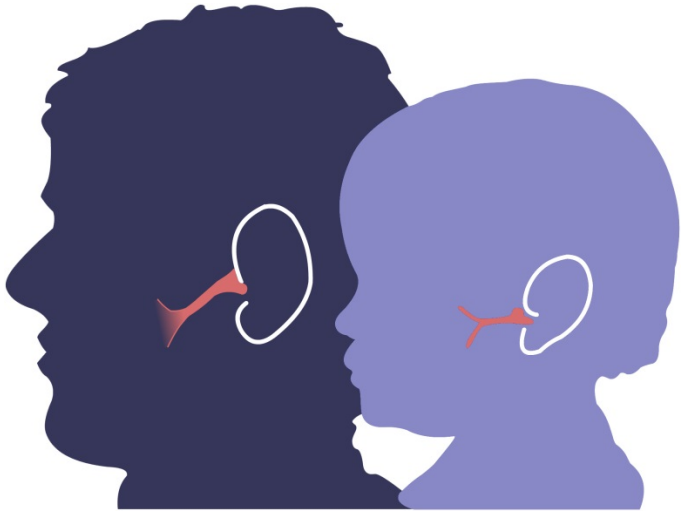

Figure 3. Position of the eustachian tube (red) as it connects the middle ear space to the back of the nose, or nasopharynx. The child's eustachian tube (right) is shorter, more floppy, and more horizontal, which makes it less effective in ventilating and protecting the middle ear than the eustachian tube in the adult (left).

Most episodes of OME resolve spontaneously within 3 months, but about 30% to 40% of children have repeated OME episodes and 5% to 10% of episodes last 1 year or longer (Stool 1994; Tos 1984; Williamson 1994). Persistent middle ear fluid from OME results in decreased mobility of the tympanic membrane and serves as a barrier to sound conduction (Williamson, 2002). At least 25% of OME episodes persist for 3 months or longer (Rosenfeld 2003) and may be associated with hearing loss, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, recurrent AOM, or reduced QOL (Rosenfeld 2013). Less often, OME may cause structural damage to the tympanic membrane that requires surgical intervention.(Rosenfeld and Kay 2003)

The high prevalence of OME – along with many issues including difficulties in diagnosis and assessing its duration, associated conductive hearing loss, potential impact

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on child development, and significant practice variations in management – make OME an important condition for up-to-date, clinical practice guidelines.

Purpose

The purpose of this multidisciplinary guideline is to identify quality improvement opportunities in managing OME and to create explicit and actionable recommendations to implement these opportunities in clinical practice. Specifically, the goals are to improve diagnostic accuracy, identify children who are most susceptible to developmental sequelae from OME (Table 3), and to educate clinicians and patients regarding the favorable natural history of most OME and the lack of efficacy for medical therapy (e.g., steroids, antihistamines, decongestants). Additional goals relate to OME surveillance, evaluating hearing and language, and managing OME detected by newborn screening.

Table 3. Risk factors for developmental difficulties in children with OME*

Permanent hearing loss independent of OME
Suspected or confirmed 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, or language delays
Blindness or uncorrectable visual impairment
Cleft palate, with or without associated syndrome
Developmental delay

*OME, otitis media with effusion

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*Sensory, physical, cognitive, or behavioral factors that place children who have OME at increased risk for developmental difficulties (delay or disorder) (Rosenfeld 2004)

The target patient for the guideline is a child aged 2 months through 12 years with OME, with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The guideline is intended for all clinicians who are likely to diagnose and manage children with OME, and applies to any setting in which OME would be identified, monitored, or managed. This guideline, however, does not apply to patients under age 2 months or over age 12 years.

The guideline does not explicitly discuss indications for tympanostomy tubes, even though OME is the leading indication for tympanostomy tube insertion, because indications are thoroughly explained in a companion clinical practice guideline from the AAO-HNS (Rosenfeld 2013). Rather, discussions of surgery focus on adjuvant procedures (e.g., adenoidectomy, myringotomy) and sequelae of OME (e.g., retraction pockets, atelectasis of the tmiddle ear) that were excluded from the tympanostomy tube guideline.

Health Care Burden

Incidence and Prevalence

Approximately 2.2 million new cases of OME are diagnosed annually in the United States (Subcommittee on OME, 2004), with 50 to 90% of children affected by 5 years of age (Tos 1984, Zielhuis 1989, Casselbrant 1985, Aydemir 2011, Martines 2011,

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Casselbrant 2003). The point prevalence is 7-13%, with a peak in the first year of life, and a per-year period prevalence of 15 to 30% (Tos 1984). About 4 episodes of new onset OME occur annually in young children with a mean duration of 17 days per episode (Mandel 2008). Longitudinal evaluation with weekly otoscopy suggests that 25% of observed days in children 0-9 years of age show evidence of otitis media (OME and AOM), with 13 to 21% having bilateral involvement (Mandel 2008).

Otitis media is a common reason for outpatient visit to pediatricians, accounting for 1 in 9 (11.4%) office encounters in primary care practices (Forrest 2013). Of these otitis media visits, about 1 in 3 are for OME, which can present as the primary diagnosis (17%), in conjunction with AOM (6.5%), or under the general heading of nonspecific otitis media (13%). The prevalence of OME, and the associated physician visits, varies with geography and season, affecting up to 84% of observed children in some studies (Aydemir 2011, Mandel 2008, Daly 2010, Rushton 1997, Morris 2005, Kiris 2012, Mahadevan 2012).

Despite the frequency of OME, surveillance data from pediatric practice networks suggests that a minority of clinicians follow clinical practice guidelines. For example, only 7 to 33% of pediatricians use pneumatic otoscopy for diagnosis and only 29% obtain an age-appropriate hearing test when the effusion persists for 3 months or longer (Forrest 2013, Lannon 2011). Moreover, 32% treat OME inappropriately with antibiotics (Lannon 2011), which results in unnecessary adverse events and bacterial resistance.

Impact on Children and Families

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OME is the most common cause of hearing impairment in children in developed nations (Quireishi 2014), and permanent hearing loss related to otitis media has a prevalence of 2-35 per 10,000 (Monasta 2012). Otitis media may be related to difficulties in speech and reading, delayed response to auditory input, limited vocabulary, and disturbances in attention (Bellussi 2005). It may also be associated with being less task-oriented and less capable of independent classroom work (Roberts 1989). Observational studies measuring caregiver reports suggest that school performance may improve after OME has been identified and treated (Rosenfeld 2011).

The impact of OME on disease-specific QOL and functional health status may be substantial, affecting both children and caregivers (Klein 2000, Brouwer 2005). According to prospectively measured parental report, 76% of children with OME suffer from otalgia, 64% from sleep disruption, 49% from behavioral problems, 33 to 62% from speech and hearing concerns, and 15% from balance symptoms (Brouwer 2005, Karkanevatos 1998). In addition, parent-child interaction may be poorer than in healthy children, and caregiver concerns (e.g. worry, concern, or inconvenience because of ear problems) are often high (Rovers, 2008, Brouwer 2005, Timmerman 2003). OME can affect the vestibular system and gross motor skills, and these problems may be reversible once the effusion has been addressed (Casselbrant 1995, Casselbrant 1998, Golz 1998, Orlin 1997).

OME has a substantial impact on child QOL, both from direct effects of persistent effusion and a rate of AOM that is up to 5 times higher than when effusion is absent (Rovers 2008, Alho 1995, Koopman 2008). The primary domains impacted by OME and

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recurrent AOM are physical suffering, emotional distress, and caregiver concerns (Rosenfeld 2000). Less often, OME, and the attendant eustachian tube dysfunction, may result in sequelae that include tympanic membrane retraction/atelectasis, ossicular erosion, cholesteatoma formation, and tympanic membrane perforation (Jung 2013). The impact of OME is increased in children with comorbidities such as Down syndrome or cleft palate (Austeng 2013, Flynn 2009).

Direct and Indirect Costs

Direct costs related to otitis media, which includes OME and AOM, are 3 to 5 billion dollars annually (Marom 2014, O'Brien 2009, Zhou 2008, Schwartz, 2003) and the true economic impact is likely higher, because indirect costs are sizable yet difficult to estimate (Rovers 2008, Alsarraf 1999). Studies of AOM suggest that the indirect cost of lost caregiver productivity may far exceed that of the direct cost of medical treatment (Alsarraf 1999). In addition, the estimated net cost of impaired well-being from otitis media is 1.1 to 2.6 billion dollars (Kong 2009, Access-Economics 2009).

The direct costs of managing OME include medical therapy, which is largely ineffective. Antibiotics, for example, have short-term efficacy, but long-term use cannot be justified because of concerns over adverse events and induced bacterial resistance (van Zon 2012). Although several studies have shown an association between gastroesophageal reflux and OME, the limited evidence regarding anti-reflux therapy does not show significant benefits (Miura 2012). Similarly, despite a high prevalence of atopic conditions, such as allergic rhinitis, in children with OME (Alles 2001, Caffarelli 2008, Loung 2008), there are no benefits to routinely treating with antihistamines,

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decongestants, or steroids (systemic or topical intranasal) (Griffin 2011, Simpson 2011, Berkman 2013). Most studies however, do not consider the allergy status of children, and it is unknown if those with proven allergies might respond differently.

Methods

General methods and literature search

In developing this update of the evidence-based clinical practice guideline, the methods outlined in the AAO-HNSF Guideline Development Manual, 3rd edition were followed explicitly. (Rosenfeld, et al, 2013)

An executive summary of the original OME guideline (Rosenfeld 2004) was sent to a panel of expert reviewers from the fields of general otolaryngology, pediatric otolaryngology, otology, family practice, pediatrics, nursing, audiology, and speech language pathology who assessed the key action statements to decide if they should be revised, be kept as stands, or removed, and to identify new research that might affect the guideline recommendations. The reviewers concluded that the original guideline action statements remained valid but should be updated with major modifications. Suggestions were also made for new key action statements.

An information specialist conducted two systematic literature searches using a validated filter strategy to identify clinical practice guidelines, systematic reviews, and randomized controlled trials (RCTs) published since the prior guideline (2004). Search terms used were "Otitis Media with Effusion"[Mesh] OR "otitis media with effusion"[tiab] OR (OME[tiab] AND otitis) OR "middle ear effusion"[tiab] OR "glue ear"[tiab]; 'otitis'/exp OR otitis AND media AND ('effusion'/exp OR effusion); MH "Otitis Media

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with Effusion" OR TI (OME and effusion) OR TI “otitis media with effusion”; and (DE "OTITIS MEDIA") OR "otitis media with effusion" OR (OME AND otitis) OR "middle ear effusion" OR "glue ear". In certain instances, targeted searches for lower level evidence were performed to address gaps from the systematic searches identified in writing the guideline. The original MEDLINE search was updated from January 2004 to January 2015 to include Medline, National Guidelines Clearinghouse, Cochrane Database of Systematic Reviews, Excerpta Medica database (EMBASE), Cumulative Index to Nursing and Allied Health (CINAHL), and the Allied and Complimentary Medicine Database (AMED).

1. The initial search for clinical practice guidelines identified 13 guidelines. Articles were excluded if they (1) were not on the topic of the guideline, (2) were not available in English, (3) did not meet the panel’s quality criteria (e.g., the review had a clear objective and method), (4) did not possess an explicit search strategy, and/or (5) did not have valid data extraction methods. The final dataset retained 4 guidelines.
2. The initial search for systematic reviews identified 138 systematic reviews or meta-analyses that were distributed to the panel members. Articles were excluded if they (1) were not on the topic of the guideline, (2) were not available in English, (3) did not meet the panel’s quality criteria (e.g., the review had a clear objective and method), (4) did not possess an explicit search strategy, and/or (5) did not have valid data extraction methods. The final data set retained was 20 systematic reviews or meta-analyses.
3. The initial search for RCTs identified 86 RCTs that were distributed to panel

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members for review. Articles were excluded if they (1) were unpublished RCTs, duplicate articles, and articles with unavailable abstracts (2) were not on the topic of the guideline, (3) were not available in English, (4) did not meet the panel's quality criteria (e.g., the review had a clear objective and method), (5) did not possess an explicit search strategy, and/or (6) did not have valid data extraction methods. The total final data set retained 49 RCTs.

The AAO-HNSF assembled a guideline update group (GUG) representing the disciplines of otolaryngology – head and neck surgery, pediatric otolaryngology, otology, pediatrics, allergy and immunology, family medicine, audiology, speech-language pathology, advanced practice nursing, and consumer advocacy. The GUG had several conference calls and one in-person meeting during which they defined the scope and objectives of updating the guideline, reviewed comments from the expert panel review for each key action statement, identified other quality improvement opportunities, and reviewed the literature search results.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with our current development standards (Rosenfeld 2013). Information was added to the action statement profiles regarding the quality improvement opportunity, level of confidence in the evidence, differences of opinion, intentional vagueness, and any exclusion to which the action statement does not apply. New key action statements were developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision

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support (BRIDGE-Wiz, Yale Center for Medical Informatics, CT) software was used to facilitate creating actionable recommendations and evidence profiles (Shiffman 2012).

The updated guideline then underwent Guideline Implementability Appraisal (GLIA) to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation (Shiffman, et al 2005). The GUG received summary appraisals and modified an advanced draft of the guideline based on the appraisal. The final draft of the updated clinical practice guideline was revised based on comments received during multidisciplinary peer review, open public comment, and journal editorial peer review. A scheduled review process will occur at five years from publication or sooner if new, compelling evidence warrants earlier consideration.

Classification of evidence-based statements

Guidelines are intended to reduce inappropriate variations in clinical care, to produce optimal health outcomes for patients, and to minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in Tables 4 and 5.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most

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opportunity for practice variability (Eddy, 1992). Clinicians should always act and decide in a way that they believe will best serve their individual patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic (AAP SCQIM, 2004).

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the GUG sought to minimize harm, diminish unnecessary and inappropriate therapy, and reduce the unnecessary use of systemic antibiotics. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

Financial disclosure and conflicts of interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call and were updated at each subsequent call and in-person meeting. After review and discussion of these disclosures (Choudry, et al, 2002), the panel concluded that individuals with potential conflicts could remain on the panel if they: (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Lastly, panelists were reminded that conflicts of interest extend beyond financial relationships, and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue (Detsky, 2006).

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397 **Table 4**. Strength of action terms in guideline statements and implied levels of obligation

Strength	**Definition**	**Implied obligation**
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (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.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (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.	Clinicians should also generally follow a recommendation, but should remain alert to new information and sensitive to patient preferences and modifying factors.

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Option	An option means that either the quality of evidence is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

*See Table 5 for definitions of evidence grades

Table 5. Aggregate grades of evidence by question type (Rosenfeld 2013, CPG Manual)

Grade	**Treatment**	**Diagnosis**	**Prognosis**
A	Systematic review‡ of randomized trials	Systematic review‡ of cross-sectional studies with consistently applied reference standard and blinding	Systematic review‡ of inception cohort studies†
B	Randomized trials, or observational studies with dramatic effects or highly consistent	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies†

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	evidence		
C	Non-randomized or historically controlled studies, including case-control and observational studies	Non-consecutive studies, case-control studies, or studies with poor, non-independent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

†A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition, or before the condition develops

‡A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision

Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: a key action statement in bold, followed by the strength of the recommendation in italics. Each key action statement is followed by an 'action statement profile' that explicitly states the quality improvement opportunity (and corresponding National Quality Strategy priority),(US Dept. HHS 2012) aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, harms, risks, costs and a benefits-harm assessment.

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412 Additionally, there are statements of any value judgments, the role of patient preferences,
413 clarification of any intentional vagueness by the panel, exceptions to the statement, any
414 differences of opinion, and a repeat statement of the strength of the recommendation.
415 Several paragraphs subsequently discuss the evidence base supporting the statement. An
416 overview of each evidence-based statement in this guideline can be found in Table 6.
417

418 Table 6. Summary of guideline key action statements

Statement	**Action**	**Strength**
1a. Pneumatic otoscopy	The clinician should document the presence of middle ear effusion with pneumatic otoscopy when diagnosing OME in a child.	Strong recommendation
1b. Pneumatic otoscopy	The clinician should perform pneumatic otoscopy to assess for OME in a child with otalgia, hearing loss, or both.	Strong recommendation
2. Tympanometry	Clinicians should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy.	Strong recommendation
3. Failed newborn hearing screen	Clinicians should document in the medical record counseling of parents of infants with OME who fail a newborn hearing screen regarding the importance of follow-up to ensure that hearing is normal when OME resolves and to exclude an underlying sensorineural hearing loss (SNHL).	Recommendation

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4a. Child at-risk	Clinicians should determine if a child with OME is at increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors (Table 3).	Recommendation
4b. Evaluating at-risk children	Clinicians should evaluate at-risk children (Table 3) for OME at the time of diagnosis of an at-risk condition and at 12 to 18 months of age (if diagnosed as being at-risk prior to this time).	Recommendation
5. Screening healthy children	Clinicians should *not* routinely screen children for OME who are not at-risk and do not have symptoms that may be attributable to OME, such as hearing difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort.	Recommendation (against)
6. Patient education	Clinicians should educate families of children with OME regarding the natural history of OME, need for follow-up, and the possible sequelae.	Recommendation
7. 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 3 months from the date of diagnosis (if onset is unknown).	Strong recommendation
8a. Steroids	Clinicians should recommend against using intranasal steroids or systemic steroids for treating OME.	Strong recommendation (against)
8b. Antibiotics	Clinicians should recommend against using systemic antibiotics for treating OME.	Strong recommendation (against)

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8c. Antihistamines or decongestants	Clinicians should recommend against using antihistamines, decongestants, or both for treating OME.	Strong recommendation (against)
9. Hearing test	Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer OR for OME of any duration in an at-risk child.	Recommendation
10. Speech and language	Clinicians should counsel families of children with bilateral OME and documented hearing loss about the potential impact on speech and language development.	Recommendation
11.Surveillance of chronic OME	Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.	Recommendation
12a. Surgery for children under age 4 years	Clinicians should recommend tympanostomy tubes when surgery is performed for OME in a *child under age 4 years*; adenoidectomy should not be performed unless a distinct indication (e.g., nasal obstruction, chronic adenoiditis) exists other than OME.	Recommendation
12b. Surgery for children age 4 years and older	Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for OME in a *child aged 4 years or older*.	Recommendation
13. Outcome assessment	When managing a child with OME clinicians should document in the medical record resolution of OME, improved hearing, or improved quality of life (QOL)	Recommendation

419 OME, otitis media with effusion

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The role of patient, parent, and/or caregiver preferences in making decisions deserves further clarification. For some statements, where the evidence base demonstrates clear benefit, although the role of patient preference for a range of treatments may not be relevant (such as with intraoperative decision-making), clinicians should provide patients with clear and comprehensible information on the benefits. This will facilitate patient understanding and shared-decision-making, which in turn leads to better patient adherence and outcomes. In cases where evidence is weak or benefits unclear, the practice of shared decision-making, again where the management decision is made by a collaborative effort between the clinician and an informed patient, is extremely useful. Factors related to patient preference include (but are not limited to) absolute benefits (number needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

STATEMENT 1a: PNEUMATIC OTOSCOPY: The clinician should document the presence of middle ear effusion with pneumatic otoscopy when diagnosing otitis media with effusion (OME) in a child. *Strong recommendation based on systematic review of diagnostic studies with a preponderance of benefit over harm.*

STATEMENT 1b: The clinician should perform pneumatic otoscopy to assess for otitis media with effusion (OME) in a child with otalgia, hearing loss, or both. *Strong recommendation based on systematic review of diagnostic studies with a preponderance of benefit over harm.*

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Action Statement Profile for Statement 1

- Quality improvement opportunity: To improve diagnostic accuracy for OME with a readily available, but likely underutilized, means of assessing middle ear status (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade A, systematic review of cross-sectional studies with a consistent reference standard
- Level of confidence in evidence: High
- Benefits: Improve diagnostic certainty; reduce false negative diagnoses caused by effusions that do not have obvious air bubbles or an air-fluid level; reduce false positive diagnoses that lead to unnecessary tests and costs; readily available equipment; document mobility of the tympanic membrane; efficient; cost-effective
- Harms, risks, costs: Costs of training clinicians in pneumatic otoscopy; false positive diagnoses from non-intact tympanic membrane; minor procedural discomfort
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Pneumatic otoscopy is underutilized for diagnosing OME, especially in primary care settings; accurate diagnosis of OME using pneumatic otoscopy is a prerequisite for managing children with OME.
- Intentional vagueness: None
- Role of patient preferences: Very limited
- Exclusions: None
- Policy level: Strong recommendation

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- Differences of opinion: None

Supporting Text

The purpose of this statement is to improve diagnostic accuracy for OME by encouraging pneumatic otoscopy as the primary diagnostic method. Accurate diagnosis is important to avoid false negative findings, because OME can be relatively asymptomatic and have a normal appearing tympanic membrane. Conversely, pneumatic otoscopy can help avoid false positive diagnoses caused by surface changes or abnormalities in the tympanic membrane without middle ear effusion.

Prior guidelines on managing OME (Stool 1994, Rosenfeld 2004) have emphasized the need to accurately diagnose OME and to differentiate OME from AOM. The hallmark of both conditions is fluid in the middle ear cavity; however AOM is associated with a bulging tympanic membrane and acute inflammation (pain, fever, erythema, otorrhea) whereas in OME the tympanic membrane may appear normal and there are no signs or symptoms of acute inflammation. Pneumatic otoscopy is especially useful in diagnosing OME because the tympanic membrane can be in a neutral or retracted position and the only sign of effusion can be reduced mobility.

Pneumatic otoscopy has been recommended as the primary method for diagnosing OME because reduced tympanic membrane mobility correlates most closely with the presence of fluid in the middle ear (Rosenfeld 2004). Even if bubbles or an air-fluid level are seen behind the tympanic membrane on initial examination, pneumatic otoscopy is

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confirmatory and can differentiate surface abnormalities from true middle ear effusion. A systematic review of nine methods for diagnosing OME (Shekelle 2003) showed that pneumatic otoscopy had the best balance of sensitivity (94%) and specificity (80%) compared to myringotomy as the gold standard. An additional study (Jones 2003) found that pneumatic otoscopy can improve diagnostic accuracy for OME, even in experienced observers, but this study utilized video presentations and did not assess the observer's skill in performing the examination.

Despite well-documented benefits of pneumatic otoscopy in diagnosing OME (Shekelle 2003), and the existence of prior guidelines (Rosenfeld 2004) recommending its use, the technique is often not utilized by physicians in making the diagnosis of OME. In one study of primary care practice networks (Lannon 2011), pneumatic otoscopy was used to diagnose OME in 33% of patients. Similarly, a randomized trial of clinical decision support found that only 7% of OME seen in a large, primary care practice network was diagnosed using pneumatic otoscopy (Forrest 2013).

Interobserver variability may be a factor in the accuracy of diagnosis by pneumatic otoscopy, given the variability of training and experience among clinicians (Pichichero 2001; Steinbach 2002). The practical tips in Table 7 may help increase success in performing pneumatic otoscopy and in making the procedure comfortable for children. When pneumatic otoscopy is inconclusive, tympanometry can be used to improve diagnostic accuracy, as outlined in the next key action statment.

Table 7. Practical tips for performing pneumatic otoscopy

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Pneumatic Otoscopy Tip	**Rationale**
After attaching the speculum to the otoscope, squeeze the pneumatic bulb fully, then firmly cover the tip of the speculum with your finger and let go of the bulb.	The bulb should stay compressed after unblocking the speculum if there are no air leaks; if the bulb opens (e.g., the pressure is released), check the speculum for a tight fit and the bulb and tubing for leaks.
Choose a speculum that is slightly wider than the ear canal to obtain an air-tight seal.	A speculum that is too narrow cannot form a proper seal and will give false-positive results.
Before inserting the speculum squeeze the pneumatic bulb halfway (about 50% of the bulb width), then insert it into the canal.	Squeezing the bulb first allows the examiner to apply both negative pressure (by releasing the bulb) and positive pressure (by further squeezing).
Insert the speculum deep enough into the ear canal to obtain an air-tight seal, but not deep enough to cause pain.	Limiting insertion to the cartilaginous (outer) portion of the ear canal is painless, but deep insertion that touches the bony ear canal and periosteum can be very painful.
Examine tympanic membrane mobility by squeezing and releasing the bulb *very slightly and very gently* several times.	Many children have negative pressure in their middle ear space, so both positive (squeezing the bulb) and negative (releasing the bulb) pressure are needed to fully assess mobility. Using slight and gentle pressure will avoid unnecessary pain.
Diagnose OME when movement of the tympanic membrane is sluggish dampened, or restricted; complete absence of mobility is not required.	When OME is absent the tympanic membrane will move briskly with minimal pressure. Motion is reduced substantially with OME, but with enough pressure some motion is almost always possible.

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STATEMENT 2: TYMPANOMETRY. Clinicians should obtain tympanometry in children with suspected otitis media with effusion (OME) for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy. *Strong recommendation based on extrapolation of systematic reviews of diagnostic studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 2

- Quality improvement opportunity: Improve diagnostic accuracy for OME and raise awareness regarding the value of tympanometry as an objective measure of middle ear status (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade B, Extrapolation from systematic review of cross-sectional studies with a consistent reference standard for tympanometry as a primary diagnostic method
- Level of confidence in evidence: High regarding the value of tympanometry for primary diagnosis; medium regarding the value as an adjunct to pneumatic otoscopy
- Benefits: Improved diagnostic accuracy; confirm a suspected diagnosis of OME; obtain objective information regarding middle ear status; differentiate OME (normal equivalent ear canal volume) vs. tympanic membrane perforation (high equivalent ear canal volume); obtain prognostic information on likelihood of

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timely spontaneous resolution (e.g., a flat, or type B, tracing has the poorest prognosis); educational value in confirming pneumatic otoscopy findings

- Harms, risks, costs: Cost; lack of access; equipment calibration and maintenance; misinterpretation of findings
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The individual who performs tympanometry is not specified, and could be the clinician or another health professional; whether to use portable or table top tympanometry is at the discretion of the clinician
- Role of patient preferences: Limited
- Exclusions: Patients with recent ear surgery or trauma.
- Policy level: Strong recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to promote tympanometry as an objective tool in diagnosing OME, both for confirming pneumatic otoscopy findings and as an alternative to otoscopy when visualization of the membrane is limited. Tympanometry can also objectively assess tympanic membrane mobility for patients who are difficult to examine, or do not tolerate insufflation.

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Understanding Tympanometry

Tympanometry provides an objective assessment of tympanic membrane mobility, eustachian tube function, and middle ear function by measuring the amount of sound energy reflected back when a small probe is placed in the ear canal [Onusko 2004]. The procedure is usually painless, relatively simple to perform, and can be done using a portable screening unit or a diagnostic desktop machine. A tympanogram (Figure 4) is a graph of energy admitted to the tympanic membrane and middle ear in response to air pressure introduced to the ear canal. Acoustic energy is transmitted to the ear canal and an internal microphone measures the reflected sound while the pressure is varied from negative to positive. The effect on middle ear function can then be recorded graphically.

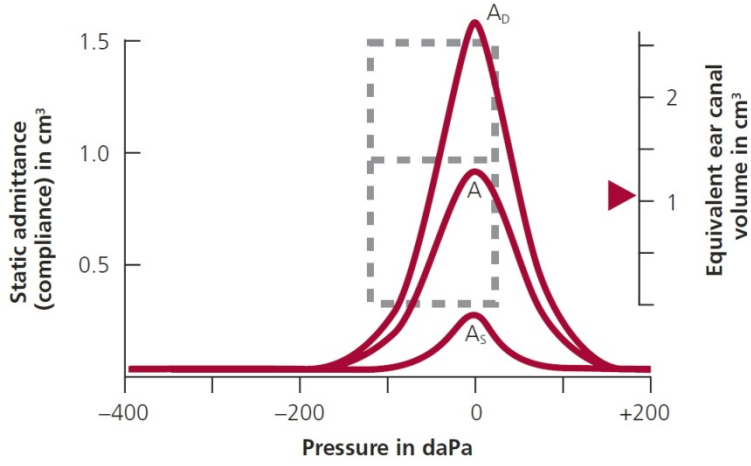

Figure 4. Normal, type A tympanogram result. The height of the tracing may vary, but is normal when the peak falls within the two stacked rectangles. The A_D tracing (upper) indicates an abnormally flexible tympanic membrane and the A_S tracing (lower) indicates an abnormally stiff tympanic membrane; the presence of a well-defined peak, however, makes the likelihood of effusion low. With permission from Onusko 2004.

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566 Tympanometric curves, or tracings, are classified into three main types: type A
567 (low probability of effusion) with a sharp peak and normal middle ear pressure, type B
568 (high probability of effusion, Figure 5) with no discernible peak and a flat tracing, and
569 type C (intermediate probability of effusion) with a discernible peak and negative middle
570 ear pressure. While subjective typing of tympanograms is often used (e.g., A, B, and C),
571 measuring static admittance and peak pressure is more objective (Figure 4). Static
572 admittance (Y) is the amount of energy absorbed by the TM and middle ear, measured in
573 mmho or mL. Peak tympanometric air pressure estimates the middle ear pressure, which is
574 normally around zero and is expressed in decaPascals (daPa) or mmH_20.

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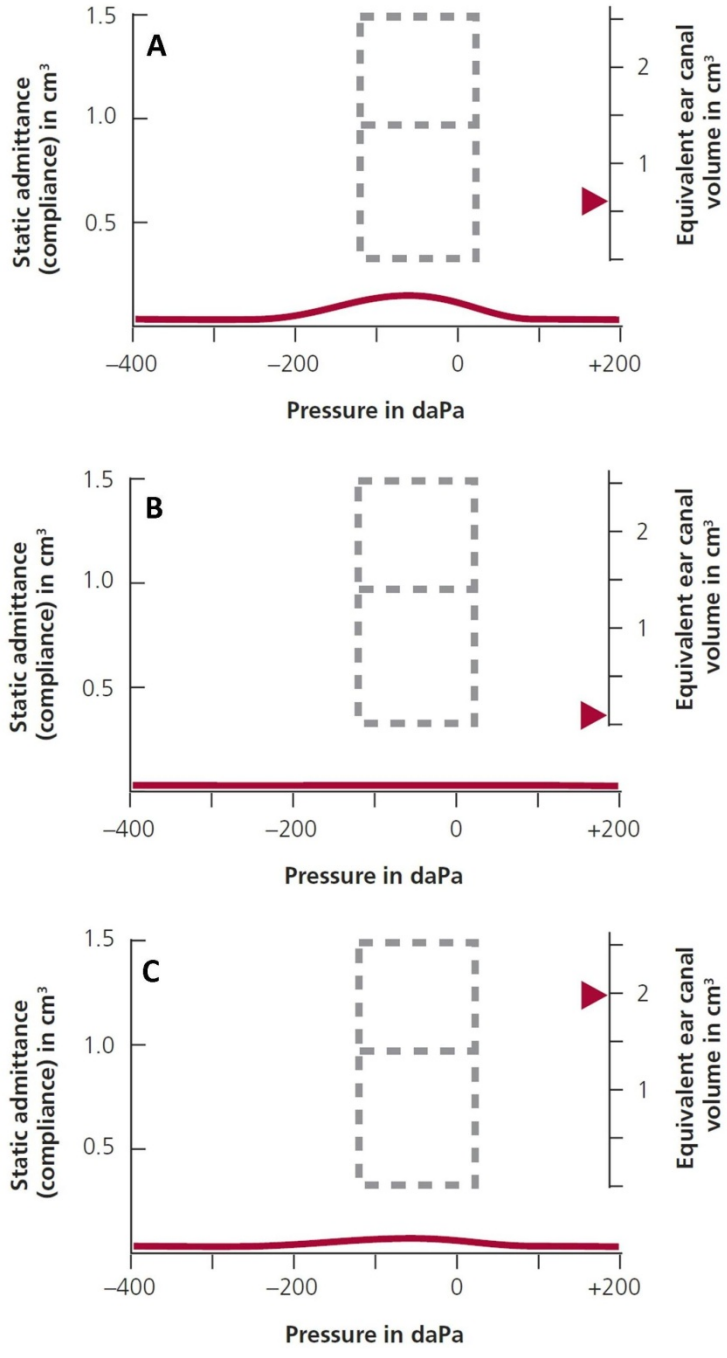

576

577 **Figure 5**. Abnormal, type B, tympanogram results. (A) A normal equivalent ear canal

578 volume usually indicates middle ear effusion, (B) a low volume indicates probe

579 obstruction by cerumen or contact with the ear canal, and (C) a high volume indicates a

patent tympanostomy tube or a tympanic membrane perforation. With permission from Onusko 2004.

Prior to performing tympanometry, the ear canal should be examined with otoscopy to assess for cerumen blockage, foreign bodies, drainage, TM perforation, or a collapsed canal. This will help the examiner correlate the findings with the tympanometry results. Proper calibration of the tympanometer is essential for accurate results.

Tympanometry as an Adjunct to Pneumatic Otoscopy

Tympanometry is a useful adjunct to pneumatic otoscopy because it provides objective evidence of middle ear status. Although recommended as a first-line diagnostic test for OME, pneumatic otoscopy has varying degrees of validity and accuracy in routine clinical practice. All studies examining test performance of pneumatic otoscopy have used experienced otoscopists with special training, validation, or both. In contrast, most often OME is diagnosed by primary care providers who are not validated against experienced otoscopists and often do not use a pneumatic attachment (Forrest 2013, Lannon 2011).

There are no specific studies that validate the performance characteristics of tympanometry as a confirmatory, or adjunctive, test with pneumatic otoscopy. We therefore recommend tympanometry when the diagnosis of OME is uncertain after using, or attempting, pneumatic otoscopy. Specific situations for which tympanometry is recommended include:

- Child intolerance of pneumatic otoscopy

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- Inability to reliably perform pneumatic otoscopy because of training or equipment considerations (e.g., inability to obtain an air-tight seal)
- Difficulty visualizing the tympanic membrane because of partially obstructing cerumen that cannot be readily removed by the clinician
- Difficulty visualizing the tympanic membrane because of a very narrow or stenotic external auditory canal (e.g., Down syndrome)
- Uncertainty about the presence or absence of OME because of equivocal findings on pneumatic otoscopy
- Need or desire to rule out OME in an at-risk (Table 3) child
- Need or desire for objective confirmation of OME before surgery

Interpretation of Tympanometry and Limitations

Proper interpretation of a type B result must consider the equivalent ear canal volume (Figure 5), which is displayed on the tympanogram printout and estimates the amount of air in front of the probe. A normal ear canal volume for children is between 0.3 and 0.9 cm [ASHA 1997], and usually indicates OME when combined with a type B result. A low equivalent ear canal volume can be caused by improper placement of the probe (e.g., pressing against the ear canal) or by obstructing cerumen. A high equivalent ear canal volume occurs when the tympanic membrane is not intact because of a perforation or tympanostomy tube. When a patent tympanostomy tube is present the volume is typically between 1.0 and 5.5 cc [ASHA 1997].

A systematic review of 52 diagnostic studies against the gold standard of myringotomy found that tympanometry, using either portable or professional (desktop)

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626 units, had sensitivity equivalent to pneumatic otoscopy for detecting OME (90 to 94%),
627 but substantially lower specificity (50 to 75% for tympanometry, 80% for otoscopy)
628 [Takata et al 2003]. Adding width measurement (Type B, or broad tympanogram) to peak
629 admittance (Type A_S or shallow tympanogram) improves sensitivity, but using peak
630 admittance alone results in lower sensitivity (67%). Abnormal tympanometric width (250
631 daPa or greater) combined with low peak admittance had a sensitivity of 83% and
632 specificity of 87% when compared to a myringotomy gold standard [Nozza 1994].
633 In infants under 6 months of age, tympanometry using a standard 226-Hz probe
634 tone is insensitive to MEE [Paradise 1976, Marchant, 1986, Hunter 2008], thus a higher
635 frequency probe tone (1000-Hz) is recommended [JCIH, 2007]. In neonate ears with
636 confirmed middle ear disease, 226-Hz tympanograms are not reliably different from those
637 obtained from normal ears. Current evidence from comparative studies using CT scanning
638 and auditory brainstem response testing shows that tympanometry using higher probe-tone
639 frequencies (e.g.., 1000-Hz) is more sensitive to OME in infants less than 6 months old
640 [Baldwin 2006] [Zhiqi 2010].
641

642 **STATEMENT 3: FAILED NEWBORN HEARING SCREEN: Clinicians should**
643 **document in the medical record counseling of parents of infants with otitis media**
644 **with effusion (OME) who fail a newborn hearing screen regarding the importance of**
645 **follow-up to ensure that hearing is normal when OME resolves and to exclude an**
646 **underlying sensorineural hearing loss (SNHL).** *Recommendation based on*
647 *observational studies with a predominance of benefit over harm.*

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Action Statement Profile for Statement 3

- Quality improvement opportunity: Increase adherence to follow-up and ensure that an underlying SNHL is not missed (National Quality Strategy domains: care coordination, patient and family engagement)
- Aggregate evidence quality: Grade C, Indirect observational evidence on the benefits of longitudinal follow-up for effusions in newborn screening programs and the prevalence of SNHL in newborn screening failures with OME
- Level of confidence in evidence: Medium
- Benefits: More prompt diagnosis of SNHL; earlier intervention for hearing loss; reduce loss to follow-up; reassure parents
- Harms, risks, costs: Time spent in counseling; parental anxiety from increased focus on child hearing issues
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The method and specifics of follow-up are at the discretion of the clinician, but should seek resolution of OME within 3 months of onset, or, if not known, diagnosis
- Role of patient preferences: Minimal role regarding the need for counseling but a large role for shared decision-making in the specifics of how follow-up is implemented and in what specific care settings
- Exclusions: None
- Policy level: Recommendation

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- Differences of opinion: None

Supporting Text

The purpose of this statement is to reduce the chance of a missed or delayed diagnosis of sensorineural hearing loss (SNHL) because a failed newborn hearing test result is attributed to OME without further investigation. We stress the importance of patient follow-up after a failed newborn screening and the need to educate parents and caregivers regarding the reasons for failure and the potential causes of hearing loss. Universal newborn screening for hearing loss is based on the premise that intervention before age 6 months can reduce the potential detrimental effects of hearing loss on speech and language acquisition (Witman-Price 2002, Calderon 1999, Kennedy 2006, Moeller 2000).

OME is an important cause of transient, moderate hearing loss in newborns that can result in a failed newborn hearing screen. In a prospective study of screening failures referred for further testing, 55% of children had OME of which 23% had spontaneous resolution of effusion (Boudewyns 2011). In the remaining infants, hearing normalized after tympanocentesis or placement of ventilation tubes, but only 69% of children had immediate return. Conversely, 31% had delayed return of hearing over several months, with a median of 4.8 months for all children combined. This study highlights that persistent hearing loss after surgery for OME does not necessarily imply SNHL, but may be the result of residual (or recurrent) OME or of delayed normalization of middle ear function.

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Although many infants who fail screening because of transient OME will normalize within several months of effusion resolution (Boudewyns 2011), some will be diagnosed with an underlying SNHL. A cohort study of screening failures with OME found that 11% had SNHL in addition to the transient conductive hearing loss from the effusion (Boone 2005). About two-thirds of failures were initially attributed to OME and one-third of children required tympanostomy tubes to resolve the fluid.

Since the 1993 National Institutes of Health (NIH) Consensus (NIH, 1993), and the Joint Commission on Infant Hearing 2000 Position Statement on infants with hearing loss that was updated in 2007 (JCIH, 2007), a concerted effort has been made to identify newborns with hearing loss and all newborns are routinely screened for hearing loss before leaving the hospital. Despite universal hearing screening programs, delays in follow-up of more than 2 months do occur between a failed newborn hearing screen and the first diagnostic auditory brainstem response (Holte, 2012). Some of the reasons cited by parents are: too many screenings, family chose to wait, or the family was assured that the failed screening was likely caused by something other than permanent hearing loss (e.g. OME). This last reason highlights the importance of not assuming that OME, if present, is always the cause of hearing loss.

Barriers to follow-up after a failed newborn hearing screen have been widely studied (Moeller 2006, Harrison 1996, Folsom 2000, Coplan 1997, Dalzell 2000) and include: limited access to pediatric audiologists and/or centers; presence of other medical co-morbidities that may delay ability to follow-up; presence of mild or unilateral hearing loss; and families' belief that their child is hearing adequately after observing their

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response to sounds in their environment. Clinicians who manage children who fail newborn screening should be aware that in one study about two-thirds *did not* return for follow-up testing. (Korres 2008) Involving parents in shared decision-making to emphasize the importance of follow-up, the options for follow-up, and to discuss the barriers to follow-up, may improve adherence to follow-up recommendations.

The following considerations apply to managing infants with OME that persists after a failed newborn hearing screen:

- Referral to an otolaryngologist is appropriate for all infants with documented persistent hearing loss after a failed newborn hearing screen, even if the cause is presumed to be secondary to OME.
- For those infants age 6 months or older with documented bilateral OME for 3 months or longer and documented hearing difficulties, clinicians should offer tympanostomy tubes (Rosenfeld 2014).
- Insertion of tympanostomy tubes to resolve effusion and facilitate better assessment of hearing status may also be appropriate on an individualized basis for children with severe hearing loss (which cannot be attributed completely to OME), a past history of congenital SNHL in the immediate family, or an at-risk status as defined in Table 3.
- The decision as to whether or not to insert tympanostomy tubes should be shared with, and explained to, patients and their families.

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733 The list of frequently asked questions in Table 8 can be distributed to parents and
734 caregivers to fulfill the obligation of counseling regarding the importance of follow-up to
735 ensure that hearing is normal when OME resolves and to exclude an underlying SNHL.

736 **Table 8**. Frequently asked questions: Ear fluid and newborn hearing screening

Question	**Suggested response**
How many babies who fail their newborn hearing screen will really have hearing loss?	Only a very small number of babies who fail will have permanent hearing loss; overall, only about 2 or 3 of every 1,000 children in the United States are born deaf or hard of hearing.
How common is middle ear fluid in children who fail a hearing screen?	Middle ear fluid is a very common cause of a failed newborn hearing screen and is found in about 6 out of every 10 children who fail. The fluid will often go away on its own in the first few months of life, but if it does not, it may require help from a doctor to remove it.
Can I assume that middle ear fluid is the reason for the failed test?	No. The newborn hearing screen cannot determine the cause of hearing loss. About 90% of the time, hearing loss goes away when the fluid does, but 10% of children may still have a hearing loss that need further medical attention. For this reason, it is very important to retest your child's hearing after fluid is gone.
If my child gets ear tubes, how long will it take before the fluid's effect on hearing goes away?	For about 70% of children, hearing loss caused by fluid will go away right after the tubes are in place; however, for about 30% of children, it could take up to several months before hearing improves. So if your child still has some hearing loss after getting tubes, keep in mind that hearing could still improve over time.
Are some babies more likely to have	Middle ear fluid is more common in children with an abnormal roof of their mouth (called "cleft palate"), those with atypical face shape or skull bones,

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problems with middle ear fluid than others?	or with those who have certain inherited (genetic) problems.
If my baby seems to hear normally, can the tests be wrong?	Parent assessment of child hearing is not always accurate, so it is important to have the child's hearing professionally tested. Just because a baby reacts to sounds does not mean the child has full range of hearing; a baby may hear certain sounds but not others. Only a professional hearing test that checks each ear separately can accurately tell how your child hears.

OME = otitis media with effusion

STATEMENT 4a. IDENTIFYING AT-RISK CHILDREN: Clinicians should determine if a child with otitis media with effusion (OME) is at increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors (Table 3). *Recommendation based on observational studies with a preponderance of benefit over harm.*

STATEMENT 4b. EVALUATING AT-RISK CHILDREN: **Clinicians should evaluate at-risk children (Table 3) for otitis media with effusion (OME) at the time of diagnosis of an at-risk condition and at 12 to 18 months of age (if diagnosed as being at-risk prior to this time).** *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statements 4a and 4b

- Quality improvement opportunity: Raise awareness of a subset of children with OME (Table 2) who are disproportionately affected by middle ear effusion

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compared to otherwise healthy children and to detect OME in at-risk children that might have been missed without explicit screening but could affect their developmental progress (National Quality Strategy domain: population/public health)

- Aggregate evidence quality: Grade C, observational studies regarding the high prevalence of OME in at-risk children and the known impact of hearing loss on child development; D, expert opinion on the ability of prompt diagnosis to alter outcomes
- Level of confidence in the evidence: Medium
- Benefits: Identify at-risk children who might benefit from early intervention for OME (including tympanostomy tubes) and from more active and accurate surveillance of middle ear status; identify unsuspected OME and reduce the impact of OME and associated hearing loss on child development
- Harms, risks, costs: Direct costs of evaluating for OME (e.g. tympanometry), identifying self-limited effusions, parental anxiety, potential for overtreatment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The guideline update group assumed that at-risk children are less likely to tolerate OME than would the otherwise healthy child, and that persistent OME could limit the benefit of ongoing therapies and education interventions for at-risk children with special needs; assumption that early identification of OME in at-risk children could improve developmental outcomes
- Intentional vagueness: The method of evaluating for OME is not specified, but should follow recommendations in this guideline regarding pneumatic otoscopy

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and tympanometry; a time interval of 12 to 18 months is stated to give the clinician flexibility and to ensure evaluation takes place at a critical time in the child's development

- Role of patient preferences: None
- Exceptions: None
- Policy level: recommendation
- Differences of opinion: None

Supporting Text

The purpose of these statements are to (a) highlight the importance of identifying children with comorbid conditions (Table 3) that warrant prompt intervention for OME and to (b) ensure that OME is not overlooked or underdiagnosed in a susceptible population. Recognizing "at-risk" children allows for individualized intervention to reduce the potential negative impact of OME with associated hearing loss on the development of speech, language, and cognition.

As recommended in statement 4a, a clinician can "determine" if the child has an at-risk condition from the medical history and review of systems. There is no expectation that clinicians examine all children for these conditions, nor that they order specialized tests or consults on every child with OME.

Identifying At-risk Children

Though definitive studies are lacking [Rosenfeld 2004, Ruben 2011], children who are at-risk for developmental difficulties (Table 3) would likely be disproportionately

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affected by hearing problems from OME. In addition, children with permanent hearing loss, independent of OME, may have added difficulty hearing due to the OME, which could worsen existing speech and/or language delays [Ruben, 1978; Brookhouser, 1993]. Similarly, children with blindness or uncorrectable visual impairment depend on hearing more than their normal-vision counterparts [Ruben 2003], making them further susceptible to OME sequelae, including imbalance, difficulty with sound localization, communication difficulties including delayed speech and/or language development, and impaired ability to interact and communicate with others [Rosenfeld 2004].

Developmental, behavioral, and sensory disorders are not uncommon among children under the age of 17 years in the United States [Sices 2004]. Hearing loss may significantly worsen outcomes for affected children, making detection of OME and management of chronic effusion of utmost importance. Frequent MEE, caused by recurrent AOM or chronic OME (unilateral or bilateral) can degrade the auditory signal causing difficulties with speech recognition, higher-order speech processing, speech perception in noise, and sound localization [Gravel 2003].

Children with Down syndrome have an increased rate of recurrent AOM, chronic OME, poor eustachian tube function, and stenotic ear canals that can impede the assessment of tympanic membrane and middle ear status. They also have a risk of mixed or sensorineural hearing loss (Iino, 1999, Selikowitz, 1993, Raut, 2011, Park, 2012, Shott, 2006). Such risks may persist throughout childhood and may require multiple tympanostomy tube placements. Hearing assessments are recommended every 6 months starting at birth and evaluation by an otolaryngologist is recommended if middle ear status is uncertain or when hearing loss is found [Bull 2011]. Children with stenotic ear canals

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819 are best assessed using an otologic microscope every 3 to 6 months to remove cerumen
820 and detect OME [Shott, 2006].

821 Cleft palate is a common malformation with a prevalence of 1 in 700 live births
822 [Vanderas, 1987]. OME occurs in nearly all infants and children with cleft palate [Broen,
823 1996, Sheahan, 2002, Kuo 2014] because of abnormal insertions of the tensor veli
824 palatini, which causes limited ability of the eustachian tube to open actively (Flynn, 2009).
825 Chronic OME in children with cleft palate is almost always associated with conductive
826 hearing loss [Flynn, 2009]. Monitoring for OME and hearing loss should continue
827 throughout childhood, including after palate repair, because of a continued high
828 prevalence [D'Mello, 2007, Ponduri, 2009].

829 eustachian tube dysfunction not only affects children with Down syndrome and
830 cleft palate, but it is commonly associated with other craniofacial syndromes and
831 malformations involving the head and neck.

832

833 *Evaluating At-risk Children*

834 A corollary to identifying children with OME who are at-risk for developmental
835 problems is to also focus on the larger population of at-risk children who may have OME
836 that is unsuspected or overlooked. Several of the at-risk conditions in Table 3 are
837 associated with a higher prevalence of OME, including cleft palate and Down or other
838 craniofacial syndromes, but for the other listed conditions the prevalence of OME may not
839 be elevated (e.g., autism spectrum disorder, general developmental delays). The impact of
840 effusion on a child's QOL and developmental progress, however, is still
841 disproportionately higher than for a child without additional risk factor (Rosenfeld 2011).

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Explicit efforts to evaluate at-risk children with OME are important because OME, by definition, is not associated with acute inflammation. Therefore, pain, discomfort, and other ear-specific or localized symptoms may not be present. Symptoms of OME may be subtle or absent, and manifest only through poor balance, behavioral problems, school performance issues, or limited progress with ongoing speech therapy.

When OME is detected in an at-risk child, tympanostomy tubes should be offered when the likelihood of spontaneous resolution is low (e.g., type B tympanogram or persistence for 3 months or longer). [Rosenfeld 2013] For children who do not receive tympanostomy tubes, a follow up schedule to monitor OME and hearing levels should be determined based on the specific needs of the child. This may be more frequent than the 3- to 6-month intervals recommended later in this guideline for children with OME who do not have any of the risk factors in Table 3. Children should be monitored until OME resolves in all affected ears.

The GUG recommends assessing for OME at 12 to 18 months of age because this is an especially critical period for language, speech, balance, and coordination development. Children progress from single words to multiple word combinations, are able to understand many types of words, and can follow simple instructions. By 18 months of age, language and speech delays are easily discerned at office exams, and delays beyond 2.5 years of age negatively impact performance in school (McLaughlin 2011). Mild to moderate hearing loss, unilateral or bilateral, may cause academic, social, and behavioral difficulties (Bess et al 1988)(Bess & Tharpe 1986), making this time frame, a critical period for identifying OME and intervening, when warranted.

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Pneumatic otoscopy, tympanometry, or both may be used to evaluate at-risk children for OME (see Statements 1 and 2). The choice of diagnostic modality depends largely on the level of cooperation of the patient and the ability to adequately visualize the tympanic membrane. Children with Down syndrome or autism-spectrum disorder may be unable to cooperate for pneumatic otoscopy, especially if the pressure applied to assess movement startles or distresses them sufficiently. Tympanometry is often better tolerated, and provides a printed result for reference. For children with stenotic ear canals, the binocular microscope is useful for removing cerumen and visualizing the tympanic membrane. Children may rarely need to be restrained (e.g., a papoose board) or sedated for satisfactory examination.

Evaluation for OME when a child is first diagnosed as being at-risk, and again between the ages of 12-18 months, constitutes the minimum surveillance for these patients. The guideline update group agreed that ideal practice would entail surveillance every 3 to 6 months for the presence of OME or hearing loss, but this could also lead to unnecessary tests or anxiety since not all at-risk children have a higher incidence of OME. Caregivers should be made aware that changes in behavior, deteriorating balance and coordination, and poorer attention spans and increased irritability should all prompt an evaluation for OME and hearing loss.

STATEMENT 5. SCREENING HEALTHY CHILDREN: Clinicians should <u>not</u> routinely screen children for otitis media with effusion (OME) who are not at-risk and do not have symptoms that may be attributable to OME, such as hearing

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difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort. *Recommendation based on randomized, controlled trials, and cohort studies with a preponderance of harm over benefit.*

Action Statement Profile for Statement 5

- Quality improvement opportunity: Avoid unnecessary tests, and treatment, for a highly prevalent and usually self-limited condition (National Quality Strategy domains: efficient use of healthcare resources, population/public health)
- Aggregate evidence quality: Grade A, systematic review of RCTs
- Level of confidence in the evidence: High
- Benefit: Avoid unnecessary tests, avoid unnecessary treatment, limit parent anxiety
- Harms, risks, costs: Potential to miss clinically relevant OME in some children
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Role of patient preferences: Limited, but a parent can request screening if desired
- Intentional vagueness: The word "routine" is used to indicate that there may be specific circumstances where screening is appropriate, for example, a child with a strong family history of otitis media or a child who is suspected to be at-risk but does not yet have a formal at-risk diagnosis
- Exceptions: None
- Policy level: Recommendation against
- Difference of opinions: None

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Supporting Text

The purpose of this statement is to prevent unnecessary testing, subsequent visits, parental or child anxiety, and expenditure for a highly prevalent, often asymptomatic condition that is usually self-limited. This statement is directed at large-scale, population-based screening programs in which all children, regardless of symptoms, comorbidities, or other concerning factors, are screened with tympanometry or related methods. This statement does not apply to at-risk children (Table 3) or those with factors placing them at higher risk for otitis media, hearing loss, or both, as discussed in the supporting text for statements 4a and 4b.

Effective screening programs reduce disease sequelae through opportunities for early intervention. Population-based screening for OME, however, does not have benefits to justify the time, expense, and potential worries raised in children and their caregivers. (Simpson 2007, Zielhuis 1989) A systematic review (Simpson 2007) found no significant differences in comprehensive language development or expressive language in children screened for OME who underwent early intervention. In addition, screening does not improve intelligence scores, behavioral problems, or strain on the parental-child relationship. (Simpson 2007, Paradise 2001)

A recommendation against population-based screening does not mean that children should not be evaluated for OME in general. Whereas normal, healthy, asymptomatic children should not be subjected to additional time, travel, and time away from school for screening, assessing the child for OME is appropriate during routine well child visits and whenever ear-specific symptoms exist (e.g., hearing loss, ear discomfort). In addition, if a

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child has a history suggestive of worrisome school performance, behavioral problems, or imbalance, then evaluation for OME is beneficial.(Rosenfeld 2013)

Screening programs are most beneficial when sensitivity and specificity are high, such that results indicate true absence or presence of disease that will benefit from early intervention. For OME, the disease state of concern is not asymptomatic fluid, but previously undetected hearing loss or other OME-induced symptoms that would benefit from treatment. For instance, OME may occur with or without hearing sequelae, and among screened children 3-7 years of age, a type B (flat) tympanogram has a sensitivity of 65 to 92% and specificity of 43 to 80% for associated hearing loss.(MRC 1999 Clin Otolaryng) Moreover, the positive predictive value of a type B tympanogram for pure tone hearing loss worse than 25 to 30 dB is only 33 to 49%.(MRC 1999 Clin Otolaryng) Thus, it is not uncommon for OME to occur without related hearing loss, and if asymptomatic OME is identified, then the initial management is watchful waiting, not early intervention.

Screening programs should also be considered with regard to implications for the population as a whole. OME is highly prevalent condition that is found in 15 to 40% of healthy preschool children. (Paradise, et al., 1997; Williamson, et al., 1994; Sorenson, et al., 1981; Fiellau-Nikolajsen, 1983; Casselbrant, et al., 1985; Zielhuis, et al., 1989; Poulsen & Tos, 1980; Tos, et al., 1981; Thomsen & Tos, 1981). Therefore, a screening program could send up to 40% of children for additional assessment, regardless of whether symptoms might prompt intervention. Such a program would potentially result in a widely felt strain on children, families, and physicians, all without evidence of proven benefit, and is therefore not recommended.

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STATEMENT 6. PATIENT EDUCATION: Clinicians should educate families of children with otitis media with effusion (OME) regarding the natural history of OME, need for follow-up, and the possible sequelae. *Recommendation based on observational studies and preponderance of benefit over harm.*

Action Statement Profile for Statement 6

- Quality improvement opportunity: Provide clear, patient-friendly education regarding OME, its natural history, and possible sequelae to empower families for shared decisions (National Quality Strategy domain: patient and family engagement)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High
- Benefits: Reduce anxiety; facilitate shared decisions; provide parents with a fuller understanding of their child's condition; emphasize the importance of follow-up; educate families about risk factors and coping strategies
- Harms, risks, costs: Time for education
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Limited
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

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Supporting Text

The purpose of this statement is to emphasize the importance of patient and family education to improve outcomes through shared decision-making. Education should take the form of verbal and written information that addresses the common questions or concerns that family members and/or caregivers of children with OME may have. This can be readily accomplished by providing a list of frequently asked questions (Table 9) and supplementing with brief discussion. Information should be provided in a way that is sensitive to the family's language, literacy, and cultural needs.

Appropriate follow-up and monitoring is important for children with OME, as disease progression can lead to complications with a negative impact on long-term outcomes. Providing information to patients and families and including them in the decision-making process improves patient satisfaction and compliance in AOM (Merenstein 2005), and it is reasonable to generalize this to OME. Important points that should be discussed with the family of a child with OME include details regarding risk factors for developing OME, the natural history of the disease, risk of damage to the ear drum and hearing, and options for minimizing the effect of OME.

Risk Factors for Developing OME

OME is a common problem affecting more than 60% of children before 2 years of age (Casselbrant 2003). The rate is even higher in children with developmental issues such as Down syndrome or cleft palate (Flynn 2009; Maris 2014). OME may occur during or after an upper respiratory tract infection, spontaneously due to poor eustachian tube function, or as a result of AOM (Paradise 1997). A major risk factor for developing OME

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is age because of the direct correlation between angulation of the eustachian tube and age. Other factors that increase the risk of developing OME include passive smoking, male gender, and attending daycare (Todberg 2014). There is also a major genetic component up to age 5 years (Casselbrant 2004). In contrast, the risk of OME is less when infants have been breast fed, and this risk continues to decrease the longer the duration of breastfeeding (Schilder 2004).

Natural History of OME

The spontaneous resolution of OME is likely but depends on the cause and onset (Rosenfeld, 2003) . About 75% of children with OME resolve by 3 months when it follows an episode of AOM. If the OME is spontaneous and the date of onset is unknown, the 3 month resolution rate is lower, at 56%. When the date of onset is known, however, this rate increases to 90%.

Resolution rates also depend on how a successful outcome is defined. In the preceding paragraph, resolution is defined broadly as any improvement in tympanogram curve, from a type B to anything else (e.g., type A or type C). Complete resolution, defined as only a type A tympanogram, is much lower, only 42% at 3 months, when the date of onset is unknown. Episode duration is similar regardless of whether it is an initial or recurrent episode. Children with onset during the summer or fall months, have a greater than 30 dB HL hearing loss, or have a history of prior tubes are less likely to resolve the effusion spontaneously (MRC Multi-centre OMSG 2001; van Balen 2000).

Options for Minimizing Effects of OME

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Several options exist for minimizing the effects of OME in terms of hearing loss, speech and language development, and classroom learning (Table 11). Clinicians should discuss these strategies for optimizing the listening and learning environment until the effusion resolves. Speaking with the child should be done in close proximity, with clear but natural enunciation, and while facing the child directly.. Additional communication strategies may include gaining the child's attention before speaking to them, reducing background noise when possible and rephrasing or repeating information when clarification is needed. Additionally, preferential classroom seating should be provided with children moved closer to the front with the better hearing ear directed toward the instructor (Roberts 2000; Roberts 2004).

Risk Factors in Managing or Preventing OME

As noted above a variety of factors can lead to an increased risk of OME and recurrence of AOM. Numerous studies indicate that breastfeeding can decrease this risk (Schilder 2004), by transmitting antibodies from mother to child and reducing environmental allergies. Additionally, removing tobacco smoke from the child's environment is recommended as the duration of exposure appears to be linked to OME risk (Todberg 2014). Good hand hygiene and pneumococcal vaccination may reduce the development of AOM in this population as well (Pavia 2009).

Limiting pacifier use in children under age 18 months decreases the incidence of AOM by about 30% (Niemela 2000), which would also reduce the prevalence of OME that routinely follows these episodes. Despite common advice to avoid supine bottle feeding in infants to prevent otitis media, there are no well-designed studies to justify this

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claim beyond one small, observational study that showed more abnormal tympanograms when children were fed supine. (Tully 1995). Similarly, feeding infants with non-ventilated or under-ventilated bottles can generate negative pressure in the middle ear, but whether this leads to increased prevalence of OME is unknown (Brown 2000).

Medical Therapy for OME

Medical therapy is discussed in more detail later in this guideline, but for purposes of counseling parents the clinician should convey that drugs and medications are not recommended for managing OME. Antihistamines, decongestants, anti-reflux therapy, and topical nasal steroids are ineffective (Griffin 2011, Simpson 2011, Miura 2012, Berkman 2013). Orally administered steroids have short-term efficacy, but after 1 or 2 months the benefit is no longer significant (Simpson 2011, Berkman 2013). Antibiotics have a small benefit in resolving OME, but they have significant adverse effects and do not improve hearing levels or reduce the need for future surgery (van Zon 2012). Last, despite the popularity of complementary and alternative therapy , there are no randomized, controlled trials to show benefits in managing OME. (Berkman 2013)

Table 9. Frequently asked questions: Treating and managing ear fluid

Question	**Answer**
What is ear fluid?	Ear fluid, also called otitis media with effusion (OME), is a build-up of mucus or liquid behind the ear drum without symptoms of infection.
Is it possible that	Fluid often goes away on its own, so your doctor will often

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the ear fluid will just go away on its own?	recommend watchful waiting for the first 3 months. Be sure to follow-up with your doctor to make sure the fluid goes away completely
Does it matter how long the fluid has been there?	The fluid is most likely to go away quickly if it has been there less than 3 months or has a known start time, such as after a cold or ear infection. Fluid is much more likely to persist when it has been there for at least 3 months or when it is found during a regular check-up visit and the start date is unknown.
How might the ear fluid affect my child?	The most common symptoms of ear fluid are mild discomfort, fullness in the ear, and mild hearing problems. Some children also have disturbed sleep, emotional distress, delayed speech, irritability, clumsiness, balance problems, or trouble learning in school.
What can I do at home to help the fluid go away?	Keep your child away from second-hand smoke, especially in closed spaces like the car or in the house. If your child is more than 12 months old and still uses a pacifier, stopping the pacifier in the daytime may help the fluid go away.
Will medications or other therapies help the fluid go away?	Medical treatment does not work well, so you should *not* give your child antibiotics, antihistamines, decongestants, steroids (by mouth or in the nose), or drugs to reduce acid reflux. No benefits have ever been shown for chiropractic, special diets, herbal remedies, complementary medicine, or alternative (natural) therapies.
Do I still need to follow-up with my doctor, even if my child seems fine?	Yes, because the fluid may still be there and could later cause problems. Fluid that lasts a long time can damage the ear and require surgery. Also, young children often do not express themselves well, even when struggling with hearing problems or other issues related to the fluid. The best way to prevent problems is to see the doctor every 3 to 6 months until the fluid goes away.
Does the fluid	The fluid can make it harder for your child to hear, especially in a

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cause hearing loss?	group setting or with background noise, but the effect is usually small and goes away when the fluid clears up. .
How can I help my child hear better?	Stand or sit close to your child when you speak and be sure to let them see your face. Speak very clearly, and if your child does not understand something, repeat it. Hearing difficulties can be frustrating for your child, so be patient and understanding. See Table 11 for specific strategies.
Will the fluid turn into an ear infection?	The fluid cannot directly turn into an ear infection, but during a cold it increases your child's risk of getting an ear infection because the fluid makes it easier for germs to grow and spread.
Can my child travel by airplane if ear fluid is present?	If the ear is completely full of fluid there is usually no problem, but when the fluid is partial or mixed with air it can hurt when the plane is coming down. Your doctor can measure the amount of fluid with a tympanogram, which gives a flat reading when the ear is full. It may help to keep your child awake when the plane is landing and encourage him or her to chew or swallow to even out the pressure.

STATEMENT 7. WATCHFUL WAITING: Clinicians should manage the child with otitis media with effusion (OME) who is not at-risk with watchful waiting for 3 months from the date of effusion onset (if known) or 3 months from the date of diagnosis (if onset is unknown). *Strong recommendation based on systematic review of cohort studies and preponderance of benefit over harm.*

Action Statement Profile for Statement 7

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- Quality improvement opportunity: Avoid interventions with potential adverse events, and cost, for a condition that is usually self-limited (National Quality Strategy domains: patient safety, efficient use of healthcare resources)
- Aggregate evidence quality: Grade A, systematic review of cohort studies
- Level of confidence in the evidence: High
- Benefit: Avoid unnecessary referrals, evaluations, and interventions, take advantage of favorable natural history
- Harms, risks, costs: Delays in therapy for OME that persists for more than 3 months, prolongation of hearing loss
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of avoiding interventions in an often self-limited condition
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: At-risk children (Table 2), who may be offered tympanostomy tubes earlier than 3 months if there is a type B tympanogram in one or both ears (Rosenfeld 2013)
- Policy level: Strong recommendation
- Differences of opinion: None

Supporting Text

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The purpose of this statement is to avoid unnecessary referral, evaluation, and surgery in children with a short duration of OME. This recommendation is based on the self-limited nature of most OME, which has been well documented in cohort studies and in control groups of randomized trials. (Shekelle, et al., 2003; Rosenfeld & Kay, 2003) Although the likelihood of spontaneous resolution of OME is determined by the cause and duration of effusion, (Rosenfeld & Kay, 2003) it is often self-limited when preceded by common risk factors such as upper respiratory infection or AOM. (Bhutta 2014)

The natural history of OME has been well described with relation to the 3-month timeframe. OME occurring after an episode of AOM resolves in 75% to 90% of cases by the third month. (Teele, et al., 1980; Mygind, et al., 1981; Burke, et al., 1991) Among 100 children with newly diagnosed OME and a type B (flat curve) tympanogram, 56 will improve to a non-B (non-flat curve) by 3 months; 72 will have improved at 6 months, and 87 will no longer have a flat tracing at 12 months. (Rosenfeld & Kay, 2003) In contrast, among 100 children with chronic OME, 19 will resolve by 3 months, 25 by 6 months, 31 by 12 months, and 33 will no longer have a flat tracing at 24 months. (Rosenfeld & Kay, 2003) Although a type B tympanogram is an imperfect measure of OME (81 to 94% sensitivity and 74 to 94% specificity vs. myringotomy), it is the most widely reported measure suitable for deriving pooled resolution rates. (Shekelle, et al., 2003; Rosenfeld & Kay, 2003; Takata, et al, 2003)

There is little potential harm associated with a specified period of observation in the child who is not at-risk for speech, language, or learning problems. When observing children with OME, clinicians should inform the parent or caregiver that the child may

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experience reduced hearing until the effusion resolves, especially if bilateral. Clinicians may discuss strategies for optimizing the listening and learning environment until the effusion resolves (See Table 11). These strategies include speaking in close proximity to the child, facing the child and speaking clearly, repeating phrases when misunderstood, and providing preferential classroom seating. (Roberts, et al., 2000; Roberts, et al., 2004)

The recommendation for a 3-month period of observation is based on a clear preponderance of benefit over harm and remains consistent with previous guidelines and the goal of avoiding unnecessary surgery. (Stool, et al., 1994; Rosenfeld, et al., 2004) Factors to consider when determining the optimal interval(s) for follow-up include clinical judgment, parental comfort level, unique characteristics of the child and/or his/her environment, access to a health care system, and hearing levels if known.

STATEMENT 8a. STEROIDS: Clinicians should recommend against using intranasal steroids or systemic steroids for treating otitis media with effusion (OME). *Strong recommendation based on systematic review of randomized, controlled trials and preponderance of harm over benefit.*

STATEMENT 8b. ANTIBIOTICS: Clinicians should recommend against using systemic antibiotics for treating otitis media with effusion (OME). *Strong recommendation based on systematic review of randomized, controlled trials and preponderance of harm over benefit.*

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STATEMENT 8c. ANTIHISTAMINES OR DECONGESTANTS: Clinicians should recommend against using antihistamines, decongestants, or both for treating otitis media with effusion (OME). *Strong recommendation based on systematic review of randomized, controlled trials and preponderance of harm over benefit.*

Action Statement Profile for Statements 8a, 8b, and 8c

- Quality improvement opportunity: Discourage medical therapy that does not impact long term outcomes for OME (resolution, hearing levels, or need for tympanostomy tubes) but does have significant cost and potential adverse events (National Quality Strategy domain: patient safety, efficient use of healthcare resources).
- Aggregate evidence quality: Grade A, systematic review of well-designed randomized, controlled trials
- Level of confidence in the evidence: High
- Benefit: Avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse; avoid societal impact of inappropriate antibiotic prescribing on bacterial resistance and transmission of resistant pathogens.
- Harms, risks, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm (in recommending against therapy)

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- Value judgments: Emphasis on long term outcomes, based on high quality systematic reviews, even though some therapies (e.g., antibiotics, systemic steroids) have documented short-term benefits
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: Patients in whom any of these medications are indicated for primary management of a coexisting condition with OME
- Policy level: Strong recommendation (against therapy)
- Differences of opinion: None

Supporting Text

The purpose of these statements is to reduce ineffective and potentially harmful medical interventions in OME when there is no long-term benefit to be gained in the vast majority of cases. Medications have long been used to treat OME, with the dual goals of improving QOL and avoiding more invasive surgical interventions. Both the 1994 guidelines (Stool et al 1994) and the 2004 guidelines (Rosenfeld et al 2004) determined that the weight of evidence did not support the routine use of steroids (either oral or intranasal), antimicrobials, antihistamines, or decongestants as therapy for OME.

Oral and topical steroids

The AHRQ review on the use of oral steroids in the treatment of OME showed steroids to be of no significant benefit in either the resolution of the effusion or in improvement of hearing levels (Berkman 2013), and adding antibiotics further failed to improve outcomes in comparison to control patients who were either untreated or treated

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with antibiotics alone (Thomas 2006, Simpson 2011). Many of the studies cited in this Cochrane review predate the prior guidelines and additional RCTs are not available to support contrary findings.

Topical (intranasal) steroids have limited side effects, especially when compared to systemically-administered steroids. In children aged 4 to 11 years, there was no difference in the resolution of effusion or hearing loss over three months between children treated with nasal mometasone or placebo (Williamson 2009); in fact, there was an economic disadvantage in the group treated with mometasone, considering the high rate of spontaneous resolution in the placebo group. Furthermore, 7 to 22% of study group patients experienced minor adverse effects. (Williamson 2009; Simpson 2011).

There may be a short-term benefit of topical intranasal steroids in children with adenoidal hypertrophy, although the magnitude of the effect is small and dosing in one report was higher than recommended (Bargava 2014, Cengel 2006). In patients with concomitant OME and allergic rhinitis there may be a role for topical intranasal steroids, since they do target the inflammatory component of allergic rhinitis which may be a contributing factor to OME (Lack 2011).

Antibiotics

A 2012 Cochrane review (van Zon 2012) of 23 studies on the use of antibiotics, either for short- or long-term use for the treatment of OME, showed a small benefit for complete resolution of the effusion. In contrast, antibiotic therapy did not have any significant impact on hearing levels or the rate of subsequent tympansotomy tube insertion. The authors conclude that antibiotic therapy should not be used to treat OME

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because of small benefits that are offset by adverse events, bacterial resistance, and no impact on hearing levels or future surgery. These findings would not preclude using antibiotic therapy when associated illnesses are present that would benefit from antibiotics, such as acute bacterial sinusitis or group A streptococcal infection.

Antihistamines and decongestants

A systematic review of RCTs (Griffin 2011) evaluating antihistamines and/or decongestants for treating OME found good inter-study agreement on the lack of short (< 1 month), intermediate (1-3 months) or long (> 3 months) term benefit on OME resolution. Further, no evidence was found of beneficial effects on hearing, although there may be some benefit in terms of improvement of nasal and ocular allergic symptomatology (Griffin, 2011). The well-recognized adverse effects of antihistamines and decongestants in children also tend to favor the placebo group over the treatment group in several analyses (Griffin 2011).

Montelukast was not found to be effective in the clearance of middle ear effusion (Schoem,2010) A smaller study on the use of leukotriene inhibitors with or without antihistamine reported a statistically significant improvement in otoscopic sign scores for subjects using both therapies, however improvement in bilateral tympanometry findings was not significant (Ertugay 2013)

Other treatments

As in the prior guidelines (Rosenfeld 2004), there remains insufficient evidence from which to formulate a recommendation on the use of complementary and alternative

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medicine (CAM) in the treatment of OME in children. Randomized controlled studies are necessary to adequately advise on the use of CAM, but do not exist. (Berkman 2013) These studies will necessarily have to be large, given the high rate of spontaneous resolution of OME in children, and may be difficult to perform.

STATEMENT 9. HEARING TEST: Clinicians should obtain an age-appropriate hearing test if otitis media with effusion (OME) persists for 3 months or longer OR for OME of any duration in an at-risk child. *Recommendation based on cohort studies and preponderance of benefit over harm.*

Action Statement Profile for Statement 9

- Quality improvement opportunity: Obtains objective information on hearing status that could influence counseling and management of OME (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade C, Systematic review of randomized control trials showing hearing loss in about 50% of children with OME and improved hearing after tympanostomy tube insertion; observational studies showing an impact of hearing loss associated with OME on children's auditory and language skills.
- Level of confidence in the evidence: Medium
- Benefit: Detect unsuspected hearing loss; quantify the severity and laterality of hearing loss to assist in management and follow-up decisions; identify children who are candidates for tympanostomy tubes

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- Harms, risks, costs: Access to audiology, cost of the audiology assessment
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Knowledge of hearing status is important for counseling and managing children with OME and optimizing their learning environment, even if this information does not determine surgical candidacy
- Intentional vagueness: The words *age-appropriate* audiologic testing are used to recognize that the specific methods will vary with the age of the child, but a full discussion of the specifics of testing is beyond the scope of this guideline
- Role of patient preferences: Small; caregivers may decline testing
- Exceptions: None
- Policy level: recommendation
- Difference of opinion: none

Supporting Text

The purpose of this statement is to promote hearing testing in infants and children as an important factor in decision-making when OME becomes chronic or when a child becomes a candidate for tympanostomy tube insertion (Rosenfeld 2013). Age-appropriate tests are available to reliably assess hearing in all children, without requiring a minimum age for participation. Chronic OME is unlikely to resolve promptly and is associated with significant hearing loss in at least 50% of children. OME, on average, produces a 10 to 15 decibel (dB) decrease in hearing levels, which results in an average hearing level of 28 dB [Hunter 1994], [Sabo 2003] [Gravel 2006]. Despite recommendations in prior guidelines

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(Rosenfeld 2004, Rosenfeld 2013), hearing testing is infrequently performed for children with OME in primary care settings (Lannon 2011, Forrest 2013).

Unresolved OME and associated hearing loss may lead language delay, auditory problems, poor school performance and behavioral problems in young children [Hunter 1996], [Shriberg 2000], [Roberts 2004] [Gravel 2006] [Rosenfeld 2003] [Lieu 2004]. Therefore, knowledge of the child's hearing status is an important part of management and should prompt the clinician to ask questions about the child's daily functioning to identify any issues or concerns, which may be attributable to OME, that might otherwise have been overlooked (Key Action **Statement 4**).

Understanding hearing testing

Hearing testing by an audiologist is needed to determine the degree, type and laterality of hearing loss to assess the functional impact of OME on a child's hearing. The degree of hearing impairment is based primarily on the accurate measurement of hearing thresholds, and secondarily by parent and school (teacher) reports describing the perceived hearing ability of the child. Objective assessment of hearing is necessary because parent assessment is inaccurate (Brody 1999) and hearing loss cannot not be predicted based on factors such as Down syndrome or other craniofacial anomalies. [Sidell, 2014]

The American Academy of Pediatrics [Harlor 2009] identified several key points relevant to hearing assessment in children that, although not related exclusively to OME, are worthy of summary here:

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- Any parental concern about hearing loss should be taken seriously and requires an objective hearing screening of the patient.
- All providers of pediatric health care should be proficient with pneumatic otoscopy and tympanometry; however, neither of these methods assess hearing.
- Developmental abnormalities, level of functioning, and behavioral problems may preclude accurate results on routine audiometric screening and testing. In this situation, referral to an otolaryngologist and audiologist should be made.
- The results of abnormal screening should be explained carefully to parents, and the child's medical record should be flagged to facilitate tracking and follow-up.
- Any abnormal objective screening result requires audiology referral and definitive testing.

Impact of OME on hearing levels

Hearing is measured (Figure 4) in dB (Figure 1), with a mean response greater than 20 dB hearing level (HL) indicating some degree of hearing loss for children [ASHA 1997]. OME impairs sound transmission to the inner ear by reducing mobility of the tympanic membrane and ossicles, thereby reflecting acoustic energy back into the ear canal instead of allowing it to pass freely to the cochlea [Marsh 1985]. The impact of OME on hearing ranges from normal hearing up to a moderate hearing loss (0 to 55 dB HL) [Sabo 2003] [Gravel 2003]. The average hearing loss associated with OME in

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children is 28 dB HL, while a lesser proportion (approximately 20%) exceed 35 dB HL [Hunter, 1994] [Gravel 2003].

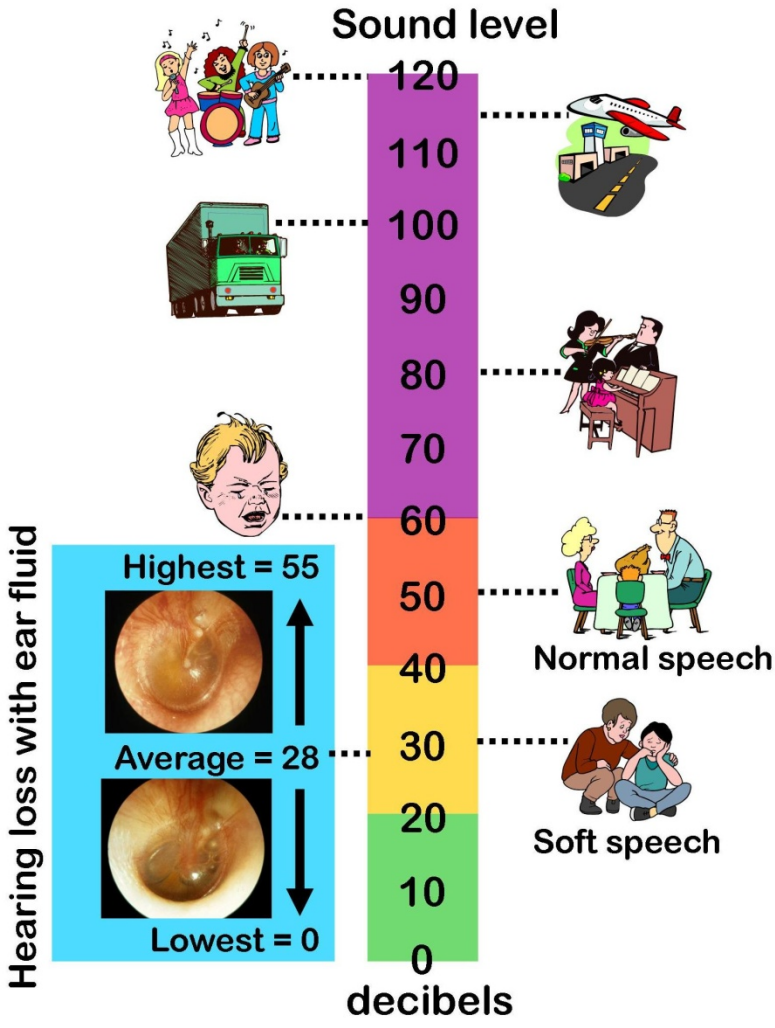

Figure 4. An average hearing level between 0 and 20 dB is normal (green), 21 to 40 is a mild hearing loss (yellow), 41 to 60 is a moderate loss (red), and 61 dB or higher is severe loss (purple). A child with average hearing loss from MEE in both ears (28dB) would

barely hear soft speech, with some children barely aware of normal speech or a baby crying. With permission, Rosenfeld 2005. A Parent's Guide to Ear Tubes.

Methods of hearing testing

The preferred method of hearing assessment is age-appropriate audiologic testing through conventional audiometry, comprehensive audiological assessment, frequency-specific auditory evoked potentials (auditory brainstem response to tone bursts or auditory steady-state response) [Harlor 2009, Rosenfeld 2004]. Typically-developing children age 4 years and older may be sufficiently mature for conventional audiometry, where the child raises his or her hand when a stimulus is heard. This can be done in the primary care setting using a fail criterion of >20 dB HL at one or more frequencies (500, 1000, 2000, 4000 Hz) in either ear.

Comprehensive audiologic evaluation by a licensed audiologist is recommended for children ages 6 months to 4 years and for any child who fails conventional audiometry in a primary care setting (Harlor 2009). Visual response audiometry (VRA) is typically used to assess hearing in children ages 8 months to 2.5 years, and has been shown to provide reliable results in infants as young as 6 months when performed by audiologists [Widen et al 2000, Gravel 2003]. It is performed by an audiologist, during which the child learns to associate speech or frequency-specific stimuli with a reinforcer, such as a lighted toy or video clips. Children ages 2.5 to 4 years are assessed using play audiometry, by having the child perform a task (e.g., placing a peg in a pegboard or dropping a block in a box) in response to a stimulus tone.

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Ear-specific information on hearing can usually be obtained by an audiologist using play audiometry or visual response audiometry with earphones. Some children, under developmental age 4 years, may not tolerate headphones or ear inserts during a hearing test. As an alternative, the test can be performed using loudspeakers in the audiology booth and thus, the result primarily reflects performance of the better hearing ear.

Clinicians should appreciate that hearing levels, as measured in dB, are a logarithmic scale of intensity. For every 3 dB increase there is a doubling in sound intensity levels. Therefore, a child with OME and an average HL of 28 dB would experience nearly an 8-fold decrease in sound intensity compared to a child with normal hearing of 20 dB. Therefore, any child with a detected hearing loss prior to tympanostomy tube insertion should have postoperative testing to confirm resolution of hearing loss that was attributed to OME, and to assess for an underlying sensorineural hearing loss.

Management of hearing loss

Knowledge of hearing levels in each ear individually will influence management for unilateral OME: e.g., listening strategies, preferential seating in the classroom, monitoring for andincrease in hearing loss or involvement of the better ear over time. Hearing levels are also important in assessing tube candidacy (Rosenfeld 2013) and in decision-making during OME surveillance (as defined later in this guideline).

At-risk infants and children

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At-risk children with OME (Table 3) require more frequent hearing assessment and prompt management to prevent additional impact on developmental outcomes. This category includes children with speech-language or academic delay, children with developmental disability of any cause, especially Down syndrome and other craniofacial anomalies in which OME is very common and persistent. Children in these categories should receive otologic and hearing screening or assessment when the speech-language delay is identified to allow prompt treatment for OME. Hearing should be re-assessed following medical or surgical treatment, at ongoing intervals (at least annually), or as recommended in relevant clinical practice guidelines.

STATEMENT 10. SPEECH AND LANGUAGE: Clinicians should counsel families of children with bilateral otits media with effusion (OME) and documented hearing loss about the potential impact on speech and language development.

Recommendation based on observational studies and preponderance of benefit over harm.

Action Statement Profile for Statement 10

- Quality improvement opportunity: Raise awareness of the potential impact of hearing loss secondary to OME on a child's speech and language and facilitate caregiver education (National Quality Strategy domains: patient and family engagement, care coordination)
- Aggregate evidence quality: Grade C, observational studies; extrapolation of studies regarding the impact of permanent mild hearing loss on child speech and language

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- Level of confidence in the evidence: Medium
- Benefit: Raise awareness among clinicians and caregivers; educate caregivers; identify and prioritize at-risk children for additional assessment
- Harms, risks, costs: Time spent in counseling
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Group consensus that there is likely an under-appreciation of the impact of bilateral hearing loss secondary to OME on speech and language development
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

Supporting Text

The purpose of this statement is to highlight the importance of counseling families about the potential effect that hearing loss associated with OME can have on speech and language development (Casby 2001, Roberts 2004). The effect of OME is greatest when repeated or persistent episodes occur during early childhood. Clinicians can use the information in Table 10 to facilitate a discussion about how bilateral OME with hearing loss might affect speech and language development.

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1388 **Table 10**. Counseling information on OME, speech, and language development

Otitis Media with Effusion (OME): Also called ear fluid, OME can affect your child's ability to hear normally. This hearing loss could affect speech and language development in some children, especially when the fluid is in both ears and lasts a long time. This information will help you better understand how ear fluid might affect your child.
Your Child's Speech: *Speech* (sometimes called *articulation*) is the physical production of sounds in sequence to form words. Children with delayed speech may omit sounds or substitute easy sounds for harder sounds (i.e., t/s as in "I tee the tun in the ty."). These errors can affect the clarity of your child's speech. *Findings that Suggest Delayed Speech Development* • Your child doesn't babble using consonants (particularly b, m, d, and n) by 9 months. • Your child uses mostly vowel sounds and gestures after 18 months. • Your child's speech is hard to understand at the age of 3 years. • Your child frequently leaves out or adds consonants in words at the age of 3 years. • Your child is not able to produce most sounds by the age of 5 or 6.
Your Child's Language: *Language* is the meaning or message conveyed back and forth through speech, writing, or even gestures. *Receptive language* is the ability to understand what others say. Children with delayed receptive language may have difficulty, compared to other children, following directions or understanding the words or sentence structures used by others. *Expressive language* is the ability to choose the right words when communicating, and then put the words together appropriately for sentences and meaning. Children with delayed expressive language may have short utterances or sentences. *Findings that Suggest Delayed Language Development* • Your child does not use any single words by 16 to 18 months. • Your child cannot follow simple instructions, such as "Give me your shoe," or cannot point to body parts or common objects following a verbal request by 18 months. • Your child does not use 3-4 word utterances by the age of 2 years.

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- Your child does not communicate with complete sentences by the age of 3 years.
- Your child's sentences are still short or noticeably incorrect at the age of 4 years.

What You Can Do: If there are delays in your child's speech or language development because of fluid, these delays usually disappear once the ear fluid goes away on its own or ear tubes are inserted. If a delay persists, your child should be referred to a speech-language pathologist for evaluation and treatment, as necessary. Reading to or with your child is also important because reading and spelling are strongly linked to speech and language development.

- Additional information on typical speech and language development in children can be found at: http://www.asha.org/public/speech/development/.
- Additional information on helping your child with reading and writing can be found at: http://families.naeyc.org/everyday-steps-to-reading-writing.

The effect of OME-related hearing loss on communication development presumably depends on several factors, including severity, laterality, duration, and age of identification. Environmental factors, such as the amount of language stimulation in the home and the quality of the caregiving environment, can also impact speech and language development. These factors can influence how OME impacts speech and language, and may help to explain the inconclusive results of studies that do not control for all of these variables. Moreover, if the primary predictor variable is OME, per se, and not the degree of hearing loss, the degree of association may be reduced or even nonsignificant.

A systematic review (Shekelle 2003) concluded that there is no evidence to suggest that OME during the first 3 years of life is related to later receptive or expressive language. This report, however, should be interpreted cautiously because the independent

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variable was OME and not hearing loss. Other systematic reviews (Casby 2001, Roberts 2004) have suggested at most a small negative effect of OME and hearing loss on receptive and expressive language of children through the elementary school years. Any effect of hearing loss due to OME on speech and language development in typically developing children will likely be magnified in children who are at-risk (Table 3) because of other developmental concerns.

One randomized trial (Paradise et al., 2003) and three systematic reviews (Browning, Rovers, Williamson, Lous, & Burton, 2010; Rovers et al., 2005; Simpson et al., 2007) concluded that prompt insertion of tympanostomy tubes for OME did not improve language development. These studies should be viewed with caution because they evaluated the effect of OME on development, and did not focus on the hearing loss. Moreover, children in these studies were identified by screening (which is not recommended for OME) and did not have preexisting delays, which makes it difficult to generalize results to children with OME in everyday clinical practice, especially those with one or more at-risk criteria (Table 3). In contrast, the authors of another systematic review (Kuo 2014) concluded that tympanostomy tubes may improve speech and language development in patients with cleft palate, and the authors of a randomized trial (Maw 1994) concluded that tympanostomy tubes have small benefits for children with bilateral OME and hearing loss.

Communication is an integral part of all aspects of human interaction and QOL. Therefore, clinicians should be vigilant about identifying patients with speech and/or

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language delays and patients who are at-risk for delays, particularly if there is a history of bilateral hearing loss (with or without OME).

- For preschool children with OME and hearing loss, clinicians should ask the parent or caregiver whether there are any concerns about the child's communication development.
- The clinician should also ask basic questions about the child's speech and language abilities and compare the child's abilities to what is considered typical for the child's chronological age. For information about normal development and developmental milestones, go to the website of the American Speech-Language-Hearing Association (www.asha.org) [ASHA] (ASHA, 2015a, 2015b).
- The clinician can use a parent questionnaire or a more formal screening test to judge speech and language development (Klee, Pearce, & Carson, 2000). For information about parent questionnaires and screening tests, go to the website of the Agency for Healthcare Research and Quality (http://www.ahrq.gov/) [AHRQ] and the ASHA website (www.asha.org) (AHRQ, 2015; ASHA, 2015a, 2015b).

When delays or disorders are identified through comprehensive testing, intervention should begin promptly for the best long-term prognosis. Without intervention, children with speech and language delays during the preschool years are at-risk for continued communication problems (Johnson et al., 1999) and later difficulties in reading and writing (Catts, 1993; Scarborough & Dobrich, 1990). Conversely, providing optimal

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treatment during the preschool years can facilitate both speech and literacy development. (Gillon 2005, Kirk 2009) Language intervention can improve communication and other functional outcomes for children with a history of OME and bilateral hearing loss (Glade, 1996).

STATEMENT 11. SURVEILLANCE OF CHRONIC OTITIS MEDIA WITH EFFUSION (OME): Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 11

- Quality improvement opportunity: Emphasize that regular follow-up is an important aspect of managing chronic OME that can help avoid sequelae by identifying children who develop signs or symptoms that would prompt intervention (National Quality Strategy domains: patient safety, clinical process/effectiveness).
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High
- Benefit: Detection of structural changes in the tympanic membrane that may require intervention; detection of new hearing difficulties or symptoms that would lead to reassessing the need for intervention, including tympanostomy tubes;

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discussion of strategies for optimizing the listening-learning environment for children with OME; as well as ongoing counseling and education of parents/caregiver.

- Harms, risks, costs: Cost of follow-up
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although it is uncommon, untreated OME can cause progressive changes in the TM that require surgical intervention. There was an implicit assumption that surveillance and early detection/intervention could prevent complications and would also provide opportunities for ongoing education and counseling of caregivers.
- Intentional vagueness: The surveillance interval is broadly defined at 3 to 6 months to accommodate provider and patient preference; "significant" hearing loss is broadly defined as one that is noticed by the caregiver, reported by the child, or interferes in school performance or QOL
- Role of patient preferences: Moderate; opportunity for shared decision regarding the surveillance interval
- Exceptions: None
- Policy level: recommendation
- Differences of opinion: None

Supporting Text

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The purpose of this statement is to avoid sequelae of chronic OME and to identify children who develop signs or symptoms for which intervention may be appropriate (Rosenfeld 2003, Rosenfeld 2013). Children with chronic OME may develop structural changes of the tympanic membrane, hearing loss, and speech and language delays. Reevaluation with otoscopy, audiologic testing, or both, at 3- to 6-month intervals facilitates ongoing counseling and education of parents and caregivers so that they can participate in shared decision-making during surveillance.

Randomized trials [Paradise 2001, Paradise 2005, Rovers 2000, Rovers 2001b] suggest that otherwise healthy children with persistent OME who *do not* have any of the at-risk criteria in Table 3 can be safely observed for 6 to 12 months with a low risk for developing sequelae or reduced QOL. The impact of longer observation periods is unknown, so active surveillance is required during prolonged observation of OME. For children who are at-risk for developmental sequelae of OME (Table 3), prolonged surveillance is not advised and tympanostomy tubes may be performed when the OME is not likely to resolve promptly (type B tympanogram or persistence for 3 months or longer) (Rosenfeld 2013).

Rationale for Chronic OME Surveillance

The natural history of OME is favorable in most cases. If OME is asymptomatic and is likely to resolve spontaneously, intervention is usually unnecessary, even if OME persists for more than 3 months. The clinician should determine if there are risk factors that would predispose to undesirable sequelae or predict persistence of the effusion. The longer the effusion is present the more the rate of resolution decreases and relapse

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becomes more common (Tos 1980, Thomsen and Tos 1981, Tos, Holm-Jensen et al. 1982, Zielhuis, Rach et al. 1990, Rosenfeld and Kay 2003, Anabousi, Bakowsky et al. 2006). The risk factors associated with reduced likelihood of spontaneous resolution of OME include: (van Balen and de Melker 2000, Medical Research Council Multicentre Otitis Media Study 2001)

- onset of OME in summer or fall season,
- hearing loss greater than 30 dB HL in the better-hearing ear,
- history of prior tympanostomy tubes, and
- not having a prior adenoidectomy.

An important reason for regular follow-up of children with OME is to ensure integrity of the tympanic membrane. OME is associated with tympanic membrane inflammation (Yellon, Doyle et al. 1995, Samuel, Burrows et al. 2008, Kim, Cha et al. 2015), which can induce epithelial migration, erode bone, or alter the mucosecretory or mucociliary clearance, especially in the presence of bacterial products (de Ru and Grote 2004, Vonk, Hiemstra et al. 2008). Adding to this problem is chronic underventilation of the middle ear, which is common in young children and may cause progressive medialization of the tympanic membrane, predisposing to focal retraction pockets, generalized atelectasis, ossicular erosion, and cholesteatoma.(Maw and Bawden 1994) The incidence of structural damage increases with effusion duration.(Maw and Bawden 1994).

Careful examination of the tympanic membrane can be performed using a hand-held pneumatic otoscope to search for abnormalities such as retraction pockets, ossicular

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erosion, areas of atelectasis or atrophy, accumulation of keratin and focal signs of infection such as granulations or aural polyp. If there is any uncertainty as to whether all of the structures are normal (other than the mild retraction that might be expected from negative middle ear pressure), further evaluation should be carried out using a binocular microscope. (Rosenfeld, Culpepper et al. 2004, Rosenfeld, Schwartz et al. 2013) All children with these tympanic membrane conditions, regardless of OME duration, should have a comprehensive audiologic evaluation (typically including air and bone conduction thresholds and speech audiometry). Conditions of the tympanic membrane that generally benefit from tympanostomy tube insertion are posterosuperior retraction pockets, ossicular erosion, adhesive atelectasis, and retraction pockets that accumulate keratin debris. (Rosenfeld. 2004, Rosenfeld 2013, Grimes 2006, Cassano 2010)

Managing Chronic OME During Surveillance

During the surveillance period, parents and clinicians may use auto-inflation of the eustachian tube (e.g.. Politzer devices), which is a safe intervention that may offer some clinical benefit (Berkman 2013, Perera 2013). Mild improvement in combined assessment of tympanogram and audiometry results was seen at one month and with an increasing benefit up to three months, after which there is a lack of data. Although the cost and risk of adverse effects are low, the inconveniences of the use of these devices could limit their acceptability to children and families. Decisions on these procedures with marginal evidence should be a part of the shared decision-making between the physician and caregiver.

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Periodic assessment of hearing status is an important aspect of OME surveillance. A perception by caregivers, teachers, medical personnel or others of suspected deterioration in hearing, speech, language, school performance or behavioral problems should prompt audiological testing (Haggard, Birkin et al. 1994, Bennett and Haggard 1999, Bennett, Haggard et al. 2001). Hearing loss has been defined by conventional audiometry as a loss of >20 dB HL at 1 or more frequencies (500, 1000, 2000, 4000 Hz) and requires a comprehensive audiologic evaluation [Rosenfeld 2004]. If a child with OME has hearing levels in the normal range (≤20 dB HL) a repeat hearing test should be performed in 3 to 6 months if OME persists. In cases of mild hearing loss (21 to 39 dB HL) or moderate (or greater) hearing loss (≥40 dB HL), a comprehensive audiologic evaluation is indicated if one has not already been done.

Mild sensorineural hearing loss is associated with difficulties in speech, language and academic performance in school, and persistent mild conductive hearing loss with OME may have a similar impact.(Davis, Elfenbein et al. 1986, Bess, Dodd-Murphy et al. 1998) Moderate or greater hearing loss has been shown to affect speech, language, and school performance. For children with hearing loss who are being observed – for reasons such as surgery having been declined or being contraindicated, or having previously failed surgery (e.g., recurrent otorrhea with tubes) – consideration for hearing enhancement should be made, including strategies for optimizing the listening-learning environment for children with OME and hearing loss (Table 11), assistive listening devices or hearing aids.(Roberts & Rosenfeld 2004)

Education of the child and caregivers should begin at the first encounter and continue as an ongoing process so that the caregiver can actively participate in shared

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decision-making where there are choices and be a better partner during the observation period. Clinicians should aim to create in them an understanding of the natural history of the disease as well as signs and symptoms of disease progression in order to facilitate prompt medical attention when indicated and to reduce the unnecessary use of antibiotics. Communication between parents and primary care providers should be encouraged. Prompt referral to an otolaryngologist is recommended when otoscopy suggests possible, or impending, structural damage of the tympanic membrane.

Table 11. Strategies for improving the listening and learning environment for children with OME and hearing loss*

Get the child's attention before speaking and, when possible, get within 3 feet of the child.
Turn off competing sounds, such as music and television in the background.
Face the child and speak clearly, using visual cues like hands or pictures in addition to speech.
Use short, simple sentences and comment on what the child is doing.
When speaking to the child, slow down, raise the sound level, and enunciate clearly.
Read to or with the child, explaining pictures and asking questions.
Call attention to the sounds and spelling of words when reading.
Patiently repeat words, phrases, and questions when misunderstood.
In the classroom, ensure the child sits near the teacher in the front of the room.
If further assistance in the classroom is necessary, use a remote microphone personal or sound field amplification system.

*Modified with permission from Roberts et al (Roberts. 2000, Roberts 2004)

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STATEMENT 12a. SURGERY FOR CHILDREN UNDER AGE 4 YEARS: Clinicians should recommend tympanostomy tubes when surgery is performed for otitis media with effusion (OME) in a child under age 4 years; adenoidectomy should not be performed unless a distinct indication (e.g., nasal obstruction, chronic adenoiditis) exists other than OME. *Recommendation based on systematic reviews of randomized controlled trials with a preponderance of benefit over harm.*

STATEMENT 12b: SURGERY FOR CHILDREN AGE 4 YEARS AND OLDER: Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for otitis media with effusion (OME) in a child aged 4 years or older. *Recommendation based on systematic reviews of randomized controlled trials and observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statements 12a and 12b

- Quality improvement opportunity: Promote effective therapy for OME (tubes at all ages; adenoidectomy age 4 years and older) and discourage therapy with limited or no benefits (adenoidectomy under age 4 years) (National Quality Strategy domains: patient safety, clinical process/effectiveness)
- Aggregate evidence quality: Grade B, systematic review of randomized controlled trials (tubes, adenoidectomy) and observational studies (adenoidectomy)
- Level of confidence in the evidence: Medium, because of limited data on long-term benefits of these interventions and heterogeneity among RCTs included in the systematic reviews

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- Benefit: promoting effective therapy; avoiding adenoidectomy in an age group where benefits have not been shown as a primary intervention for OME; benefits of surgery that include improved hearing reduced prevalence of OME, and less need for additional tympanostomy tube insertion (after adenoidectomy)
- Harms, risks, costs: Risks of anesthesia and specific surgical procedures, sequelae of tympanostomy tubes and adenoidectomy
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although some studies suggest benefits of adenoidectomy for children under age 4 years as primary therapy for OME, the data are inconsistent and relatively sparse; the additional surgical risks of adenoidectomy (e.g., velopharyngeal insufficiency, more complex anesthesia) were felt to outweigh the uncertain benefits in this group
- Intentional vagueness: For children aged 4 years and older the decision to offer tympanostomy tubes, adenoidectomy, or both is based on shared decision-making
- Role of patient preferences: Moderate role in the choice of surgical procedure for children aged 4 years or older (tubes, adenoidectomy, or both)
- Exceptions: Adenoidectomy may be contraindicated in children with cleft palate or syndromes associated with a risk of velopharyngeal insufficiency
- Policy level: Recommendation
- Difference of opinion: None

Supporting Text

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The purpose of these statements is to promote tympanostomy tubes as the primary surgical intervention for OME, reserving adenoidectomy for children aged 4 years or older or those with a distinct indication for the procedure other than OME (e.g., nasal obstruction, chronic adenoiditis). These statements differ from recommendations in the first version of this guideline (Rosenfeld 2004), which did not stratify indications for adenoidectomy by child age. For example, adenoidectomy was previously recommended for repeat OME surgery in children as young as age 2 years, but more recent evidence and systematic reviews suggest that age 4 years is a more appropriate cut-point (as discussed below).

Surgery for Children Under 4 Years of Age

If a decision is reached to manage OME in a child *under age 4 years* with surgery, then tympanostomy tube insertion is the procedure of choice. This recommendation is consistent with the initial version of the OME guideline (Rosenfeld 2004) and offers the potential benefits of improved hearing, reduced prevalence of middle ear effusion, reduced incidence of AOM, and improved patient and caregiver QOL (Rovers 2005, Hellstrom 2011, Rosenfeld 2013). Specific recommendations for tympanostomy tube insertion are summarized in Table 12 based on the AAO-HNSFclinical practice guideline on tympanostomy tubes (Rosenfeld 2013).

Table 12. Evidence-based recommendations for tympanostomy tube insertion*

Statement	Action	Strength
Recommendations for performing tympanostomy tube insertion:		

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Chronic bilateral OME with hearing difficulty	Clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer (chronic OME) AND documented hearing difficulties.	Recom-mendation
Chronic OME with symptoms	Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable to OME that include, but are not limited to, vestibular problems, poor school performance, behavioral problems, ear discomfort, or reduced QOL.	Option
Recurrent AOM with middle ear effusion (or OME)	Clinicians should offer bilateral tympanostomy tube insertion to children with recurrent AOM who have unilateral or bilateral middle ear effusion (or OME) at the time of assessment for tube candidacy.	Recom-mendation
Tympanostomy tubes in at-risk children	Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly as reflected by a type B (flat) tympanogram or persistence of effusion for 3 months or longer (chronic OME).	Option
Recommendations for NOT performing tympanostomy tube insertion:		
OME of short duration	Clinicians should not perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months duration.	Recom-mendation (against tubes)
Recurrent AOM without middle ear	Clinicians should not perform tympanostomy tube insertion in children with recurrent AOM who do not have middle ear effusion (or OME) in either ear at the	Recom-mendation (against

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effusion (or OME)	time of assessment for tube candidacy.	tubes)

AOM, acute otitis media; OME, otitis media with effusion

*From AAO-HNSFclinical practice guideline on tympanostomy tubes (Rosenfeld 2013); refer to the guideline for details on the evidence and rationale underlying each recommendation.

Adenoidectomy is not recommended for a primary indication of OME in children under age 4 years because benefits are limited and of questionable clinical significance (Boonacker 2014, Mikals 2014). The original OME guideline (Rosenfeld 2004) suggested a role for adenoidectomy when repeat surgery was needed for OME relapse after prior tympanostomy tubes in children as young as age 2 years, but this was based on limited evidence that is challenged by later publications (Boonacker 2014, Mikals 2014, Casselbrant 2009, Hammaren-Malmi 2005). Therefore, we have raised the threshold for adenoidectomy as repeat surgery to age 4 years. Adenoidectomy may be performed concurrent with tympanostomy tube insertion when there is a distinct indication, such as chronic adenoiditis or nasal obstruction (caused by adenoid hypertrophy).

Adverse events from tympanostomy tubes relate to the procedure and to general anesthesia. Whereas no mortality has been reported in tympanostomy tube trials, the incidence of anesthesia-related death for children undergoing diverse procedures ranges from 1 in 10,000 to 1 in 45,000 anesthetics delivered (van der Griend 2011). The most common tube-related sequela is otorrhea, which is seen in approximately 16% of children

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within 4 weeks of surgery and 26% of children at any time the tube remains in place (mean 12 to 14 months) (Kay 2001). Complications include an obstructed tube lumen in 7% of intubated ears, premature extrusion of the tube in 4%, and tube displacement into the middle ear in 0.5%. (Kay 2001)

Longer-term sequelae of tympanostomy tubes include visible changes in the appearance of the tympanic membrane (e.g., atrophy, retraction, perforation, myringosclerosis) and, in some studies, a decrease in hearing of a few dB (although hearing levels still remain in the normal range). These outcomes do not appear to be clinically important or require intervention in the overwhelming majority of patients. (Rosenfeld 2013) The post-tympanostomy tube sequela most likely to require intervention is persistent perforation, which occurs in about 2% to 3% of children. (Rosenfeld 2013) Myringoplasty or tympanoplasty has an 80% to 90% success rate for surgical closure of persistent performation with a single procedure (Mohamad 2012).

Surgery for Children 4 Years of Age or Older

If a decision is reached to manage OME in a child aged 4 years or older with surgical intervention, then adenoidectomy, tympanostomy tube insertion, or both can be recommended. The availability of at least 3 surgical options for this age group (tubes alone, adenoidectomy alone, or adenoidectomy plus tubes) creates an opportunity for shared decision-making with caregivers.

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The rationale for recommending adenoidectomy as a management option for OME in children aged 4 years or older is based on systematic reviews that may be summarized as follows:

- Boonacker and colleagues (2014) performed an individual patient data meta-analysis using 1,761 children from 10 randomized trials, 9 of which compared adenoidectomy with or without tubes to no surgery or tubes alone. For children under age 4 years no clinically important benefits were found for adenoidectomy. Conversely, children aged 4 years or older spent 50 less days with OME over the next 12 months, had lower failure rates (51% vs. 70%), and a lower rate of future surgery (2% vs. 19%). In this study, failure at 12 months was defined as additional surgery, recurrent AOM, MEE at least 50% of the time, or average hearing improvement less than 10 dB HL.
- Mikals and Brigger (2014) reviewed 15 randomized trials and observational studies of tympanostomy tubes, with, or without, adenoidectomy as primary therapy for OM. Adenoidectomy reduced the rate of repeat tympanostomy tube insertion (from 36% to 17%) for children aged 4 years or older, but when only younger children were studied there was no significant effect.
- Wallace and colleagues (2014) reviewed randomized trials and found that adenoidectomy increased OME resolution as measured by otoscopy (27% at 6 months) and tympanometry (22% at 6 months, 29% at 12 months). Outcomes were unchanged whether tubes were, or were not, performed concurrently. In this analysis, the authors were unable to stratify results by child age.

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The primary benefits of adenoidectomy are to reduce failure rates, reduce time with middle ear effusion, and to decrease the need for repeat surgery (e.g., future tubes). These benefits are independent of adenoid volume and may relate to improved microflora in the nasopharynx when adenoid tissue and associated pathogenic bacteria (planktonic and in biofilms) are removed. Additionally, contact of the adenoid with the torus tubarius may be predictive of increased benefit from adenoidectomy. (Nguyen 2004) When compared to tube insertion alone, these benefits are offset, in part, by additional anesthetic time (intubation, intravenous fluids), a small potential for hemorrhage, and a longer recovery period (24 to 48 hours). In addition, velopharyngeal insufficiencyoccurs rarely after adenoidectomy. .

Shared Decision-Making for OME Surgery

There are two aspects of shared surgical decision-making for treatment of OME: deciding between surgery or additional observation, and if surgery is chosen, selecting the appropriate procedure(s).Surgical candidacy for OME depends largely on hearing status, associated symptoms, the child's developmental risk (Table 3), and the anticipated chance of timely spontaneous resolution of the effusion. The poorest rates of spontaneous resolution for OME occur when the effusion is chronic (3 months or longer) or associated with a type B (flat curve) tympanogram (Rosenfeld 2003). Indications for tubes (summarized in Table 12) are fully discussed in the AAO-HNSF clinical practice guideline on tympanostomy tubes (Rosenfeld 2013). Ultimately the recommendation for surgery must be individualized, based on discussion among the primary care physician,

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otolaryngologist, and parent or caregiver that a particular child would benefit from intervention.

Once a decision to proceed with surgery is reached, the role of shared decision-making is limited below age 4 years (tympanostomy tubes are recommended), but increases significantly for older children. Surgical options for managing OME in children aged 4 years or older include:

1. *Tympanostomy tube placement alone*, which offers the most reliable short- and intermediate-term resolution of hearing loss associated with OME (Browning 2010, Hellstrom 2011, Wallace 2014), but has minor complications as noted above. Caregivers of children with speech and language delays and OME perceive large improvements after tube placement (Rosenfeld 2011), making tubes desirable for at-risk children.
2. *Adenoidectomy alone*, which offers comparable rates of OME control compared to tympanostomy tubes at 6 months and 12 months (Wallace 2014), but may have a less reliable impact in the short-term. Adenoidectomy also reduces the need for repeat surgery (Mikals 2014), but has more potential anesthetic and procedure-related complications than tubes alone (see above). Last, some children with persistent OME despite adenoidectomy may need additional surgery for tympanostomy tube insertion.
3. *Adenoidectomy plus myringotomy (without tubes)*, which includes aspiration of effusion and possible lavage of the middle ear space with saline solution, has

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outcomes comparable to tubes with less otorrhea and tympanic membrane sequelae (Gates 1987). Tympanostomy tube insertion, however, offers more reliable short-term effusion resolution and middle ear ventilation, making it preferable to myringotomy when potential relapse of effusion must be minimized (e.g., at-risk children) or when pronounced inflammation of the tympanic membrane and middle ear mucosa is present (Rosenfeld 2004).

4. *Adenoidectomy plus tympanostomy tube placement*, which offers the combined benefits of both procedures, especially the ability to reduce repeat surgery in children with a prior history of tympanostomy tube placement (Paradise 1990). This dual approach may be of particular benefit in children with nasal obstruction or recurrent sinonasal infections that are bothersome but insufficient on their own to justify adenoidectomy.

An option grid (Table 13) can help caregivers and patients participate in shared decision-making. Option grids are single-page summary tables of frequently asked questions that can be used during a clinical encounter to efficiently compare management options. The grids benefit clinicians by standardizing information transfer, facilitating patients' understanding of treatment options, and by making consultations easier (Elwyn 2013).

Table 13. Shared decision grid for parents and caregivers regarding surgical options for OME

Frequently asked	**Watchful waiting (surveillance)**	**Ear (tympanostomy) tube placement**	**Adenoidectomy**

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questions			
Are there any age restrictions?	Watchful waiting can be done at any age	Ear tubes can be done at any age	Adenoidectomy is not recommended below age 4 years for treating ear fluid that persists for at least 3 months
What does it involve?	Checking the eardrum every 3 to 6 months in your doctor's office. Periodic hearing tests may also be performed.	Placing a tiny tube in the eardrum to reduce fluid build-up that causes hearing loss, then checking the tube in your doctor's office until it falls out.	Removing most of the adenoids, a clump of tissue in the back of the nose that stores germs then checking the ears in your doctor's office to be sure the ear fluid is gone.
How long does the treatment take?	Regular check-ups until the fluid in the middle ear goes away (months to years).	The operation takes about 10 to 20 minutes and usually requires general anesthesia.	The operation takes about 30 minutes and requires general anesthesia.
How long does it take to recover?	Does not apply.	A few hours.	About 1 or 2 days.
What are the benefits?	Gives your child a chance to recover on his/her own.	Relieves fluid and hearing loss promptly and prevents relapse of fluid while the tube is in place and stays open.	Reduces time with fluid in the future, reduces the need for future ear surgery. Relieves nasal blockage and infections (if applicable).

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What are the potential risks and side effects?	Persistent fluid can reduce hearing, bother your child, and can rarely damage the eardrum and cause it to collapse. If the fluid does not eventually go away on its own then watchful waiting could delay more effective treatments.	About 1 in 4 children get an ear infection (drainage) that is treated with eardrops. About 2 or 3 in 100 children have a tiny hole in the eardrum that does not close after the tube falls out and may need surgery. There is a very small risk of serious problems from the anesthesia.	There is a small chance of bleeding (that could require a visit to the office or hospital), infection (that is treated with antibiotics), or delayed recovery. There is a very small risk of abnormal voice (too much air through the nose) or serious problems from the anesthesia.
What usually happens in the long term?	The fluid and hearing loss eventually go away or another treatment is tried.	Most tubes fall out in about 12 to 18 months. About 1 in every 4 children may need to have them replaced.	The chance that your child may need future ear tubes is reduced by about 50% after adenoidectomy.
Are there any special precautions?	Baths and swimming are fine. Air travel can result in ear pain or damage to the eardrum depending on how much fluid is present.	Baths, swimming, and air travel are fine. Some children need earplugs if water bothers their ears in the bathtub (with head dunking), when diving (more than 6 feet underwater), or when swimming in lakes or	Baths and swimming are fine. Air travel can result in ear pain or damage to the eardrum depending on how much fluid is present.

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		dirty water.	

Adapted from Calkins and colleagues (Calkins 2015).

Clinicians should inform patients, parents, and/or caregivers that the goal of the grid is to initiate a conversation about options and ask if they wish to read it themselves or have the comparisons vocalized. If the patient, parent, and/or caregiver wishes to read the grid it is best to create space by asking permission to perform other tasks so they do not feel observed or under pressure (Elwyn 2013). Questions and discussion are encouraged, and the patient, parent and/or caregiver is given a copy of the grid for future reference. Since surgery for OME is nearly always elective, patients, parents, and/or caregivers who express uncertainty are often best managed by delaying the management decision and readdressing the issue at a subsequent office visit.

In some situations a decision regarding tympanostomy tube insertion is driven less by patient choice and more by findings on physical examination. For example, children with chronic OME should have prompt tympanostomy tube insertion when there is real, or impending, structural damage to the tympanic membrane caused by retraction (from negative middle ear pressure) or collapse (from atrophy or atelectasis). Although there are no randomized trials to support this approach, inserting the tube will equalize middle ear pressure and eliminate MEE, which may help avoid more extensive otologic surgery for ears with retraction pockets, atelectasis, or early signs of cholesteatoma.

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STATEMENT 13. OUTCOME ASSESSMENT: When managing a child with otitis media with effusion (OME) clinicians should document in the medical record resolution of OME, improved hearing, or improved quality of life (QOL).

Recommendation based on randomized trials and cohort studies with a preponderance of benefit over harm.

Action Statement Profile for Statement 13

- Quality improvement opportunity: Focus on patient-centered outcome assessment when managing children with OME (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade C, randomized trials and before-and-after studies showing resolution, improved hearing, or improved QOL after management of OME
- Level of confidence in the evidence: High
- Benefit: Document favorable outcomes in management
- Harms, risks, costs: Cost of follow-up visits and audiometry; administrative burden for QOL surveys
- Benefit-harm assessment: Predominance of benefit over harm
- Value judgments: None
- Intentional vagueness: The time frame for assessing outcome is not stated; the method of demonstrating OME resolution (otoscopy or tympanometry) is at the discretion of the clinician.
- Role of patient preferences: Small

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- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to encourage clinicians to document patient-centered outcomes when managing children with OME, regardless of the management option chosen (e.g., surgery, watchful waiting, or surveillance). Common goals of managing OME are to resolve effusion, restore optimal hearing, and improve disease-specific QOL (Rosenfeld 2003, Brouwer 2005, Wallace 2014). Documenting these outcomes is important to ensure patient follow-up and to assess the effectiveness of management strategies.

For children with an intact tympanic membrane, resolution of OME can be documented by showing normal tympanic membrane mobility with pneumatic otoscopy (key action statement 1) or by recording a sharp peak on tympanometry (key action statement 2) with either normal middle ear pressure (type A curve) or negative pressure (type C1 curve). For children with tympanostomy tubes, resolution of OME can be documented by showing an intact and patent tube with otoscopy or by recording a large ear canal volume with tympanometry. Improved hearing can be documented using age-appropriate, comprehensive audiometry (key action statement 9).

Documenting improved QOL for children with OME can be accomplished by using a valid and reliable disease-specific survey that is able to measure clinical change.

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The most appropriate instrument currently available for this purpose is the OM-6 (Brouwer 2005), which has six brief questions reflecting the domains of physical suffering, hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns (Rosenfeld 1997). The child's caregiver completes the survey at baseline and then again after a minimum follow-up period of one month. A change score is calculated as the difference between surveys and can be used to rate clinical change as trivial, small, moderate, or large (Rosenfeld 1997).

The time interval for assessing OME outcomes is at the discretion of the clinician. For children managed with watchful waiting (key action statement 7) or surveillance (key action statement 11) the outcome assessment can take place at a follow-up visit. For children managed with surgery (key action statement 12) the outcome assessment can take place at the postoperative visit or a subsequent follow-up visit.

If documentation of outcome is not possible because of loss to follow-up, this should be noted in the medical record along with any attempts to contact the family. For children who are seen only once (e.g. a child referred by the primary care clinician to a specialist for evaluation only), the clinician should document the specific circumstance in the medical record as to why follow-up was not possible.

Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology – Head and Neck Surgery*, and an executive summary will be simultaneously published in the

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main journal. A full-text version of the guideline will also be accessible free of charge at www.entnet.org, the AAO-HNSF website. The guideline will be presented to AAO-HNS members as a miniseminar at the 2015 Annual Meeting. Existing brochures, publications, and patient information sheets from the AAO-HNSF will be updated to reflect guideline recommendations.

Although pneumatic otoscopy and tympanometry were recommended for diagnosing OME in the first version of this guideline (Rosenfeld 2004), pneumatic otoscopy, in particular, continues to be underused in primary care settings. We provide expanded information on both of these diagnostic modalities in the new guideline, but enhanced efforts will still be needed in primary care settings to teach and promote accurate OME diagnosis. The degree to which specialists use pneumatic otoscopy has not been studied, but educational efforts would likely be of benefit to this population as well.

OME is one of the most common reasons that infants fail a newborn hearing test, but ensuring follow-up to assess for resolution of the effusion and to exclude an underlying sensorineural hearing loss can be challenging. We provide counseling materials in this regard that clinicians who see children with OME can distribute to families, but continued education of hospital providers who administer the newborn testing is an additional challenge. We hope that the new attention focused on this issue by the guideline will promote investigation and change in this area.

The new guideline reaffirms a prior recommendation against routine screening of children for OME, but adds a new recommendation that clinicians evaluate at-risk children for OME when the at-risk condition is diagnosed and again at 12 to 18 months of

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age (if diagnosed as being at-risk prior to this time). This new recommendation imposes some additional burden on providers, both in terms of remembering to do the assessment and in performing the actual evaluation for OME. The guideline update group showed strong consensus and support for this recommendation as a means to improve quality of care for at-risk children. Implementing this in practice will require continuing medical education strategies and integration into clinical decision support systems.

Whereas antibiotics and oral steroids are used infrequently to treat OME, there is a perception that topical intranasal steroids and anti-reflux medications are relatively common interventions, despite a lack of evidence for their efficacy. We recommend explicitly against using these for a primary indication of OME, but reinforcement will be needed to implement this strategy, especially through performance measures. This is especially important to avoid costly, ineffective, and potentially harmful care.

Last, we make a new recommendation that adenoidectomy should not be done for a primary indication of OME in children under age 4 years. This contradicts established practice for many clinicians and some information in the prior guideline (e.g., offering adenoidectomy when repeat surgery is required for children aged 2 years or older). Continuing medical education will be needed to explicitly focus on the rationale for this change (e.g., new randomized trials and systematic reviews) to promote uptake in routine clinical practice.

Figure X. Algorithm

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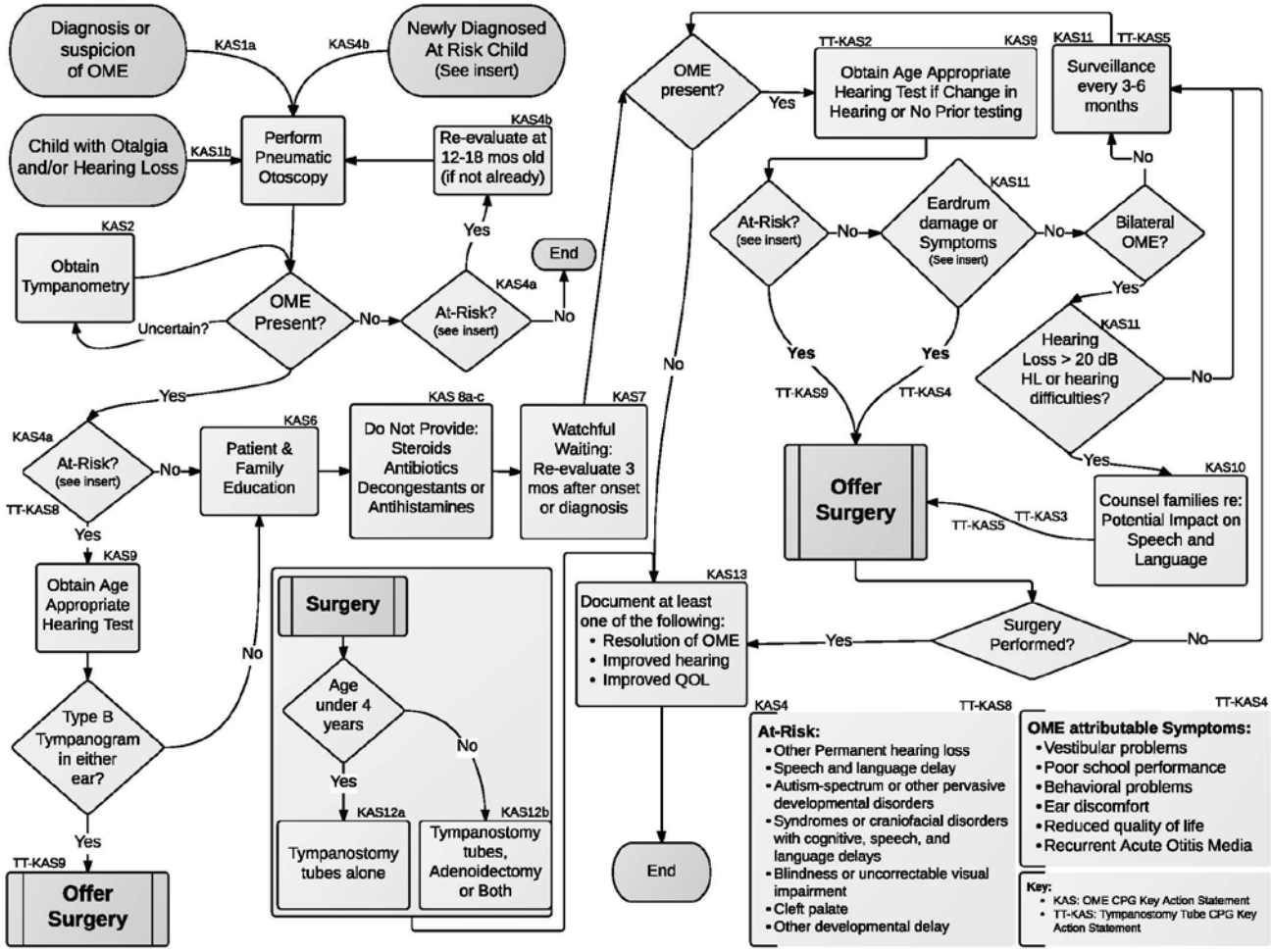

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Research Needs

Diagnosis

1. Further standardize the definition of OME and distinctions with regard to fluid from varying etiologies.

2. Assess the performance characteristics of pneumatic otoscopy as a diagnostic test for OME when performed by primary care physicians and advanced practice nurses in the routine office setting.
3. Determine the optimal methods for teaching pneumatic otoscopy to residents and clinicians.
4. Develop a brief, reliable, objective method for diagnosing OME, beyond pneumatic otoscopy.
5. Develop cost-effective tympanometry that facilitates testing in non-audiology settings.
6. Develop a classification method for identifying the presence of OME for practical use by clinicians that is based on quantifiable tympanometric characteristics.
7. Assess the usefulness of algorithms combining pneumatic otoscopy and tympanometry for detecting OME in clinical practice.
8. Conduct additional validating cohort studies of acoustic reflectometry as a diagnostic method for OME, particularly in children younger than 2 years.

Newborn Hearing Screen

1. Determine whether neonatal middle ear fluid has a differential rate of resolution or natural history than fluid in older infants and children
2. Optimization of counseling to maximize rates of return for follow-up for those who fail neonatal hearing screening and have OME.

Child At-Risk

1. Better define the child with OME who is at-risk for speech, language, and learning problems.

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2. Conduct large, multicenter observational cohort studies to identify the child at-risk who is most susceptible to potential adverse sequelae of OME.
3. Conduct large, multicenter observational cohort studies to analyze outcomes achieved with alternative management strategies for OME in children at-risk.

Watchful Waiting

1. Define the anticipated rate of spontaneous resolution of OME in infants and young children (existing data are limited primarily to children aged 2 years or older).
2. Conduct large-scale, prospective cohort studies to obtain current data on the spontaneous resolution of newly diagnosed OME of unknown prior duration (existing data are primarily from the late 1970s and early 1980s).
3. Develop prognostic indicators to identify the best candidates for watchful waiting.
4. Determine if the lack of impact from prompt insertion of tympanostomy tubes on speech and language outcomes seen in asymptomatic young children with OME identified by screening or intense surveillance can be generalized to older children with OME or to symptomatic children with OME referred for evaluation.
5. Determine whether children with an OME duration exceeding 1-2 years have an increased risk of hearing loss, balance problems, discomfort, or other findings that would prompt intervention.
6. Define straightforward and efficient metrics to elucidate OME-related vestibular disturbance in patients too young to articulate related symptoms. Develop better tools for monitoring children with OME, suitable for routine clinical care.

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7. Assess the value of new strategies for monitoring OME, such as acoustic reflectometry performed at home by the parent or caregiver.
8. Promote early detection of structural abnormalities in the tympanic membrane associated with OME that may require surgery to prevent complications.
9. Clarify and quantify the role of parent or caregiver education, socioeconomic status, and quality of the caregiving environment as modifiers of OME developmental outcomes.
10. Develop methods for minimizing loss to follow-up during OME watchful waiting.

Medication

1. Evaluate previously unstudied discrete patient subgroups who may have a differential effect in response to antimicrobials, steroids, antihistamines, or a combination thereof for OME.
2. Investigate the lack of efficacy of nasal steroids for OME in relation to their demonstrated capacity to decrease adenoid size
3. Invesitgate the efficacy of adenoidectomy in children above 4 years of age.
4. Investigate the role of mucosal surface biofilms in refractory or recurrent OME and develop targeted interventions.

Hearing, Speech, and Language

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1. Conduct longitudinal studies on the natural history of hearing loss accompanying OME.
2. Develop improved methods for describing and quantifying the fluctuations in hearing of children with OME over time.
3. Conduct prospective controlled studies on the relation of hearing loss associated with OME to later auditory, speech, language, behavioral, and academic sequelae.
4. Develop reliable, brief, objective methods for estimating hearing loss associated with OME.
5. Develop reliable, brief, objective methods for estimating speech, language, or literacy delay associated with OME.
6. Agree on the aspects of speech, language, and literacy that are vulnerable to, or affected by, hearing loss caused by OME, and reach a consensus on the best tools for measurement.
7. Determine if OME and associated hearing loss place children from special populations at greater risk for speech and language delays.

Surgery

1. Define the role of adenoidectomy in children aged 3 years or younger as a specific OME therapy.
2. Conduct controlled trials on the efficacy of tympanostomy tubes for developmental outcomes in children with hearing loss, other symptoms, or speech and language delay.

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3. Conduct randomized, controlled trials of surgery versus no surgery that emphasize patient-based outcome measures (QOL, functional health status) in addition to objective measures (effusion prevalence, hearing levels, AOM incidence, reoperation).
4. Identify the optimal ways to incorporate parent or caregiver preference into surgical decision-making.

Allergy Management

1. Evaluate whether there is a causal role of atopy in OME.
2. Evaluate whether age impacts any relationship between allergy and OME.
3. Conduct randomized, controlled trials on the efficacy of immunotherapy and non-antihistamine allergy therapy for OME that are generalizable to the primary care setting.
4. Determine whether the subgroup with active allergy manifestations and positive allergy testing have a distinct natural history or response to interventions, including immunotherapy, compared to children without allergy.

Conclusion

This evidence-based practice guideline offers recommendations for identifying, monitoring, and managing the child with OME. The guideline emphasizes appropriate diagnosis and provides options for various management strategies including observation, medical intervention, and referral for surgical intervention. These recommendations

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should provide primary care physicians and other health care providers with assistance in managing children with OME.

Disclaimer

The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing OME. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible provider, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNSF emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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