American Academy of Family Physicians
Clinical Practice Guideline: Otitis Media With Effusion

These recommendations are provided only as assistance for physicians making clinical decisions regarding the care of their patients. As such, they cannot substitute for the individual judgment brought to each clinical situation by the patient's family physician. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but they should be used with the clear understanding that continued research may result in new knowledge and recommendations.

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AMERICAN ACADEMY OF FAMILY PHYSICIANS

American Academy of Family Physicians, American Academy of Otololaryngology-Head and Neck Surgery, and American Academy of Pediatrics Subcommittee on Otitis Media With Effusion

Clinical Practice Guideline: Otitis Media With Effusion

ABSTRACT. The clinical practice guideline on otitis media with effusion (OME) provides evidence-based recommendations on diagnosing and managing OME in children. This is an update of the 1994 clinical practice guideline "Otitis Media With Effusion in Young Children," which was developed by the Agency for Healthcare Policy and Research (now the Agency for Healthcare Research and Quality). In contrast to the earlier guideline, which was limited to children aged 1 to 3 years with no craniofacial or neurologic abnormalities or sensory deficits, the updated guideline applies to children aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The American Academy of Pediatrics, American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery selected a subcommittee composed of experts in the fields of primary care, otolaryngology, infectious diseases, epidemiology, hearing, speech and language, and advanced practice nursing to revise the OME guideline.

The subcommittee made a strong recommendation that clinicians use pneumatic otoscopy as the primary diagnostic method and distinguish OME from acute otitis media (AOM).

The subcommittee made recommendations that clinicians should 1) document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME; 2) distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and more promptly evaluate

hearing, speech, language, and need for intervention in children at risk; and 3) 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 from the date of diagnosis (if onset is unknown).

The subcommittee also made recommendations that 4) hearing testing be conducted when OME persists for 3 months or longer, or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME; 5) children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected; and 6) when a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure. Adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis); repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME.

The subcommittee made negative recommendations that 1) population-based screening programs for OME not be performed in healthy, asymptomatic children and 2) antihistamines and decongestants are ineffective for OME and should not be used for treatment; antimicrobials and corticosteroids do not have long-term efficacy and should not be used for routine management.

The subcommittee gave as options that 1) tympanometry can be used to confirm the diagnosis of OME and 2) when children with OME are referred by the primary clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery), and provide additional relevant information such as history of AOM and developmental

status of the child. The subcommittee made no recommendations for 1) complementary and alternative medicine as a treatment for OME based on a lack of scientific evidence documenting efficacy and 2) allergy management as a treatment for OME based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME. Last, the panel compiled a list of research needs based on limitations of the evidence reviewed.

The purpose of this guideline is to inform clinicians of evidence-based methods to identify, monitor, and manage OME in children aged 2 months through 12 years. The guideline may not apply to children older than 12 years because OME is uncommon and the natural history is likely to differ from younger children who experience rapid developmental change. The target population includes children with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The guideline is intended for use by providers of health care to children, including primary care and specialist physicians, nurses and nurse practitioners, physician assistants, audiologists, speech-language pathologists, and child development specialists. The guideline is applicable to any setting in which children with OME would be identified, monitored, or managed.

This guideline is not intended as a sole source of guidance in evaluating children with OME. Rather, it is designed to assist primary care and other clinicians by providing an evidence-based framework for decision-making strategies. It is not intended to replace clinical judgment or establish a protocol for all children with this condition, and may not provide the only appropriate approach to diagnosing and managing this problem.

ABBREVIATIONS. OME, otitis media with effusion; AOM, acute otitis media; AAP, American Academy of Pediatrics; AHRQ, Agency for Healthcare Research and Quality; EPC,

Southern California Evidence-Based Practice Center; HL, hearing level; CAM, complementary and alternative medicine.

INTRODUCTION

Otitis media with effusion (OME) as discussed in this guideline is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection.[1,2] OME is considered distinct from acute otitis media (AOM), which is defined as a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation. Persistent middle-ear fluid from OME results in decreased mobility of the tympanic membrane and serves as a barrier to sound conduction.[3] About 2.2 million diagnosed episodes of OME occur annually in the United States, yielding a combined direct and indirect annual cost estimate of $4.0 billion.[2]

OME may occur spontaneously because of poor eustachian tube function, or as an inflammatory response following AOM. About 90% of children (80% of individual ears) have OME at some time before school age,[4] most often between ages 6 months and 4 years.[5] In the first year of life, more than 50% of children will experience OME, increasing to more than 60% by age 2 years.[6] Many episodes resolve spontaneously within 3 months, but about 30% to 40% of children have recurrent OME and 5% to 10% of episodes last 1 year or longer.[1,4,7]

The primary outcomes considered in the guideline include hearing loss; effects on speech, language, and learning; physiologic sequelae; health care utilization (medical, surgical); and quality of life.[1,2] The high prevalence of OME, difficulties in diagnosis and assessing duration, increased risk of conductive hearing loss, potential impact on language and cognition, and significant practice variations in management[8] make OME an important condition for the use

of up-to-date evidence-based practice guidelines.

METHODS

General Methods and Literature Search

In developing an evidence-based clinical practice guideline on managing OME, the American Academy of Pediatrics (AAP), American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery worked with the Agency for Healthcare Research and Quality (AHRQ) and other organizations. This effort included representatives from each partnering organization along with liaisons from audiology, speech-language pathology, informatics, and advanced practice nursing. The most current literature on managing children with OME was reviewed, and research questions were developed to guide the evidence review process.

The AHRQ report on OME from the Southern California Evidence-Based Practice Center (EPC) focused on key questions of natural history; diagnostic methods; and long-term speech, language, and hearing outcomes.[2] Searches were conducted through January 2000 in MEDLINE, EMBASE, and the Cochrane Library. Additional articles were identified by review of reference listings in proceedings, reports, and other guidelines. The EPC accepted 970 articles for full review after screening 3200 abstracts. The EPC reviewed articles using established quality criteria[9,10] and included randomized trials, prospective cohorts, and validations of diagnostic tests (validating cohort studies).

The AAP subcommittee on OME updated the AHRQ review with articles identified by an electronic MEDLINE search through April 2003 and with additional material identified manually by subcommittee members. Copies of relevant articles were distributed to the

subcommittee for consideration. A specific search for articles relevant to complementary and alternative medicine (CAM) was performed using MEDLINE and AMED through April 2003. Articles relevant to allergy and OME were identified using MEDLINE through April 2003. The subcommittee met 3 times over a 1-year period, ending in May 2003, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.[11]

In May 2003 the Guidelines Review Group of the Yale Center for Medical Informatics used the Guideline Elements Model[12] to categorize content of the present draft guideline. Policy statements were parsed into component decision variables and actions, then assessed for decidability and executability. Quality appraisal using established criteria[13] was performed with Guideline Elements Model-Q Online.[14,15] Implementation issues were predicted using the Implementability Rating Profile, an instrument under development by the Yale Guidelines Review Group (R. Shiffman, MD, written communication, May 2003). OME subcommittee members received summary results and modified an advanced draft of the guideline.

The final draft practice guideline underwent extensive peer review by numerous entities identified by the subcommittee. Comments were compiled and reviewed by the subcommittee cochairpersons. The recommendations contained in the practice guideline are based on the best available published data through April 2003. Where data are lacking, a combination of clinical experience and expert consensus was used. A scheduled review process will occur at 5 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, produce optimal health outcomes for patients, and 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 the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The AAP definitions for evidence-based statements[16] are listed in Tables 1 and 2.

TABLE 1. Guideline Definitions for Evidence-based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation, but should remain alert to new information and sensitive to patient preferences.

Option	An option means that either the quality of evidence that exists is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach versus another.	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.
No Recommendation	No recommendation means there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*See Table 2 for definition of evidence grades.

TABLE 2. Evidence Quality for Grades of Evidence

Grade	Evidence Quality
A	Well-designed randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case control and cohort design)
D	Expert opinion, case reports, reasoning from first principles (bench research or animal studies)

Guidelines are never intended to overrule 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 opportunity for practice variability.[17] All clinicians should always act and decide in a way that they believe will best serve their 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.[16]

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the OME subcommittee sought to minimize harm and diminish unnecessary therapy. Emphasis was placed on promptly identifying and managing children at risk for speech, language, or learning problems to maximize opportunities for beneficial outcomes. Direct costs were also considered in the statements concerning diagnosis and screening, and to a lesser extent in other statements.

1A. PNEUMATIC OTOSCOPY: Clinicians should use pneumatic otoscopy as the primary diagnostic method for OME. OME should be distinguished from AOM. *Strong Recommendation based on systematic review of cohort studies and preponderance of benefit over harm.*

1B. TYMPANOMETRY: Tympanometry can be used to confirm the diagnosis of OME. *Option based on cohort studies and a balance of benefit and harm.*

Diagnosing OME correctly is fundamental to proper management. Moreover, OME must be differentiated from AOM to avoid unnecessary antimicrobial use.[18,19]

OME is defined as fluid in the middle ear *without* signs or symptoms of acute ear

infection.[2] The tympanic membrane is often cloudy with distinctly impaired mobility,[20] and an air-fluid level or bubble may be visible in the middle ear. Conversely, diagnosing AOM requires a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation. The critical distinguishing feature is that only AOM has acute signs and symptoms. Distinct redness of the tympanic membrane should not be a criterion for antibiotic prescribing because it has poor predictive value for AOM and is present in about 5% of ears with OME.[20]

The AHRQ evidence report[2] systematically reviewed the sensitivity, specificity, and predictive values of 9 diagnostic methods for OME. Pneumatic otoscopy had the best balance of sensitivity and specificity, consistent with the 1994 guideline.[1] Meta-analysis revealed a pooled sensitivity of 94% (95% CI, 91%–96%) and specificity of 80% (95% CI, 75%–86%) for validated observers using pneumatic otoscopy versus myringotomy as the gold standard. Pneumatic otoscopy should therefore remain the primary method of OME diagnosis because the instrument is readily available in practice settings, cost effective, and accurate in experienced hands. Non-pneumatic otoscopy is not advised for primary diagnosis.

The accuracy of pneumatic otoscopy in routine clinical practice may be less than that shown in published results because clinicians have varying training and experience.[21,22] When the diagnosis of OME is uncertain, tympanometry or acoustic reflectometry should be considered as an adjunct to pneumatic otoscopy. Tympanometry with a standard 226-Hz probe tone is reliable for infants aged 4 months or older and has good interobserver agreement of curve patterns in routine clinical practice.[23,24] Younger infants require specialized equipment with a higher probe tone frequency. Tympanometry generates costs related to instrument purchase, annual calibration, and test administration. Acoustic reflectometry with spectral gradient analysis

is a low-cost alternative to tympanometry that does not require an airtight seal in the ear canal; however, validation studies primarily have used children aged 2 years or older with a high prevalence of OME.[25–27]

While no research studies have examined whether pneumatic otoscopy causes discomfort, expert consensus suggests that the procedure does not have to be painful, especially when symptoms of acute infection (AOM) are absent. A non-traumatic examination is facilitated by using a gentle touch, restraining the child properly when necessary, and inserting the speculum only into the outer one third (cartilaginous portion) of the ear canal.[28] The pneumatic bulb should be slightly compressed before insertion because OME is often associated with a negative middle-ear pressure, which can be more accurately assessed by releasing the already compressed bulb. The otoscope must be fully charged, the bulb (halogen or xenon) bright and luminescent,[29] and the insufflator bulb attached tightly to the head to avoid the loss of an air seal. The window must also be sealed.

Evidence Profile: Pneumatic Otoscopy

- Aggregate evidence quality: A, diagnostic studies in relevant populations
- Benefit: improved diagnostic accuracy; inexpensive equipment
- Harm: cost of training clinicians in pneumatic otoscopy
- Benefits-harms assessment: preponderance of benefit over harm
- Policy level: strong recommendation

Evidence Profile: Tympanometry

- Aggregate evidence quality: B, diagnostic studies with minor limitations
- Benefit: increased diagnostic accuracy beyond pneumatic otoscopy; documentation

- Harm: acquisition cost, administrative burden, recalibration
- Benefits-harms assessment: balance of benefit and harm
- Policy level: option

1C. SCREENING: Population-based screening programs for OME are not recommended in healthy, asymptomatic children. *Recommendation based on randomized, controlled trials and cohort studies with a preponderance of harm over benefit.*

This recommendation concerns population-based screening programs of all children in a community or a school without regard to any preexisting symptoms or history of disease. This recommendation does not address hearing screening or monitoring of specific children with previous or recurrent OME.

OME is highly prevalent in young children. Screening surveys of healthy children ranging in age from infants to age 5 years show a 15% to 40% point prevalence of middle-ear effusion.[5,7,30–36] Among children examined at regular intervals for a year, about 50% to 60% of child care center attendees[32] and 25% of school-aged children[37] were found to have a middle-ear effusion at some time during the examination period, with peak incidence during the winter months.

Population-based screening has not been found to influence short-term language outcomes,[33] and its long-term effects have not been evaluated in a randomized clinical trial. Therefore, the recommendation against screening is based not only on the ability to identify OME, but more importantly on a lack of demonstrable benefits from treating children so identified that exceed the favorable natural history of the disease. The New Zealand Health Technology Assessment[38] could not determine whether preschool screening for OME was

effective. More recently, the Canadian Task Force on Preventive Health Care[39] reported that insufficient evidence was available to recommend including or excluding routine early screening for OME. Although screening for OME is not inherently harmful, potential risks include inaccurate diagnoses, overtreating self-limited disease, parental anxiety, and the costs of screening and unnecessary treatment.

Population-based screening is appropriate for conditions that are common, can be detected by a sensitive and specific test, and benefit from early detection and treatment.[40] The first 2 requirements are fulfilled by OME, which affects up to 80% of children by school entry[2,5,7] and can be easily screened with tympanometry (see Recommendation 1B). Early detection and treatment of OME identified by screening, however, has not been shown to improve intelligence, receptive language, or expressive language.[2,39,41,42] Therefore, population-based screening for early detection of OME in asymptomatic children has not been shown to improve outcomes and is not recommended.

Evidence Profile: Screening

- Aggregate evidence quality: B, randomized, controlled trials with minor limitations and consistent evidence from observational studies
- Benefit: potentially improved developmental outcomes, which have not been demonstrated in the best current evidence
- Harm: inaccurate diagnosis (false positive, false negative), overtreating self-limited disease, parental anxiety, cost of screening and unnecessary treatment
- Benefits-harms assessment: preponderance of harm over benefit
- Policy level: recommendation against

2. DOCUMENTATION: Clinicians should document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME. *Recommendation based on observational studies and strong preponderance of benefit over harm.*

Documentation in the medical record facilitates diagnosis and treatment, and communicates pertinent information to other clinicians to ensure patient safety and reduce medical errors.[43] Management decisions in children with OME depend on effusion duration and laterality plus the nature and severity of associated symptoms. Therefore, these features should be documented at every medical encounter for OME. Although no studies have specifically addressed documentation for OME, there is room for improvement in documentation of ambulatory care medical records.[44]

Ideally, the time of onset and laterality of OME can be defined through diagnosis of an antecedent AOM, a history of acute onset of signs or symptoms directly referable to fluid in the middle ear, or the presence of an abnormal audiogram or tympanogram closely following a previously normal test. Unfortunately, these conditions are often lacking, and the clinician is forced to speculate on the onset and duration of fluid in the middle ear(s) in a child found to have OME at a routine office visit or school screening audiometry.

In about 40% to 50% of cases of OME, neither the affected children nor their parents or caregivers describe significant complaints referable to a middle-ear effusion.[45,46] In some children, however, OME may have associated signs and symptoms caused by inflammation or the presence of effusion (not acute infection) that should be documented, such as

- Mild intermittent ear pain, fullness or “popping”
- Secondary manifestations of ear pain in infants, which may include ear rubbing,

excessive irritability, and sleep disturbances

- Failure of infants to respond appropriately to voices or environmental sounds, such as not turning accurately toward the sound source
- Hearing loss, even when not specifically described by the child, suggested by seeming lack of attentiveness, behavioral changes, failure to respond to normal conversational level speech, or the need for excessively high sound levels when using audio equipment or viewing television
- Recurrent episodes of AOM with persistent OME between episodes
- Problems with school performance
- Balance problems, unexplained clumsiness, or delayed gross motor development[47–50]
- Delayed speech or language development

The laterality (unilateral vs bilateral), duration of effusion, and the presence and severity of associated symptoms should be documented in the medical record at each assessment of the child with OME. When OME duration is uncertain, the clinician must take whatever evidence is at hand and make a reasonable estimate.

Evidence Profile: Documentation

- Aggregate evidence quality: C, observational studies
- Benefits: defines severity, duration has prognostic value, facilitates future communication with other clinicians, supports appropriate timing of intervention, and if consistently unilateral may identify a problem with specific ear other than OME (eg, retraction pocket or cholesteatoma)
- Harm: administrative burden

- Benefits-harms assessment: preponderance of benefit over harm
- Policy level: recommendation

3. CHILD AT RISK: Clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME, and should more promptly evaluate hearing, speech, language, and need for intervention. *Recommendation based on case series, preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.*

The panel defines the child at risk as one who is at increased risk for developmental difficulties (delay or disorder) because of sensory, physical, cognitive, or behavioral factors listed in Table 3. These factors are not caused by OME but can make the child less tolerant of hearing loss or vestibular problems secondary to middle-ear effusion. In contrast the child with OME who is not at risk is otherwise healthy and does not have any of the factors in Table 3.

TABLE 3. Risk Factors for Developmental Difficulties*

Permanent hearing loss independent of otitis media with effusion
Suspected or diagnosed speech and language delay or disorder
Autism-spectrum disorder and other pervasive developmental disorders
Syndromes (eg, Down) or craniofacial disorders that include cognitive, speech, and language delays
Blindness or uncorrectable visual impairment
Cleft palate, with or without associated syndrome
Developmental delay

*Sensory, physical, cognitive, or behavioral factors that place children who have otitis media

with effusion at increased risk for developmental difficulties (delay or disorder).

Earlier guidelines for managing OME have applied only to young children who are healthy and exhibit no developmental delays.[1] Studies of the relationship between OME and hearing loss or speech/language development typically exclude children with craniofacial anomalies, genetic syndromes, and other developmental disorders. Therefore, the available literature mainly applies to otherwise healthy children who meet inclusion criteria for randomized, controlled trials. Few, if any, existing studies dealing with developmental sequelae caused by hearing loss from OME can be generalized to children who are at risk.

Children who are at risk for speech or language delay would likely be further affected by hearing problems from OME,[51] even though definitive studies are lacking. For example, small comparative studies of children or adolescents with Down syndrome[52] or cerebral palsy[53] show poorer articulation and receptive language associated with a history of early otitis media. Large studies are unlikely to be forthcoming because of methodologic and ethical difficulties inherent in studying children who are delayed or at risk for further delays. Therefore, clinicians who manage children with OME should determine whether other conditions coexist that put a child at risk for developmental delay (Table 3), and then take these conditions into consideration when planning assessment and management.

Children with craniofacial anomalies (eg, cleft palate; Down syndrome; Robin sequence; coloboma, heart defect, choanal atresia, retarded growth and development, genital anomaly, and ear defect with deafness [CHARGE] association) have a higher prevalence of chronic OME, hearing loss (conductive and sensorineural), and speech or language delay than do children without these anomalies.[54–57] Other children may not be more prone to OME but are likely to have speech and language disorders, such as those children with permanent hearing loss

independent of OME,[58,59] specific language impairment,[60] autism-spectrum disorders,[61] or syndromes that adversely affect cognitive and linguistic development. Some retrospective studies[52,62,63] have found that hearing loss caused by OME in children with cognitive delays, such as Down syndrome, has been associated with lower language levels. Children with language delays or disorders with OME histories perform poorer on speech perception tasks than do children with OME histories alone.[64,65]

Children with severe visual impairments may be more susceptible to the effects of OME because they depend on hearing more than children with normal vision.[51] Any decrease in their most important remaining sensory input for language (hearing) may significantly compromise language development and their ability to interact and communicate with others. All children with severe visual impairments should be considered more vulnerable to OME sequelae, especially in the areas of balance, sound localization, and communication.

Management of the child with OME who is at increased risk for developmental delays should include hearing testing and speech and language evaluation, and may include speech and language therapy concurrent with managing OME, hearing aids or other amplification devices for hearing loss independent of OME, tympanostomy tube insertion,[54,63,66,67] and hearing testing after OME resolves to document improvement, because OME can mask a permanent underlying hearing loss and delay detection.[59,68,69]

Evidence Profile: Child At Risk

- Aggregate evidence quality: C, observational studies of children at risk; D, expert opinion on the ability of prompt assessment and management to alter outcomes
- Benefits: optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; avoiding limitations on the benefits of educational

interventions because of hearing problems from OME

- Harm: cost, time, and specific risks of medications or surgery
- Benefits-harms assessment: exceptional preponderance of benefits over harm based on subcommittee consensus because of circumstances to date precluding randomized trials
- Policy level: recommendation

4. 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 from the date of diagnosis (if onset is unknown). *Recommendation based on systematic review of cohort studies and preponderance of benefit over harm.*

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.[2,70]

The likelihood of spontaneous resolution of OME is determined by the cause and duration of effusion.[70] For example, about 75% to 90% of residual OME after an AOM episode resolves spontaneously by 3 months.[71–73] Similar outcomes of defined onset during a period of surveillance in a cohort study are observed for OME.[32,37] Another favorable situation involves improvement (not resolution) of newly detected OME defined as change in tympanogram from type B (flat curve) to non-B (anything other than a flat curve). About 55% of children so defined improve by 3 months,[70] but one third will have OME relapse within the next 3 months.[4] Although a type B tympanogram is an imperfect measure of OME (81% sensitivity and 74% specificity vs myringotomy), it is the most widely reported measure suitable for deriving pooled resolution rates.[2,70]

About 25% of newly detected OME of unknown prior duration in children aged 2 to 4

years resolves by 3 months when resolution is defined as a change in tympanogram from type B to type A/C1 (peak pressure >200 daPa).[2,70,74–77] Resolution rates may be higher for infants and young children in whom the preexisting duration of effusion is generally shorter, and particularly for those observed prospectively in studies or in the course of well-child care. Documented bilateral OME of 3 months' duration or longer resolves spontaneously after 6 to 12 months in about 30% of children aged primarily 2 years or older, with only marginal benefits if observed longer.[70]

Any intervention for OME (medical or surgical) other than observation carries some inherent harm. There is little 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 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. 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.[78,79]

The recommendation for a 3-month period of observation is based on a clear preponderance of benefit over harm and is consistent with the original OME guideline intent of avoiding unnecessary surgery.[1] At the discretion of the clinician, this 3-month period of watchful waiting may include interval visits at which OME is monitored using pneumatic otoscopy, tympanometry, or both. Factors to consider in determining the optimal interval(s) for follow-up include clinical judgment, parental comfort level, unique characteristics of the child and/or his environment, access to a health care system, and hearing levels (HLs) if known.

After documented resolution of OME in all affected ears, further follow-up is

unnecessary.

Evidence Profile: Watchful Waiting

- Aggregate evidence quality: B, systematic review of cohort studies
- Benefit: avoid unnecessary interventions, take advantage of favorable natural history, avoid unnecessary referrals and evaluations
- Harm: delays in therapy for OME that will not resolve with observation; prolongation of hearing loss
- Benefits-harms assessment: preponderance of benefit over harm
- Policy level: recommendation

5. MEDICATION: Antihistamines and decongestants are ineffective for OME and are not recommended for treatment. Antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management. *Recommendation based on systematic review of randomized, controlled trials and preponderance of harm over benefit.*

Therapy for OME is appropriate only if persistent and clinically significant benefits can be achieved beyond spontaneous resolution. Although statistically significant benefits have been demonstrated for some medications, they are short term and relatively small in magnitude. Moreover, significant adverse events may occur with all medical therapies.

The prior OME guideline[1] found no data supporting antihistamine-decongestant combinations in treating OME. Meta-analysis of 4 randomized trials showed no significant benefit for antihistamines or decongestants versus placebo. No additional studies have been published since 1994 to change this recommendation. Adverse effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood

pressure variability.

Long-term benefits of antimicrobial therapy for OME are unproved despite a modest short-term benefit for 2 to 8 weeks in randomized trials.[1,80,81] Initial benefits, however, can become nonsignificant within 2 weeks of stopping the medication.[82] Moreover, about 7 children would need to be treated with antimicrobials to achieve one short-term response.[1] Adverse effects of antimicrobials are significant and may include rashes, vomiting, diarrhea, allergic reactions, alteration of the child's nasopharyngeal flora, development of bacterial resistance,[83] and cost. Societal consequences include direct transmission of resistant bacterial pathogens in homes and child care centers.[84]

The prior OME guideline[1] did not recommend oral steroids for treating OME in children. A later meta-analysis[85] showed no benefit for oral steroid versus placebo within 2 weeks, but did show a short-term benefit for oral steroid plus antimicrobial versus antimicrobial alone in 1 out of 3 children treated. This benefit became nonsignificant after several weeks in a prior meta-analysis[1] and in a large randomized trial.[86] Oral steroids can produce behavioral changes, increased appetite, and weight gain.[1] Additional adverse effects may include adrenal suppression, fatal varicella infection, and avascular necrosis of the femoral head.[3] Although intranasal steroids have fewer adverse effects, one randomized trial[87] showed statistically equivalent outcomes at 12 weeks for intranasal beclomethasone plus antimicrobials versus antimicrobials alone for OME.

Antimicrobial therapy, with or without steroids, has not been demonstrated to be effective in long-term resolution of OME, but in some cases this therapy can be considered an option because of short-term benefit in randomized trials, when the parent or caregiver expresses a strong aversion to impending surgery. In this circumstance a single course of therapy for 10 to 14 days may be used. The likelihood that the OME will resolve long term with these regimens is

small, and prolonged or repetitive courses of antimicrobials or steroids are strongly not recommended.

Other nonsurgical therapies that are discussed in the OME literature include autoinflation of the eustachian tube, oral or intratympanic use of mucolytics, and systemic use of pharmacologic agents other than antimicrobials, steroids and antihistamine-decongestants. Insufficient data exist for any of these therapies to be recommended in treating OME.[3]

Evidence Profile: Medication

- Aggregate evidence quality: A, systematic review of well-designed randomized, controlled trials
- Benefit: avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse
- Harm: adverse effects of specific medications as listed previously; societal impact of antimicrobial therapy on bacterial resistance and transmission of resistant pathogens
- Benefits-harms assessment: preponderance of harm over benefit
- Policy level: recommendation against

6. HEARING AND LANGUAGE: Hearing testing is recommended when OME persists for 3 months or longer, or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME. Language testing should be conducted for children with hearing loss. *Recommendation based on cohort studies and preponderance of benefit over risk.*

Hearing Testing

Hearing testing is recommended when OME persists for 3 months or longer, or at any time that language delay, learning problems, or a significant hearing loss is suspected.

Conductive hearing loss often accompanies OME[1,88] and may adversely affect binaural processing,[89] sound localization,[90] and speech perception in noise.[91–94] Hearing loss caused by OME may impair early language acquisition,[95–97] but the child's home environment has a greater impact on outcomes[98]; recent randomized trials[41,99,100] suggest no impact on children with OME who are not at risk identified by screening or surveillance.

Studies examining hearing sensitivity in children with OME report that average pure tone hearing loss at 4 frequencies (500, 1000, 2000, and 4000 Hz) ranges from normal hearing to moderate hearing loss (0–55 dB). The 50th percentile is about 25 dB hearing level (HL) and about 20% of ears exceed 35 dB HL.[101,102] Unilateral OME with hearing loss results in overall poorer binaural hearing than in infants with normal middle-ear function bilaterally.[103,104] Although based on limited research, there is evidence that children experiencing the greatest conductive hearing loss for the longest periods may be more likely to exhibit developmental and academic sequelae.[1,95,105]

Initial hearing testing for children aged 4 years or older can be done in the primary care setting.[106] Testing should be performed in a quiet environment, preferably in a separate closed or soundproofed area set aside specifically for that purpose. Conventional audiometry with earphones is performed with a fail criterion of >20 dB HL at 1 or more frequencies (500, 1000, 2000, 4000 Hz) in either ear.[106,107] Methods not recommended as substitutes for primary care hearing testing include tympanometry and pneumatic otoscopy[102]; caregiver judgment regarding hearing loss[108,109]; speech audiometry; and tuning forks, acoustic reflectometry, and behavioral observation.[1]

Comprehensive audiologic evaluation is recommended for children who fail primary care testing, are younger than 4 years, or cannot be tested in the primary care setting. Audiologic

assessment includes evaluating air-conduction and bone-conduction thresholds for pure tones, speech detection or speech recognition thresholds,[102] and measuring speech understanding if possible.[94] The method of assessment depends on the developmental age of the child and might include visual reinforcement or conditioned orienting response audiometry for infants aged 6 to 24 months, play audiometry for children aged 24 to 48 months, or conventional screening audiometry for children aged 4 years and older.[106] The auditory brain stem response and otoacoustic emission are tests of auditory pathway structural integrity, not hearing, and should not substitute for behavioral pure tone audiometry.[106]

Language Testing

Language testing should be conducted for children with hearing loss (pure tone average greater than 20 dB HL on comprehensive audiometric evaluation). Testing for language delays is important because communication is integral to all aspects of human functioning. Young children with speech and language delays during the preschool years are at risk for continued communication problems and later delays in reading and writing.[110–112] In one study, 6% to 8% of children aged 3 years and 2% to 13% of kindergartners had language impairment.[113] Language intervention can improve communication and other functional outcomes for children with histories of OME.[114]

Children who experience repeated and persistent episodes of OME and associated hearing loss during early childhood may be at a disadvantage for learning speech and language.[79,115] Although Shekelle and colleagues[2] concluded there was no evidence to support the concern that OME during the first 3 years of life was related to later receptive or expressive language, this meta-analysis should be interpreted cautiously because it did not examine specific language domains, such as vocabulary, and because the independent variable was OME and not

hearing loss. Other meta-analyses[79,115] have suggested at most a small negative association of OME and hearing loss on children's receptive and expressive language through the elementary school years. The clinical significance of these effects for language and learning is unclear for the child not at risk. For example, in one randomized trial,[100] prompt insertion of tympanostomy tubes for OME did not improve developmental outcomes at age 3 years, regardless of baseline hearing levels. In another randomized trial,[116] however, prompt tube insertion achieved small benefits for children with bilateral OME and hearing loss.

Clinicians should ask the parent or caregiver about specific concerns regarding their child's language development. Children's speech and language can be tested at ages 6 to 36 months by direct engagement of a child and interviewing the parent using the Early Language Milestone Scale.[117] Other approaches require interviewing only the child's parent or caregiver, such as the MacArthur Communicative Development Inventory[118] and the Language Development Survey.[119] For older children the Denver Developmental Screening Test II[120] can be used to screen general development, including speech and language. Comprehensive speech and language evaluation is recommended for children who fail testing or whenever the child's parent or caregiver expresses concern.[121]

Evidence Profile: Hearing and Language

- Aggregate evidence quality: B, diagnostic studies with minor limitations; C, observational studies
- Benefit: to detect hearing loss and language delay and identify strategies or interventions to improve developmental outcomes
- Harm: parental anxiety, direct and indirect costs of assessment, false-positive results
- Balance of benefit and harm: preponderance of benefit over harm

- Policy level: recommendation

7. SURVEILLANCE: Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. *Recommendation based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.*

If OME is asymptomatic, and is likely to resolve spontaneously, intervention is unnecessary even if OME persists for more than 3 months. The clinician should determine if risk factors exist that would predispose to undesirable sequelae or predict non-resolution of the effusion. As long as OME persists, the child is at risk for sequelae and must be periodically reevaluated for factors that would prompt intervention.

The 1994 OME guideline[1] recommended surgery for OME persisting 4 to 6 months with hearing loss, but requires reconsideration because of later data on tubes and developmental sequelae.[122] For example, selecting surgical candidates using duration-based criteria (eg, OME more than 3 months or exceeding a cumulative threshold) does not improve developmental outcomes in infants and toddlers who are not at risk.[41,42,99,100] Further, the 1994 OME guideline did not specifically address managing effusion without significant hearing loss persisting more than 6 months.

Asymptomatic OME usually resolves spontaneously, but resolution rates decrease the longer the effusion has been present,[36,76,77] and relapse is common.[123] Risk factors that make spontaneous resolution less likely include[124,125]

- Onset of OME in the summer or fall season

- Hearing loss greater than 30 dB HL in the better-hearing ear
- History of prior tympanostomy tubes
- Not having had an adenoidectomy

Children with chronic OME are at risk for structural damage of the tympanic membrane[126] because the effusion contains leukotrienes, prostaglandins, and arachidonic acid metabolites that invoke a local inflammatory response.[127] Reactive changes may occur in the adjacent tympanic membrane and mucosal linings. A relative underventilation of the middle ear produces a negative pressure that predisposes to focal retraction pockets, generalized atelectasis of the tympanic membrane, and cholesteatoma.

Structural integrity is assessed by carefully examining the entire tympanic membrane, which, in many cases, can be accomplished by the primary care clinician using a handheld pneumatic otoscope. A search should be made for retraction pockets, ossicular erosion, and areas of atelectasis or atrophy. If there is any uncertainty that all observed structures are normal, the patient should be examined using an otomicroscope. All children with these tympanic membrane conditions, regardless of OME duration, should have a comprehensive audiologic evaluation.

Conditions of the tympanic membrane that generally mandate inserting a tympanostomy tube are posterosuperior retraction pockets, ossicular erosion, adhesive atelectasis, and retraction pockets that accumulate keratin debris. Ongoing surveillance is mandatory because the incidence of structural damage increases with effusion duration.[128]

As noted in Recommendation 6, children with persistent OME for 3 months or longer should have their hearing tested. Based on these results, clinicians can identify 3 levels of action based on hearing levels obtained for the better-hearing ear using earphones, or in sound field using speakers if the child is too young for ear-specific testing.

1. *Hearing levels ≥40 dB (at least a moderate hearing loss).* Comprehensive audiologic evaluation is indicated if not previously performed. If moderate hearing loss is documented, and persists at this level, surgery is recommended because persistent hearing loss of this magnitude that is permanent in nature has been shown to impact speech, language, and academic performance.[129–131]
2. *Hearing levels 21 to 39 dB (mild hearing loss).* Comprehensive audiologic evaluation is indicated if not previously performed. Mild sensorineural hearing loss has been associated with difficulties in speech, language, and academic performance in school,[129,132] and persistent mild conductive hearing loss from OME may have similar impact. Further management should be individualized based on effusion duration, severity of hearing loss, and parent or caregiver preference, and may include strategies to optimize the listening and learning environment (Table 4) or surgery. Repeat hearing testing should be performed in 3 to 6 months if OME persists at follow-up evaluation or tympanostomy tubes have not been placed.
3. *Hearing levels ≤20 dB (normal hearing).* Repeat hearing test should be performed in 3 to 6 months if OME persists at follow-up evaluation.

TABLE 4. Strategies for Optimizing the Listening-Learning Environment for Children With OME and Hearing Loss*

Get within 3 feet of the child before speaking.
Turn off competing audio signals, such as unnecessary music and television in the background.
Face the child and speak clearly, using visual clues (hands, pictures) in addition to speech.
Slow the rate, raise the level, and enunciate speech directed at the child.

Read to or with the child, explaining pictures and asking questions.
Repeat words, phrases, and questions when misunderstood.
Assign preferential seating in the classroom near the teacher.
Use a frequency modulated personal or sound field amplification system in the classroom.

*Modified with permission from Roberts et al.[78,79]

In addition to hearing loss and speech or language delay, other factors may influence the decision to intervene for persistent OME. Roberts and coworkers[98,133] showed that the caregiving environment is more strongly related to school outcome than was OME or hearing loss. Risk factors for delays in speech and language development caused by a poor caregiving environment included low maternal educational level, unfavorable child care environment, and low socioeconomic status. In such cases, these factors may be additive to the hearing loss in affecting lower school performance and classroom behavior problems.

Persistent OME may be associated with physical or behavioral symptoms, including hyperactivity, poor attention, and behavioral problems in some studies[134–136] and reduced child quality of life.[46] Conversely, young children randomized to early versus late tube insertion for persistent OME showed no behavioral benefits from early surgery.[41,100] Children with chronic OME also have significantly poorer vestibular function and gross motor proficiency when compared with non-OME controls.[48–50] Moreover, vestibular function, behavior, and quality of life can improve after tympanostomy tube insertion.[47,137,138] Other physical symptoms of OME that, if present and persistent, may warrant surgery include otalgia, unexplained sleep disturbance, and coexisting recurrent AOM. Tubes reduce the absolute incidence of recurrent AOM by about 1 episode per child per year, but the relative risk reduction is 56%.[139]

The risks of continued observation of children with OME must be balanced against the

risks of surgery. Children with persistent OME examined regularly at 3- to 6-month intervals, or sooner if OME-related symptoms develop, are most likely at low risk for physical, behavioral, or developmental sequelae of OME. Conversely, prolonged watchful waiting of OME is not appropriate when regular surveillance is impossible or when the child is at risk for developmental sequelae of OME because of comorbidities (Table 3). For these children, the risks of anesthesia and surgery (see Recommendation 9) may be less than continued observation.

Evidence Profile: Surveillance

- Aggregate evidence quality: C, observational studies and some randomized trials
- Benefit: avoiding interventions that do not improve outcomes
- Harm: allowing structural abnormalities to develop in the tympanic membrane, underestimating the impact of hearing loss on a child, failing to detect significant signs or symptoms that require intervention
- Balance of benefit and harm: preponderance of benefit over harm
- Policy level: recommendation

8. REFERRAL: When children with OME are referred by the primary care clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery), and provide additional relevant information such as history of AOM and developmental status of the child. *Option based on panel consensus and a preponderance of benefit over harm.*

This recommendation emphasizes the importance of communication between the referring primary care clinician and the otolaryngologist, audiologist, and speech-language pathologist. Parents and caregivers may be confused and frustrated when a recommendation for

surgery is made for their child because of conflicting information about alternative management strategies. Choosing among management options is facilitated when primary care physicians and advanced practice nurses who best know the patient's history of ear problems and general medical status provide the specialist with accurate information. Although there are no studies showing improved outcomes from better documentation of OME histories, there is a clear need for better mechanisms to convey information and expectations from primary care clinicians to consultants and subspecialists.[140–142]

When referring a child for evaluation to an otolaryngologist, the primary care physician should explain the following to the parent or caregiver of the patient:

- Reason for referral—Explain that the child is seeing an otolaryngologist for evaluation, which is likely to include ear examination and audiologic testing, and not necessarily simply to be scheduled for surgery.
- What to expect—Explain that surgery may be recommended and let the parent know that the otolaryngologist will further explain the options, benefits, and risks.
- Decision-making process—Explain that there are many alternatives for management and that surgical decisions are elective; the parent or caregiver should be encouraged to express to the surgeon any concerns they may have about recommendations made.

When referring a child to an otolaryngologist, audiologist, or speech-language pathologist, the minimum information that should be conveyed in writing includes the following:

- Duration of OME—State how long fluid has been present.
- Laterality of OME—State whether 1 or both ears have been affected.
- Results of prior hearing testing or tympanometry.
- Suspected speech or language problems—State if there had been a delay in speech and

language development or if the parent or a caregiver has expressed concerns about the child's communication abilities, school achievement, or attentiveness.

- Conditions that might exacerbate the deleterious effects of OME—State if the child has conditions such as permanent hearing loss, impaired cognition, developmental delays, cleft lip or palate, or unstable or nonsupportive family or home environment.
- AOM history—State if the child has a history of recurrent AOM.

Additional medical information that should be provided to the otolaryngologist by the primary care clinician includes

- Parental attitude toward surgery—State if the parents have expressed a strong preference for or against surgery as a management option.
- Related conditions that might require concomitant surgery—State if there have been other conditions that might warrant surgery if the child is going to have general anesthesia (eg, nasal obstruction and snoring that might be an indication for adenoidectomy, or obstructive breathing during sleep that might mean tonsillectomy is indicated).
- General health status—State if there are any conditions that might present problems for surgery or administering general anesthesia such as congenital heart abnormality, bleeding disorder, asthma or reactive airway disease, or family history of malignant hyperthermia.

After evaluating the child, the otolaryngologist, audiologist, or speech-language pathologist should inform the referring physician regarding their diagnostic impression, plans for further assessment, and recommendations for ongoing monitoring and management.

Evidence Profile: Referral

- Aggregate evidence quality: C, observational studies
- Benefit: better communication, improved decision making
- Harm: confidentiality concerns, administrative burden, increased parent or caregiver anxiety
- Benefits-harms assessment: balance of benefit and harm
- Policy level: option

9. SURGERY: When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis). Repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME. *Recommendation based on randomized, controlled trials with a preponderance of benefit over harm.*

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. Candidates for surgery include children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of hearing status, and OME and structural damage to the tympanic membrane or middle ear. Ultimately the recommendation for surgery must be individualized, based on consensus between the primary care physician, otolaryngologist, and parent or caregiver that a particular child would benefit from intervention. Children with OME of any duration who are at risk are candidates for earlier surgery.

Tympanostomy tubes are recommended for initial surgery because randomized trials show a mean 62% relative decrease in effusion prevalence and an absolute decrease of 128 effusion days per child during the next year.[139,143–145] Hearing levels improve by a mean of 6 to 12 dB while the tubes remain patent.[146,147] Adenoidectomy plus myringotomy (without tube insertion) has comparable efficacy in children aged 4 years or older,[143] but is more invasive with additional surgical and anesthetic risks. Similarly, the added risk of adenoidectomy outweighs the limited, short-term benefit for children aged 3 years or older without prior tubes.[148] Consequently, adenoidectomy is not recommended for initial OME surgery unless a distinct indication exists, such as adenoiditis, postnasal obstruction, or chronic sinusitis.

About 20% to 50% of children who have had tympanostomy tubes have OME relapse after tube extrusion that may require additional surgery.[144,145,149] When a child needs repeat surgery for OME, adenoidectomy is recommended (unless the child has an overt or submucous cleft palate) because it confers a 50% reduction in the need for future operations.[143,150,151] The benefit of adenoidectomy is apparent at age 2 years,[150] greatest for children aged 3 years or older, and independent of adenoid size.[143,151,152] Myringotomy is performed concurrent with adenoidectomy. Myringotomy plus adenoidectomy is effective for children aged 4 years or older,[143] but tube insertion is advised for younger children, when potential relapse of effusion must be minimized (eg, children at risk), or when pronounced inflammation of the tympanic membrane and middle-ear mucosa is present.

Tonsillectomy or myringotomy alone (without adenoidectomy) is not recommended to treat OME. Although tonsillectomy is either ineffective[152] or of limited efficacy,[148,150] the risks of hemorrhage (about 2%) and additional hospitalization outweigh any potential benefits unless a distinct indication for tonsillectomy exists. Myringotomy alone, without tube placement or

adenoidectomy, is ineffective for chronic OME[144,145] because the incision closes within several days. Laser-assisted myringotomy extends the ventilation period several weeks,[153] but randomized trials with concurrent controls have not been conducted to establish efficacy. In contrast, tympanostomy tubes ventilate the middle ear for an average of 12 to 14 months.[144,145]

Anesthesia mortality has been reported to be about 1:50 000 for ambulatory surgery,[154] but the current fatality rate may be lower.[155] Laryngospasm and bronchospasm occur more often in children receiving anesthesia than adults. Tympanostomy tube sequelae are common[156] but are generally transient (otorrhea) or do not affect function (tympanosclerosis, focal atrophy, or shallow retraction pocket). Tympanic membrane perforations, which may require repair, are seen in 2% of children after placement of short-term (grommet-type) tubes and 17% after long-term tubes.[156] Adenoidectomy has a 0.2% to 0.5% incidence of hemorrhage[150,157] and 2% incidence of transient velopharyngeal insufficiency.[148] Other potential risks of adenoidectomy, such as nasopharyngeal stenosis and persistent velopharyngeal insufficiency, can be minimized with appropriate patient selection and surgical technique.

There is a clear preponderance of benefit over harm when considering the impact of surgery for OME on effusion prevalence, hearing levels, subsequent incidence of AOM, and the need for reoperation after adenoidectomy. Information about adenoidectomy in children younger than 4 years, however, remains limited. Although the cost of surgery and anesthesia is nontrivial, it is offset by reduced OME and AOM after tube placement and by reduced need for reoperation after adenoidectomy. About 8 adenoidectomies are needed to avoid a single instance of tube reinsertion; however, each avoided surgery probably represents a larger reduction in the number of AOM and OME episodes, including those in children who did not require additional surgery.[150]

Evidence Profile: Surgery

- Aggregate evidence quality: B, randomized, controlled trials with minor limitations
- Benefit: improved hearing, reduced prevalence of OME, reduced incidence of AOM, and less need for additional tube insertion (after adenoidectomy)
- Harm: risks of anesthesia and specific surgical procedures, sequelae of tympanostomy tubes
- Benefits-harms assessment: preponderance of benefit over harm
- Policy level: recommendation

10. CAM: No recommendation is made regarding CAM as a treatment for OME. *No recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.*

The 1994 OME guideline[1] made no recommendation regarding CAM as a treatment for OME, and no subsequent controlled studies have been published to change this conclusion. The current statement of "no recommendation" is based on lack of scientific evidence documenting efficacy plus a balance of benefit and harm.

Evidence concerning CAM is insufficient to determine if the outcomes achieved for OME differ from those achieved by watchful waiting and spontaneous resolution. There are no randomized, controlled trials with adequate sample size on the efficacy of CAM for OME. While many case reports and subjective reviews on CAM treatment of AOM were found, little is published on OME treatment or prevention. Homeopathy[158] and chiropractic treatments[159] were assessed in pilot studies with small numbers of patients that failed to show clinically or statistically significant benefits. Consequently, there is no research base on which to develop a

recommendation concerning CAM for OME.

The natural history of OME in childhood (discussed previously) is such that almost any intervention can be "shown" to have helped in an anecdotal, uncontrolled report or case series. The efficacy of CAM, or any other intervention for OME, can only be shown with parallel group randomized, controlled trials with valid diagnostic methods and adequate sample size. Unproved modalities that have been claimed to provide benefit in middle-ear disease include osteopathic and chiropractic manipulation, dietary exclusions (such as dairy), herbal and other dietary supplements, acupuncture, traditional Chinese medicine, and homeopathy. None of these modalities, however, have yet been subjected to a published, peer-reviewed clinical trial.

The absence of any published clinical trials also means that all reports of CAM adverse effects are anecdotal. A systematic review of recent evidence[160] found significant serious adverse effects of unconventional therapies for children, most of which were associated with inadequately regulated herbal medicines. One report on malpractice liability associated with CAM therapies[161] did not specifically address childhood issues. Allergic reactions to echinacea occur but seem to be rare in children.[162] A general concern about herbal products is the lack of any governmental oversight into product quality or purity.[160,163,164] Further, herbal products may alter blood levels of allopathic medications, including anticoagulants. A possible concern with homeopathy is the worsening of symptoms, which is viewed as a positive, early sign of homeopathic efficacy. The adverse effects of manipulative therapies (such as chiropractic treatments and osteopathy) in children are difficult to assess because of scant evidence, but a case series of 332 children treated for AOM or OME with chiropractic manipulation did not mention any side effects.[165] Quadriplegia has been reported, however, following spinal manipulation in an infant with torticollis.[166]

Evidence Profile: Complementary and Alternative Medicine

- Aggregate evidence quality: D, case series without controls
- Benefit: not established
- Harm: potentially significant, depending on the intervention
- Benefits-harms assessment: uncertain balance of benefit and harm
- Policy level: no recommendation

11. ALLERGY MANAGEMENT: No recommendation is made regarding allergy management as a treatment for OME. *No recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.*

The 1994 OME guideline[1] made no recommendation regarding allergy management as a treatment for OME and no subsequent controlled studies have been published to change this conclusion. The current statement of "no recommendation" is based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME, plus a balance of benefit and harm.

A linkage between allergy and OME has long been speculated but to date remains unquantified. The prevalence of allergy among OME patients has been reported to range from less than 10% to more than 80%.[167] Allergy has long been postulated to cause OME through its contribution to eustachian tube dysfunction.[168] The cellular response of respiratory mucosa to allergens has been well studied. Therefore, like other parts of respiratory mucosa, the mucosa lining the middle-ear cleft is capable of an allergic response.[169,170] Sensitivity to allergens varies among individuals, and atopy may involve neutrophils in type I allergic reactions that enhance the inflammatory response.[171]

The correlation between OME and allergy has been widely reported, but no prospective studies have examined the effects of immunotherapy compared with observation alone or other management options. Reports of OME cure after immunotherapy or food elimination diets[172] are impossible to interpret without concurrent control groups because of the favorable natural history of most untreated OME. The documentation of allergy in published reports has been defined inconsistently (medical history, physical examination, skin-prick testing, nasal smears, serum IgE and eosinophil counts, inflammatory mediators in effusions). Study groups have been drawn primarily from specialist offices, likely lack heterogeneity, and are not representative of general medical practice.

Evidence Profile: Allergy Management

- Aggregate evidence quality: D, case series without controls
- Benefit: not established
- Harm: adverse effects and cost of medication, physician evaluation, elimination diets, and desensitization
- Benefits-harms assessment: balance of benefit and harm
- Policy level: no recommendation

RESEARCH NEEDS

Diagnosis

- Further standardize the definition of OME.
- 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.

- Determine the optimal methods for teaching pneumatic otoscopy to residents and clinicians.
- Develop a brief, reliable, objective method for diagnosing OME.
- Develop a classification method for identifying the presence of OME for practical use by clinicians that is based on quantifiable tympanometric characteristics.
- Assess the usefulness of algorithms combining pneumatic otoscopy and tympanometry for detecting OME in clinical practice.
- Conduct additional validating cohort studies of acoustic reflectometry as a diagnostic method for OME, particularly in children younger than 2 years.

Child At Risk

- Better define the child with OME who is at risk for speech, language, and learning problems.
- Conduct large, multicenter observational cohort studies to identify the child at risk who is most susceptible to potential adverse sequelae of OME.
- Conduct large, multicenter observational cohort studies to analyze outcomes achieved with alternative management strategies for OME in children at risk.

Watchful Waiting

- Define the spontaneous resolution of OME in infants and young children (existing data are limited primarily to children aged 2 years or older).
- 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).

- Develop prognostic indicators to identify the best candidates for watchful waiting.
- 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.

Medication

- Clarify which children, if any, should receive antimicrobials, steroids, or both for OME.
- Conduct a randomized, placebo-controlled trial on the efficacy of antimicrobial therapy, with or without concurrent oral steroid, in avoiding surgery in children with OME who are surgical candidates and have not received recent antimicrobials.
- Investigate the role of mucosal surface biofilms in refractory or recurrent OME and develop targeted interventions.

Hearing and Language

- Conduct longitudinal studies on the natural history of hearing loss accompanying OME.
- Develop improved methods for describing and quantifying the fluctuations in hearing of children with OME over time.
- Conduct prospective controlled studies on the relation of hearing loss associated with OME to later auditory, speech, language, behavioral, and academic sequelae.
- Develop reliable, brief, objective methods for estimating hearing loss associated with OME.
- Develop reliable, brief, objective methods for estimating speech or language delay associated with OME.

- Evaluate the benefits and administrative burden of language testing by primary care clinicians.
- Agree on the aspects of language that are vulnerable to, or affected by, hearing loss caused by OME, and reach a consensus on the best tools for measurement.
- Determine if OME and associated hearing loss place children from special populations at greater risk for speech and language delays.

Surveillance

- Develop better tools for monitoring children with OME, suitable for routine clinical care.
- Assess the value of new strategies for monitoring OME, such as acoustic reflectometry performed at home by the parent or caregiver, in optimizing surveillance.
- Improve our ability to identify children who would benefit from early surgery instead of prolonged surveillance.
- Promote early detection of structural abnormalities in the tympanic membrane associated with OME that may require surgery to prevent complications.
- Clarify and quantify the role of parent or caregiver education, socioeconomic status, and quality of the caregiving environment as modifiers of OME developmental outcomes.
- Develop methods for minimizing loss to follow-up during OME surveillance.

Surgery

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

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

Complementary and Alternative Medicine

- Conduct randomized, controlled trials on the efficacy of CAM modalities for OME.
- Develop strategies to identify parents or caregivers who use CAM therapies for their child's OME, and encourage surveillance by the primary care clinician.

Allergy Management

- Evaluate the causal role of atopy in OME.
- Conduct randomized, controlled trials on the efficacy of allergy therapy for OME that are generalizable to the primary care setting.

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

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Conflicts of Interest

S. Michael Marcy, MD: consultant to Abbott Laboratories; consultant to GlaxoSmithKline (vaccines).

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