

Clinical Practice Guideline: Tympanostomy Tubes in Children

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Abstract

Objective. Insertion of tympanostomy tubes is the most common ambulatory surgery performed on children in the United States. Tympanostomy tubes are most often inserted because of persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy. Despite the frequency of tympanostomy tube insertion, there are currently no clinical practice guidelines in the United States that address specific indications for surgery. This guideline is intended for any clinician involved in managing children, aged 6 months to 12 years, with tympanostomy tubes or being considered for tympanostomy tubes in any care setting, as an intervention for otitis media of any type.

Purpose. The primary purpose of this clinical practice guideline is to provide clinicians with evidence-based recommendations on patient selection and surgical indications for and management of tympanostomy tubes in children. The development group broadly discussed indications for tube placement, perioperative management, care of children with indwelling tubes, and outcomes of tympanostomy tube surgery. Given the lack of current published guidance on surgical indications, the group focused on situations in which tube insertion would be optional, recommended, or not recommended. Additional emphasis was placed on opportunities for quality improvement, particularly regarding shared decision making and care of children with existing tubes.

Action Statements. The development group made a *strong recommendation* that clinicians should prescribe topical antibiotic

eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea. The panel made *recommendations* that (1) clinicians should not perform tympanostomy tube insertion in children with a single episode of otitis media with effusion (OME) of less than 3 months' duration; (2) clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer (chronic OME) or prior to surgery when a child becomes a candidate for tympanostomy tube insertion; (3) clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer (chronic OME) and documented hearing difficulties; (4) clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME who did not receive tympanostomy tubes until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected; (5) clinicians should not perform tympanostomy tube insertion in children with recurrent acute otitis media (AOM) who do not have middle ear effusion in either ear at the time of assessment for tube candidacy; (6) clinicians should offer bilateral tympanostomy tube insertion to children with recurrent AOM who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy; (7) clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors; (8) in the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications; (9) clinicians should not encourage routine, prophylactic water precautions (use of earplugs, headbands; avoidance of swimming or water sports) for children with tympanostomy tubes.

The development group provided the following *options*: (1) 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 including, but not limited to, vestibular problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life and (2) 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).

Keywords

otitis media, tympanostomy tubes, grommets, otorrhea, middle ear effusion, pediatric otolaryngology, developmental delay disorders

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Introduction

Insertion of tympanostomy tubes is the most common ambulatory surgery performed on children in the United States. The tympanostomy tube, which is approximately 1/20th of an inch in width, is placed in the child's eardrum (tympanic membrane) to ventilate the middle ear space (**Figures 1 and 2**). Each year, 667,000 children younger than 15 years receive tympanostomy tubes, accounting for more than 20% of all ambulatory surgery in this group.¹ By the age of 3 years, nearly 1 of every 15 children (6.8%) will have tympanostomy tubes, increasing by more than 2-fold with day care attendance.²

Tympanostomy tubes are most often inserted because of persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy. All of these conditions are encompassed by the term *otitis media* (middle ear inflammation), which is second in frequency only to acute upper respiratory infection (URI) as the most common illness diagnosed in children by health care professionals.⁴ Children younger than 7 years

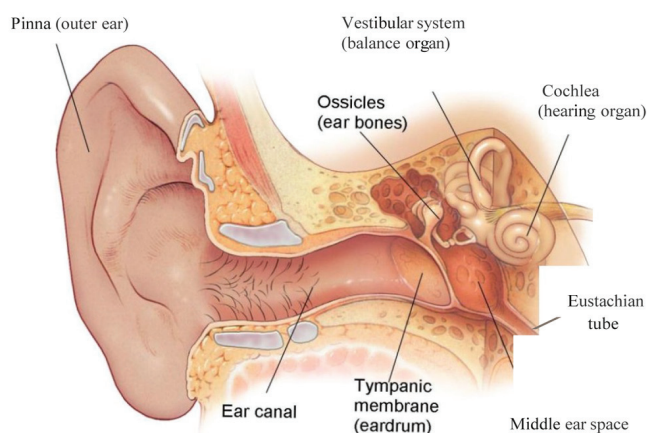


Figure 1. Relationship of the outer ear (pinna and ear canal), middle ear (ossicles and tympanic membrane), and inner ear (cochlea vestibular system). Tubes are inserted into the tympanic membrane (eardrum). Reproduced with permission.³

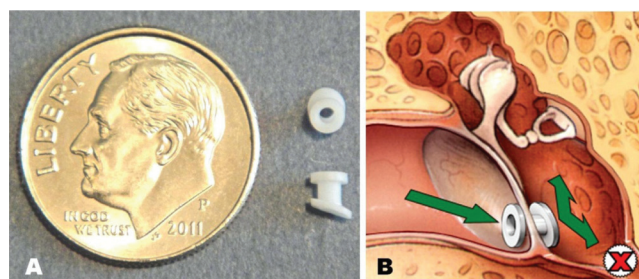


Figure 2. (A) Size of tympanostomy tube compared to a dime. (B) Tympanostomy tubes are also called “ventilation tubes” because the opening allows air to enter the middle ear directly from the ear canal (arrows), which bypasses the child's poorly functioning eustachian tube (X). Reproduced with permission.³

are at increased risk of otitis media because of their immature immune systems and poor function of the eustachian tube, a slender connection between the middle ear and back of the nose that normally ventilates the middle ear space and equalizes pressure with the external environment.⁵

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Table 1. Abbreviations and definitions of common terms.

Term	Definition
Myringotomy	A surgical procedure in which an incision is made in the tympanic membrane for the purpose of draining fluid or providing short-term ventilation
Tympanostomy tube insertion	Surgical placement of a tube through a myringotomy incision for purposes of temporary middle ear ventilation. Tympanostomy tubes generally last several months to several years, depending on tube design and placement location in the tympanic membrane. Synonyms include <i>ventilation tubes</i> , <i>pressure equalization tubes</i> , <i>grommets</i> (United Kingdom), and <i>bilateral myringotomy and tubes</i>
Otitis media with effusion (OME) Chronic OME	The presence of fluid in the middle ear without signs or symptoms of acute ear infection (AOM) OME persisting for 3 months or longer from the date of onset (if known) or from the date of diagnosis (if onset unknown)
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 the use of noisemakers or other nonstandardized methods
Acute otitis media (AOM) Persistent AOM	The rapid onset of signs and symptoms of inflammation of the middle ear Persistence of symptoms or signs of AOM during antimicrobial therapy (treatment failure) and/or relapse of AOM within 1 month of completing antibiotic therapy. When 2 episodes of otitis media occur within 1 month, it may be difficult to distinguish recurrence of AOM (ie, a new episode) from persistent otitis media (ie, relapse)
Recurrent AOM	Three or more well-documented and separate AOM episodes in the past 6 months or at least 4 well-documented and separate AOM episodes in the past 12 months with at least 1 in the past 6 months ⁹
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
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
Sensorineural hearing loss (SNHL)	Hearing loss that results from abnormal transmission of sound from the sensory cells of the inner ear to the brain
Tympanostomy tube otorrhea (TTO)	Discharge from the middle ear through the tube, usually caused by AOM or external contamination of the middle ear from water entry (swimming, bathing, or hair washing)
Retraction pocket	A collapsed area of the tympanic membrane into the middle ear or attic with a sharp demarcation from the remainder of the tympanic membrane
Tympanogram ¹⁰	An objective measure of how easily the tympanic membrane vibrates and at what pressure it does so most easily (pressure-compliance function). If the middle ear is filled with fluid (eg, OME), vibration is impaired and the line will be flat; 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)

Despite the frequency of tympanostomy tube insertion, there are currently no clinical practice guidelines in the United States that address specific indications for surgery. When children require surgery for otitis media with effusion (OME; **Table 1**), insertion of tympanostomy tubes is the preferred initial procedure, with candidacy dependent primarily on hearing status, associated symptoms, and the child's developmental risk.⁶ Placement of tympanostomy tubes significantly improves hearing, reduces effusion prevalence,⁷ may reduce the incidence of recurrent acute otitis media (AOM), and provides a mechanism for drainage and administration of topical antibiotic therapy for persistent AOM (**Table 1**). In addition, research indicates that tympanostomy tubes also can improve disease-specific quality of life (QOL) for children with chronic OME, recurrent AOM, or both (**Table 1**).⁸

Risks and potential adverse events of tympanostomy tube insertion are related to general anesthesia usually required for

the procedure and the effect of the tympanostomy tube on the tympanic membrane and middle ear.¹¹ Tympanostomy tube sequelae are common but 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 about 2% of children after placement of short-term tympanostomy tubes.¹¹

When making clinical decisions, the risks of tube insertion must be balanced against the risks of prolonged or recurrent otitis media, which include suppurative complications, damage to the tympanic membrane, adverse effects of antibiotics, and potential developmental sequelae of hearing loss. Additional information on the potential benefits and risks of tympanostomy tubes is detailed in the Health Care Burden section of this guideline, and recommendations for clinical care are provided in the section titled Guideline Key Action Statements.

Table 2. Risk factors for developmental difficulties.^a

Permanent hearing loss independent of otitis media with effusion
Suspected or confirmed speech and language delay or disorder
Autism-spectrum disorder and other pervasive developmental disorders
Syndromes (eg, 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

^aSensory, physical, cognitive, or behavioral factors that place children who have otitis media with effusion at increased risk for developmental difficulties (delay or disorder).⁵

The frequency of tympanostomy tube insertion combined with variations in accepted indications for surgery create a pressing need for evidence-based guidelines to aid clinicians in identifying the best surgical candidates and optimizing subsequent care.

Purpose

The primary purpose of this clinical practice guideline is to provide clinicians with evidence-based recommendations on patient selection and surgical indications for and management of tympanostomy tubes in children. A clinical practice guideline is defined, as suggested by the Institute of Medicine, as “statements that include recommendations intended to optimize patient care that are informed by systematic review of the evidence and an assessment of the benefits and harms of alternative care options.”¹²

This guideline is intended for any clinician involved in managing children, aged 6 months to 12 years, with tympanostomy tubes or children being considered for tympanostomy tubes in any care setting as an intervention for otitis media of any type. The target audience includes specialists, primary care clinicians, and allied health professionals, as represented by this multidisciplinary guideline development group (see the Methods section).

Children younger than 6 months are excluded from this guideline because evidence is extremely limited (they have also been excluded from nearly all randomized trials of tube efficacy), and their treatment requires individualized decision making based on specific clinical circumstances. This guideline also does not pertain to children diagnosed as having retraction-type ear disease (atelectasis or adhesive otitis media), complications of AOM, or barotrauma nor to children prescribed medications instilled into the middle ear for conditions such as sudden idiopathic sensorineural hearing loss or Meniere’s disease. Children older than 12 years are excluded because they have not been included in any randomized trials of tube efficacy.⁷

Although children considered at risk for developmental delays or disorders (**Table 2**) are often excluded for ethical reasons from clinical research involving tympanostomy tubes, the guideline development group decided to include them in the scope because these patients may derive enhanced benefit

from tympanostomy tubes.¹³ This decision was based on clinical experience of the guideline development group and a recommendation from a multidisciplinary guideline on OME that “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,” including tympanostomy tubes.⁶

In planning the content of the guideline, the development group broadly discussed indications for tube placement, perioperative management, care of children with indwelling tubes, and outcomes of tympanostomy tube surgery (**Table 3**). Given the lack of current published guidance on surgical indications, despite a substantial evidence base of randomized trials and systematic reviews on which to base such guidance, the group decided early in the development process to identify situations for which tube insertion would be optional, recommended, or not recommended. Additional emphasis was placed on opportunities for quality improvement, particularly regarding shared decision making and care of children with existing tubes. Last, knowledge gaps were identified to guide future research.

Health Care Burden

Tympanostomy tube insertion is the primary surgical intervention for otitis media, which is a worldwide pediatric health problem. Most children have experienced at least 1 AOM episode by age 3 years, and by age 6 years, nearly 40% have experienced 3 or more infections.¹⁴ At any given time, approximately 20% of young school-aged children have middle ear effusion (MEE), with nearly all school-aged children having at least 1 episode during their childhood.¹⁴

The financial impact of otitis media on health care is enormous. Otitis media–related Medicaid expenditures in the United States were \$555 million for the 12.5 million covered children younger than 14 years in 1992.¹⁵ Concurrently, national expenditures for treatment and disability associated with otitis media exceeded \$4 billion. Direct costs associated with childhood otitis media include office visits, diagnostic tests, medical treatment, and surgical procedures. Indirect costs for AOM are substantial, estimated at 61% to 83% of the total expense,¹⁶ and include child school absence, caregiver absence from work or school, and canceled family activities because of child illness.

With nearly 670,000 tympanostomy tube insertions annually in children in the United States¹ and an average cost of \$2700 per procedure,¹⁷ the contribution to health care costs is approximately \$1.8 billion. This does not include additional costs related to follow-up care (which continues until after the tube extrudes), treatment of otorrhea, and management of any other sequelae or complications. A cost analysis based on chart review from one managed care organization showed that tympanostomy tube insertion is cost-effective for otitis media in children,¹⁷ but no large-scale studies or formal cost-effectiveness analyses are available to assess the generalizability of this claim.

Table 3. Topics and issues considered in tympanostomy tube guideline development.^a

Indications for Tube Placement	Perioperative Management	Care of Children with Tubes	Outcomes
Otitis media with effusion	Baseline hearing assessment	Early extrusion of tubes	Quality of life (child and caregiver)
Recurrent acute otitis media	Optimal conditions for general anesthesia (impact of upper respiratory infections)	Dry ear (water) precautions	School performance, attendance
Persistent acute otitis media	Assessment for surgery	Tube otorrhea	Long-term sequelae (perforation, retraction pocket, hearing loss)
Hearing loss caused by middle ear effusion	Assessment of anesthetic complications including laryngospasm, hypoxemia, bronchospasm	Tube granuloma or granulation tissue	Vestibular function
Unacceptable antibiotic burden for treating acute otitis media	Need for intravenous access during surgery	Obstructed tube lumen	Hearing levels and outcomes during life of tube and after tube extrusion
Situations in which tube insertion would be recommended	Need to sterilize ear canal prior to tube placement	Postoperative hearing assessment	Physical suffering (pain, sleep disturbance)
Situations in which tube insertion would be an option	Tube duration: short-term, intermediate, long-term	Frequency of follow-up for indwelling tubes	Speech and language development
Situations in which tube insertion would not be recommended	Tube composition	Setting for follow-up; which clinician is responsible or best suited	Listening in complex environments
	Tube location in the tympanic membrane	Frequency of hearing assessment (postoperative and for surveillance)	Prevalence of middle ear effusion
	Need to irrigate middle ear with saline		Need for additional tube surgery
	Use of perioperative topical otic preparations		Need for oral antibiotics
	Adenoidectomy as an alternative or adjunct to tubes		Incidence of acute otitis media
	Pain management after surgery		Incidence of otorrhea
	Alternatives to general anesthesia		Chronic suppurative otitis media
	Recovery room issues: emergent delirium, nausea/vomiting, parental/caregiver anxiety		Retained tube
	Learning curve for tube surgery		Medialized tube

^aThis list was created by the guideline development group to refine content and prioritize action statements; not all items listed were ultimately included or discussed in the guideline.

Benefits of Tympanostomy Tubes

Tympanostomy tube insertion is associated with short-term QOL improvements.¹⁸ Otitis media can affect QOL for the child and caregiver. In one study of children with chronic OME or recurrent AOM, 88% of caregivers were worried or concerned about their child's ear infections or middle ear fluid at least some of the time, with 42% spending most or all of their time preoccupied with their child's condition.¹⁹ Physical suffering was a problem for 85% of children, emotional distress for 76%, and activity limitations for 57%. Another investigation of children with otitis media noted that 31% of caregivers had to cancel family activities, 29% reported lack of sleep, and 12% missed work or school.²⁰

The efficacy of tympanostomy tubes in managing chronic OME, recurrent AOM, or both has been studied in randomized controlled trials (RCTs) and systematic reviews. For children

with chronic OME, tube insertion reduces the prevalence of MEE by 32% in the first year and improves average hearing levels (HLs) by 5 to 12 dB.^{7,13} Although RCTs have, in general, not found a significant impact of tympanostomy tube insertion on speech, language, or cognitive outcomes,^{7,13,18} the trials typically included only healthy children without developmental delays at entry. A nonrandomized study, however, did show improved caregiver perception of speech and language after tympanostomy tube placement, especially for children with developmental delays.²¹

The efficacy of tympanostomy tubes for preventing recurrent AOM is unclear, with systematic reviews reporting insufficient evidence,¹⁸ small short-term benefits,^{22,23} or moderate benefits of similar magnitude to antibiotic prophylaxis.²⁴ Part of this debate relates to inclusion criteria for RCTs in the reviews, some of which excluded children with chronic OME between AOM episodes and others that did not. When limited

to trials with AOM that clears between episodes (without chronic OME), the effect is no longer significant. Specific recommendations for tympanostomy tube insertion in children with recurrent AOM are discussed later in this guideline.

No studies have evaluated the effects of tympanostomy tubes for managing severe or persistent AOM because of difficulties enrolling these children in RCTs. Increasing problems with bacterial resistance,²⁵ however, have created a role for tympanostomy tube placement to allow drainage of infected secretions, obtain middle ear fluid for culture, and provide a direct route for delivering antibiotic eardrops to the middle ear. Similarly, when children with tympanostomy tubes continue to experience AOM episodes, they can usually be managed with topical antibiotic drops,¹⁸ avoiding the adverse effects of systemic therapy.

Risks and Adverse Events Associated with Tympanostomy Tubes

Potential benefits of tubes must be balanced against the associated risks, including general anesthesia and direct tube-related sequelae. The incidence of anesthesia-related death for children undergoing diverse surgical procedures (including tympanostomy tube insertion) ranges from 1 in 10,000 to 1 in 45,000 anesthetics delivered.²⁶ In the perioperative period, children are more prone to laryngospasm and bronchospasm than adults are, which may increase the risk of anesthetic complications.

The most common sequela of tympanostomy tubes is otorrhea (TTO), seen in approximately 16% of children within 4 weeks of surgery and 26% of children at any time the tympanostomy tube remains in place.¹¹ Most tympanostomy tubes used in the United States remain in place for 12 to 14 months, during which approximately 7% of children experience recurrent TTO. Other complications include blockage of the tympanostomy tube lumen in 7% of intubated ears, granulation tissue in 4%, premature extrusion of the tympanostomy tube in 4%, and tympanostomy tube displacement into the middle ear in 0.5%.¹¹

Longer-term sequelae of tympanostomy tube placement include visible changes in the appearance of the tympanic membrane. Myringosclerosis consists of white patches in the ear drum from deposits of calcium and can be seen while the tube is in place or after extrusion. Myringosclerosis is more common in intubated ears than in controls,^{7,11,18} is usually confined to the drum, and very rarely causes clinically significant hearing issues. Tympanic membrane atrophy, atelectasis, and retraction pockets are all more commonly observed in children with otitis media who are treated with tympanostomy tubes than in those who are not.²⁷ These tympanic membrane changes, with the exception of tympanosclerosis, appear to resolve over time in many children and rarely require medical or surgical treatment. Persistent perforation of the tympanic membrane is seen in 1% to 6% of ears after tympanostomy tubes are placed.¹⁸ When perforations persist, surgical closure may be required.

The long-term impact of tympanostomy tubes on hearing acuity has been studied. Children in a longitudinal otitis media

study had their hearing measured at 6 years of age.²⁸ Children who had tympanostomy tubes in the past had a 1- to 2-dB worsening in hearing thresholds compared with those who did not have tympanostomy tubes. This hearing worsening is trivial, and it should be noted that the mean HLs in these children with or without a history of tubes was 4.3- to 6.2-dB HL, which is well within the range of normal hearing. Another study of children aged 8 to 16 years who had participated in an RCT of tympanostomy tubes versus medical treatment for otitis media 6 to 10 years prior found hearing thresholds 2.1 to 8.1 dB poorer in those children who had a history of tympanostomy tubes. The greatest hearing deficits were seen when testing low-frequency tones.²⁹

In summary, tympanostomy tubes do produce visible changes in the appearance of the tympanic membrane and may cause measurable long-term hearing loss. These outcomes do not appear to be clinically important or require intervention in the overwhelming majority of patients. The post-tympanostomy tube sequela most likely to require intervention is persistent perforation, with 80% to 90% success rates for surgical closure with a single outpatient procedure.³⁰

Some investigators have questioned the appropriateness of tympanostomy tube surgery based on audits and chart review.^{31,32} Most criticism has centered on surgery in children with OME of less than 3 months' duration, determined by extrapolation of findings at discrete office visits. Additional criticism concerns the appropriateness of tympanostomy tubes for recurrent AOM. The frequency of tube surgery, associated health care burden, and concerns over the appropriateness of surgery create a clear need for evidence-based surgical indications and management strategies regarding tympanostomy tube placement.

Generalizability of Evidence Regarding Risks and Benefits

Most high-quality evidence on tympanostomy tube efficacy and adverse events comes from published studies that have been conducted using otherwise healthy children without comorbid illnesses, syndromes, or disorders. Therefore, we have included several recommendations in the guideline related to managing children with coexisting conditions that may put them at added risk for speech, language, or developmental sequelae of otitis media. These recommendations must therefore be interpreted with the caveat that they may involve extrapolations from studies performed in otherwise healthy children.

Methods

This guideline was 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.³³ Members of the panel included a pediatric and adult otolaryngologist, otologist/neurotologist, anesthesiologist, audiologist, family physician, behavioral pediatrician, pediatrician, speech/language pathologist, advanced nurse practitioner, physician assistant, resident physician, and consumer advocates.

Literature Search

An information specialist with the Cochrane ENT Disorders Group conducted 2 literature searches using a validated filter strategy. The initial literature search identified clinical practice guidelines, systematic reviews, and meta-analyses related to tympanostomy tubes in children published between 2005 and February 2012. The search was performed in multiple databases including the National Guidelines Clearinghouse (www.guideline.gov), The Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database, Agency for Healthcare Research and Quality, EMBASE, PubMed, Guidelines International Network, Health Services/Technology Assessment Tools, CMA Infobase, NHS Evidence ENT and Audiology, National Library of Guidelines, National Institute of Clinical Excellence, Scottish Intercollegiate Guidelines Network, New Zealand Guidelines Group, Australian National Health and Medical Research Council, and the TRIP database. The search yielded 10 guidelines and 19 systematic reviews or meta-analyses. After removing duplicates, articles not obviously related to tympanostomy tubes, those not indicating or explicitly stating a systematic review methodology, and non-English language articles, 4 guidelines and 15 systematic reviews or meta-analyses remained.

A second literature search identified RCTs published between 1980 and March 2012. The following databases were used: MEDLINE, EMBASE, CINAHL, and CENTRAL. The search identified 171 RCTs. After removing duplicates, non-English language articles, and animal model studies, 113 articles remained.

The following parameters were used to define the search questions:

1. Population: Children
2. Intervention: Tympanostomy tube insertion, including indications for tube placement, preoperative care, and postoperative care
3. Comparison: Any techniques
4. Outcome: Any
5. Setting: Inpatient, outpatient

Final results of both literature searches were distributed to panel members, including electronic full-text versions, if available, of each article. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through July 2012.

In a series of conference calls, the guideline development group defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in September 2012, 2 in-person meetings were held during which electronic decision support (BRIDGE-Wiz) software was used to facilitate the creation of actionable recommendations and action statement profiles.³⁴ Internal electronic review and feedback for each guideline draft was used to ensure accuracy of content and consistency with standardized criteria for creating clinical practice guidelines.³⁵

After completing the action statement profile, the group rated their level of confidence in the aggregate evidence underpinning the recommendation as “high,” “medium,” or “low” based on the quantity, consistency, precision, and generalizability of the evidence. Any differences of opinion among guideline development group members concerning any aspect of the action statement, accompanying profile, or amplifying text were also documented with a rating of “none,” “minor,” or “major,” with an explanation of any differences that occurred.

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor software to appraise adherence of the draft guideline to methodological standards, ensure clarity of recommendations, and predict potential obstacles to implementation.³⁶ Guideline panel members received summary appraisals in September 2012 and modified an advanced draft of the guideline based on the appraisal.

The final guideline draft underwent extensive external peer review. Comments were compiled and reviewed by the panel’s chair; a modified version of the guideline was distributed and approved by the guideline development panel. Recommendations contained in the guideline are based on the best available data published through September 2012. Where data were 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 produce optimal health outcomes for patients, to minimize harms, and to reduce inappropriate variations in clinical care. The evidence-based approach to guideline development requires 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**.³⁷

Guidelines are not intended to supersede professional judgment but rather 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.³⁷ Clinicians should always act and decide in a way that they believe will best serve their patients’ interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary

Table 4. Guideline definitions for evidence-based statements.

Statement	Definition	Implication
Strong recommendation	A strong recommendation means 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). ^a 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 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). ^a 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 be sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (Grade D) ^a or that well-done studies (Grade A, B, or C) ^a 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) ^a 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.

^aSee **Table 5** for definition of evidence grades.

Table 5. Levels for grades of evidence.^a

Grade	Treatment and Harm	Diagnosis
A	Well-designed randomized controlled trials performed on a population similar to the guideline's target population	Systematic review of cross-sectional studies with consistently applied reference standard and blinding
B	Randomized controlled trials; overwhelmingly consistent evidence from observational studies	Individual cross-sectional studies with consistently applied reference standard and blinding
C	Observational studies (case control and cohort design)	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards
D	Mechanism-based reasoning or case reports	
X	Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit over harm	

^aAmerican Academy of Pediatrics classification scheme³⁷ updated for consistency with current level of evidence definitions.³⁸

and inappropriate therapy. 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 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,³⁹ 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.⁴⁰

Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: **an evidence-based key action statement in bold**, followed by the *strength of the recommendation in italic*. Each

Table 6. Summary of guideline action statements.

Statement	Action	Strength
1. OME of short duration	Clinicians should <i>not</i> perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months' duration.	Recommendation (against)
2. Hearing testing	Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer (chronic OME) OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion.	Recommendation
3. 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.	Recommendation
4. 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 quality of life.	Option
5. Surveillance of chronic OME	Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME who did not receive tympanostomy tubes, until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected.	Recommendation
6. Recurrent AOM without MEE	Clinicians should <i>not</i> perform tympanostomy tube insertion in children with recurrent AOM who do not have middle ear effusion in either ear at the time of assessment for tube candidacy.	Recommendation (against)
7. Recurrent AOM with MEE	Clinicians should offer bilateral tympanostomy tube insertion to children with recurrent AOM who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy.	Recommendation
8. At-risk children	Clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors (see Table 2).	Recommendation
9. 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
10. Perioperative education	In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications.	Recommendation
11. Acute tympanostomy tube otorrhea	Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute TTO.	Strong recommendation
12. Water precautions	Clinicians should <i>not</i> encourage routine, prophylactic water precautions (use of earplugs, headbands; avoidance of swimming or water sports) for children with tympanostomy tubes.	Recommendation (against)

Abbreviations: AOM, acute otitis media; MEE, middle ear effusion; OME, otitis media with effusion.

key action statement is followed by an “action statement profile” of aggregate evidence quality, level of confidence in the evidence, benefit-harm assessment, and statement of costs. In addition, there is an explicit statement of any value judgments, the role of patient (caregiver) preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of each evidence-based statement in this guideline can be found in **Table 6**.

The role of patient preference in making decisions deserves further clarification. For some statements, for which the evidence base demonstrates clear benefit, although the role of patient preference for a range of treatments may not be

relevant, clinicians should provide patients with clear and comprehensible information on the benefits of facilitating patient understanding and shared decision making, which leads to better patient adherence and outcomes. In cases in which evidence is weak or benefits are 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 (numbers needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

STATEMENT 1. 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, from the date of onset (if known) or from the date of diagnosis (if onset is unknown).

Recommendation against based on systematic review of observational studies of natural history and an absence of any randomized controlled trials on efficacy of tubes for children with OME less than 2 to 3 months' duration and a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on a systematic review of observational studies and control groups in RCTs on the natural history of OME and an absence of any RCTs on efficacy of tympanostomy tubes for children with OME less than 2 months' duration
- Level of confidence in evidence: High
- Benefits: Avoidance of unnecessary surgery and its risks, avoidance of surgery in children for whom the benefits of tympanostomy tubes have not been studied and are uncertain, avoidance of surgery in children with a condition that has reasonable likelihood of spontaneous resolution, cost savings
- Risks, harms, costs: Delayed intervention in children who do not recover spontaneously and/or in children who develop recurrent episodes of MEE
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Exclusion of children with OME of less than 2 months' duration from all published RCTs of tube efficacy was considered compelling evidence to question the value of surgery in this population, especially considering the known risks of tympanostomy tube surgery
- Intentional vagueness: None
- Role of patient (caregiver) preferences: Limited, because of good evidence that otherwise healthy children with OME of short duration do not benefit from tympanostomy tube insertion
- Exceptions: At-risk children (**Table 2**); see Statements 6 and 7 for explicit information on at-risk children
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to avoid unnecessary surgery in children with OME of short duration that is likely to resolve spontaneously because of favorable natural history. When a clinician first diagnoses OME in a child, the cause of the effusion is often unknown. Otitis media with effusion is often self-limited when caused by a URI or when it follows a recent episode of AOM. An observation period of 3 months will distinguish OME that is usually self-limited from OME that may have been present for months prior to diagnosis and is unlikely to resolve spontaneously.

Otitis media with effusion is commonly seen in association with a viral URI or may be either a prelude to, or sequela of,

AOM.⁴¹ The latter circumstance is common, with a 70% prevalence rate of OME at 2 weeks, 40% at 1 month, 20% at 2 months, and 10% at 3 months.⁴² Otitis media with effusion is also seen in conjunction with acute nasopharyngitis, without prior middle ear disease; there are no data about spontaneous resolution in this case, but, overall, the natural history of OME shows rates of spontaneous resolution or improvement ranging from 28% to 52% within three⁴³ or four months⁴⁴ of diagnosis.

Most studies of tympanostomy tube efficacy required documented bilateral OME for at least 3 months before entry into the study,⁴⁵⁻⁴⁸ and one group of investigators enrolled children with at least 2 months of bilateral OME.^{49,50} Because of these restrictions, there are no data to support tympanostomy tube insertion in children with OME of brief duration (less than 2 to 3 months), and no conclusions regarding potential risks versus benefits can be drawn in this group. In addition, since spontaneous resolution of brief OME is common, observation until the OME has been documented for at least 3 months can avoid unnecessary surgery.⁴³ Children with chronic OME despite observation would be candidates for tympanostomy tubes, as described later in this clinical practice guideline.

Children with OME who are at risk for developmental delays or disorders, as defined in **Table 2**, are excluded from this recommendation. While no studies specifically addressing tympanostomy tube insertion in at-risk children with OME of shorter duration exist, these children have other factors making OME with attendant hearing loss a significantly greater added risk to their speech and language development⁷ and should therefore be managed on an individual basis when OME is diagnosed (see Statements 6 and 7).

STATEMENT 2. HEARING TESTING: Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion.

Recommendation based on observational and cross-sectional studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational and cross-sectional studies assessing the prevalence of conductive hearing loss with OME
- Level of confidence in evidence: High
- Benefits: Documentation of hearing status, improved decision making regarding the need for surgery in chronic OME, establishment of baseline hearing prior to surgery, detection of coexisting sensorineural hearing loss
- Risks, harms, costs: Cost of the audiologic assessment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- 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 (caregiver) preferences: Some, caregivers may decline testing
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to promote hearing testing as an important factor in decision making when OME becomes chronic or when a child becomes a candidate for tympanostomy tube insertion (see Statements 4, 6, and 9). Chronic unilateral or bilateral OME is unlikely to resolve promptly and may lead to poor school performance and behavioral problems.^{43,51} 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 (Statement 4).

The degree of hearing impairment is based primarily on the accurate measurement of hearing thresholds and secondarily by parent/caregiver and school (teacher) reports describing the perceived hearing ability of the child. The American Academy of Pediatrics⁵² identified several key points relevant to hearing assessment in children, which, although not related exclusively to OME, are worthy of summary here:

- Any parental/caregiver 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 audiologic screening and testing. In this situation, referral to an otolaryngologist and pediatric audiologist should be made.
- The results of abnormal audiologic screening should be explained carefully to parents/caregivers, and the child's medical record should be flagged to facilitate tracking and follow-up.
- Any abnormal objective screening result requires audiologic referral and definitive testing.

When tympanostomy tube insertion is planned, an age-appropriate preoperative hearing test is recommended to establish appropriate expectations for the change in hearing anticipated after surgery and can also alert the clinician and family to a previously undiagnosed permanent (sensorineural) hearing loss if present. Normal hearing requires sound from the environment to efficiently reach the inner ear. Otitis media with effusion impairs sound transmission by reducing the 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.⁵³ Hearing is measured (**Figure 3**) in

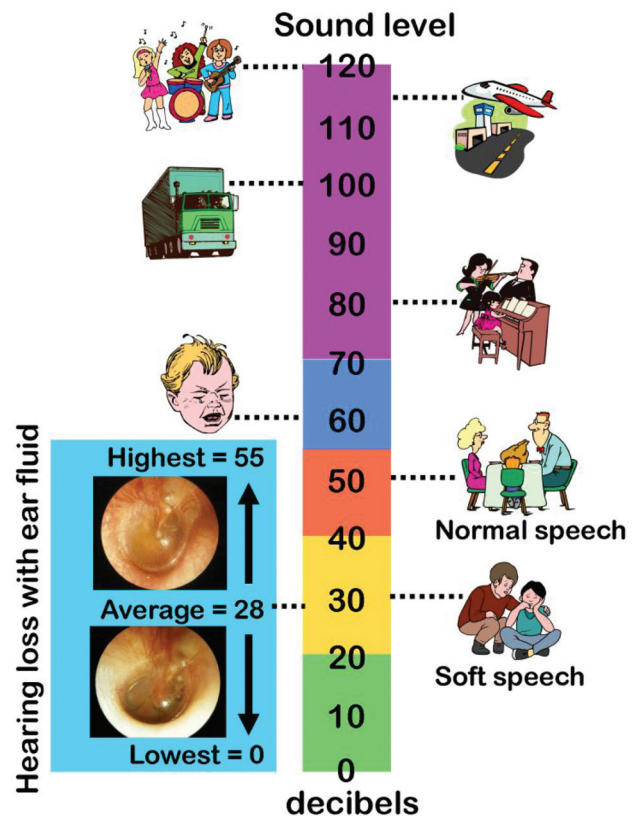


Figure 3. An average hearing level between 0 and 20 dB (hearing level) is normal (green), 21 to 40 dB is a mild hearing loss (yellow), 41 to 55 dB is a moderate loss (red), 56 to 70 dB is a moderately-severe loss, and 71 dB or higher is a severe or profound loss (purple). A child with average hearing loss from middle ear effusion in both ears (28 dB) would barely hear soft speech, with some children barely aware of normal speech or a baby crying. Reproduced with permission.³

decibels (dB), with a mean response greater than 20 dB HL indicating some degree of hearing loss for children.⁵⁴ The impact of OME on hearing ranges from no hearing loss up to a moderate hearing loss (0 to 55 dB HL).⁵⁵ The average hearing loss associated with OME in children is 28 dB HL, while a lesser proportion (approximately 20%) exceed 35 dB HL.^{55,56}

When considering the impact of OME on a child's hearing, clinicians should appreciate that HLs, as measured in decibels, are a logarithmic scale of intensity: for every 3-dB increase, there is a doubling in sound intensity levels. Therefore, even small reductions in hearing thresholds can have a significant impact on sound intensity and the child's ability to understand speech. For example, a child with OME and an average HL of 28 dB would experience nearly an 8-fold decrease in sound intensity compared with a child with normal hearing thresholds of 20 dB.

The preferred method of hearing assessment is age-appropriate audiologic testing, through conventional audiometry or comprehensive audiologic assessment.^{6,52} Children aged 4 years or older are suitable for conventional audiometry, in which 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 1 or more frequencies (500, 1000, 2000, 4000 Hz) in either ear.

Comprehensive audiologic evaluation by an audiologist is recommended for children aged 6 months to 4 years and for any child who fails conventional audiometry in a primary care setting.⁵² This assessment includes evaluating air-conduction and bone-conduction thresholds for pure tones, speech detection or speech recognition thresholds, and measuring speech understanding if possible.⁷ Visual response audiometry is typically used to assess hearing in children aged 6 months to 2.5 years. 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 aged 2.5 to 4 years are assessed using play audiometry, by having the child perform a task (eg, placing a peg in a pegboard or dropping a block in a box) in response to a stimulus tone. Ear-specific audiologic testing is recommended whenever possible using insert earphones to detect unilateral or asymmetrical hearing loss.

Although not the focus of this section, the importance of postoperative hearing testing in children who receive tympanostomy tubes deserves some emphasis. The consensus of the guideline development group was that any child with a hearing loss detected prior to tympanostomy tube insertion should have postoperative testing to confirm resolution of hearing loss. A hearing loss that was initially attributed to OME but persists after tube placement requires additional assessment to determine the cause of the loss and whether it is conductive, sensorineural, or mixed.

STATEMENT 3. CHRONIC BILATERAL OME WITH HEARING DIFFICULTY: Clinicians should offer tympanostomy bilateral tube insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties. *Recommendation based on randomized controlled trials and observational studies, with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, based on well-designed RCTs showing reduced MEE prevalence and improved hearing after tympanostomy tube insertion; observational studies documenting improved QOL; and extrapolation of research and basic science principles for optimizing auditory access
- Level of confidence in the evidence: High
- Benefits: Reduced prevalence of MEE, improved hearing, improved child and caregiver QOL, optimization of auditory access for speech and language acquisition, elimination of a potential barrier to focusing and attention in a learning environment
- Risks, harms, costs: Risk of anesthesia, sequelae of the indwelling tympanostomy tubes (eg, otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket,

persistent perforation), failure of or premature tympanostomy tube extrusion, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs

- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Assumption that optimizing auditory access would improve speech and language outcomes, despite inconclusive evidence regarding the impact of MEE on speech and language development
- Intentional vagueness: The term *hearing difficulty* is used instead of *hearing loss* to emphasize that a functional assessment of how a child uses hearing and engages in their environment is important, regardless of what specific threshold is used to define hearing loss based on audiologic criteria
- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: Minor differences regarding the role of caregiver report as a surrogate for audiologic assessment and whether the action taken by the clinician should be to “recommend” tubes (minority opinion) versus to “offer” tubes (majority opinion)

Supporting Text

The purpose of this statement is to identify children with chronic OME and associated hearing difficulties who should be offered tympanostomy tubes as part of management. Although the preceding statement (Statement 2) is also concerned with the impact of OME on hearing, the focus of this statement is on surgical candidacy and not diagnosis of hearing loss. In contrast, the preceding statement on hearing testing applies to OME regardless of laterality and is concerned more with gathering information to assist in management, not with the immediate use of that information in surgical decision making.

Once OME has persisted in both ears for 3 months or longer, the chance of spontaneous resolution is low: approximately 20% within 3 months, 25% after 6 months, and only 30% after 1 year of additional observation.⁴³ Therefore, most children diagnosed with chronic, bilateral OME will fail to improve in a timely fashion, even with prolonged observation. This low probability of resolution creates a need to assess the impact of persistent effusion on a child’s quality of life and functional health status, particularly with regard to hearing status.

When OME becomes chronic, the child’s HLs have traditionally been a major determinant factor in deciding whether to proceed with tympanostomy tube insertion.^{6,57} Whereas earlier clinical practice guidelines had *recommended* tympanostomy tube insertion for children with chronic bilateral OME and hearing loss,⁵⁷ more recent guidelines⁵⁸ advise that such children be *considered for* surgical intervention. This

Table 7. Validated questions for assessing hearing difficulty by caregiver report.^a

Question	Responses	Pass	Fail
How would you describe your child's hearing?	Normal, slightly below normal, poor, very poor	Normal	Slightly below normal, poor, or very poor
Has he/she misheard words when not looking at you?	No, rarely, often, always	No or rarely	Often or always
Has he/she had difficulty hearing when with a group of people (ie, not one-to-one)?	No, rarely, often, always	No or rarely	Often or always

^aA hearing difficulty is present when there is a fail response for 2 or more questions.

change was based on randomized trials showing that many otherwise healthy children with mild hearing loss from OME do not necessarily benefit from more prompt tympanostomy tube insertion.^{48,59-61} Our guideline development group agreed that children with chronic, bilateral OME and hearing loss should be *offered* tympanostomy tube surgery, with the final surgical decision based on shared decision making between the clinician and the child's caregiver.

A clinician fulfills the obligation of "offering" tympanostomy tube insertion to a child with bilateral OME and hearing loss by documenting in the medical record discussion of the following:

- Poor natural history of chronic, bilateral OME, which will likely persist in most children even after 1 year of observation
- Benefits and risk of tympanostomy tube insertion, as defined earlier in the Health Care Burden section of this guideline
- Alternatives to tympanostomy tube insertion are largely limited to surveillance (Statement 5), because medical therapy (antibiotics, antihistamines, decongestants, systemic steroids, and topical nasal steroids) is ineffective and not recommended^{6,58}
- The final decision reached by the clinician and caregiver regarding further management: proceed with tympanostomy tube insertion, surveillance at 3- to 6-month intervals (Statement 5), or further evaluation and testing (audiologist, otolaryngologist, or both)

The preferred method for documenting hearing difficulty for children with chronic OME is age-appropriate audiologic testing,⁶ as described in Statement 2. When conventional audiometry or comprehensive audiologic assessment produces inconclusive results or is not obtainable because of access or availability problems, one method of assessing hearing difficulties in children at least 3 years of age is by asking the 3 questions in **Table 7**. These questions are from the reported hearing difficulty (RHD) domain of the OM8-30 survey, which was developed for a large, randomized trial of tympanostomy tube efficacy for chronic OME.^{47,62} Although caregiver surveys of child hearing, in general, are often inaccurate,^{63,64} the questions in **Table 7** have demonstrated psychometric validity for children ages 3 to 9 years with chronic,

bilateral OME.⁶⁵ The clinical relevance of these questions in children with OME is supported by the strong correlation of RHD responses with the Health Utilities Index, a widely used generic scoring system for calculating quality-adjusted life years.⁶⁶

Clinicians can rapidly assess for hearing difficulty by asking the questions in **Table 7** and assigning a "pass" or "fail" outcome to each with the criteria specified. A hearing difficulty is likely when 2 or more failed responses are recorded. This cut point is based on a secondary analysis conducted specifically to support development of this guideline (Mark Haggard, unpublished data, June 19, 2012), using data from the original randomized trial in which the survey was used.⁴⁷ When applied to this cohort of children with chronic OME and documented hearing loss, 79% would fail 2 or more questions and be considered by caregiver report to have a hearing difficulty.

Children who have hearing difficulty based on the questions in **Table 7** should ideally have confirmation with audiologic testing. Conversely, pass responses to the questions in **Table 7** do not rule out the possibility of an underlying hearing loss. For example, there is evidence that caregivers tend to underestimate the impact of OME on child hearing, which may become apparent only after seeing how their child functions after the tympanostomy tubes have been placed.⁶⁷

The primary benefits of tympanostomy tube placement are reduced prevalence of MEE resulting in improved hearing, improved patient and caregiver QOL,^{13,18} and possible improved language acquisition through better hearing across the speech frequencies, binaural processing, and sound localization.^{18,68,69} Systematic reviews of RCTs consistently describe improved hearing in the first 6 to 9 months^{13,18} following tube placement as well as improved children's QOL the initial 2 to 9 months following tube surgery.¹⁸

Caregivers of children who meet the criteria for tympanostomy tube placement as described above should be informed of the potential risks of surgery. Risks of tympanostomy tube placement have been outlined under the section Health Care Burden. Tympanostomy tube otorrhea (TTO) occurs in up to 26% of children and is the most common complication of tympanostomy tube surgery.¹¹ In considering the benefits and harms of this procedure, the panel deemed that the benefits of improved hearing, speech and language development, and QOL outweigh the potential risks.

STATEMENT 4. 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, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life. *Option based on randomized controlled trials and before-and-after studies with a balance between benefit and harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C, based on before-and-after studies on vestibular function and QOL, RCTs on reduced MEE after tubes for chronic OME, and observational studies regarding the impact of MEE on children as related, but not limited to, school performance, behavioral issues, and speech delay
- Level of confidence in evidence: High for vestibular problems and QOL; medium for poor school performance, behavioral problems, and ear discomfort, because of study limitations and the multifactorial nature of these issues
- Benefits: Reduced prevalence of MEE, possible relief of symptoms attributed to chronic OME, elimination of MEE as a confounding factor from efforts to understand the reason or cause of a vestibular problem, poor school performance, behavioral problem, or ear discomfort
- Risks, harms, costs: None related to offering surgery, but if performed, tympanostomy tube insertion includes risks from anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), premature tympanostomy tube extrusion, retained tympanostomy tube, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Equilibrium
- Value judgments: Chronic MEE has been associated with problems other than hearing loss; intervening when MEE is identified can reduce symptoms. The group's confidence in the evidence of a child benefiting from intervention was insufficient to conclude a preponderance of benefit over harm and instead found at equilibrium
- Intentional vagueness: The words *likely attributable* are used to reflect the understanding that the symptoms listed may have multifactorial causes, of which OME may be only one factor, and resolution of OME may not necessarily resolve the problem
- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None

- Policy level: Option
- Differences of opinion: None.

Supporting Text

The purpose of this statement is to facilitate intervention for children with chronic OME and associated symptoms that are likely attributable to OME, when the child does not meet criteria for intervention in the preceding action statement (eg, bilateral OME with documented hearing difficulty). This is consistent with current guidelines from the United Kingdom that state “exceptionally, healthcare professionals should consider surgical intervention in children with chronic bilateral OME with a hearing loss less than 25–30 dB HL where the impact of the hearing loss on a child’s developmental, social or educational status is judged to be significant.”⁵⁸ In contrast, the guideline development group for this document also considered chronic unilateral OME as a surgical indication if they also presented with symptoms likely attributable to OME.

OME has a direct and reversible impact on the vestibular system.^{69–73} Children with chronic OME have significantly poorer vestibular function and gross motor proficiency when compared with non-OME controls. Moreover, these deficiencies tend to resolve promptly following tympanostomy tube insertion, although 1 case-control study did not show vestibular benefits with rotational chair testing.⁷⁴ In aggregate, however, evidence suggests tympanostomy tube insertion is a reasonable option for children with chronic OME who have unexplained clumsiness, balance problems, or delayed motor development. Since most parents/caregivers do not appreciate the potential relation of these symptoms with OME, clinicians must often ask specific and targeted questions about clumsiness, balance (eg, frequent falls), or motor development (eg, delays in walking) to elucidate symptoms.

Certain behavioral problems occur disproportionately with OME, including distractibility, withdrawal, frustration, and aggressiveness.⁷⁵ In a large cohort study, for example, OME severity from age 5 to 9 years correlated with a lower intelligence quotient to age 13 years and with hyperactive and inattentive behavior until age 15 years.⁷⁶ The largest effects were observed for defects in reading ability between 11 and 18 years. An RCT of children treated with tympanostomy tubes for chronic OME had fewer documented behavioral problems compared with nonsurgical controls.⁴⁶ Children with OME have also been found to have more attention disorders and anxiety/depression-related disorders when compared with children without OME.⁷⁷

Two prospective cohort studies evaluated QOL outcomes among children undergoing tympanostomy tube placement for otitis media using a disease-specific QOL measure, the OM-6 survey.^{8,67} Rosenfeld and colleagues⁸ found physical symptoms, caregiver concerns, emotional distress, hearing loss, and speech impairment significantly improved after tympanostomy tube placement. Timmerman and colleagues⁶⁷ also noted improved QOL among children after tympanostomy tube placement and concluded further that caregivers tend to underestimate their child’s degree of baseline hearing impairment; when asked to reassess their preoperative rating of their

child's hearing after having seen the difference after surgery, most parents/caregivers increased their perception of initial hearing difficulty. Rovers and colleagues⁶¹ did not find improved QOL outcomes after tympanostomy tube insertion for asymptomatic infants aged 1 to 2 years with chronic OME identified by screening; however, they used a generic QOL measure with unknown sensitivity to change for otitis media that may have missed clinically important disease-specific changes.

Children with OME may be at risk for poor school performance because of hearing loss, problems with behavior or attention, and difficulties understanding speech in noisy classroom settings. Recurrent or chronic otitis media is associated with emotional symptoms and hyperactive behavior in young school children, resulting in poorer attention skills and few social interactions.⁷⁸ Chronic OME has been correlated with delayed answering, limited vocabulary, and difficulties in speech and reading.⁷⁹ There are no randomized trials assessing the impact of tympanostomy tube insertion on these children, but such trials are unlikely to be performed because of ethical concerns. One observational study, however, showed that caregivers perceived improved school performance in children after tympanostomy tube insertion.²¹

The guideline development group concluded that the potential benefits of tympanostomy tubes for children with unilateral or bilateral OME with associated symptoms were partially offset by the costs and potential adverse outcomes related to the procedure. The decision to proceed with tympanostomy tube placement should be based on realistic expectations by the parent or caregiver about how a reduced prevalence of MEE after tympanostomy tube insertion might affect the child's QOL and functional health status.

STATEMENT 5. SURVEILLANCE OF CHRONIC OME: Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME who do not receive tympanostomy tubes, until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected.

Recommendation based on observational studies, with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High
- Benefits: 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 tympanostomy tube insertion, discussion of strategies for optimizing the listening-learning environment for children with OME, as well as ongoing counseling and education of parents/caregiver
- Risks, harms, costs: Cost of examination(s)
- Benefit-harm assessment: Preponderance of benefit over harm

- Value judgments: Although it is uncommon, untreated OME can cause progressive changes in the tympanic membrane 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 quality of life
- Role of patient (caregiver) preferences: Opportunity for shared decision making regarding the surveillance interval
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

Supporting Text

The purpose of this statement is to avoid the sequelae of chronic OME and to identify children who develop signs or symptoms that would prompt intervention. Although the natural history of most OME is favorable, resolution rates decrease the longer the effusion is present, and relapse is common.⁴³

Children with chronic OME may develop structural changes of the tympanic membrane, hearing loss, and speech and language delay. Reevaluation at 3- to 6-month intervals facilitates ongoing counseling and education with the parents/caregiver to avoid such sequelae and should include otologic examination, with audiologic assessment as needed. Children with chronic OME are at risk for structural changes of the tympanic membrane because the effusion contains mucin, leukotrienes, prostaglandins, cytokines, and arachidonic acid metabolites that invoke a local inflammatory response.^{80,81} Reactive changes may occur in the adjacent tympanic membrane and mucosal lining. Underventilation of the middle ear, which is common in young children, produces a negative pressure that over time may predispose to focal retraction pockets, generalized atelectasis of the tympanic membrane, and cholesteatoma.

Careful examination of the tympanic membrane can be performed using a handheld pneumatic otoscope to search for retraction pockets, ossicular erosion, and areas of atelectasis and atrophy. If there is any uncertainty that all structures are normal, further evaluation should be carried out using an otomicroscope. All children with these tympanic membrane conditions, regardless of OME duration, should have an audiologic evaluation. Conditions of the tympanic membrane that may benefit from tympanostomy tube insertion are posterosuperior retraction pockets, ossicular erosion, and adhesive atelectasis.⁶ Ongoing surveillance is mandatory because the incidence of structural damage increases with effusion duration.

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.⁶ Any child with evidence of hearing impairment on screening or hearing testing should be referred for comprehensive audiologic evaluation, including thresholds and speech recognition, by a licensed audiologist in a soundproof booth. If a child with OME has HLs in the normal range (<20 dB HL), a repeat hearing test should be performed in 3 to 6 months if OME persists. Studies have shown mild sensorineural hearing loss to be associated with difficulties in speech, language, and academic performance in school, and persistent mild conductive hearing loss with OME may have similar impact.⁶ With HLs >40 dB (moderate hearing loss), the child is at risk for problems with speech, language, and school performance,⁶ and tympanostomy tube insertion should be recommended.

Randomized trials suggest that otherwise healthy children with persistent OME, who do not have any of the at risk criteria in **Table 2**, can be safely observed for 6 to 12 months without developmental sequelae or reduced overall QOL.^{45,59-61} The impact of longer observation periods is unknown, so children for whom prolonged observation of OME is undertaken should have periodic assessment of speech, language, and QOL through targeted questions by the clinicians, validated disease-specific QOL surveys,²¹ or formal language testing. Prior guidelines⁸ recommend language testing for children with chronic OME and hearing loss (pure-tone average greater than 20 dB HL) on comprehensive audiologic evaluation.

Education of the child and parents/caregiver should begin at the first encounter and be an ongoing process. Clinicians should aim to create 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 and reduction in unnecessary antibiotic use. Communication between parents/caregivers and primary care providers should be encouraged, as should prompt referral to the otolaryngologist if otoscopy does not clearly demonstrate a normal tympanic membrane.

STATEMENT 6. RECURRENT AOM WITHOUT MEE: Clinicians should *not* perform tympanostomy tube insertion in children with recurrent acute otitis media who *do not* have MEE in either ear at the time of assessment for tube candidacy. *Recommendation against based on systematic reviews and randomized controlled trials with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade A, based on a meta-analysis of RCTs, a systematic review of RCT control groups regarding the natural history of recurrent AOM, and other RCTs
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary surgery and its risks, avoid surgery in children for whom RCTs have not demonstrated any benefit for reducing AOM incidence or in children with a condition that has

reasonable likelihood of spontaneous resolution, cost savings

- Risks, harms, costs: Delay in intervention for children who eventually require tympanostomy tubes, need for systemic antibiotics among children who continue to have episodes of recurrent AOM
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Implicit in this recommendation is the ability to reassess children who continue to have AOM despite observation and to perform tympanostomy tube insertion if MEE is present (Statement 7); risk of complications or poor outcomes from delayed tube insertion for children who continue to have recurrent AOM is minimal
- Intentional vagueness: The method of confirming the absence of MEE should be based on clinician experience and may include tympanometry, simple otoscopy, and/or pneumatic otoscopy
- Role of patient (caregiver) preferences: Limited, because of favorable natural history and good evidence that otherwise healthy children with recurrent AOM without MEE do not have a reduced incidence of AOM after tympanostomy tube insertion
- Exceptions: At-risk children (see **Table 2**), children with histories of severe or persistent AOM, immunosuppression; prior complication of otitis media (mastoiditis, meningitis, facial nerve paralysis); multiple antibiotic allergy or intolerance
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to help children and families avoid surgical intervention for recurrent AOM (as defined in **Table 1**) without MEE because the natural history is quite favorable and benefits of tympanostomy tubes for this clinical indication are uncertain.

The best evidence on the natural history of recurrent AOM without MEE comes from RCTs of antibiotic prophylaxis for recurrent AOM, all of which exclude children with OME or persistent MEE from participation. A systematic review of 15 such trials found highly favorable rates of improvement in the placebo groups: children with recurrent AOM entered these trials with a mean baseline rate of 5.5 or more annual episodes but averaged only 2.8 annual episodes while on placebo.⁴³ Furthermore, 41% had no additional episodes of AOM while on placebo for a median duration of 6 months, and 83% had only 2 or fewer episodes. Individual AOM episodes, if they did occur in these trials, were treated with a 7- to 10-day course of oral antibiotic.

Systematic reviews of tympanostomy tube insertion for recurrent AOM have shown either a transient benefit of questionable clinical significance,²² no additional benefit compared with antibiotic use,²⁴ or no benefit at all.^{18,23} In addition, an RCT that specifically excluded children with baseline MEE found no benefit of tympanostomy tube insertion for reducing the subsequent

incidence of AOM.⁹ This trial, did, however, find that tubes decreased the mean percentage time with otitis media (of any type) over the next 2 years, but the absolute decrease was modest, about 8% or 30 days per year.⁶ Conversely, an RCT published after the systematic reviews noted above found significant benefits of tympanostomy tubes for preventing recurrent AOM in children aged 10 months to 2 years. This study, however, included children with persistent MEE, and these effusions were aspirated during tympanostomy tube surgery.⁸²

This guideline statement applies to children with recurrent AOM not found to have MEE at the time they are assessed for tympanostomy tube candidacy. When implemented in clinical practice, it is understood that some children will be referred by their primary care provider based on their evaluation finding an effusion is present, only to have that effusion resolve prior to the surgical consultation.

The absence of MEE at the time of assessment for tube candidacy, even if recently documented by another clinician, suggests favorable eustachian tube function and a good prognosis, based on evidence cited earlier in this section for the natural history of recurrent AOM without baseline effusion. Tympanostomy tube insertion is not recommended in this situation, but the child should be reassessed if he or she continues to have recurrent AOM episodes. Clinicians should note that the subsequent guideline statement (recurrent AOM with MEE) allows for tympanostomy tubes to be placed in these patients, should MEE be documented in subsequent clinical evaluations.

The risks of not performing tympanostomy tube placement lie mostly in exposure to additional courses of systemic antibiotics for the subset of children who continue to have recurrent episodes and in delay of eventual tympanostomy tube placement in those children who may go on to have persistent AOM or recurrent AOM with MEE. Children with recurrent AOM without MEE who are observed but later develop persistent MEE may be offered tympanostomy tubes as outlined in the subsequent guideline action statement.

The guideline development group concluded that tympanostomy tube insertion should not be performed in children having recurrent AOM without MEE given the high likelihood of spontaneous improvement, quantifiable risks, and lack of convincing evidence for benefit. This guideline statement, however, does not apply to children with complications of otitis media or multiple antibiotic allergies/intolerances, severe/chronic OME, or immunosuppression or children at risk for, or already experiencing, developmental delays as outlined in **Table 2**.

STATEMENT 7. RECURRENT AOM WITH MEE: Clinicians should offer bilateral tympanostomy tube insertion in children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy.

Recommendation based on randomized controlled trials with minimal limitations and a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on RCTs with minor limitations

- Level of confidence in evidence: Medium; some uncertainty regarding the magnitude of clinical benefit and importance, because of heterogeneity in the design and outcomes of clinical trials
- Benefits: Mean decrease of approximately 3 episodes of AOM per year, ability to treat future episodes of AOM with topical antibiotics instead of systemic antibiotics, reduced pain with future AOM episodes, improved hearing during AOM episodes
- Risks, harms, costs: Risks from anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), premature tympanostomy tube extrusion, retained tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: In addition to the benefits seen in RCTs, the presence of effusion at the time of assessment served as a marker of diagnostic accuracy for AOM
- Intentional vagueness: The method of confirming the presence of middle ear effusion should be based on clinician experience and may include tympanometry, simple otoscopy, and/or pneumatic otoscopy
- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to offer tympanostomy tubes as a management option for children with a history of recurrent AOM (as defined in **Table 1**) who have MEE at the time of assessment for tube candidacy. In contrast to the previous action statement (recurrent otitis media *without* MEE), this statement requests that clinicians offer tympanostomy tubes to children who have an effusion present in 1 or both ears when evaluated for possible tube placement. This effusion serves as both a marker for diagnostic accuracy of AOM and an indicator of underlying eustachian tube dysfunction with decreased ability to clear middle ear fluid following an episode of AOM. Bilateral insertion of tympanostomy tubes is recommended even if only unilateral effusion is present because more than 70% of children have similar eustachian tube function on the right and left sides.⁸³

The difficulty in accurately diagnosing AOM has been well documented, relating primarily to confirming the presence of MEE.⁸⁴ Symptoms of otalgia and fever are nonspecific for AOM, making them unreliable for primary diagnosis.^{85,86} Clinicians often rely on simple otoscopy for diagnosis, but obstructing cerumen and poor lighting may compromise

visibility, and a child's crying can induce tympanic membrane erythema, leading to overdiagnosis.⁸⁷ Although pneumatic otoscopy can improve diagnostic certainty for MEE, it is not widely used, and may be unavailable, in the primary care setting.⁸⁷ Repeated overdiagnosis of AOM may lead to an unwarranted referral to an otolaryngologist for surgical intervention.

Middle ear effusion following an episode of AOM often takes time to resolve, with persistence of effusion in 70% of ears at 2 weeks, 40% at 1 month, 20% at 2 months, and 10% at 3 months.⁴² The natural history of persistent MEE is favorable, but when middle ear fluid persists, it is thought to be an indicator of underlying eustachian tube dysfunction that may possibly predispose to future AOM recurrence. Moreover, persistent MEE in a child with recurrent AOM provides some reassurance regarding diagnostic certainty (at least for the most recent AOM episode), although it is not possible to distinguish chronic OME from MEE after AOM.

Tympanostomy tube insertion in children with recurrent AOM decreased the average number of AOM episodes by about 2.5 per child-year in 2 RCTs that did not exclude children with persistent effusion at the time of trial entry.^{88,89} Another RCT of children younger than 2 years with recurrent AOM, including those with persistent MEE at trial entry but excluding children with histories of chronic OME, also found that tympanostomy tube insertion resulted in a significant, but modest, reduction in subsequent AOM episodes (0.55 per child-year).⁸² Similarly, when children with OME lasting 2 months or longer receive tympanostomy tubes, there is a modest reduction in subsequent AOM episodes (0.20 to 0.72 per child-year).^{49,50} In contrast, a trial of tympanostomy tubes in children with a history of recurrent AOM but without MEE found no reduction in subsequent AOM after insertion of tympanostomy tubes.⁹

Several systematic reviews have attempted to assess the efficacy of tympanostomy tubes for recurrent AOM, but there has been widespread disagreement regarding trial selection and inclusion criteria, with most reviews excluding studies that allowed children to have MEE or OME at baseline.^{18,19,22-24} For this reason, we have focused on individual trial results, as summarized in the preceding paragraph. The issue of whether or not tubes benefit children with recurrent AOM who present

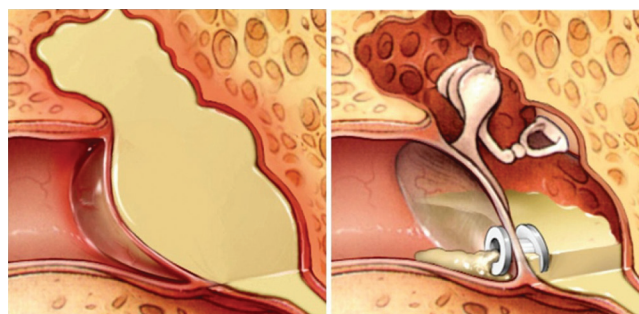


Figure 4. Acute otitis media without a tympanostomy tube (left) and with a tube (right). Without a tube, the tympanic membrane is bulging and inflamed, which causes pain and sometimes rupture. Reproduced with permission.³

without persistent effusion is discussed in the prior guideline action statement.

Although the primary rationale for offering tympanostomy tubes to children with recurrent AOM and persistent MEE is to reduce the incidence of future infections, there are additional benefits including decreased pain, should AOM occur with tubes in place, as well as the ability to manage such infection with topical antibiotic eardrops (**Figure 4; Table 8**). Tympanostomy tubes can serve as a drug-delivery mechanism, allowing concentrated antibiotic eardrops to reach the middle ear space directly through the tube lumen. Eardrops alone are highly effective for AOM with tubes.¹⁸ Please refer to Statement 10 later in this document for additional information on managing TTO.

Clinicians should offer tympanostomy tubes to children with recurrent AOM and MEE, but whether or not to proceed with surgery is largely dependent on shared decisions with the child's caregiver. The benefits of tympanostomy tube insertion are significant, but modest, and are offset by procedural and anesthetic risks, as discussed earlier. Children with more severe AOM episodes, multiple antibiotic allergies, or any of the comorbid conditions in **Table 2** may derive greater benefit from timely tympanostomy tube insertion. A period of surveillance (Statement 5), with reassessment at 3- to 6-month intervals, can be employed when there is any uncertainty

Table 8. Comparison of acute otitis media with and without a tympanostomy tube.^a

Issue	AOM without a Tube	AOM with a Tube
Ear pain	Mild to severe	None, unless skin irritated or tube occluded
Drainage from the ear canal (otorrhea)	No, unless eardrum ruptures	Yes, unless tube obstructed
Duration of middle ear effusion after infection	Can last weeks or months	Usually resolves promptly
Needs oral antibiotics	Often	Rarely
Needs antibiotic eardrops	No benefit	Often
Risk of eardrum rupture	Yes	No, unless tube obstructed
Risk of suppurative complications	Rare	Exceedingly rare

Abbreviation: AOM, acute otitis media.

^aAdapted.³

about the appropriateness of surgery, since improvements may occur from natural history, especially when chronic OME is not present.^{9,82}

STATEMENT 8. AT RISK CHILDREN: Clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors (see Table 2). *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High for Down syndrome, cleft palate, and permanent hearing loss; medium for other risk factors
- Benefits: Facilitation of future decisions about tube candidacy, identification of children who might benefit from early intervention (including tympanostomy tubes), identification of children who might benefit from more active and accurate surveillance of middle ear status as well as those who require more prompt evaluation of hearing, speech, and language
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Despite the limited high-quality evidence about the impact of tubes on this population (nearly all RCTs exclude children who are at risk), the panel considered it important to use at-risk status as a factor in decision making about tube candidacy, building on recommendations made in the OME guideline.⁶ The panel assumed that at-risk children would be less likely to tolerate OME or recurrent AOM than would the otherwise healthy child
- Intentional vagueness: None
- Role of patient (caregiver) preferences: None, since this recommendation deals only with acquiring information to assist in decision making
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to highlight the importance of identifying children with comorbid conditions that alter their susceptibility to AOM, OME, or potential developmental sequelae from MEE. This statement builds on multidisciplinary guidance first introduced in an OME clinical practice guideline in 2004 that recommended that “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, and the need for intervention.”⁶

Children who are at risk for developmental difficulties (Table 2) would likely be adversely affected by the conductive hearing loss that accompanies OME, even though definitive studies are lacking.^{6,90} Whereas a child with baseline normal hearing might tolerate a 15- to 20-dB hearing decrease from OME without problems, one with permanent hearing loss, independent of OME, would have substantial difficulty that could worsen existing speech and language delays.^{91,92} In addition, the benefits of hearing aids in children with permanent hearing loss could be reduced by the presence of MEE.⁹¹ Similarly, a child with blindness or uncorrectable visual impairment would be more susceptible to OME sequelae, including imbalance, sound localization, communication, delayed language development, and impaired ability to interact and communicate with others.⁶

Developmental, behavioral, and sensory disorders are not uncommon among children younger than 17 years in the United States.⁹³ These include children with primary language impairments and others with autism-spectrum disorders or syndromes that adversely affect cognitive and linguistic development. Hearing loss of any type (conductive, sensorineural, or mixed) 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.⁵⁵ Last, children with developmental disabilities may lack the communication skills or sensory perception to reliably express pain or discomfort associated with AOM and would benefit from more active monitoring.

Children with Down syndrome have poor eustachian tube function associated with recurrent AOM and chronic OME. They also have a risk of mixed or sensorineural hearing loss as well as stenotic ear canals that can impede assessment of tympanic membrane and middle ear status.⁹⁴⁻⁹⁸ Such risks may persist throughout childhood, requiring multiple tympanostomy tube placements if a surgical option is chosen. Hearing loss also can be difficult to document accurately in very young children with Down syndrome, except when evaluated by pediatric audiologists, often using electrophysiologic (auditory brainstem response) tests. Hearing assessments are recommended for these children every 6 months starting at birth. Otolaryngologic evaluation is also recommended for recurrent AOM and OME, if middle ear status cannot be determined or if hearing loss is found.⁹⁹ Children with stenotic ear canals are best assessed using an otologic microscope every 3 to 6 months to remove cerumen and detect OME.⁹⁹

Cleft palate is a common orofacial malformation, with a prevalence of 1 in 700 live births.¹⁰⁰ Otitis media with effusion occurs in nearly all infants and children with cleft palate^{101,102} because of the limited ability of the eustachian tube to open actively, resulting from abnormal insertions of the tensor veli palatini and the levator veli palatini muscles.¹⁰³ Chronic OME in children with cleft palate is almost always associated with

some degree of conductive hearing loss.¹⁰³ Children with cleft palate should be managed by a multidisciplinary cleft palate team. Continued monitoring for OME and hearing loss should continue throughout childhood, including after palate repair, because of a continued high prevalence of effusion and hearing loss.¹⁰⁴

Children with special health care needs (**Table 2**) require closer monitoring for OME and attendant hearing loss. Such close monitoring should begin once the child is identified as high risk. Eustachian tube dysfunction not only affects children with Down syndrome and cleft palate but is commonly associated with craniofacial syndromes or malformations involving the head and neck. By determining if a child with any degree of OME has any of the risk factors in **Table 2**, clinicians can better counsel families about the potential impact of otitis media on their child's development and on tympanostomy tubes as a management option (see Statement 9).

STATEMENT 9. TYMPANOSTOMY TUBES AND 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. *Option based on a systematic review and observational studies with a balance between benefit and harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C based on a systematic review of cohort studies regarding natural history of type B tympanograms and observational studies examining the impact of MEE on at-risk children
- Level of confidence in evidence: Moderate to low, because of methodological concerns with the conduct, outcome reporting, and follow-up of available observational studies.
- Benefits: Improved hearing, resolution of MEE in at-risk children who would otherwise have a low probability of spontaneous resolution, mitigates a potential obstacle to child development
- Risks, harms, costs: Risk of anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), failure of or premature tympanostomy tube extrusion, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Equilibrium
- Value judgments: Despite the absence of controlled trials identifying benefits of tympanostomy tube placement in at-risk children (such children were excluded from the reviews cited), the panel agreed that tympanostomy tubes were a reasonable intervention for reducing the prevalence of MEE that would otherwise have a low likelihood of prompt

spontaneous resolution. Untreated persistent MEE would place the child at high risk for hearing loss from suboptimal conduction of sound through the middle ear, which could interfere with subsequent speech and language progress

- Intentional vagueness: None
- Role of patient (caregiver) preferences: Substantial role for shared decision making with caregivers regarding whether or not to proceed with tympanostomy tube insertion
- Exclusions: None
- Policy level: Option
- Differences of opinion: None regarding the action statement; a minor difference of opinion about whether children with Down syndrome or cleft palate should be considered independently of children with speech and language delays/disorders

Supporting Text

The purpose of this statement is to facilitate prompt management of children with OME who have sensory, physical, cognitive, or behavioral factors that place them at increased risk for developmental delays or disorders (**Table 2**). In contrast to Statement 2 (chronic bilateral OME with hearing difficulties), this statement gives clinicians the option to perform tympanostomy tube insertion in at-risk children with OME that is unilateral or may not have apparent hearing difficulties but is unlikely to resolve promptly. Although the at-risk conditions listed in **Table 2** represent diverse disorders that are managed very differently, they are considered jointly in this guideline because all children with 1 or more of these conditions are likely to be more sensitive to an impact of chronic OME on development than would children who are not at risk.

Chronic OME and at-risk children. The rationale for offering tympanostomy tubes to at-risk children is to minimize the potential impact of chronic OME on child development by improving hearing quality and reducing effusion prevalence.⁶ Children with OME typically have mild hearing loss (about 25-28 dB HL), with 20% of affected ears having levels exceeding 35 dB HL.⁵⁵ After tympanostomy tube insertion, HLs improve by a mean of 5 to 12 dB while the tubes are patent,^{7,13,18} and the prevalence of MEE is reduced by 32% to 73%.^{7,13,18}

Otitis media with effusion that is unilateral or not associated with hearing loss, however, may still affect an at-risk child because of degraded auditory input that reduces binaural processing and speech perception.⁵⁵ Other effects of chronic effusion include problems with speech recognition, higher-order speech processing, and speech perception in noise. For example, children with bilateral OME and normal hearing for the better ear have substantial difficulties recognizing words at soft listening levels and at normal levels with background noise, a problem that resolves after placement of tympanostomy tubes.⁶³

When unilateral OME is present, the decision to perform unilateral or bilateral tympanostomy tube insertion should be

based on caregiver preference and the likelihood of persistent OME developing in the opposite ear. Unilateral tube insertion should be performed only when the caregiver understands the risk of subsequent OME in the contralateral ear and the potential need for a second tube insertion procedure should this occur. Bilateral tube insertion is preferred if the risk of future OME is high (eg, very young child, frequent AOM accompanying the OME) or the caregiver wishes to have the child undergo only a single surgical procedure.

At-risk children with syndromes or craniofacial anomalies often have eustachian tube dysfunction that predisposes to otitis media, chronic OME, and recurrent episodes of infection. The natural history of otitis media in this population is largely unknown but is likely worse than for an otherwise healthy child. Acute otitis media, especially if recurrent, can be difficult to manage in at-risk children because of a lack of obvious symptoms (eg, high tolerance to pain seen in some children with autistic spectrum disorders), inability to communicate about pain (eg, autistic spectrum disorders, speech and language disorders), poor cooperation with examination (eg, with aggressive or self-injurious behavior), narrow external ear canals (eg, Down syndrome), or difficulty taking oral antibiotics (eg, multiple medication allergies, medication refusal).

Predictors of OME persistence. Otitis media with effusion is unlikely to resolve quickly when present for 3 months or longer, regardless of tympanogram type. When children with OME for 3 months are observed in randomized trials, spontaneous resolution occurs in only 19% of ears after an additional 3 months, 25% at 6 months, and 31% at 12 months.⁴³ This is in stark contrast to OME persisting after a documented episode of AOM, which has about 75% to 90% resolution after 3 months.^{42,43} Persistence of OME for 3 months or longer can be documented by review of medical records, review of prior audiometry or tympanometry results, or by the caregiver reporting when a clinician first diagnosed the effusion and whether it was present at subsequent evaluations.

Otitis media with effusion with a type B (flat) tympanogram is also unlikely to resolve quickly, regardless of prior effusion duration, based on cohort studies of otherwise healthy young children.⁴³ Preschool children with OME on tympanometric screening (type B) have effusion resolution rates (conversion to a normal type A tympanogram) of only 20% after 3 months and 28% after 6 months.⁴³ When the criteria for resolution are relaxed, allowing some degree of negative middle ear pressure, resolution rates remain modest at 28% after 3 months and 42% after 6 months. Although a type B tympanogram is not recommended as the primary diagnostic test for OME (pneumatic otoscopy is easier to use and has comparable sensitivity and specificity),¹⁰⁵ it does have significant utility as a prognostic indicator, even when the prior duration of effusion is unknown.

Understanding tympanometry. Tympanometry provides an objective assessment of tympanic membrane mobility and middle ear function by measuring the amount of sound energy reflected back when a small probe is placed in the ear canal.¹⁰⁶

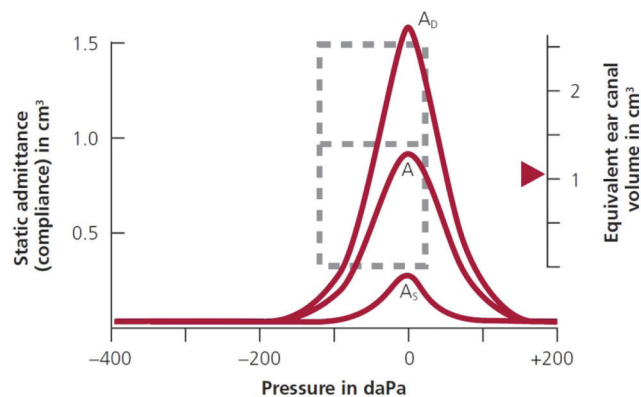


Figure 5. Normal type A tympanogram result. The height of the tracing may vary but is normal when the peak falls within the 2 stacked rectangles. The A_D tracing (upper) indicates an abnormally flexible tympanic membrane, and the A_S tracing (lower) indicates stiffness; the presence of a well-defined peak, however, makes the presence of effusion low. Reproduced with Permission.¹⁰⁶

The procedure is painless, is relatively simple to perform, and can be done using a handheld unit (slightly larger than a traditional otoscope) or a desktop machine. The resulting graphical display shows how the tympanic membrane responds to varying pressure (negative and positive). A normal type A tympanogram (**Figure 5**), with peak pressure greater than -100 mm water, is associated with effusion in only 3% of ears at myringotomy.^{107,108} Proper calibration of the tympanometer is essential for accurate results.

A type B, or flat curve, tympanogram (**Figure 6**) is associated with MEE in 85% to 100% of ears.^{107,108} Proper interpretation of a type B tympanogram result must also consider the equivalent ear canal volume, 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 and usually indicates MEE when combined with a type B result (**Figure 6A**).⁵⁴ A low equivalent ear canal volume (**Figure 6B**) can be caused by improper placement of the probe (eg, pressing against the ear canal) or by obstructing cerumen. The ear canal should be cleaned and the probe repositioned before retesting. Last, a high equivalent ear canal volume (**Figure 6C**) 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 cm³.⁵⁴

Last, clinicians should note that a type B tympanogram may occur in children without MEE because of rigidity or immobility of the tympanic membrane, which can occur because of extensive myringosclerosis or after surgical closure of a tympanic membrane perforation with a cartilage graft.

Tympanostomy tubes and at-risk children. Evidence regarding the impact of tympanostomy tubes on at-risk children with OME is limited, because these children are often considered ineligible for randomized trials based on ethical concerns.^{18,21,109} The

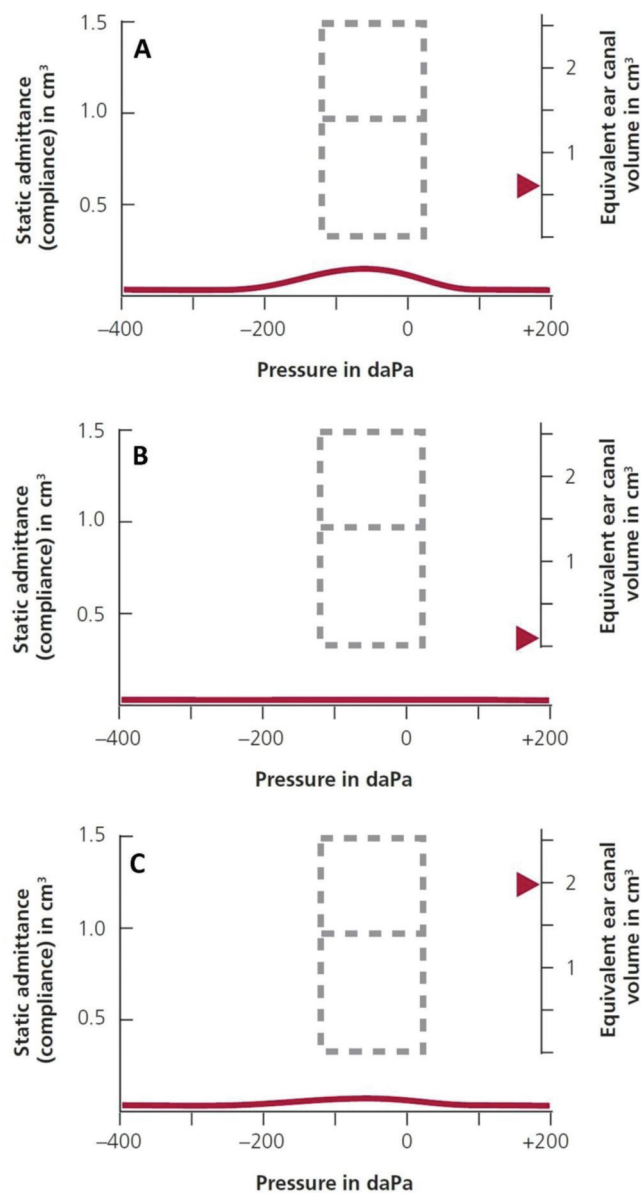


Figure 6. Abnormal type B tympanogram results. (A) A normal equivalent ear canal volume usually indicates middle ear effusion. (B) A low volume indicates probe obstruction by cerumen or contact with the ear canal. (C) A high volume indicates a patent tympanostomy tube or a tympanic membrane perforation. Reproduced with permission.¹⁰⁶

2004 OME guideline concluded that there was significant potential benefit to reducing OME in at-risk children by “optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; and avoiding limitations on the benefits of educational interventions because of hearing problems from OME.” The guideline development group found an “exceptional preponderance of benefits over harm based on subcommittee consensus because of circumstances to date precluding randomized trials.”⁶

An observational study of tympanostomy tubes found better outcomes by parental/caregiver report in at-risk children (about 50% of the study sample) for speech, language, learning, and school performance.²¹ The odds of a caregiver providing a “much better” response after tubes for speech and language was 5.1 times higher (95% confidence interval [CI], 2.4 to 10.8) if the child was at risk, even after adjusting for age, gender, hearing, and effusion duration. Similarly, the odds of a “much better” response for learning and school performance were 3.5 times higher (95% CI, 1.8 to 7.1). Conversely, caregivers did not report any differences in other outcomes (hearing, life overall, or things able to do) for at-risk versus non-at-risk children, making it less likely that expectancy bias was responsible for the differences in developmental outcomes.

The impact of tympanostomy tubes on children with Down syndrome has been assessed in observational studies^{93-96,110} but there are no RCTs to guide management. All studies have shown a high prevalence of OME and associated hearing loss, but the impact of tympanostomy tubes has been variable regarding hearing outcomes, surgical complications (perforated tympanic membrane, recurrent or chronic otorrhea), and need for reoperation. One study achieved excellent hearing outcomes through regular surveillance (every 3 months if the ear canals were stenotic, every 6 months if not stenotic) and with prompt replacement of nonfunctioning or extruded tubes if OME recurred.¹¹⁰ Hearing aids have been proposed as an alternative to tympanostomy tubes,⁵⁸ but no comparative trials have assessed outcomes or to what degree the aids were used successfully by the children.

A systematic review of observational studies concluded that there is currently inadequate evidence to support routine tympanostomy tube insertion in children with cleft palate at the time of surgical repair.¹¹¹ The evidence, however, was generally of low quality and insufficient to support not inserting tympanostomy tubes when clinically indicated (eg, hearing loss and flat tympanograms). Whether cleft palate with attendant OME and hearing loss results in speech and language impairment is also unclear, since many of the studies looking at speech and language outcomes studied children who had had tubes inserted.¹¹² Children with cleft palate require long-term otologic monitoring throughout childhood because of eustachian tube dysfunction and risk of cholesteatoma, but decisions regarding tympanostomy tube placement must be individualized and involve caregivers. Hearing aids are an alternative to tympanostomy tubes when hearing loss is present.

Shared decision making. Whether or not a specific child who is at risk (**Table 2**) should have tympanostomy tubes placed is always a process of shared decision making with the caregiver and other clinicians involved in the child’s care. The final decision should incorporate provider experience, family values, and realistic expectations about the effect of reduced MEE and improved hearing on the child’s developmental progress. The presence or duration of MEE may be difficult to

establish in some at-risk children because of limited ability to communicate, stenotic ear canals, and lack of cooperation for cerumen removal or tympanometry. These children are candidates for examination under anesthesia with the option of placing tympanostomy tubes if MEE is confirmed.

STATEMENT 10. PERIOPERATIVE EDUCATION: In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications. *Recommendation based on observational studies, with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies with limitations
- Level of confidence in evidence: Medium; there is good evidence and strong consensus on the value of patient education and counseling, in general, but evidence on how this education and counseling affect outcomes of children with tympanostomy tubes is limited
- Benefits: Define appropriate caregiver expectations after surgery, enable caregivers to recognize complications early, and improve caregiver understanding of the importance of follow-up
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of patient education in promoting optimal outcomes
- Intentional vagueness: None
- Role of patient (caregiver) preferences: None, since this recommendation deals only with providing information for proper management
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

Patient and family education is the process of providing verbal and written information to the family and addressing any questions or concerns. Effective communication should aim to improve the family's understanding of optimal care of the child with tympanostomy tubes, improving the child's follow-up care, and allowing prevention or early identification of complications. Not discussing necessary care and follow-up with a patient and family may increase the risk of complications and lead to a negative impact on long-term outcomes. Important points that should be discussed with the family of a child with tympanostomy tubes include the importance of follow-up visits, the management of common tube problems, the expected tube duration, and the potential complications thereof.

The importance of follow-up visits. Routine follow-up ensures that the tubes are in place and functioning and can determine whether the ears are healthy, hearing is maximized, and no complications are present.⁶² Generally, the child should be evaluated periodically by an otolaryngologist while the tympanostomy tubes are in place. After extrusion, an additional follow-up appointment with the otolaryngologist should occur to ensure the ears are healthy and to identify any need for further surveillance or treatment.

The primary care provider has an important role in evaluating the child's ears during follow-up visits. Although tympanostomy tubes are safe and beneficial for most children who are candidates for placement, they can be associated with significant sequelae, most of which are easily treated once identified and are not associated with long-term morbidity.^{11,19,58} Referral to the otolaryngologist should be made if the tympanostomy tubes cannot be visualized or are occluded, if there are concerns about a change in hearing status, or if other complications are identified (ie, granuloma, persistent or recurrent otorrhea following treatment, perforation at the tube site, persistent tube for greater than 2-3 years, retraction pocket, or cholesteatoma).^{11,18,113}

Parents/caregivers of children with tympanostomy tubes should be given information regarding longevity of the tympanostomy tubes. This will vary depending on the type of tube that is placed (short-term versus long-term tubes). Short-term tubes generally last 10 to 18 months, but long-term tubes typically remain in place for several years.¹¹⁴ It is important for the caregiver to understand that there is no definite way to predict the duration of tube function; some will unfortunately extrude prematurely in the first couple of months, and some will persist and need removal.¹¹ Rarely, the tube will displace into the middle ear space and require surgical removal.¹⁹ The ultimate goal is for the tubes to last long enough for the child to outgrow his or her middle ear disease. Up to 50% of children, however, will require reoperation within 3 years.^{49,50,115}

Managing common tube problems. It is also important to educate parents/caregivers on the presentation and treatment of ear infections with tympanostomy tubes in place. Although tympanostomy tubes reduce AOM incidence, nearly 15% to 26% will have additional episodes.^{11,19} Children will rarely experience pain or fever from AOM with tympanostomy tubes in place; otorrhea is typically their only symptom. Management of TTO is fully discussed within Statement 11 of this guideline; however, parents/caregivers should be counseled that TTO may occur, responds to topical antibiotic ear drops, does not usually require oral antibiotics, and benefits from water precautions until the discharge is no longer present.

Although many parents/caregivers may believe they know when to initiate treatment for acute TTO, it is important that they notify the primary care provider or otolaryngology specialist to ensure appropriate action is taken. Parents/caregivers should also be instructed as to how to properly administer ear drops. Pumping of the tragus following placement of the drops

may help with penetration of the drops to the ear canal and middle ear space.¹¹⁶ Aural toilet may be required prior to drop administration when otorrhea is filling the canal. If the drops are not able to penetrate the canal because of debris or crusting, the child may require suctioning of the canal by the otolaryngologist. When drainage is persistent following treatment, or recurs frequently, the child should be evaluated by an otolaryngologist. Caution should be advised regarding prolonged use of ototopical drops, as this may potentiate a fungal infection requiring different treatment.

Clinicians should review expectations with families. Parents/caregivers and children are frequently concerned about the possibility of discomfort. Educating and reassuring parents/caregivers/children regarding comfort, tube extrusion, and appropriate circumstances for reevaluation are important. As well, reminding families and children that the ear will typically clear cerumen naturally and does not require any special cleaning with cotton swabs or other manipulation is important.¹¹⁷ Furthermore, families should be told to use only eardrops that are specifically approved for use with tympanostomy tubes, because nonapproved ear drops may induce pain, infection, or even damage hearing. Over-the-counter otic drops are not safe for use with tympanostomy tubes, regardless of the indication (eg, earwax, swimmer's ear, discomfort).

Families should also be educated concerning water exposure, as discussed in Statement 11. Water precautions are unnecessary for most children with tympanostomy tubes but should be implemented for children who develop TTO or experience discomfort upon exposure to water. Protection with earplugs, headbands, or water avoidance may be necessary during periods of active TTO.¹¹⁸

In summary, parent/caregiver and patient education is a fundamental component of the care of children with tympanostomy tubes. Education is essential at the time of tympanostomy tube insertion, and ideally, the information should be discussed and reviewed at all subsequent visits. Spoken information should be supplemented by clear, concise written information specific to the needs of the child with tympanostomy tubes (**Figures 7** and **8**), and there should be ample opportunity for families to ask questions and review their concerns. Education and efficient communication will improve the family's understanding of how to best care for the child with ear tubes, encourage follow-up care, and allow prevention or early identification of complications, all of which will ultimately improve outcomes (**Figure 9**).

STATEMENT 11. ACUTE TYMPANOSTOMY TUBE OTORRHEA: Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea. *Strong recommendation based on randomized controlled trials with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, based on RCTs demonstrating equal efficacy of topical versus oral antibiotic therapy for otorrhea as well as improved

outcomes with topical antibiotic therapy when different topical preparations are compared

- Level of confidence in evidence: High
- Benefits: Increased efficacy by providing appropriate coverage of otorrhea pathogens, including *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus* (MRSA), avoidance of unnecessary overuse and adverse effects of systemic antibiotics, including bacterial resistance
- Risks, harms, costs: Additional expense of topical otic antibiotics compared with oral antibiotics, potential difficulties in drug delivery to the middle ear if presence of obstructing debris or purulence in the ear canal
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Emphasis on avoiding systemic antibiotics due to known adverse events and potential for induced bacterial resistance
- Intentional vagueness: None
- Role of patient (caregiver) preferences: Limited, because there is good evidence that topical antibiotic eardrops are safer than oral antibiotics and have equal efficacy
- Exceptions: Children with complicated otorrhea, cellulitis of adjacent skin, concurrent bacterial infection requiring antibiotics (eg, bacterial sinusitis, group A strep throat), or those children who are immunocompromised
- Policy level: Strong recommendation
- Difference of opinion: None

Supporting Text

The purpose of this statement is to promote topical antibiotic therapy and discourage systemic antibiotics in managing uncomplicated acute TTO. In this context, *acute* refers to otorrhea of less than 4 weeks' duration, and *uncomplicated* refers to TTO that is not accompanied by high fever (38.5°C, 101.3°F), concurrent illness requiring systematic antibiotics (eg, streptococcal pharyngitis, bacterial sinusitis), or cellulitis extending beyond the external ear canal to involve the pinna or adjacent skin.

Otorrhea is the most common sequela of tympanostomy tubes, with a mean incidence of 26% (range, 4%-68%) in observational studies¹³ and up to 83% with prospective surveillance.¹¹⁹ Otorrhea may be further categorized as early postoperative otorrhea (within 4 weeks of tympanostomy tube insertion), delayed otorrhea (4 or more weeks after tympanostomy tube insertion), chronic otorrhea (persisting 3 months or longer), and recurrent otorrhea (3 or more discrete episodes). Most otorrhea is sporadic, brief, and relatively painless, with recurrent otorrhea affecting only about 7% of patients and chronic otorrhea occurring in about 4%.¹¹

Acute delayed TTO in young children with tympanostomy tubes is usually a manifestation of AOM and is caused by the typical nasopharyngeal pathogens *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*.^{120,121}

How to Care for Your Child's Ear Tubes

Ear tubes help protect your child from ear infections, middle-ear fluid (liquid behind the eardrum), and the hearing problems that go along with them. Most tubes last about 6 to 18 months, allowing many children time to outgrow their ear problems. Most tubes fall out by themselves. The chance of a tube falling in, instead of out, is very rare. Tubes that do not come out after 3 or more years may need to be removed by your doctor.

Possible Complications of Ear Tubes

Complications of ear tubes are usually minor. Some children develop a white mark or patch on the eardrum which is called sclerosis. It *does not* affect your child's hearing or future chance of ear infections. Some children develop a small depression or pocket in the eardrum at the tube site after it falls out. Again, this does not affect hearing and rarely requires treatment. About 1-2 out of every 100 children will develop a small hole (perforation) of the eardrum after the tube falls out. The hole will often close on its own over time, but if it does not, it can be patched in the operating room.

Ear Tubes and Water Precautions

Some children with ear tubes wear ear plugs when swimming. The ear plugs keep water out of the ear canal and out of the ear tube. However, water does not usually go through the tube during swimming. As a result, ear plugs are not necessary for most children.

Although most children with tubes do not need ear plugs, they may be necessary in the following situations:

- Pain or discomfort when water enters the ear canal
- Discharge or drainage is observed coming out of the ear canal
- Frequent or prolonged episodes of ear discharge

Other times when ear plugs may be needed on an individual basis are:

- Swimming more than 6 feet under water
- Swimming in lakes or non-chlorinated pools
- Dunking head in the bathtub (soapy water has a lower surface tension than plain water)

A variety of soft, fitted ear plugs are available, if needed, as are special neoprene headbands to cover the ears. *Never* use Playdoh or silly putty as an earplug, because it can become trapped in the ear canal and require surgical removal. Once the tube becomes blocked or comes out, ear plugs are not needed if there is no hole in the eardrum.

Ear Tube Follow-Up and Aftercare

Routine follow-up with your doctor every 4 to 6 months is important to make sure that your child's tubes are in place and to check for any possible problems. All children need follow-up no matter how well they are doing. Children often feel well even when there is a problem with the tube. Once the tubes fall out, your child should return for a final re-check after 6-12 months so your doctor can check the ears and be sure that fluid has not built up again.

Figure 7. Sample education sheet (page 1) for tympanostomy tube care, which may be modified to suit individual needs.

Conversely, when acute TTO occurs after water exposure (bathing, head dunking, underwater swimming) or in older children, it is often caused by external auditory canal pathogens such as *P aeruginosa* and *S aureus*.^{120,121} Viral

co-infection is often present when young children present with acute TTO.¹²²

Three RCTs have compared topical antibiotic eardrops (ofloxacin, ciprofloxacin, or ciprofloxacin-dexamethasone) to

Ear Tubes and Ear Infections

Your child may still get an ear infection (acute otitis media) with a tube. If an infection occurs, you will usually notice drainage or a bad smell from the ear canal.

If your child gets an ear infection *with* visible drainage or discharge from the ear canal:

1. Do not worry: the drainage indicates that the tube is working to drain infection from the middle ear space. Most children do not have pain or fever with an infection when the tube is in place and working.
2. Ear drainage can be clear, cloudy, or even bloody. There is no danger to hearing.
3. The best treatment is antibiotic ear drops *alone* (ofloxacin or ciprofloxacin-dexamethasone). Place the drops in the ear canal two times a day for up to 10 days. "Pump" the flap of skin in front of the ear canal (tragus) a few times after placing the drops. This will help the drops enter the ear tube.
4. Ear drainage may build up or dry at the opening of the ear canal. Remove the drainage with a cotton-tipped swab dipped in hydrogen peroxide or warm water, a cotton ball to absorb drainage, or gently suction with an infant nasal aspirator.
5. Prevent water entry into the ear canal during bathing or hair washing by using a piece of cotton saturated with Vaseline to cover the opening; do not allow swimming until the drainage stops.
6. To avoid yeast infections of the ear canal, do not use antibiotic eardrops frequently or more than 10 days at a time.
7. Oral antibiotics are *unnecessary* for most ear infections with tubes unless your child is very ill, has another reason to be on an antibiotic, or the infection does not go away after using ear drops.

If your child gets an ear infection *without* visible drainage from the ear canal:

1. Ask your primary doctor if the tube is open (functioning); if it is, the infection should resolve *without* a need for oral antibiotics or antibiotic ear drops.
2. If your doctor gives you an antibiotic or ear drop prescription anyway, ask if you can wait a few days before filling it; chances are high you will not need the medication. Use acetaminophen or ibuprofen to relieve pain, if necessary, during the first few days.
3. If the tube is not open, the ear infection is treated as if the tube was not there; the blocked tube does not do any harm (and will not cause a problem), but it also does not do any good.

When to Call the Ear Doctor (Otolaryngologist)

Call the ear doctor if any of the following occur:

1. your child's regular doctor can't see the tube in the ear
2. your child has hearing loss, continued ear infections or continued ear pain/discomfort
3. ear drainage continues for more than 7 days
4. drainage from the ears occurs frequently
5. there is excessive wax build-up in the ear canal

Figure 8. Sample education sheet (page 2) for tympanostomy tube care, which may be modified to suit individual needs.

systemic oral antibiotics (amoxicillin or amoxicillin-clavulanate) for treating acute TTO in children.¹²³⁻¹²⁵ Superior outcomes with topical therapy were achieved in some studies for clinical cure,¹²³⁻¹²⁵ bacterial eradication,¹²⁴ and patient satisfaction.¹²⁴ Rates of clinical cure upon completion of therapy

after 7 to 10 days ranged from 77% to 96% with topical therapy and from 30% to 67% with systemic antibiotic therapy. Explanations for improved outcomes with topical antibiotic therapy include increased drug concentration at the site of infection and improved coverage of likely pathogens,

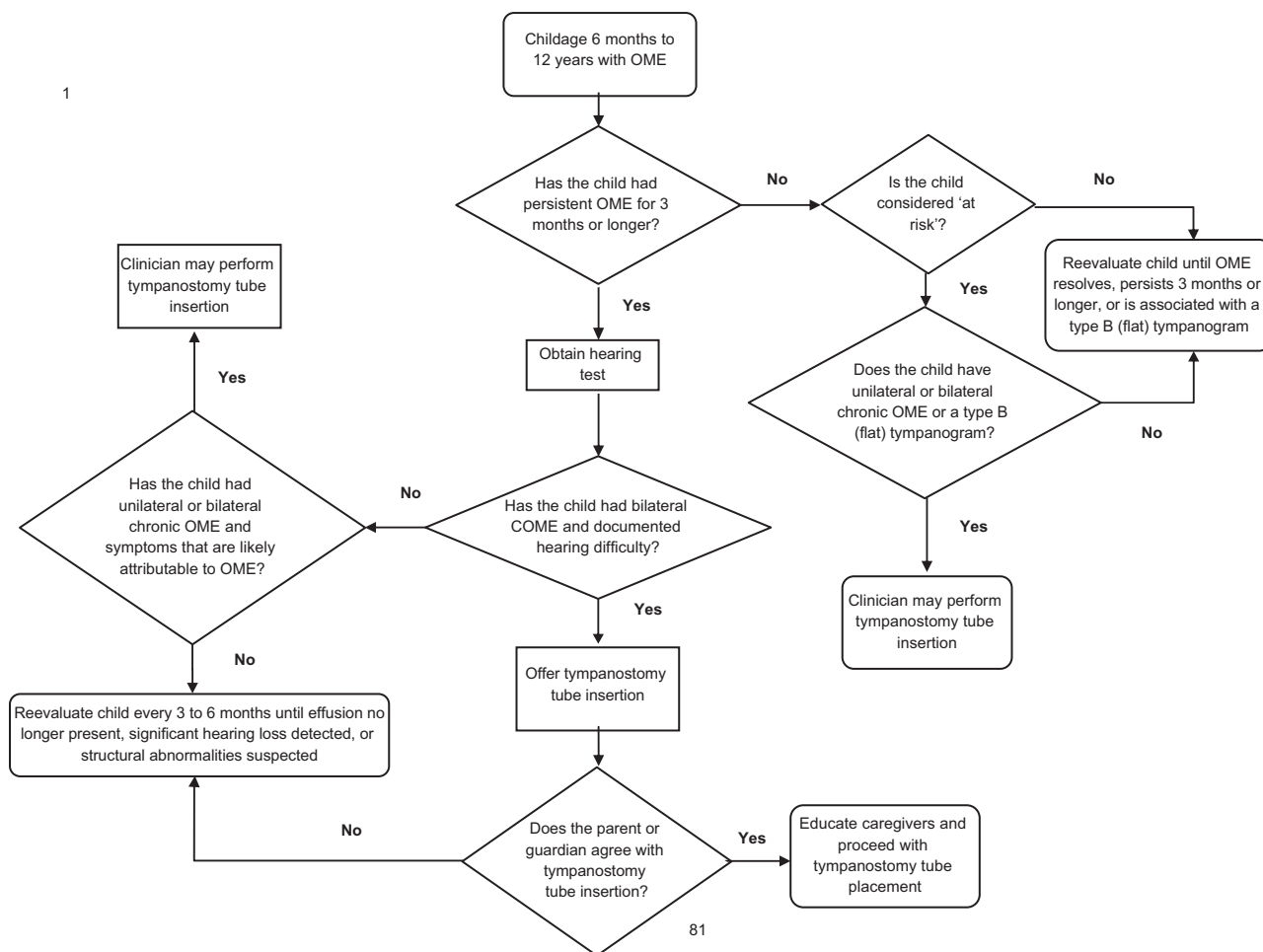


Figure 9. Algorithm of guideline's key action statements for children with otitis media with effusion.

especially *P aeruginosa*. One additional RCT assessed topical antibiotics with and without concurrent oral antibiotics but did not find any advantage to combination therapy.¹²⁶

Topical antibiotic therapy avoids adverse events associated with systemic antibiotics including dermatitis,^{123,124} allergic reactions, gastrointestinal upset,^{123,124} oral thrush,¹²⁴ and increased antibiotic resistance.¹²¹ Only topical drops approved for use with tympanostomy tubes should be prescribed (eg, ofloxacin or ciprofloxacin-dexamethasone) to avoid potential ototoxicity from aminoglycoside-containing eardrops, which are often used to treat acute otitis externa.¹²⁷ Otomycosis has not been reported after topical therapy in RCTs of acute TTO,¹²³⁻¹²⁵ but prolonged or frequent use of quinolone eardrops may induce fungal external otitis.^{128,129} Caregivers should be advised to limit topical therapy to a single course of no more than 10 days. Last, although systemic quinolone antibiotics are not approved for children aged 14 years or younger, topical drops are approved because they do not have significant systemic absorption.

Acute TTO usually improves rapidly with topical antibiotic therapy, provided that the drops can reach the middle ear space.¹⁸ This is most likely to occur if the ear canal is cleaned of any debris or discharge before administering the drops, by

blotting the canal opening or using an infant nasal aspirator to gently suction away any visible secretions.³ Any dry crust or adherent discharge can be cleaned using a cotton-tipped swab and hydrogen peroxide, which can be used safely when a tympanostomy tube is present.¹³⁰ Persistent debris despite these measures can often be removed by suctioning through an open otoscope head or by using a binocular microscope for visualization. In addition, having the child's caregiver "pump" the tragus several times after the drops have been instilled will aid delivery to the middle ear.^{116,131} Last, caregivers should be advised to prevent water entry into the ear canal during periods of active TTO.

Systemic antibiotic therapy is not recommended for first-line therapy of uncomplicated, acute TTO but is appropriate, with or without concurrent topical antibiotic therapy, when:

1. Cellulitis of the pinna or adjacent skin is present
2. Concurrent bacterial infection (eg, sinusitis, pneumonia, or streptococcal pharyngitis) is present
3. Signs of severe infection exist (high fever, severe otalgia, toxic appearance)
4. Acute TTO persists, or worsens, despite topical antibiotic therapy

5. Administration of eardrops is not possible because of local discomfort or lack of tolerance by the child
6. A patient has an immune-compromised state
7. Cost considerations prevent access to non-ototoxic topical antibiotic drops

Nearly 4% to 8% of children treated with topical quinolone otic drops require oral antibiotic rescue therapy for persistent symptoms.^{123,124} Children who fail topical therapy should be assessed for obstructing debris in the ear canal or in the tympanostomy tube that can impair drug delivery. Culture of persistent drainage from the ear canal may help target future therapy, detecting pathogens such as fungi and MRSA. Most often, however, culture results of persistent TTO despite topical or systemic antibiotic therapy identify organisms (eg, *S aureus*, *S pneumoniae*, *P aeruginosa*, MRSA) that are susceptible to topical quinolone eardrops.¹³² Clinicians should also be aware that sensitivity results from otorrhea culture typically relate to serum drug levels achieved from systemic antibiotic therapy, but the antibiotic concentration at the site of infection with topical drops can be up to 1000-fold higher and will typically overcome this level of resistance.

About 4% of children with tympanostomy tubes develop granulation tissue at the junction of the tympanostomy tube with the tympanic membrane, which can present as persistent, usually painless, otorrhea that is pink or bloody.¹¹ The treatment of choice is a topical quinolone drop, with or without dexamethasone¹³³; systemic antibiotics should not be prescribed.

STATEMENT 12. WATER PRECAUTIONS: Clinicians should *not* encourage routine, prophylactic water precautions (use of earplugs or headbands; avoidance of swimming or water sports) for children with tympanostomy tubes. *Recommendation against based on randomized controlled trials with limitations, observational studies with consistent effects, and a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, based on 1 randomized controlled trial and multiple observational studies with consistent effects
- Level of confidence in evidence: High
- Benefits: Allows for normal activity and swimming, reduced anxiety, cost savings
- Risk, harm, cost: Potential for slight increase in otorrhea rates in some children
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of not restricting or limiting children's water activity in the absence of proven, clinically significant benefits of routine water precautions
- Intentional vagueness: The word *routine* is used to soften the recommendation since individual children may benefit from water precautions in specific situations (eg, lake swimming, deep diving, recurrent

otorrhea, head dunking in the bathtub, or otalgia from water entry into the ear canal)

- Role of patient (caregiver) preferences: Significant role in deciding whether or not to use water precautions based on the child's specific needs, comfort level, and tolerance of water exposure.
- Exceptions: Children with tympanostomy tubes and (1) an active episode of otorrhea or (2) recurrent or prolonged otorrhea episodes, as well as those with a history of problems with prior water exposure
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to avoid unnecessary restrictions on child activity because of attempts to theoretically prevent contamination of the middle ear from water exposure during bathing and swimming. These restrictions include avoidance or prohibition of swimming, modification of swimming behaviors (no diving, no swimming in lakes or streams), use of ototopical antibiotics as a prophylactic measure after swimming, and use of earplugs and head bands to limit entry of water into the ear canal. Water precautions have been traditionally advised by most otolaryngologists,¹³⁴ but more recent evidence has shown this to be unnecessary.

The most compelling evidence against routine water precautions for tympanostomy tubes comes from a large RCT comparing swimming/bathing with routine ear plug use to swimming/bathing without such plugs over a period of 9 months.¹¹⁸ Although there were some statistically significant benefits to routine ear plug use, the clinical benefit was trivial: a child would need to wear plugs for 2.8 years, on average, to prevent a single episode of TTO. Routine use of ear plugs slightly reduced the chance of having any otorrhea episodes from 56% to 47%, and the mean incidence of otorrhea episodes decreased from 0.10 per month to 0.07 per month. The authors recommended against routine water precautions for children after tympanostomy tubes because of the large effort involved to obtain an extremely small benefit.

Prior to this RCT, several systematic reviews of observational studies reached similar conclusions. Lee and colleagues¹³⁵ examined 5 controlled trials of water precautions after tympanostomy tube placement. The rate of otorrhea was not statistically different between swimmers without water precautions and nonswimmers in any of the trials, and 4 of 5 trials showed favorable trends toward the swimmer groups. With their pooled analysis, these authors concluded that the incidence of otorrhea did not increase for children who swam without water protection.

Carbonell and Ruiz-Garcia¹³⁶ reviewed 11 trials and commented on concerns about quality of studies, including inherent inability to blind participants, significant loss of subjects to follow-up, and lack of intention-to-treat analyses. The risk of infection was no different between those children allowed to swim without ear protection and those who did not swim and was also no different between those children instructed to swim with ear plugs or swimming caps and those allowed to

swim without such protection. No difference was found in TTO between those who used ototopical antibiotics after swimming and those who used a swimming cap and/or ear plugs.

While it is appealing to recommend water avoidance or ear plug use for children after tympanostomy tubes, the available clinical evidence in aggregate finds no clinically significant reduction in otorrhea with such practice. Water avoidance is at a minimum a social inconvenience and at worst a detriment to developing water safety skills for young children. It is unlikely that surface swimming or shallow diving creates pressures at the eardrum large enough to allow middle ear penetration.¹³⁷ In addition, water contamination in the middle ear does not invariably cause mucosal injury or infection. Ear plugs and other devices can be inconvenient and an unwarranted expense.

Water precautions may be prudent for some children in defined clinical situations. Children with recurrent or persistent otorrhea, particularly those with *P aeruginosa* or *S aureus* in middle ear cultures during such infections, may benefit from measures to keep the middle ear space free from water contamination. In addition, children with risk factors for infection and complications, such as those with immune dysfunction, may benefit from water precautions after placement of tympanostomy tubes. Water precautions may also be useful to avoid exposure to heavily contaminated water (eg, certain lakes), for deep diving, or for children who experience ear discomfort during swimming.

While the evidence against routine water precautions after tympanostomy tubes has solidified, clinical practice has lagged behind. A survey of physicians in the northwestern United States reported 47% of responding otolaryngologists allowed swimming without any water precautions for patients with tympanostomy tubes.¹³⁸ Moreover, while 47% of otolaryngologists recommended ear plugs or other barrier devices, 73% of primary care physicians recommended these water precautions. The recommendation for routine water precautions after tympanostomy tubes is unnecessary for the great majority of children. This action statement should be incorporated into the preoperative counseling of families of children before surgery and into the knowledge base of all practitioners who care for children after such surgery.

Implementation Considerations

This clinical practice guideline is published as a supplement to *Otolaryngology—Head and Neck Surgery*, to facilitate reference and distribution. A full-text version of the guideline will also be accessible, free of charge, at <http://www.entnet.org>. In addition, all AAO-HNSF guidelines are now available via the *Otolaryngology—Head and Neck Surgery* app for smart phones and tablets. The guideline will be presented to AAO-HNS members as a miniseminar at the AAO-HNSF Annual Meeting & OTO EXPO. Existing brochures and publication by the AAO-HNSF will be updated to reflect the guidelines recommendations.

The guideline development group agreed that the recommendations likely to generate the most discussion among clinicians are the 2 statements regarding tympanostomy tube

insertion for recurrent AOM. We have distinguished for the first time between recurrent AOM with and without persistent MEE, with tubes indicated only when the effusion persists. This rationale is supported by existing RCTs and evidence about the natural history of recurrent AOM when effusion is absent but is not part of the management paradigm for most practicing clinicians. Education and supporting materials will be required to justify why a child with recurrent AOM but no MEE is unlikely to benefit from tympanostomy tubes, despite parental/caregiver pressure or “traditional” practice.

In the circumstance described, along with other situations in which tympanostomy tubes are not initially recommended, educational materials should be developed to help caregivers and families understand the benefits of watchful waiting instead of immediate tube insertion. This material should include the importance of follow-up visits and monitoring for signs or symptoms related to OME or recurrent AOM that would make the child a potential candidate for tubes and benefit from reassessment by the clinician. Information should also be provided to assist caregivers in detecting child behavior that would suggest a hearing loss is present, which might include the questions for reported hearing difficulty in **Table 7**.

Another implementation concern relates to using topical antibiotic eardrops for acute, uncomplicated TTO. The drops must reach the middle ear space to have the desired benefits, but this can occur only if the drops pass freely through the ear canal and penetrate the tympanostomy tube. An educational video, or other teaching aid, should be developed to illustrate how parents/caregivers should instill the drops (eg, the importance of “pumping” the tragus) and how parents/caregivers or clinicians can clean otorrhea and crusts from the ear canal and adjacent skin, if necessary.

Research Needs

Chronic OME with Hearing Difficulty

- Identify alternatives to formal audiologic assessment, including clinical measures, so that we can identify children with hearing difficulties
- Study of the benefits of postoperative assessment (when, how often, by whom)
- Better understand variations in access to audiometry services, particularly access to pediatric audiometry
- Better understand differential effect on speech and language outcomes based on children’s age at intervention for hearing loss
- Study of actual clinical significance of effects of tympanostomy tubes on long-term HLs and the presence of tympanic membrane structural changes

Chronic OME with Symptoms

- Study of differences in effects of OME on children of varying ages
- Study of effects of unilateral versus bilateral OME
- Better understand the effect of unilateral OME on outcomes: vestibular, school performance, behavior, and ear discomfort

- Among children with OME, obtain data on the magnitude and effect size of the long-term hearing deficits well as the presence of tympanic membrane structural changes
- Among children with OME, study of the long-term effects of middle ear fluid on the ear drum in absence of hearing issues—determine the natural history of asymptomatic middle ear fluid

Recurrent AOM without MEE

- Research is needed to develop criteria to identify the subset of recurrent AOM patients, without current effusion, who will develop additional ear infections or long-term effusions in the future

Recurrent AOM with MEE

- Improve documentation of AOM diagnosis and recurrent AOM diagnostic accuracy
- Determine whether the precision with which AOM is diagnosed changes the predicted effectiveness of tympanostomy tubes for recurrent AOM; determine whether studies that demand such diagnostic accuracy and stricter entry criteria show a greater benefit for tympanostomy tubes in children with recurrent AOM
- Characterize QOL for recurrent AOM with tympanostomy tubes versus without tube placement
- Randomized controlled trials to provide effect sizes for benefit of surgery over observation among this patient population; existing studies are deficient in that they have not clearly separated patients with AOM based on presence or absence of fluid at diagnosis

Distinguishing At-Risk Children

- Need better data on the prevalence of at-risk conditions and strategies to identify at-risk children
- Need epidemiological evidence for the prevalence of MEE and sequelae of MEE in at-risk children with conditions other than Down syndrome or cleft palate as well as the acceptability, effectiveness, and consequences of various treatment strategies
- Among at-risk children with OME of medium duration, clarify the role for more aggressive management of ear disease

Tympanostomy Tubes and At-Risk Children

- Better understand the impact of tympanostomy tube placement among children with speech/language delay
- Better understand the indications and outcomes for tympanostomy tube placement in children with Down syndrome or with cleft palate, since existing randomized trials cannot be generalized to these populations; ideally, these studies should be prospective, include long-term follow-up, distinguish children younger than 24 months from older children, and have children treated with tympanostomy tubes matched to control children by age and HLs

- Additional data regarding the efficacy of tubes in preventing sequelae of MEE in at-risk patients
- Compare the efficacy of hearing aids versus tympanostomy tubes for at-risk children with chronic OME and hearing loss
- Determine the role of long-term versus short-term tubes in children with cleft palate or Down syndrome
- Develop educational materials for patients, parents/caregivers, and primary care providers and surgical/medical specialists to raise awareness of the at-risk status of these patients
- Assess whether at-risk children have the same risk profile for surgical and anesthetic complications

Hearing Resting

- Potential implementation hurdles with regard to access to hearing testing and audiometry; need a study to understand possible barriers to audiologic testing
- Determine the role for formal audiologic testing versus a hearing screening test—such as performed by primary care physicians—for follow-up for otherwise low-risk children
- Validation of a clinical proxy for detecting the probable presence of hearing loss when audiology is not available or is unreliable
- Assess the validity of parental/caregiver reports regarding improved hearing following tube placement and whether there is added benefit of objective assessment
- Evidence for best use of postoperative audiologic assessment; determine patient population needs postoperative audiologic assessment: assess all children, only those with preoperative hearing loss, or only those children with parent/caregiver concern regarding persistent hearing loss

Acute TTO

- Determine the impact of tympanostomy tube placement on middle ear bacteriology and whether these changes affect selection of treatment of AOM after tympanostomy tubes
- Determine the ideal duration of topical therapy for posttympanostomy otorrhea
- In the setting of recurrent, persistent, or chronic otorrhea, determine when is it advisable to remove a tube

Water Precautions

- Studies of clinical indicators (swimming locale, host factors such as age, number of AOM episodes, immune status, etc) for more routine recommendation of water precautions after tubes

Perioperative Education

- Research is needed to characterize the effectiveness of various methods of perioperative education about tubes; modalities to include voice, written, video, web-based, other; timing to include preoperative, at

surgery, postoperative; educators to include nurse, surgeon, primary care physician, other

Anesthesia

- Need for more information about the morbidity and mortality of general mask anesthesia for tympanostomy tube placement in children

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 children with tympanostomy tubes or being considered for tympanostomy tubes. 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 physician, 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-HNS, Inc 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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