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Clinical Practice Guideline: Tympanostomy Tubes in Children (Update)

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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. All these conditions are encompassed by the term *otitis media* (middle ear inflammation). This guideline update provides evidence-based recommendations for patient selection and surgical indications for managing tympanostomy tubes in children. The 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.

Purpose. The purpose of this clinical practice guideline update is to reassess and update recommendations in the prior guideline from 2013 and to provide clinicians with trustworthy, evidence-based recommendations on patient selection and surgical indications for managing tympanostomy tubes in children. In planning the content of the updated guideline, the guideline update group (GUG) affirmed and included all the original key action statements (KASs), based on external review and GUG assessment of the original recommendations. The guideline update was supplemented with new research evidence and expanded profiles that addressed quality improvement and implementation issues. The group also discussed and prioritized the need for new recommendations based on gaps in the initial guideline or new evidence that would warrant and support KASs. The GUG further sought to bring greater coherence to the guideline recommendations by displaying relationships in a new flowchart to facilitate clinical decision making. Last, knowledge gaps were identified to guide future research.

Methods. In developing this update, the methods outlined in the American Academy of Otolaryngology–Head and Neck Surgery Foundation's "Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence Into Action" were followed explicitly. The GUG was convened with representation from the disciplines of otolaryngology–head and neck surgery, otology, pediatrics, audiology, anesthesiology, family medicine, advanced practice nursing, speech-language pathology, and consumer advocacy.

Action Statements. The GUG made *strong recommendations* for the following KASs: (14) clinicians should prescribe topical antibiotic ear drops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea; (16) the surgeon or designee should examine the ears of a child within 3 months of tympanostomy tube insertion AND should educate families regarding the need for routine, periodic follow-up to examine the ears until the tubes extrude.

The GUG made *recommendations* for the following KASs: (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, from the date of onset (if known) or from the date of diagnosis (if onset is unknown); (2) clinicians should obtain a hearing evaluation if OME persists for 3 months or longer 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 AND documented hearing difficulties; (5) 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; (6) clinicians should not perform tympanostomy tube insertion in children with recurrent acute otitis media who do not have middle ear effusion in either ear at the time of assessment for tube candidacy; (7) clinicians should offer bilateral tympanostomy tube insertion in children with recurrent acute otitis media who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy; (8) clinicians should determine if a child with recurrent acute otitis media 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; (10) the clinician should not place long-term tubes as initial surgery for children who meet criteria for tube insertion unless there is a specific reason based on an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube; (12) 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; (13) clinicians should not routinely prescribe postoperative antibiotic ear drops after tympanostomy tube placement; (15) clinicians should not encourage routine, prophylactic water precautions (use of earplugs or headbands, avoidance of swimming or water sports) for children with tympanostomy tubes.

The GUG offered the following KASs as *options*: (4) 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, all or in part, to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life; (9) clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is likely to persist as reflected by a type B (flat) tympanogram or a documented effusion for 3 months or longer; (11) clinicians may perform adenoidectomy as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoids (adenoid infection or nasal obstruction) OR in children aged 4 years or older to potentially reduce future incidence of recurrent otitis media or the need for repeat tube insertion.

Keywords

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

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Update Rationale and Scope

This clinical practice guideline (CPG) is an update and replacement for the earlier guideline ''Tympanostomy Tubes in Children,'' published in 2013 by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF).[1] An update was necessitated by an >5-year lapse and by subsequent original research and systematic reviews that might modify existing recommendations or support new ones. Changes in content and methodology from the prior guideline include the following:

- New evidence from 6 CPGs, 18 systematic reviews, and 27 randomized controlled trials (RCTs)
- Emphasis on patient education and shared decision making with new tables of counseling opportunities and frequently asked questions
- Expanded key action statement (KAS) profiles to explicitly state quality improvement opportunities and implementation considerations
- New flowchart to clarify decision making and show the relationships among KAS recommendations
- A new strong recommendation that the surgeon or designee should examine the ears of a child within 3 months after tympanostomy tube insertion to assess outcomes and should educate families regarding the

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need for routine, periodic follow-up to examine the ears until the tubes extrude
- A new option for the clinician to perform adenoidectomy as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoid (adenoid infection or nasal obstruction) or in children aged 4 years or older to reduce future incidence of recurrent otitis media or the need for repeat tube insertion
- A new recommendation against placing long-term tubes as initial surgery for children who meet criteria for tube insertion unless there is an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube
- A new recommendation against routinely prescribing prophylactic antibiotic ear drops after tympanostomy tube surgery to prevent or reduce otorrhea
- Addition of *intellectual disability*, *learning disorder*, or *attention-deficit/hyperactivity disorder* to the list of risk factors that place children who have otitis media with effusion (OME) at increased risk for developmental difficulties (at-risk child)
- Updated categories of normal to mild hearing loss in children, with normal hearing as 0 to 15 decibels (dB), slight hearing loss as 16 to 25 dB, and mild hearing loss as 26 to 40 dB

The original guideline[1] offered the first trustworthy recommendations[2] on tympanostomy tube indications and was prompted, in part, by overuse concerns from the Joint Commission and American Medical Association.[3] Subsequent research showed excellent adherence by clinicians to guideline recommendations for tube insertion and for watchful waiting to reduce unnecessary surgery.[4-6] These recommendations have been adopted, in part, by other countries publishing guidelines on OME that secondarily discuss tympanostomy tubes.[7-11] As such, the AAO-HNSF guideline remains the only publication explicitly focused on tympanostomy tube indications and managing children who receive tubes.

This update will undergo a planned review 5 years after publication or sooner if new evidence or developments might alter recommendations or suggest a need for additional guidance.

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**). Tubes were inserted into 667,000 children under the age of 15 years in 2006 (more than 20% of all ambulatory surgery in this age group),[12] declining to 413,000 procedures in 2010,[13] most likely because of universal immunization with pneumococcal conjugate vaccine.[14,15] Despite this decline, in 2014

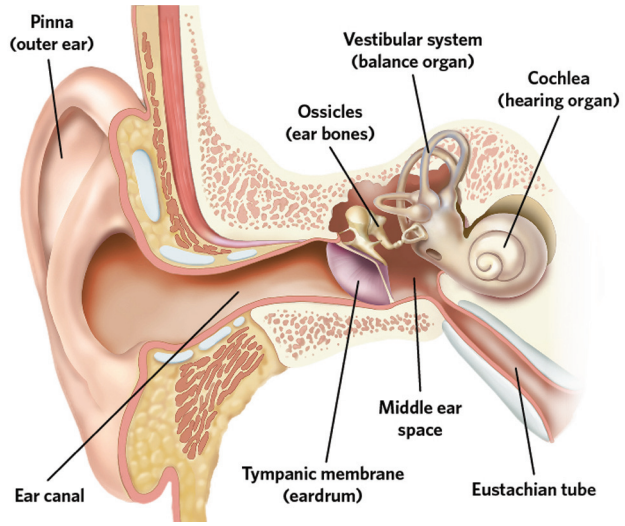


Figure 1. Relationship of the outer ear (pinna and ear canal), middle ear (ossicles and tympanic membrane), and inner ear (cochlea vestibular system). Tubes are inserted into the tympanic membrane (eardrum).

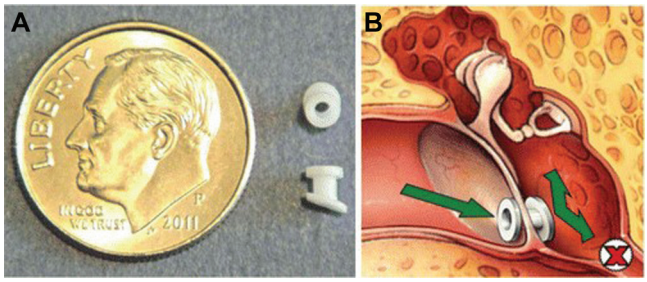


Figure 2. (A) Size of tympanostomy tube as compared with a dime. (B) Tympanostomy tubes are also called ventilation tubes because the opening allows air to enter the middle ear directly from the ear canal (arrows), which supplements ventilation through the child's poorly functioning eustachian tube (X). Adapted from Rosenfeld.[257]

about 9% of children under the age of 17 years had undergone tube surgery, and tubes were placed in 25% to 30% of children with frequent ear infections.[16,17]

Tympanostomy tubes are most often inserted because of persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy. All these conditions are encompassed by the term *otitis media* (middle ear inflammation), which is second in frequency only to acute upper respiratory infection as the most common illness diagnosed in children by health care professionals.[18] Children younger than 7 years 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 nasopharynx that normally ventilates the middle ear space and equalizes pressure with the external environment.[19]

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 from the middle ear space 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 ventilation tubes, pressure equalization (PE) tubes, grommets (UK), and bilateral myringotomy and tubes (BMT).
Otitis media with effusion (OME)	The presence of fluid in the middle ear without signs or symptoms of acute otitis media (AOM).
Chronic OME	OME persisting for 3 months or longer from the date of onset (if known) or from the date of diagnosis (if onset 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, whether automated or manual. Does not include use of noisemakers or other nonstandardized methods.
Acute otitis media (AOM)	The rapid onset of signs and symptoms of inflammation of the middle ear, usually diagnosed by a distinctly bulging tympanic membrane and the presence of a middle ear effusion.
Persistent AOM	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 last 6 months OR at least 4 well-documented and separate AOM episodes in the last 12 months with at least 1 in the last 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, often caused by AOM.
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[285]	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 tracing 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).

When children receive surgery for 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.[20] Placement of tympanostomy tubes significantly reduces middle ear effusion (MEE) prevalence, resolves hearing loss caused by MEE, reduces the incidence of recurrent acute otitis media (AOM), and provides a mechanism for drainage and administration of topical antibiotic therapy should acute tube otorrhea occur.[21,22] Tympanostomy tubes also can improve disease-specific quality of life (QOL) for children with chronic OME, recurrent AOM, or both.[23]

Risks and potential adverse events of tympanostomy tube insertion are related to general anesthesia, usually required for the procedure, and the effects of the tympanostomy tube on the tympanic membrane and middle ear.[24] Risks associated with general anesthesia can be eliminated by inserting tubes in the office setting without general anesthesia, when appropriate, based on shared decision making between the clinician and family.[25] Tympanostomy tube sequelae are common but

generally transient (otorrhea) or usually do not affect function (myringosclerosis, focal atrophy, or shallow retraction pocket of the tympanic membrane). Tympanic membrane perforations, which may require repair, are seen on average in 3% of children after placement of tympanostomy tubes.[21]

When clinical decisions are being made, the risks of tube insertion must be balanced against the risks of chronic OME, recurrent otitis media, or both, which include suppurative complications, damage to the tympanic membrane, adverse effects of antibiotics, and potential developmental sequelae of the mild to moderate hearing loss that is often associated with MEE. 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.

The frequency of tympanostomy tube insertion creates a continuing need for evidence-based guidelines to aid clinicians in identifying children likely to benefit most from tubes and in optimizing their subsequent care. We expect that this need will be fulfilled by our update to the original 2013 tympanostomy tube guideline.[1]

Guideline Purpose

The purpose of this CPG update is to reassess and update recommendations in our prior guideline[1] and to provide clinicians with trustworthy, evidence-based recommendations on patient selection and surgical indications for managing tympanostomy tubes in children. A CPG 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.''[26]

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. This applies to all KASs unless otherwise specified. The target audience includes specialists, primary care clinicians, and allied health professionals, as represented by this multidisciplinary guideline update group (GUG; refer to the Methods section). The guideline does not discuss evaluation or medical management of AOM, recurrent AOM, or OME but assumes instead that prior to consideration for tube insertion, all underlying conditions, including allergies and other potential contributing factors, have already been addressed and properly managed.

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 or to children who have tubes placed for drug delivery to the middle ear for conditions such as sudden idiopathic sensorineural hearing loss or Ménière's disease. These conditions were excluded because tympanostomy tubes are often clearly indicated for management, with minimal practice variations, and the guideline group instead sought to focus on issues with practice variations, evidence gaps, or both. Children older than 12 years are excluded because they have not been included in any randomized trials of tube efficacy.[22]

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
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
Intellectual disability, learning disorder, or attention-deficit/hyperactivity disorder[b]

[a]Sensory, physical, cognitive, or behavioral factors that place children who have otitis media with effusion at increased risk for developmental difficulties (delay or disorder).[20]
[b]The conditions in this row are a new addition to the list.

Although children considered at risk for developmental delays or disorders (**Table 2**) are often excluded from clinical research involving tympanostomy tubes, the GUG decided to include them in the target audience for this update because these patients may derive enhanced benefit from tympanostomy tubes.[27] This builds on a similar decision for the original tube guideline[1] 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.[20]

In planning the content of the updated guideline, the update group affirmed and included all of the original KASs, based on external review and GUG assessment of the original recommendations, and supplemented them with new research evidence and expanded profiles that addressed quality improvement and implementation issues. The GUG also discussed and prioritized the need for new recommendations based on gaps in the initial guideline or new evidence that would warrant and support KASs. The group further sought to bring greater coherence to the guideline recommendations by displaying relationships in a new flowchart to facilitate clinical decision making. Last, knowledge gaps were identified to guide future research.

This update does not include any recommendations regarding office insertion of tubes in children without general anesthesia, despite this issue being deemed a high-priority topic by the GUG and triggering a position statement from AAO-HNSF.[25] The group consensus was that the quality and breadth of published research (November 2020) was insufficient to facilitate evidence-based recommendations on in-office tube insertion but instead would warrant a distinct commentary article[28] published as a companion to the CPG update.

Health Care Burden

Incidence, Prevalence, and Cost

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.[29] At any given time, approximately 20% of young school-aged children have MEE, with nearly all school-aged children having at least 1 episode during their childhood.[29] In a study of National Health Interview Survey data from 2014, 8.6% of children under the age of 18 years had prior tympanostomy tubes, and frequent ear infections (3 or more) were reported in 9.1% of children under the age of 2 years and in 3.9% of children aged 3 to 17 years.[16] Twenty-five percent of children under the age of 2 years who had frequent ear infections had received tympanostomy tubes.

The financial impact of otitis media on health care is enormous. Direct costs associated with managing 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,[30] and include child school absence, caregiver absence from work or school, and canceled family activities because of child illness. A study of >81 million children in the 2009 Medical Expenditure Panel Survey found that 10.7% were diagnosed with AOM and, once diagnosed, had an additional 2 office visits, 0.2 emergency room visits, and 1.6 prescriptions per year as compared with those without AOM.[31] The incremental health care expense from AOM in this study was $2.88 billion annually.

One analysis of ambulatory tympanostomy tube surgery in children under the age of 5 years showed annual rates of 0.9 procedures per 100 children in New York and 1.8 procedures per 100 children in Florida from 2010 to 2014.[32] With nearly 670,000 tympanostomy tube insertions annually in children in the United States[12] and an average cost of $2700 per procedure,[33] 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. Moreover, about 14% of children have tubes placed a second time within 5 years of the first surgery.[34] A chart review from one managed care organization showed that tympanostomy tube insertion is cost-effective for otitis media in children,[33] but no large-scale studies or formal cost-effectiveness analyses are available to assess the generalizability of this claim.

Health Disparities and Tympanostomy Tubes

The recommendation to place tympanostomy tubes in children, as well as the access to such surgery, is likely influenced by factors other than disease frequency, duration, or severity. An analysis of the 2014 National Health Interview Survey showed that the adjusted prevalence of tympanostomy tubes for non-Hispanic White children (10.8%) was greater than for non-Hispanic Black (5.4%) and Hispanic (5.8%) children.[17] Indications for tympanostomy tube placement vary based on poverty status, with chronic OME as the primary reason for surgery in high-poverty neighborhoods and recurrent AOM in low-poverty neighborhoods.[35]

A cohort study of children with TRICARE insurance, a health program for military service members and their families, showed increased likelihood for tympanostomy tube placement in children who attended day care, were younger than age 6 years, or were non-Hispanic White.[36] There was no association, however, of tube surgery with parental education or household income, which may be related to the lack of any premium payments, coinsurance, or copayments passed on to the subscriber. An analysis of the National Ambulatory Medical Care Survey–Ambulatory Surgery from 2010 showed no significant demographic differences (gender, race, ethnicity, or insurance status) in the incidence of tympanostomy tube insertion for children with otitis media.[13]

These studies show that non-Hispanic White children have the highest prevalence of otitis media and the highest incidence of tympanostomy tubes as compared with Hispanic or Black children. There is no published research to suggest disparate health care access bias to tympanostomy tube surgery, but given the well-documented presence of health disparities for other conditions and procedures, clinicians should remain alert that such disparities may exist for tympanostomy tubes despite a paucity of research evidence.

Benefits of Tympanostomy Tubes

Tympanostomy tube insertion is associated with short-term QOL improvements.[37] 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 their time preoccupied with their child's condition.[38] Physical suffering was a problem for 85% of children, emotional distress for 76%, and activity limitations for 57%. An 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.[39]

For children with chronic OME, tube insertion reduces the prevalence of MEE by 32% in the first year and improves average hearing levels by 5 to 12 decibels (dB).[22,27] A meta-analysis noted a 9.1-dB improvement in hearing levels 1 to 3 months after tympanostomy tubes but did not note any longer-term hearing improvement in studies that included 12- to 24-month follow-up.[21] Although RCTs have, in general, not found a significant impact of tympanostomy tube insertion on speech, language, or cognitive outcomes,[22,27,37] the trials typically included only healthy children without developmental delays at entry. A comparative effectiveness review supported by the Agency for Healthcare Research and Quality published in 2017 did not find consistent evidence of improved developmental outcomes with treatment of OME with tympanostomy tubes.[40] A nonrandomized study, however, did show improved caregiver perception of speech and language after tympanostomy tube placement, especially for children with developmental delays.[41]

The efficacy of tympanostomy tubes for preventing recurrent AOM is variable, with systematic reviews reporting insufficient evidence,[37] small short-term benefits,[42,43] or moderate benefits of similar magnitude to antibiotic prophylaxis.[44] Two more recent systematic reviews did not identify any additional studies of tympanostomy tubes for recurrent AOM, and analysis of prior studies suggested modest reduction of AOM incidence after tubes based on evidence.[21,45] 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. A randomized trial published after these reviews found no benefit of tympanostomy tubes on AOM incidence as compared with medical management, but only 36% of children had OME at baseline and 45% of the children managed medically eventually received tubes, mostly for AOM treatment failures and less often for parental request.[46]

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,[47] 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,[37] avoiding the adverse effects of systemic therapy.

Risks and Adverse Events Associated With Tympanostomy Tubes

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.[48] It is likely that the incidence of anesthesia-related death is lower for children undergoing tympanostomy tube placement, where anesthesia duration is brief, intubation is rarely necessary, and most patients are well vetted for this elective procedure. In the last 2 decades, concerns have been raised about potential long-term neurocognitive effects of general anesthesia in young children,[49] leading to a drug safety warning from the Food and Drug Administration in 2016 for surgery more than 3 hours' duration or when multiple procedures are performed in children under the age of 3 years.[50] While these concerns remain debated and the subject of ongoing research, one study of sibling pairs found no differences in a battery of outcomes after a single general anesthesia before 36 months of age.[51] Food and Drug Administration concerns over general anesthesia have encouraged new protocols for local anesthesia and automated devices to facilitate tube insertion as an in-office procedure in appropriately selected awake children.[52,53]

The most common sequela of tympanostomy tubes is otorrhea (TTO), seen in approximately 16% of children within 4 weeks of surgery and in 26% of children at any time that the tympanostomy tube remains in place.[24] Most tympanostomy tubes used in the United States remain in place for 8 to 18 months, during which approximately 7% of children experience recurrent TTO.[24] A study of children in the Netherlands who had tympanostomy tubes placed between 2009 and 2011 showed a 52% incidence of TTO with planned surveillance, of which 3.9% was chronic (3 months or longer).[54] In this study, TTO incidence was associated with young age, tube placement for a primary indication of recurrent AOM, older siblings in the household, and frequent upper respiratory infections.

Other complications of tympanostomy tubes include blockage of the tube lumen in about 7% to 10% 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% or lower.[24,55] Some children with ear tubes develop white patches in the middle (fibrous) layers of the tympanic membrane from deposits of calcium that can be seen while the tube is in place or after extrusion. This myringosclerosis, sometimes called ''scarring'' of the eardrum, is more common in intubated ears than in controls,[22,24,37] is usually confined to the drum, and does not typically cause any hearing difficulties or produce a clinically significant hearing loss.[56]

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.[57] These tympanic membrane changes, except for myringosclerosis, 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.[37] For example, a review of a large Medicaid database showed a persistent perforation rate near 3%, 7 years after tube placement, when based on the criteria that perforation was diagnosed twice at periods at least 6 months apart.[58] Repeat tympanostomy tube insertion and older age at tube surgery were associated with persistent perforation. A recent study showed a persistent perforation rate of 1% after tube extrusion, and 2.6% of children required removal of retained tubes that failed to extrude.[59] When perforations persist, surgical closure with myringoplasty or tympanoplasty may be required.

Children assessed at age 5 years who had tympanostomy tubes in the past had a 1- to 2-dB worsening in hearing thresholds when compared with those who did not have tympanostomy tubes.[60] This hearing worsening is not clinically significant, and it should be noted that the mean hearing level in these children with or without a history of tubes was 4.3 to 6.2 dB HL (hearing level), which is well within the range of normal hearing. A 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, especially at lower frequencies.[61] With long-term follow-up, one study found normal hearing (better than 20 dB HL) in 89% of ears 25 years after tympanostomy tube placement.[62]

In summary, tympanostomy tubes do produce visible changes in the appearance of the tympanic membrane and may cause a small or trivial decrease in long-term hearing levels. These outcomes do not appear to be clinically significant or require intervention in most patients.

The posttympanostomy tube sequela most likely to require intervention is persistent perforation, with 80%-90% success rates for surgical closure with a single outpatient procedure.[63] One study compared the frequency of subsequent chronic ear surgery after tympanostomy tube placement in cohorts with middle ear disease treated with tubes, middle ear disease not treated with tubes, and a control group without middle ear disease.[64] Treatment with tubes was associated with a 9.5-times greater risk of subsequent tympanoplasty when compared with middle ear disease not treated with tubes and a >200-times greater risk of tympanoplasty when compared with no ear disease.

Appropriateness of Tympanostomy Tube Surgery

Some investigators have questioned the appropriateness of tympanostomy tube surgery based on audits and chart review.[2,65] 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, with additional concerns over the appropriateness of tympanostomy tubes for recurrent AOM. To address these concerns, the 2013 CPG[1] was the first to propose evidence-based KAS recommendations for tympanostomy tube placement. A study of children from the Boston metropolitan area who had tubes placed in 2012 to 2013 prior to publication of the guideline found 75% adherence to guideline recommendations.[4] Another study found near 80% adherence to recommendations about indications for tubes to treat recurrent AOM, although it did not show a significant change when practice was compared before and after the guideline was published.[66]

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. The 2013 AAO-HNSF tympanostomy tube guideline[1] included several recommendations related to managing children with coexisting conditions that may put them at added risk for speech, language, or developmental sequelae of otitis media. The need to identify at-risk children for intervention with tubes was reaffirmed in this guideline update, and the scope of underlying conditions was expanded (**Table 2**). The recommendations in this guideline update must therefore be interpreted with the caveat that they may involve extrapolations from studies performed in otherwise healthy children.

Methods

General Methods

In developing this update, the methods outlined in the AAO-HNSF's ''Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence Into Action'' were followed explicitly.[2]

The original KASs from the ''Clinical Practice Guideline: Tympanostomy Tubes in Children''[1] were sent to a panel of expert reviewers from the fields of general otolaryngology, otology, pediatric otolaryngology, family practice, and pediatrics, who assessed the KASs to decide if they should be kept in their current form, revised, or removed and to identify new research that might affect the guideline recommendations. The reviewers concluded that the original guideline action statements remained valid but should be updated with minor modifications. Suggestions were also made for new KASs.

Literature Search

An information specialist conducted 2 systematic literature searches using a validated filter strategy to identify CPGs, systematic reviews, RCTs, and observational studies. The date range for the first search (CPGs, systematic reviews, and RCTs) was February 2012 (when the prior guideline ended) to November 2019, and the second search (observational studies) was February 2012 to April 2020. The following databases were searched for relevant studies: PubMed, Embase, CINAHL, Web of Science, BIOSIS, TRIP Database, NHS Evidence ENT, Agency for Healthcare Research and Quality, HSTAT, ECRI, CMA Infobase, National Library of Guidelines, NICE, SIGN (Scotland), New Zealand Guidelines Group, Australian National Health and Medical Research Council, and GIN. The full search strategy is found in Appendixes A and B (available online).

The initial English-language search identified 62 CPGs, 22 systematic reviews, and 43 RCTs published in February 2012 or later. CPGs were included if they met quality criteria of (1) an explicit scope and purpose, (2) multidisciplinary stakeholder involvement, (3) systematic literature review, (4) explicit system for ranking evidence, and (5) explicit system for linking evidence to recommendations. The final data set retained 6 guidelines that met inclusion criteria. Systematic reviews were included if they met quality criteria of (1) clear objective and methodology, (2) explicit search strategy, and (3) valid data extraction methods. RCTs were included if they met the following quality criteria: (1) trials involved study randomization; (2) trials were described as double blind; or (3) trials denoted a clear description of withdrawals and dropouts of study participants. After removal of duplicates, irrelevant references, and non-English-language articles, 6 CPGs, 18 systematic reviews, and 27 RCTs were retained prior to the update of the guideline (Appendix C, available online).

Additional evidence was identified, as needed, with targeted searches to support the needs of the GUG in updating sections of the guideline text from December 2020 through January 2021. Therefore, in total, the evidence supporting this guideline includes 8 new CPGs, 20 new systematic reviews, and 14 new RCTs. This new evidence, combined with that identified in the prior guideline, was used to inform KAS recommendations, using the highest-level aggregate evidence available.

The AAO-HNSF assembled a GUG representing the disciplines of otolaryngology–head and neck surgery,

otology, pediatrics, audiology, anesthesiology, family medicine, advanced practice nursing, speech-language pathology, and consumer advocacy. The GUG had 3 conference calls and one 2-day virtual meeting, during which it defined the scope and objectives for the updated guideline, reviewed stakeholder comments for the original KASs, identified other quality improvement opportunities, reviewed the literature search results and assessed the quality of the literature, revised the original statement evidence profiles, and drafted new KASs.

The evidence profile for each KAS from the earlier guideline was updated with additional components to ensure consistency with the current guideline methodology of the AAO-HNSF.[2] Additionally, a new domain was added to each evidence profile directly addressing implementation considerations for each KAS. The GUG also updated quality improvement opportunities, specifically linking them to quality improvement domains.

New KASs were developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision support software (BRIDGE-Wiz; Yale Center for Medical Informatics) was used to facilitate the creation of actionable recommendations and evidence profiles.[67]

The updated guideline then underwent GuideLine Implementability Appraisal to appraise adherence to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.[68] The GUG received summary appraisals and modified an advanced draft of the guideline based on the appraisal. The guideline then underwent extensive peer review from a group of stakeholders, as well as a period for open public comment. Revisions to the manuscript were made to address the comments from peer review and the public. Finally, the guideline was subject to journal editorial review. 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 that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. **Table 3** defines the grades of aggregate evidence,[69] and **Table 4** defines the strength of action (obligation) based on the interaction of evidence grade and benefit-harm balance.[70]

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 what might be expected with a recommendation. Options offer the most opportunity for practice variability.[70] 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.[70]

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the GUG sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the GUG was to be transparent and explicit about how values were applied and to document the process by explicitly stating value judgments as an element of the KAS profiles.

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline 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,[71] 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. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, the way(s) that a participant earns a living, and the participant's previously established stake in an issue.[72] Conflicts were again delineated at the start of the virtual meeting and each teleconference meeting, with the same caveats followed. All potential conflicts are disclosed at the end of the document. None of the GUG members had conflicts that required exclusion from discussion of any specific KAS or section of this guideline.

Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: an evidence-based KAS is in bold, followed by the strength of the recommendation in italic and an action statement profile that explicitly states the quality improvement opportunity, aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, harms, risks, costs, and a benefits-harm assessment. Additionally, there are statements of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion among panel members, a repeat statement of the strength of the recommendation, and implementation considerations. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of the recommendations from each KAS in this guideline can be found in **Table 5**, and the flowchart in **Figure 3** shows how each statement applies to the process of care for a child who is a tympanostomy tube candidate.

Table 3. Grades of Aggregate Evidence.[a]

Grade	OCEBM level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials, or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case series, case-control, or historically controlled studies	Nonconsecutive studies; case-control studies; or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	—	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

Abbreviation: OCEBM, Oxford Centre for Evidence-Based Medicine
[a]Adapted from OCEBM Levels of Evidence Working Group.[69]
[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.
[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

For the purposes of this guideline, *shared decision making* refers to the exchange of information regarding treatment risks and benefits, as well as the expression of patient/caregiver preferences and values, which result in mutual responsibility in decisions regarding treatment and care.[73] The role of patient/caregiver preferences in making decisions deserves further clarification. When a KAS is supported by evidence that demonstrates clear benefit, the role of patient/caregiver preferences may not be relevant. Clinicians should still provide patients with clear information on the benefits to facilitate patient understanding and shared decision making, which in turn leads to better patient adherence and outcomes.[73] When KASs are supported by weaker evidence or when benefits are less certain, the practice of shared decision making is extremely useful. In these cases, management decisions are made by a collaborative effort between the clinician and an informed patient.[73] Factors related to patient preference include, but are not limited to, absolute benefits (numbers needed to treat), cost of drugs or procedures, frequency and duration of treatment, as well as certain less tangible factors, such as religious and/or cultural beliefs or personal levels of desire for intervention.

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

- Quality improvement opportunity: Prevent overuse of tympanostomy tubes in children unlikely to derive benefit from surgery (National Quality Strategy Domain: Patient Safety, Effective Prevention and Treatment)
- 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

Table 4. Strength of Action Terms in Guideline Statements and Implied Levels of Obligation.

Strength	Definition	Implied obligation
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be 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 that the benefits exceed the harms (or, in the case of a negative recommendation, the harms exceed the benefits), but the quality of evidence is not as high (grade B or C).[a] In some clearly identified circumstances, recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option[b]	An option means that either the quality of evidence is suspect (grade D)[a] or well-done studies (grade A, B, or C)[a] show little clear advantage to one approach vs 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.

[a]Adapted from the American Academy of Pediatrics classification scheme.[70] **Table 3** provides definitions of evidence grades.
[b]Option is similar to the "weak recommendation" used in the GRADE classification (Grading of Recommendations Assessment, Development and Evaluation).

tubes for children with OME less than 2 months' duration
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary surgery and its risks, avoid surgery in children for whom the benefits of tympanostomy tubes have not been studied and are uncertain, avoid 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 OME
- Benefit-harm assessment: Preponderance of benefit over harm
- 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**); refer to KASs 8 and 9 for explicit information on at-risk children
- Policy level: Recommendation
- Differences of opinion: None
- Implementation considerations: 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 a favorable natural history. When a child is diagnosed initially with OME, the cause of the effusion is often unknown. OME is often self-limited when caused by a upper respiratory infection 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. Prior to the publication of the original guideline, the rate of clinician nonadherence to this recommendation in the United States was only about 2.5%,[6] and a later study from Denmark showed 4.7% nonadherence.[74]

OME is commonly seen in association with a viral upper respiratory infection, or it may be a prelude to, or sequela of, AOM.[75] 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.[76] Even when unrelated to an antecedent AOM episode, OME still has a favorable

Table 5. Summary of Guideline Key Action Statements.

Statement	Action	Strength	Comment
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)	KAS unchanged
2. Hearing evaluation	Clinicians should obtain a hearing evaluation if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion.	Recommendation	KAS now refers to hearing evaluation (instead of testing) and normal hearing now up to 15 decibels (20 prior)
3. Chronic bilateral OME with hearing difficulty	Clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties.	Recommendation	KAS unchanged; new questions to assess for hearing difficulties
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, all or in part, 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	KAS "likely attributable" now qualified by "all or in part" to emphasize multifactorial causes, not just OME
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	KAS unchanged
6. Recurrent AOM without MEE	Clinicians should *not* perform tympanostomy tube insertion in children with recurrent AOM who do not have MEE in either ear at the time of assessment for tube candidacy.	Recommendation (against)	KAS unchanged; new patient information sheet
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	KAS unchanged
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 (**Table 2**).	Recommendation	KAS unchanged; criteria expanded in **Table 2**
9. Tympanostomy tubes in at-risk children	Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is likely to persist as reflected by a type B (flat) tympanogram or a documented effusion for 3 months or longer.	Option	KAS unchanged; new text on cochlear implantation

(continued)

Table 5. (continued)

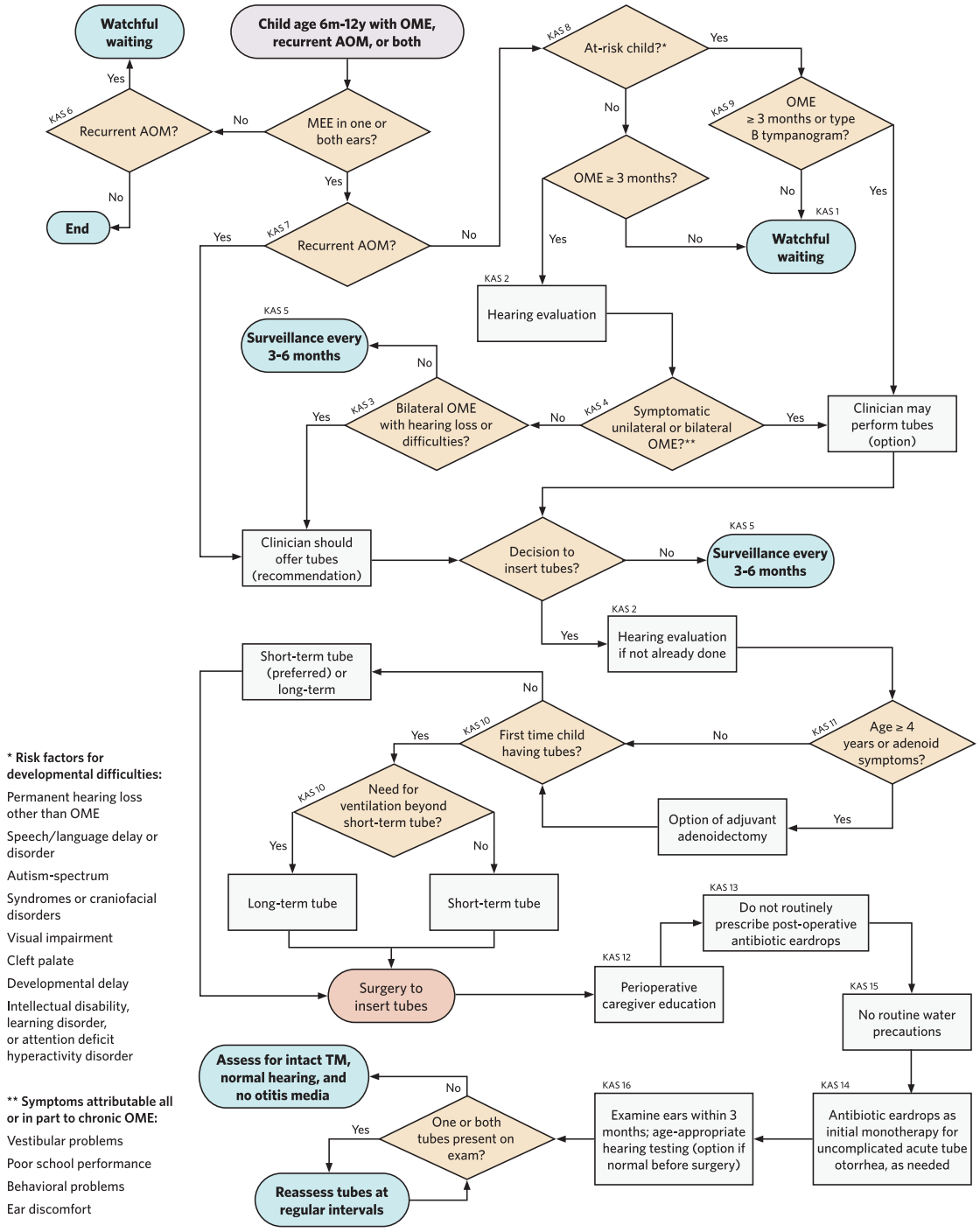
Statement	Action	Strength	Comment
10. Long-term tubes	The clinician should *not* place long-term tubes as initial surgery for children who meet criteria for tube insertion unless there is a specific reason based on an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube.	Recommendation (against)	New KAS for guideline update
11. Adjuvant adenoidectomy	Clinicians may perform adenoidectomy as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoids (adenoid infection or nasal obstruction) OR in children aged 4 years or older to potentially reduce future incidence of recurrent otitis media or the need for repeat tube insertion.	Option	New KAS for guideline update
12. 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	KAS unchanged; expanded caregiver information sheets
13. Perioperative ear drops	Clinicians should *not* routinely prescribe postoperative antibiotic ear drops after tympanostomy tube placement.	Recommendation (against)	New KAS for guideline update
14. Acute tympanostomy tube otorrhea	Clinicians should prescribe topical antibiotic ear drops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea.	Strong recommendation	KAS unchanged; new text on tissue spears
15. 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)	KAS unchanged
16. Follow-up	The surgeon or designee should examine the ears of a child within 3 months of tympanostomy tube insertion AND should educate families regarding the need for routine, periodic follow-up to examine the ears until the tubes extrude.	Strong recommendation	New KAS for guideline update

Abbreviations: AOM, acute otitis media; KAS, key action statement; MEE, middle ear effusion; OME, otitis media with effusion.

short-term natural history, with rates of spontaneous resolution or improvement ranging from 28% to 52% within 3 or 4 months of diagnosis.[77,78]

Most studies of tympanostomy tube efficacy required documented bilateral OME for at least 3 months before entry into the study,[79-82] and one group of investigators enrolled children with at least 2 months of bilateral OME.[83,84] 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.[77]

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 exist specifically addressing tympanostomy tube insertion in at-risk children with OME of shorter duration, these children have other factors making OME with attendant hearing loss a significantly greater added risk to their speech and language development[22] and should therefore be managed on an individual basis when OME is diagnosed (refer to KASs 8 and 9).



AOM, acute otitis media; KAS, key action statement; MEE, middle-ear effusion; OME, otitis media with effusion; TM, tympanic membrane

Figure 3. Flowchart showing key action statements and process of care.

STATEMENT 2. HEARING EVALUATION: Clinicians should obtain a hearing evaluation 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

- Quality improvement opportunity: Facilitate informed care decisions based on hearing levels; engage caregivers in decisions; detect preexisting hearing loss (National Quality Strategy Domain: Effective

Communication and Care Communication; Person- and Family-Centered Care)
- 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 mixed or sensorineural hearing loss
- Risks, harms, costs: Cost of the audiologic assessment
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: The words *hearing evaluation* refer to audiologic testing, typically performed by an audiologist, but the specific methods will vary with the age of the child, and 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
- Implementation considerations: Resource limitations and access to care may allow for only a single perioperative audiogram; if resources permit only a single audiometric assessment, this would ideally be performed after tympanostomy tube insertion to assess for normal hearing (following resolution of OME) or to identify any residual or underlying hearing loss

Supporting Text. The purpose of this statement is to promote hearing evaluation as an important factor in decision making when OME becomes chronic or when a child becomes a candidate for tympanostomy tube insertion (refer to KASs 4, 6, and 9). A systematic review of hearing levels in toddlers and older children with diagnosed OME showed mostly bilateral mild to moderate hearing loss (average, 18-35 dB HL) in the most important frequencies for speech perception.[85] This degree of hearing loss is of concern for listening in real-world noisy home and learning environments because children with OME and hearing loss have impaired word recognition ability, especially when background noise is present.[86,87] Furthermore, children with OME and hearing loss, even if mild and transient, may be at increased risk for persistent auditory processing deficits.[88,89]

Importance of Hearing Testing for Children With Chronic OME. Although hearing loss due to OME is often cited as a cause of adverse speech, language, and behavioral development, evidence for such a link in otherwise healthy children is lacking,[90] and the benefit of tube surgery is unknown in children with speech-language delays.[22] Since benefit is predicated on improving hearing, postoperative hearing evaluation should be completed after tympanostomy tube placement to determine resolution of a preoperative hearing loss but may not be necessary following normal preoperative test results[91] (KAS 4).

Failure to obtain audiometry preoperatively is common despite national guidelines predicating the need for surgery based on hearing levels.[6,92] Without preoperative hearing testing, necessity of surgery may be unclear, and hearing improvement after surgery cannot be ascertained.[92] Postoperative hearing loss was found in 14% of children receiving tympanostomy tubes[93] and in 23% of children with preoperative hearing loss.[91] However, if the decision to undergo tube placement has been made on the basis of risk criteria or subjective hearing difficulties and only a single hearing test can be obtained, a postoperative hearing test may be the best use of resources in such cases to determine if postoperative hearing function is normal and if further treatment is needed.[93]

Screening for hearing loss is important in the primary care setting and can indicate the need for referral to a qualified audiologist for diagnostic hearing assessment.[94] The degree of hearing loss is based primarily on the accurate measurement of hearing thresholds by an audiologist and secondarily by parent/caregiver and school (teacher) reports describing the perceived hearing ability of the child. The American Academy of Pediatrics[94] identified several key points relevant to hearing assessment in children that, 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 assesses 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 audiology referral and age-appropriate audiologic testing.

Impact of Hearing Loss on Children. 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 efficient sound transmission from the environment through the middle ear to the inner ear. OME 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.[95] Hearing is measured (**Figure 4**) in decibel hearing levels (dB HL), with an average 3-frequency (ie, 500, 1000, 200 Hz) pure tone average greater than 15 dB HL indicating some degree of hearing loss for children.[96,97]

The impact of slight hearing loss is more significant than the term indicates, as children aged 6 to 11 years with hearing levels between 15- and 30-dB pure tone average have significantly poorer cognitive, language, and reading skills than children with better hearing levels.[98] Children under the age of 3 years have ''normal thresholds'' that are up to 15 dB greater because of developmental effects and test method.[99] The impact of OME on hearing ranges from no hearing loss up to moderate hearing loss (0-55 dB HL).[100] The average hearing loss associated with OME in children is 28 dB HL, but about 20% of children with OME have hearing thresholds >35 dB HL.[100,101]

Methods for Assessing Hearing in Children. The preferred method of hearing assessment is age-appropriate audiologic testing through conventional audiometry or comprehensive audiologic assessment.[102] Children aged 4 years or older are usually able to reliably respond to conventional audiometry. This can be done in the primary care setting by 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.[94] This assessment includes evaluating air- and bone-conduction thresholds for pure tones, determining speech detection and recognition thresholds, and measuring speech understanding.[22] Visual reinforcement 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 with play audiometry, by having the child perform a task in response to a stimulus tone (eg, placing a peg in a pegboard or dropping a block in a box). Ear-specific audiologic testing is recommended whenever possible, by using insert earphones to detect unilateral or asymmetrical hearing loss.

A physiologic screening test, evoked otoacoustic emissions (OAEs), may be used when behavioral audiometry is not feasible or as a cross-check measure. OAEs are minute sounds, generated by outer hair cells within the cochlea in response to acoustic stimuli, which can be measured via a sensitive probe when the pathway from the outer to inner ear is functioning properly. OAEs provide objective assessment of inner ear functioning and are sensitive to OME and other causes of peripheral hearing loss. In cases of OME, OAE responses may be present; however, the presence of effusion can prevent them from being recorded.[103] The OAE test can be performed by a trained paraprofessional in the outpatient setting in awake, quiet infants and children and is a useful screening test for possible hearing loss due to middle or inner ear causes. OAE testing is highly sensitive to mild or greater conductive and sensorineural hearing loss.[104]

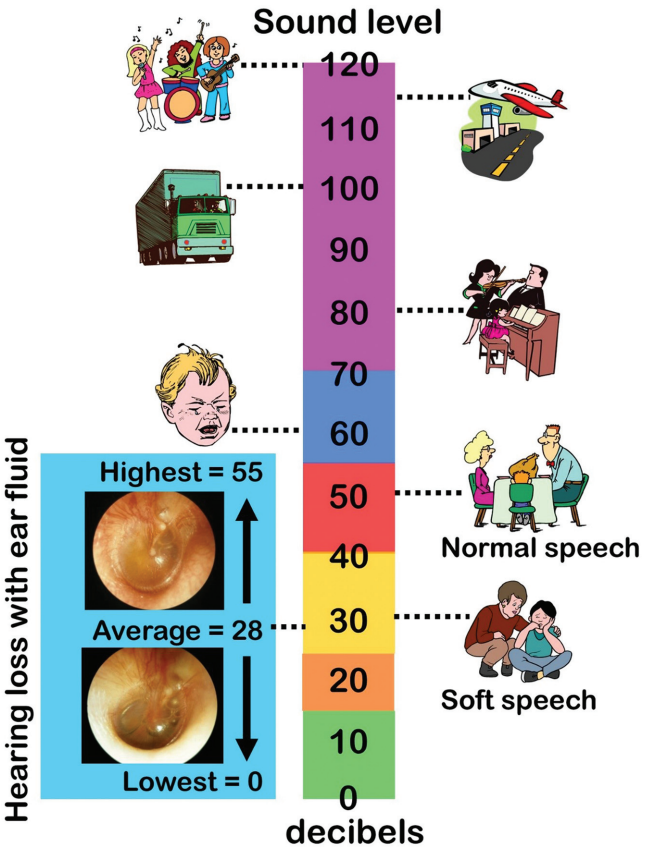


Figure 4. An average hearing level between 0 and 15 dB (hearing level) is normal (green); 16 to 25 dB, slight hearing loss (orange); 26 to 40 dB, mild hearing loss (yellow); 41 to 55 dB, moderate loss (red); 56 to 70 dB, moderate-severe loss (blue); and 71 dB or higher, severe or profound loss (purple). 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. Adapted from Rosenfeld.[257]

Auditory brainstem response (ABR) testing is another physiologic measure of hearing that might be useful when behavioral audiometry is not feasible. Unlike that with OAEs, the validity of ABR results is not affected by the presence of OME, beyond the impact of any conductive hearing loss that the OME may be causing.[105] Although some have advocated for performing ABR testing under general anesthesia concurrent with tympanostomy tube insertion, some children with OME have worse ABR thresholds following tube insertion, and results must be interpreted with caution.[106,107] Further discussion of ABR in hearing assessment related to tympanostomy tubes is beyond the scope of this guideline and should be based on shared decisions with the clinician, family, and audiologist.

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 GUG was that any child with hearing loss detected prior to

tympanostomy tube insertion should have postoperative testing to confirm resolution of hearing loss. Hearing loss may still be present after tube insertion, especially in certain risk factors, including those with hearing loss prior to tube surgery, smaller tympanometric volumes after surgery, and Down syndrome.[93] Hearing loss that is 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. Depending on the cause, additional evaluation and management may be indicated, including amplification when appropriate.

STATEMENT 3. CHRONIC BILATERAL OME WITH HEARING DIFFICULTY: Clinicians should offer bilateral tympanostomy 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

- Quality improvement opportunity: Promote effective treatment and focus attention on hearing difficulties, in addition to audiometric hearing thresholds, as a criterion for tube insertion (National Quality Strategy Domain: Effective Communication and Care Coordination and Promoting Effective Prevention/Treatments; Patient Safety; Person- and Family-Centered Care)
- 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 the 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 decline tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Differences 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 ''offer'' tubes (majority opinion)
- Implementation considerations: None

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 (KAS 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 chronic 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.[77] 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 QOL and functional health status. Minimal or slight hearing loss, which can result from persistent effusion, can arguably have a negative effect on normal speech-language development, as well as on educational performance and functional status of young children.[108-110] There remains, however, some concern whether slight hearing loss will necessarily result in speech-language delays in otherwise typical children[90] or whether speech-language delays will necessarily resolve with tube placement.[22] Nonetheless, speech-language delays should be a concern, especially if complete or comprehensive audiologic assessment is unattainable.

When OME becomes chronic, the child's hearing status has traditionally been a major determining factor in deciding whether to proceed with tympanostomy tube insertion.[20,111] Whereas earlier CPGs had *recommended* tympanostomy tube insertion for children with chronic bilateral OME and hearing loss,[111] more recent guidelines[112] advise that such children be *considered for* surgical intervention. This change was based

Table 6. Validated Questions for Assessing Hearing Difficulty by Caregiver Report.[a]

Question	Degree of a problem	Pass	Fail
How much of a problem over the past 4 weeks has your child had with hearing difficulties, asking questions to be repeated, saying "what" frequently, or needing the television excessively loud?	1. Not present/none 2. Hardly at all 3. Somewhat 4. Moderate 5. Quite a bit 6. Very much 7. Extreme	1 or 2	3, 4, 5, 6, or 7
How much of a problem over the past 4 weeks has your child had with speech delay, poor pronunciation, speech that is difficult to understand, or inability to repeat words clearly?	1. Not present/none 2. Hardly at all 3. Somewhat 4. Moderate 5. Quite a bit 6. Very much 7. Extreme	1 or 2	3, 4, 5, 6, or 7

[a]Adapted from Rosenfeld et al.[116]

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.[82,113-115] The GUG 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:

- Unfavorable 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 in the Health Care Burden section of this guideline
- Alternatives to tympanostomy tube insertion are largely limited to surveillance (KAS 5), because medical therapy (antibiotics, antihistamines, decongestants, systemic steroids, and topical nasal steroids) is ineffective and not recommended[20,112]
- The final decision reached by the clinician and caregiver regarding further management: proceed with tympanostomy tube insertion, surveillance at 3- to 6-month intervals (KAS 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,[20] as described in KAS 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 is by asking the questions in **Table 6**, drawn from the OM-6 QOL questionnaire.[116,117] The OM-6 has been validated for measuring change in disease-specific QOL following tympanostomy tube surgery.[117]

Children who have hearing or speech-language concerns based on the questions in **Table 6** should ideally be referred for audiologic assessment, as parental concern is a primary reason to refer for hearing testing even if newborn hearing screening was passed.[118] This is also advised for children with conditions such as autism spectrum disorder and other developmental delays or learning disabilities, who may display ''hearing loss behaviors'' in the absence of organic or actual hearing loss.[119] Conversely, pass responses to the questions in **Table 6** do not rule out underlying hearing loss. For example, caregivers tend to underestimate the impact of OME on a child's hearing, which may become apparent only after seeing how the child functions after the tympanostomy tubes have been placed.[120]

The primary benefits of tympanostomy tube placement are reduced prevalence of MEE, resulting in improved hearing and improved patient and caregiver QOL,[27,37] as well as possible improved language acquisition through better hearing across the speech frequencies, binaural processing, and sound localization.[37,121,122] Systematic reviews of RCTs consistently describe improved hearing in the first 6 to 9 months[27,37] following tube placement, as well as improved children's QOL the initial 2 to 9 months following tube surgery.[37] Benefits beyond these times are variable because many of the studies in these reviews use short-term tubes that often extrude within 6 to 9 months.

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, all or in part, 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

- Quality improvement opportunity: promote effective care and improve child quality of life (National Quality Strategy Domain: Effective Communication and Care Coordination; Person- and Family-Centered Care; Promoting Effective Prevention/Treatments)
- Aggregate evidence quality: Grade C, based on before-and-after studies on vestibular function and QOL, RCTs on reduced MEE prevalence 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 costs of surgery and follow-up care
- Benefit-harm assessment: Equilibrium (balance) of benefit vs harm
- 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 benefitting 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 decline tympanostomy tube insertion
- Exceptions: None
- Policy level: Option
- Differences of opinion: None.
- Implementation considerations: availability of audiology; access/familiarity with office-based measures to assess behavior, speech, language, or other aspects of child development; ability to assess vestibular issues and OME-related quality-of-life deficits (refer to earlier comments)

Supporting Text

The purpose of this statement is to facilitate intervention for children with chronic OME and associated symptoms that are likely attributable, all or in part, 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 to 30 dB HL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.''[112] In contrast, the GUG for the AAO-HNSF CPG also considered chronic *unilateral* OME as a surgical indication if presented with symptoms likely attributable to OME and whether hearing loss is present.

OME has a direct and reversible impact on the vestibular system in children aged 3 years and older.[122-128] 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 one case-control study did not show vestibular benefits with rotational chair testing in children.[129] In aggregate, however, evidence suggests that tympanostomy tube insertion is a reasonable option for children with chronic OME who have unexplained clumsiness, balance problems, or delayed motor development. Since some parents and caregivers may not appreciate the potential association 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.

The impact of OME on vestibular function in children under the age of 3 years has not been well studied, but protracted vomiting and failure to thrive have been described in some infants, with improvement or resolution after tympanostomy tube insertion.[130,131] The vestibular effects of OME may also affect developmental milestones in young children related to gross motor skills, such as difficulty in sitting without support, standing alone and taking several independent steps, maintaining balance in sitting when throwing objects,

or walking independently without falls.[132] Infants and children with chronic OME and any of the aforementioned symptoms should be evaluated for other underlying causes before attributing any vestibular-related symptoms, all or in part, as potentially caused by OME.

Certain behavioral problems occur disproportionately with OME, including distractibility, withdrawal, frustration, and aggressiveness.[133] 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.[134] The largest effects were observed for defects in reading ability between 11 and 18 years. In an RCT, children treated with tympanostomy tubes for chronic OME had fewer documented behavioral problems than nonsurgical controls.[80] Children with OME have also been found to have more attention disorders and anxiety/depression-related disorders when compared with children without OME.[135]

One systematic review addressed the QOL improvement (apart from improvement in hearing loss) and found limited consistent or significant data to demonstrate changes following tympanostomy tube placement.[40] However, 2 earlier 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.[23,120] Rosenfeld et al[23] found that physical symptoms, caregiver concerns, emotional distress, hearing loss, and speech impairment significantly improved after tympanostomy tube placement. Timmerman et al[120] also noted improved QOL among children after tympanostomy tube placement and concluded that caregivers tend to underestimate their child's degree of baseline hearing loss; 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.

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. Otitis media, in general, can be associated with negative effects on auditory processing, school readiness, and social competence.[136] Unilateral hearing loss may also contribute to these issues, in addition to causing problems with sound localization. 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.[137] Chronic OME has been correlated with delayed answering, limited vocabulary, and difficulties in speech and reading.[138] 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.[41]

The GUG 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. Because the level of recommendation is only an ''option'' for this KAS, these indications to perform tympanostomy tubes should involve shared decision making and caregiver input,[139] particularly since the etiology of these symptoms, while potentially attributable all or in part to OME, is often multifactorial.

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

- Quality improvement opportunity: Promote continuity of care; avoid preventable complications through surveillance; gain insight into natural history of chronic middle ear fluid (National Quality Strategy Domain: Promoting Effective Prevention/Treatments; Person- and Family-Centered Care; Effective Communication and Care Coordination; Patient Safety)
- 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: Untreated OME can cause progressive changes in the tympanic membrane that require surgical intervention, including atelectasis, retraction pocket, or cholesteatoma. There was an implicit assumption that surveillance and early detection/intervention could prevent these and other 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
- Differences of opinion: None
- Implementation considerations: 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 with longer effusion duration, and relapse is common.[77]

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.[140,141] 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 with 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 with 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[20] (retraction of a thin, atrophic tympanic membrane to the medial wall of the middle ear). Ongoing surveillance is mandatory because the incidence of structural damage increases with effusion duration.

Any child with evidence of hearing loss on screening or hearing testing should be referred for comprehensive audiologic evaluation, including thresholds and speech recognition, by a licensed audiologist in a sound-treated booth.

- If a child with OME has hearing levels in the normal range (<15 dB HL), the clinician should assess for signs or symptoms of OME that would make tube insertion an option (KAS 4), and if watchful waiting is continued, a repeat hearing test should be performed in 3 to 6 months if OME persists.
- If a child with OME has mild hearing loss (16-40 dB HL) and bilateral effusions for 3 months or longer (chronic), the clinician should offer bilateral tympanostomy tube insertion (KAS 3).
- If a child with OME has mild hearing loss (16-40 dB HL) with a unilateral effusion or with bilateral effusions for less than 3 months, the clinician should assess for signs or symptoms of OME that would make tube insertion an option (KAS 4). 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.[142]
- If a child with OME has moderate hearing loss (>40 dB HL), the child is at risk for problems with speech, language, and school performance,[142] and tympanostomy tube insertion should be recommended.

One systematic review[40] showed early improvement in hearing levels after tympanostomy tube placement (postoperative 1-3 months), but by 12 to 24 months, the hearing outcomes were equivalent in tympanostomy tubes placement and watchful waiting groups. 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.[79,113-115] 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,[41] or formal language testing. Prior guidelines[23] recommend language testing for children with chronic OME and hearing loss on comprehensive audiologic evaluation.

Education of the child and parent/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, 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 AOM 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

- Quality improvement opportunity: Avoid ineffective care; promote appropriate care (watchful waiting) (National Quality Strategy Domain: Promoting Effective Prevention/Treatments; Patient Safety; Effective Communication and Care Coordination)
- 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 (KAS 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. The timing to otolaryngology assessment of effusion after initial referral has been widely variable across studies and remains open to clinician experience and system-based scheduling patterns.
- 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 (**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
- Implementation considerations: Fact sheet explaining to families and primary care clinicians (1) why tube insertion for recurrent AOM in the absence of MEE is unlikely to benefit their child and (2) what role patient preference and future infections might have in altering this decision (**Figure 5**)

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. 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**.

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.[77] Furthermore, 41% had no additional episodes of AOM while on placebo for a median 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.

Regarding prevention of future episodes of AOM, systematic reviews of tympanostomy tube insertion for recurrent AOM have shown a transient benefit of questionable clinical significance,[42,45,143] no additional benefit when compared with antibiotic use,[44] or no benefit at all.[37,43] 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.[144] This trial did, however, find that tubes decreased the mean percentage time with otitis media (of any type) over the next 2 years by about 8%, or 30 days per year.[142] Conversely, an RCT published after the systematic reviews noted earlier 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.[145]

Since the publication of the original CPG in 2013, one study assessed outcomes after watchful waiting in patients with recurrent AOM and no MEE at the time of assessment of tube candidacy, finding that only 34% of 123 children went on to tympanostomy tube placement regardless of preexisting risk factors.[5] The authors concluded that the recommendation for watchful waiting when no persistent MEE was present is valid, given that about two-thirds of children were managed successfully without requiring tympanostomy tube insertion. This conclusion draws support from an RCT showing no impact of tube insertion on future AOM incidence, where two-thirds of children did not have baseline MEE and 45% who were managed medically had subsequent tube insertion.[46] Future RCTs, however, are warranted to validate the generalizability of this recommendation and outcomes obtained in a variety of practice settings.

This KAS applies to children with recurrent AOM not found to have MEE at the time when they are assessed for tympanostomy tube candidacy. When this is implemented in clinical practice, it is understood that some children will be referred by their primary care providers based on the evaluation finding that effusion is present, only to have that effusion resolve prior to the surgical consultation. The time to surgical evaluation has been widely variable, if noted at all, in the previously referenced studies. When possible, care systems

CLINICAL PRACTICE GUIDELINES

PATIENT INFORMATION

What should I do if my child has frequent ear infections but no persistent fluid (effusion) behind the eardrum in the middle ear?

Why am I receiving this information sheet?

You are receiving this information sheet because your doctor has not recommended ear tubes for your child, even though they have had frequent ear infections in the past and may have been referred to the specialist specifically for ear tube surgery. The information that follows will clarify why it is in your child's best interest to hold off on ear tubes for now, recognizing that this decision could change if your child continues to suffer from frequent ear infections.

What is middle ear fluid, also called effusion?

When a child has acute otitis media or an ear infection, they have fluid and germs in their middle ear, behind the eardrum. Middle ear fluid is also called an effusion, which is typically cloudy and full of bacteria and white blood cells in the worst part of the ear infection. We call this a purulent effusion, commonly known as pus. As the ear infection goes away the effusion is absorbed by the body or drains through the eustachian tube, a connection in the skull between the ear and back of the nose. This process can take several weeks, but within 3 months about 90% of children no longer have middle ear fluid. So, it would be perfectly normal for a child to have an effusion when an ear infection is first diagnosed but they may not have a persistent effusion when they are examined days or weeks later.

What does it mean if my child has repeated ear infections, but doesn't have middle ear fluid (effusion) when they are seen by an otolaryngologist (ear, nose, and throat doctor)?

For most children, if their effusions completely clear up between their last infection and the time they are seen in a surgeon's office, it means that their eustachian tubes work well. Even if these children meet the definition of having had frequent ear infections (3 or more in the past 6 months, or 4 in the past 12 months), we know from research studies that nearly half will not have more ear infections and only about 1 in 3 will continue to have frequent infections. Other research shows that 2 out of every 3 children who see an otolaryngologist for repeated ear infections, but who have a normal examination (no middle ear fluid) in the office, do not require ear tubes in the future. If your child, however, continues to have frequent ear infections, they should be reevaluated by the otolaryngologist and may qualify for ear tubes in the future.

Are there any children who should still get ear tubes for recurrent infections even without an effusion on the day of their examination by the otolaryngologist?

Yes, there are some exceptions. If any of the following apply to your child, you should discuss with your doctor whether ear tubes may still be of benefit:

- Weak immune system or other problems putting them at higher risk for infections
- Prior complications of ear infections including seizures (from high fever) or infections spreading to the neck, bone behind the ear, or the brain
- Adverse antibiotic reactions, allergies, or inability to take oral antibiotics that make it difficult to treat ear infections when antibiotics are needed
- High risk of developmental problems including permanent hearing loss, delays in speech or language, delays in learning, autism-spectrum disorder, syndromes (e.g., Down) or structural problems with the face and head (e.g., cleft palate), or severe vision loss

What if my family doctor specifically sent me to the otolaryngologist for the purpose of getting ear tubes, but there is no middle ear fluid and the doctor wishes to wait before surgery?

Although your child may have had a tough time with frequent ear infections in the past, the real question is whether inserting ear tubes will help them by reducing future ear infections. The best research evidence we have suggests that inserting tubes will not reduce future ear infections when there is no persistent effusion, but the procedure does involve some minor risks related to the ear tube and general anesthesia. Waiting a bit more to see how your child does on their own does not carry any risk or harm, since many children will not have any further ear infections at all and most will never need tubes. As noted previously, if your child continues to have ear infections they can be reevaluated and tubes can be arranged at that time if middle ear fluid is present.

SOURCE: Rosenfeld RM, Tunkel DE, Schwartz SR, et al. Clinical Practice Guideline: Tympanostomy Tubes in Children (Update). *Otolaryngol Head Neck Surg*. 2022;166(1_suppl):S1-S55.

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Figure 5. Patient information sheet for recurrent ear infections without persistent middle ear fluid.

should embrace standardization of the time to evaluation after last noted AOM, and subsequent research on this topic should document the transition period from primary referral to specialist evaluation.

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 for tube candidacy.

The disadvantages of not performing tympanostomy tube placement in children with a history of recurrent AOM without persistent MEE relate to a potential need for systemic antibiotics should AOM recur and in delay of tube insertion for the subset of children who later become tube candidates. Children who are observed but later develop persistent MEE may be offered tympanostomy tubes as outlined in the subsequent KAS. Many episodes of nonsevere AOM, however, can be managed successfully without systemic antibiotics,[146] making continued watchful waiting an attractive option to many caregivers.

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

- Quality improvement opportunity: Promote effective care with improved quality of life by reducing the need for systemic antibiotics by facilitating topical antibiotic therapy of future infections (National Quality Strategy Domain: Promoting Effective Prevention/Treatments; Person- and Family-Centered Care; Effective Communication and Care Coordination; Promoting Patient Safety by Reducing Harm)
- 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), 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 MEE 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 decline tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None
- Implementation considerations: 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 KAS (recurrent otitis media *without* MEE), this statement requests that clinicians offer tympanostomy tubes to children who have an effusion present in one 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 both sides.[147]

The difficulty in accurately diagnosing AOM has been well documented, relating primarily to confirming the presence of MEE.[148] Symptoms of otalgia and fever are nonspecific for AOM, making them unreliable for primary diagnosis.[149,150] 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.[151] Although pneumatic otoscopy can improve diagnostic certainty for MEE, it is not widely used and may be unavailable in the primary care setting.[151] Repeated overdiagnosis of AOM may lead to an unwarranted referral to an otolaryngologist for surgical intervention.

MEE following an episode of AOM often takes time to resolve, with persistence of effusion in 70% of ears at 2

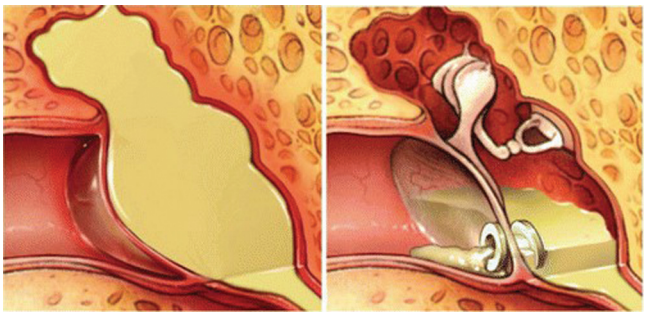


Figure 6. Acute otitis media without a tympanostomy tube (left) and with a tube (right). Without a tube, the tympanic membrane is bulging and inflamed, which causes pain and sometimes rupture. Adapted from Rosenfeld.[257]

weeks, 40% at 1 month, 20% at 2 months, and 10% at 3 months.[76] 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 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.[152,153] An 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).[145] Similarly, when children with OME lasting 2 months or longer receive tympanostomy tubes, there is a modest reduction in subsequent AOM episodes (0.20-0.72 per child-year).[83,84] In contrast, one 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, while a population-level study noted overall reduction in antibiotic usage in patients receiving tympanostomy tubes as compared with those undergoing observation.[144,154] Systematic review of studies comparing prophylactic (eg, low-dose daily) antibiotics to tympanostomy tubes for recurrent AOM have shown that children with tubes have lower AOM recurrence rates, fewer AOM episodes, and a reduced duration of infections.[45,143] Despite these benefits, antibiotic prophylaxis for recurrent AOM is rarely used today because of a dramatic increase in bacterial resistance.[155]

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.[37,38,42-44] For this reason, we have focused on individual trial results, as summarized in the preceding paragraph. The issue of whether tubes benefit children with recurrent AOM who present 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. These include decreased pain, should AOM occur with tubes in place, as well as the ability to manage such infection with topical antibiotic eardrops (**Figure 6**, **Table 7**) instead of systemic therapy. 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.[37] Please refer to KAS 14 for additional information on managing TTO. Further, significant benefit is noted in audiometric outcomes for patients receiving tympanostomy tubes in the setting of recurrent AOM with MEE, although this benefit is no longer present after 2 years.[21,156]

Clinicians should offer tympanostomy tubes to children with recurrent AOM and MEE, but whether to proceed with surgery is largely dependent on shared decisions with the child's caregiver.[157] 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 (KAS 5), with reassessment at 3- to 6-month intervals, can be employed when there is any uncertainty about the appropriateness of surgery, since improvements may occur from natural history, especially when chronic OME is not present.[144,145]

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 (refer to Table 2). *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Raise awareness of underlying conditions that might lower the threshold for tube insertion; ensure clinician awareness of, and attention, to these conditions when making decisions about tube insertion (National Quality Strategy Domain: Patient Safety; Effective Communication and Care Coordination)
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High for children with Down syndrome, cleft palate, and/or permanent hearing loss; medium for other at-risk groups

Table 7. Comparison of AOM 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 MEE after infection	Can last weeks or months	Usually resolves promptly
Needs oral antibiotics	Often	Rarely
Needs antibiotic eardrops	No benefit	First-line treatment
Risk of eardrum rupture	Yes	No, unless tube obstructed
Risk of suppurative complications	Rare but reported, since the infection occurs in a closed space	Likely very rare since infection can drain through the tube
Impact of therapy on bacterial resistance	Systemic antibiotics can promote resistance	Topical antibiotics generally do not cause resistance

Abbreviations: AOM, acute otitis media; MEE, middle ear effusion.
[a]Adapted from Rosenfeld.[257]

- 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 for these populations (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.[20] The panel assumed that most 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
- Implementation considerations: Potential to add this list of conditions to the electronic health record to facilitate identifying at-risk children when OME is diagnosed

Supporting Text. The purpose of this statement is to highlight the importance of identifying children with comorbid conditions that alter their susceptibility to AOM or OME or who may suffer disproportionately from developmental sequelae of unrecognized and untreated MEE. This statement builds on multidisciplinary guidance first introduced in an OME CPG in 2004 and reaffirmed in 2013 that recommended, ''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.''[142] The clinician can evaluate for the presence of any conditions in **Table 2** through discussion with the caregivers and by examination of the child, but should any uncertainty remain, additional discussion with the primary care clinician is recommended.

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.[20,158] For this guideline update, the GUG agreed to add ''intellectual disability, learning disorder, or attention-deficit/hyperactivity disorder'' to the list of risk factors that place children who have OME at increased risk for developmental difficulties. Children with hearing difficulties who are at risk for developmental difficulties have poorer social, communication, and educational functioning, even when hearing aids are not needed.[159,160]

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.[161,162] In addition, the benefits of hearing aids in children with permanent hearing loss could be reduced by the presence of MEE.[161,163] 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.[20]

About 18% of children aged 3 to 17 years in the United States have a developmental disability, with increasing prevalence over the past decade.[164] These include children with primary language impairments and others with autism spectrum disorders or conditions 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.[100] Furthermore, 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.

There is some evidence that middle ear disease and conductive hearing loss are more common in children with autism, which could have a significant adverse effect on progress with multiple ongoing therapies.[165] Children with autism, however, have rates of tympanostomy tube insertion that are twice the general population,[166] suggesting that additional research is needed to determine which at-risk children are the best candidates for tympanostomy tube placement.[167] Until this research is available, the GUG agreed that the best candidates for tube insertion in the at-risk population are those with OME that is unlikely to resolve promptly, as specified in the subsequent KAS.

Children with Down syndrome have poor eustachian tube function associated with chronic OME and, less often, recurrent AOM. They also have a risk of mixed or sensorineural hearing loss and can have stenotic ear canals that impede assessment of tympanic membrane and middle ear status.[168-172] Such ear disease may persist throughout childhood, requiring multiple tympanostomy tube placements if a surgical option is chosen.[173] Hearing loss also can be difficult to document accurately in very young children with Down syndrome (and many children with developmental delays), except when evaluated by pediatric audiologists, often using electrophysiologic tests (auditory brainstem response). Hearing assessments are recommended for children with Down syndrome every 6 months, starting at birth until the age of 3 or 4 years, then annually through childhood. Otolaryngologic evaluation is also recommended if middle ear disease, hearing loss, or both are identified or if normal middle ear function cannot be confirmed. Children with stenotic ear canals are best assessed with an otologic microscope every 3 to 6 months to remove cerumen and assess tympanic membrane appearance and middle ear aeration.

Cleft palate is a common orofacial malformation, with a prevalence of 1 in 700 live births.[174] OME occurs in nearly all infants and children with cleft palate[175,176] 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.[177,178] Chronic OME in children with cleft palate is almost always associated with conductive hearing loss.[177] 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.[179,180]

At-risk children (**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 OME on their children's development and on tympanostomy tubes as a management option (refer to KAS 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 likely to persist as reflected by a type B (flat) tympanogram or a documented 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

- Quality improvement opportunity: Optimize the acoustic signal for children at risk for behavioral, learning, or developmental issues from middle ear fluid (National Quality Strategy Domain: Promoting Effective Prevention/Treatments; Effective Communication and Care Coordination; Person- and Family-Centered Care)
- Aggregate evidence quality: Grade C based on a systematic review of cohort studies regarding the 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 and uncertainty regarding the importance of hearing loss as a mediating factor
- 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 (balance) of benefits vs harms
- 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
- Exceptions: 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
- Implementation considerations: greater difficulty in accurately documenting middle ear fluid in at-risk children with sensory, tactile, or behavioral issues

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 KAS 3 (chronic bilateral OME with hearing difficulties), this statement gives clinicians the option to perform tympanostomy tube insertion in at-risk children who have OME that is unilateral or who may not have apparent hearing difficulties but whose OME 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 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.[142] Children with OME typically have mild hearing loss (about 25-28 dB HL), with 20% of affected ears having levels exceeding 35 dB HL.[100] After tympanostomy tube insertion, hearing levels improve by a mean of 5 to 12 dB while the tubes are patent,[22,27,37] and the prevalence of MEE is reduced by 32% to 73%.[22,27,37]

There is a lack of studies on the effects of treatment of OME in children with disabilities.[40] However, hearing difficulties or hearing loss, even if mild, can have a substantial negative impact on developmental outcomes.[159,181] Therefore, the determination of hearing loss in one or both ears through audiometry would indicate a more pressing indication for intervention. If there is no hearing loss, one might be more likely to engage in watchful waiting, keeping in mind that persistent or chronic MEE may still degrade the auditory signal with an impact on auditory processing, understanding speech in noisy environments, and the child's progress with speech and language therapy.

Tympanometry is usually feasible for at-risk children, but audiometry can be difficult and require several testing sessions. Cooperation with audiometry may be enhanced by engaging a child life specialist, a speech-language pathologist, or an applied behavioral analysis specialist.[119] Evidence-based strategies such as Social Stories (ie, individually tailored stories designed to promote cooperation) may help to prepare children with autism for the audiologic appointment.[182] Clinicians should be aware of a high prevalence of hearing loss in children with severe cognitive delays who are unable to complete reliable behavioral testing, approaching 50% when sedated auditory brainstem response is used as an alternative test modality.[183]

While the presence of hearing loss and duration of MEE may be the most significant factors in recommending tympanostomy tube placement, OME that is unilateral or not associated with hearing loss may still affect an at-risk child because of degraded auditory input that reduces binaural processing and speech perception.[100] Other effects of chronic OME 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.[184]

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. Other than children with cleft palate,[180] the natural history of otitis media in this population is largely unknown but is likely worse than for an otherwise healthy child. AOM, especially if recurrent, can be difficult to manage in at-risk children because of a lack of obvious symptoms (eg, the sensory disturbances seen in some children with autism spectrum disorders), inability to communicate about pain (eg, autism 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. OME is unlikely to resolve quickly when present for 3 months or longer. 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.[77] This is in stark contrast to OME persisting after a documented episode of AOM, which has about 75%-90% resolution after 3 months.[76,77] Persistence of OME for 3 months or longer can be documented by review of medical records, by 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.

OME with a type B (flat) tympanogram is unlikely to resolve spontaneously, regardless of prior effusion duration, based on cohort studies of otherwise healthy young children.[77] Preschool children with OME on tympanometric screening (type B) have effusion resolution rates (ie, conversion to a normal type A tympanogram) of only 20% after 3 months and 28% after 6 months.[77] 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),[185] 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.[186] The procedure is noninvasive and painless but may be bothersome and frightening to some children. It is relatively simple to perform and can be done with a handheld unit (slightly larger than a traditional otoscope) or a desktop machine. Standard tympanometry uses a 226-Hz probe tone for patients 6 months and older.[187] The resulting graphic display shows how the tympanic membrane responds to varying pressure (negative and positive). A normal type A tympanogram (**Figure 7**), with peak pressure greater than −100 mm water, is associated with effusion in only 3% of ears at myringotomy.[188,189] Proper calibration of the tympanometer is essential for accurate results.

A type B, or flat curve, tympanogram (**Figure 8**) is associated with MEE in 85% to 100% of ears.[188,189] 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 8A**).[96] A low equivalent ear canal volume (**Figure 8B**) can be caused by improper placement of the probe (eg, pressing against the ear canal), by obstructing cerumen, or by a stenotic ear canal. The ear canal should be cleaned and the probe repositioned before retesting. Last, a high equivalent ear canal volume (**Figure 8C**) 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[96] between 1.0 and 5.5 cm^3.

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.

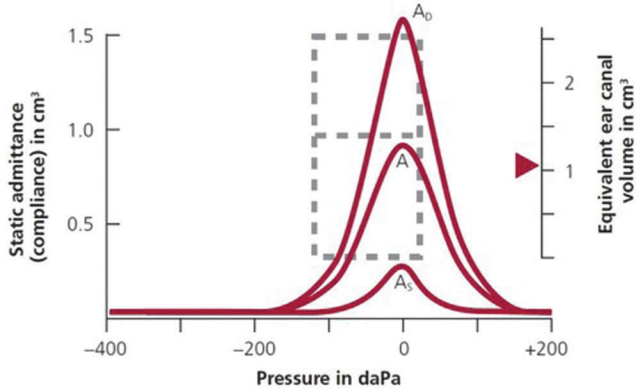


Figure 7. Normal type A tympanogram result. The height of the tracing may vary but is normal when the peak falls within the 2 stacked rectangles. The A_D tracing (upper) indicates an abnormally flexible tympanic membrane, and the A_S tracing (lower) indicates stiffness; the presence of a well-defined peak, however, makes the presence of effusion low. Adapted from Onusko.[186]

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 RCTs. The 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 GUG found an ''exceptional preponderance of benefits over harm based on subcommittee consensus because of circumstances to date precluding randomized trials.''[142] These recommendations are supported in this guideline update.

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.[41] The odds of a caregiver providing a ''much better'' response after tubes for speech and language was 5.1 times higher (95% CI, 2.4-10.8) 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, 1.8-7.1). 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.

Children With Down Syndrome. Hearing loss, which usually accompanies OME, negatively affects language development in children with Down syndrome.[160] The impact of tympanostomy tubes on children with Down syndrome has been assessed in observational studies,[170,190,191] but there are no RCTs to guide management. All studies have shown a high prevalence of OME and associated hearing loss. A case series[173] found that most children with Down

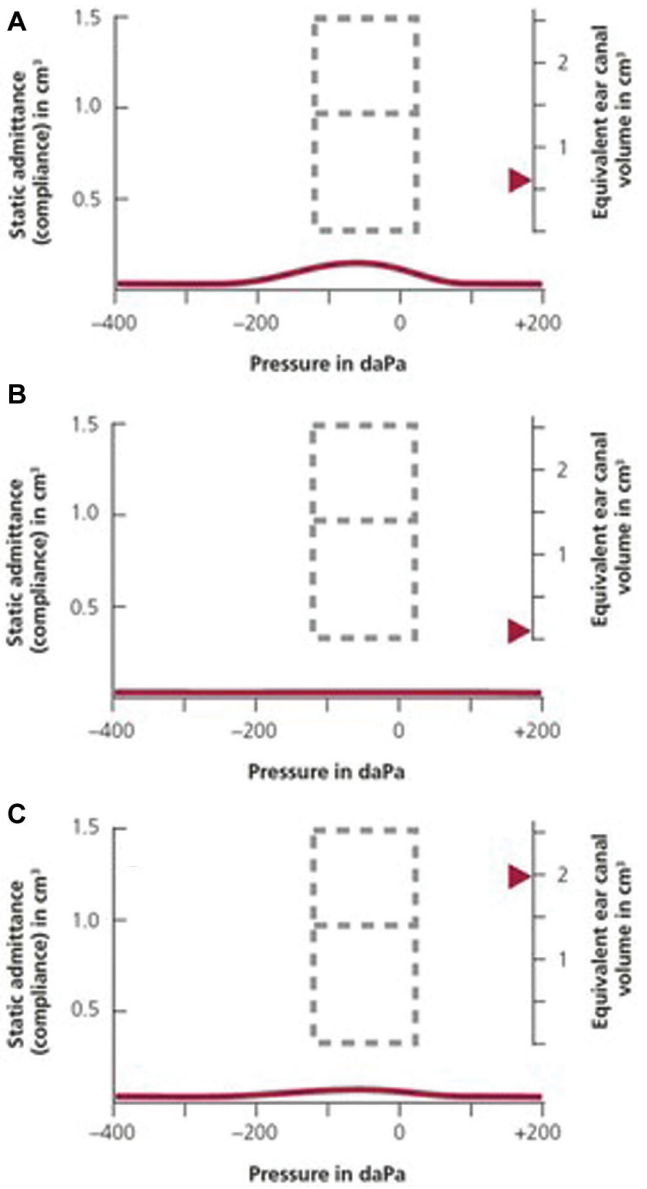


Figure 8. Abnormal type B tympanogram results. (A) A normal equivalent ear canal volume usually indicates MEE. (B) A low volume indicates probe obstruction by cerumen or contact with the ear canal. (C) A high volume indicates a patent tympanostomy tube or a tympanic membrane perforation. Adapted from Onusko.[186]

syndrome will require 2 or more sets of tubes during their childhood, with 71% achieving normal postoperative hearing in both ears.

Long-term complications (eg, tympanic membrane perforation) are more common as compared with age-matched children without Down syndrome and appear to correlate with increasing number of tubes placed. A 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.[191] Hearing aids have been proposed as an alternative to tympanostomy tubes,[112] but no comparative trials have assessed outcomes or to what degree the aids were used successfully by the children.

Children With Cleft Palate. Almost all children with cleft palate and cleft lip and palate have OME as infants.[192] Individual characteristics of the child, caregiver input, and multidisciplinary management can help to determine optimal timing for tube placement,[193] especially when there is hearing loss present. A systematic review of observational studies concluded that there is inadequate evidence to support routine tympanostomy tube insertion in children with cleft palate at the time of initial cleft surgery, and more recent studies still support this approach.[178,193,194] There is no evidence for the timing of tube insertion, but general consensus is to insert 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 examining speech and language outcomes focused on children who had had tubes inserted.[195] Nevertheless, children with cleft palate have a high incidence of speech and language disorders, continued middle ear disease, and hearing loss even after early tube placement.[180]

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.

OME and Cochlear Implantation. When a child who is a candidate for cochlear implantation also has chronic OME or a history of recurrent AOM, a question arises whether tympanostomy tube insertion is appropriate prior to the implant surgery. Since these children typically have severe to profound sensorineural hearing loss that is not suitable for amplification, the issue of how the effusion, if present, might affect hearing is not the primary concern. Rather, the concerns relate to whether MEE could influence how the implant functions or if opening the middle ear space to the external environment with a tube could provide a route for infection or complications.

A review by Preciado and Choi[196] supports the recommendations of using a tympanostomy tube in otitis-prone children undergoing cochlear implantation.[197] The authors concluded that the preponderance of published evidence and policy statements argue in favor of using tubes in children with recurrent AOM undergoing cochlear implantation, with no evidence showing increased infectious complications from the presence of a tube. The issue of tympanostomy tubes for OME prior to cochlear implantation is less well studied, with a case series[198] concluding that infectious complications are rarely associated with the presence of tubes and that tube insertion is safe. A more recent literature review concluded that chronic OME and recurrent AOM should have tympanostomy tubes placed to treat any middle ear infection before cochlear implantation.[199]

STATEMENT 10. LONG-TERM TUBES: The clinician should *not* place long-term tubes as initial surgery for children who meet criteria for tube insertion unless there is a specific reason based on an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube. *Recommendation against based on observational studies, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To reduce perceived overuse of long-term tubes, which have higher adverse event rates than short-term tubes, as initial surgery for children who meet criteria for tube insertion (National Quality Strategy Domain: Promoting Effective Prevention/Treatments)
- Aggregate evidence quality: Grade B, based on observational studies
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary adverse events that are more common with long-term tubes, including a higher incidence of otorrhea, granulation tissue, tympanic membrane perforation; reduce the need for long-term follow-up; reduce the risk of having a retained tube beyond the necessary period of ventilation.
- Risks, harms, costs: None related to initial management; some potential for repeat tubes in children that may have been avoided if a long-term tube had been used; risk of missing or delayed diagnosis of OME after short-term tube extrudes.
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perception that long-term tubes are overused by some clinicians for treating recurrent AOM or chronic OME when tube insertion is first performed and that this overuse results in preventable tympanic membrane perforations and other sequelae.
- Intentional vagueness: Clinicians must make an informed prediction, based on the child's history and status of the tympanic membrane and middle ear, whether a period of ventilation beyond that of a short-term tube is required.
- Role of patient (caregiver) preferences: Small to moderate, based on family history and values related to the potential need for further surgery and anesthesia.
- Exceptions: None
- Policy level: Recommendation
- Differences of Opinion: No differences of opinion on the statement as written, but 4 of 16 panel members (25%) felt that this statement could have the unintended consequence of increasing the use of long-term tubes because of intentional vagueness in determining a need for ventilation beyond the duration of a short-term tube.
- Implementation considerations: Should provide guidance on reasonable indications for initial use of a long-term tube; table comparing the duration and outcomes of long- vs short-term tubes

Supporting Text. The purpose of this statement is to avoid unnecessary placement of long-term tympanostomy tubes as first-line surgery in children who have not demonstrated a need for prolonged middle ear ventilation beyond the usual 8 to 18 months afforded by a short-term tube.[200] Examples of short-term tubes include Shepard (usually extrudes by 8 months), Armstrong, Paparella type I, Sheehy, and Reuter Bobbin. Commonly used long-term tubes, which typically remain in place for 2 years or longer, include Goode T-tube, Butterfly, Triune, and Paparella type II. A short-term tube is recommended for initial surgery because only a minority of children require repeat tube surgery[201] with the expectation of improved eustachian tube function while the tympanostomy tube is in place. This section does not discuss subannular ventilation tube placement, which is another means of achieving long-term middle ear ventilation (median 35 months) in carefully selected children.[202]

The main benefit of T-tubes, the most frequently used long-term tube, is prolonged ventilation of the middle ear, but they are accompanied by increased risk of perforation, myringosclerosis, granulation tissue, cholesteatoma, and chronic otorrhea.[24,203] Of note, the intention of the T-tube was for a *controlled period* of short- or long-term middle ear ventilation, by allowing easy removal of the silastic tube in the office by the clinician when the need for ventilation was no longer deemed necessary.[204] The intent was *not* specifically for long-term ventilation, because the tube had a low rate of spontaneous extrusion that led to overretention and potential complications.

About 25% of children will need a second set of short-term tympanostomy tubes, and about 8% require a third set.[201] Risk factors associated with repeat tube placement, as determined by systematic review of the literature, include craniofacial disease and shorter retention time (eg, early extrusion) of the first set of ear tubes.[201] Additional risk factors for repeat tympanostomy tube surgery, identified by other studies, include having a parent who is a smoker, daycare attendance, breastfeeding for under 3 months, pacifier use, tympanic membrane atelectasis, male sex, asthma, gastrointestinal disease, prematurity, and age.[205-207] With numerous risk factors identified from observational studies of varying risk of bias, it is difficult to predict which child would benefit from a longer duration of middle ear ventilation. Moreover, there are no prospective studies to identify specific risk factors that identify children who would benefit from initial long-term tube placement.

Consideration for placement of long-term tympanostomy tubes (**Table 8**) may be reserved for a subset of children with conditions such as cleft palate,[192,208-210] Trisomy 21,[173,207] or stenotic ear canals, which make short-term tube placement difficult or impossible. Other relative indications for a long-term tube include an atrophic or atelectatic tympanic membrane, which may not retain a short-term tube, or a child with a history of premature extrusion of at least 2 sets of prior short-term tubes. Less often, a long-term tube may be chosen on the basis of family preference to avoid multiple exposures to general anesthesia.

Table 8. Comparison of Short- vs Long-term Tympanostomy Tubes.

Characteristic	Short-term tube	Long-term tube
Examples (not exhaustive)	Shephard, Armstrong, Paparella I, Sheehy, Reuter Bobbin, grommet	Goode T-tube, modified Richard's T-tube, other T-tubes, butterfly, Paparella II, Triune
Duration of ventilation[a]	8 to 18 months, on average; some stay in place 3 years or longer	15 months or longer, usually 2 to 3 years; some stay in place 5 years or longer
Indications	Routine choice for first ear tube surgery for a child	Selective choice for first ear tube surgery for a child when a need for prolonged ventilation is anticipated; option for repeat tube surgery
Other common uses (relative indications)	Repeat ear tube surgery in children without significant risk factors or anatomic changes in the eardrum that would warrant a long-term tube	Cleft palate, stenotic ear canal, abnormal tympanic membrane (atrophy, atelectasis, retraction pocket), premature extrusion of multiple prior short-term tubes
Advantages	Reduced incidence (vs long-term tubes) of perforation, chronic otorrhea, granulation tissue, myringosclerosis; ease of insertion	Longer period of middle ear ventilation, potential to avoid repeat insertion of short-term tubes and exposure to general anesthesia; ability to insert silastic T-tube in stenotic canal
Disadvantages	Potential for early extrusion and need for repeat tube surgery	Increased incidence (vs short-term tube) of perforation, chronic otorrhea, granulation tissue, myringosclerosis, medialization (if short shaft with no outer flange); more difficult to insert

[a]Typical duration listed, recognizing that duration may differ by the specific tube used.

If long-term tubes are chosen for initial tube surgery, the surgeon or designee should discuss the potential risks of long-term tubes with the caregiver and the ability to avoid or minimize complications through regular follow-up visits (even if the child is asymptomatic) until the tube extrudes or is removed. Particular emphasis should be placed on a higher incidence of otorrhea, local irritation (granuloma or granulation tissue), and perforation rates that may approach 20% (vs about 2% for a short-term tube). Some long-term tubes, such as the T-tube, do not have an outer flange and may be more prone to medialization than short-term grommet-type tubes, especially when the outer shaft is relatively short. The discussion with the caregiver should facilitate shared decision making and meaningful informed consent.[157]

STATEMENT 11. ADJUVANT ADENOIDECTOMY: Clinicians may perform adenoidectomy as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoids (adenoid infection or nasal obstruction) OR in children aged 4 years or older to potentially reduce future incidence of recurrent otitis media or the need for repeat tube insertion. *Option based on randomized controlled trials, meta-analyses, and population-level studies, with a balance of benefits and harms.*

Action Statement Profile

- Quality improvement opportunity: To discourage adenoidectomy for treating or preventing otitis media in children under the age of 4 years, for whom efficacy has not been established (National Quality Strategy Domain: Promoting Effective Prevention/Treatments)
- Aggregate evidence quality: Grade B, based on RCTs for persistence of OME postsurgically, rate of repeat tube insertion, and hearing outcomes; observational studies regarding the rate of tube reinsertion and hearing outcomes; and meta-analyses on the benefit of adenoidectomy in patients greater than 4 years of age as compared with those younger than 4 years of age.
- Level of confidence in evidence: High for symptoms related to adenoids and children over the age of 4 years; medium for role as primary treatment in select populations and role in second tube insertion procedures in patients younger than 4 years.
- Benefits: Optimize management of adenoid-related disease (nasal obstruction, bacterial infection, chronic rhinitis); reduce need for further surgery and anesthesia; optimize hearing outcomes; decreased persistence of MEE after surgery.
- Risks, harms, costs: Surgical risks of adenoidectomy, additional anesthetic risk related to need for intubation during procedure, bleeding, hypernasality, velopharyngeal insufficiency, nasopharyngeal scarring/stenosis, Grisel's syndrome, longer recovery
- Benefit-harm assessment: Equilibrium (balance) of benefits vs harms
- Value judgments: None
- Intentional vagueness: None
- Role of patient (caregiver) preferences: Large role whether to perform adenoidectomy as an adjunctive

procedure based on the preferences of the patient and family.
- Exceptions: Contraindications to adenoidectomy (eg, cleft palate, velopharyngeal insufficiency, bleeding disorder).
- Policy level: Option
- Differences of opinion: None
- Implementation considerations: Education materials for otolaryngologists and other clinicians who have traditionally used adenoidectomy as a primary surgical treatment for middle ear disease

Supporting Text. The purpose of this statement is to promote discussion with families of patients to the potential benefits and limitations of concurrent adenoidectomy with tympanostomy tube insertion. The GUG's intent is not to encourage or promote concurrent adenoidectomy but instead to advocate for selective and judicious use in children who meet criteria for tympanostomy tube insertion and are most likely to benefit from this added procedure. Adjuvant adenoidectomy may be offered to patient families in those meeting criteria for tympanostomy tube insertion (based on previous KAS) who are greater than 4 years old if the indication is for otitis media or for children of any age when there are symptoms, not responsive to medical management, directly related to the adenoids (adenoid infection or nasal obstruction). Similarly, adenoidectomy should *not be offered* in the absence of symptoms directly related to the adenoid (infection or obstruction) to treat middle ear disease in children under 4 years of age at the time of tympanostomy tube placement.

Systematic reviews, including individual patient meta-analysis, and subsequent RCTs have indicated the benefit of adjuvant adenoidectomy for otitis media in patients older than 4 years but not for those in the younger cohort.[211-215] Adjuvant adenoidectomy for children aged 4 years or older reduces the prevalence of MEE, can achieve hearing outcomes comparable to tube insertion alone,[156,214-218] and doubles the length of benefit seen from tube insertion alone from 12 to 24 months.[40,212,213] Multiple studies have shown no benefit in episodes of AOM with adjuvant adenoidectomy when compared with tube insertion alone,[145,219] whereas one meta-analysis did show a small benefit in episodes for patients younger than 2 years.[211] This level of benefit, however, was small (number needed to treat of 9 to prevent future recurrent AOM) and considered insufficient to justify adjuvant surgery.

The benefit of adenoidectomy on otitis media is unrelated to adenoid size but instead relates to the ability of adenoid tissue to serve as a reservoir of bacterial pathogens that gain access to the middle ear through the eustachian tube. Removal of the adenoid pad therefore serves as an adjunct to tube placement by reducing bacterial load in the nasopharynx.[211,214,217] One study noted that risk factors for increased upper respiratory inflammation (parental smoking, attendance of large day care, pacifier use, and <3 months of breast feeding) were independently associated with an increased risk of tube reinsertion, a risk that may be partially mitigated through adjuvant adenoidectomy.[206] The benefits of adjuvant adenoidectomy for otitis media have not been established for children with Down syndrome, craniofacial anomalies, or cleft palate.

The risks of adenoidectomy are important to discuss with caregivers. Although uncommon, velopharyngeal insufficiency, refractory bleeding, and Grisel's syndrome are unique risks of adenoidectomy that do not occur with tube insertion alone. Adding adenoidectomy to tympanostomy tube insertion changes anesthesia technique from mask to intubation, with additional risks of difficult airway, postoperative nausea and vomiting, pain control, and death.[220-222] Although one RCT showed no increased pain after adenoidectomy,[223] the investigators excluded children who underwent cauterization of the adenoid pad, and most children had general anesthesia by mask without endotracheal intubation.

The GUG concluded that the potential benefits of adjuvant adenoidectomy on otitis media in certain patients at high risk for recurrence or greater than 4 years of age are offset by the risks of adenoidectomy and frequent need for airway manipulation beyond mask ventilation. Other indications for adenoidectomy, independent of child age, include chronic infection (adenoiditis, nasopharyngitis, recurrent or chronic rhinosinusitis) or nasal airway obstruction associated with open mouth posture, hyponasal speech, exercise intolerance, sleep-disordered breathing, or obstructive sleep apnea. The presence of significant infectious or obstructive adenoid symptoms would increase the benefit of adenoidectomy for a child, beyond any potential impact on otitis media, and should be considered in surgical decisions.

STATEMENT 12. 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

- Quality improvement opportunity: To emphasize and facilitate caregiver engagement in the child's care with the goal of improved outcomes, better communication, and reduced complications (National Quality Strategy Domain: Effective Communication and Care Coordination; Person- and Family-Centered Care)
- 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: Improve health literacy and shared decision making, define appropriate caregiver expectations at the time of and after surgery, reduce family anxiety, optimize outcomes, avoid complications, and improve caregiver understanding of the importance of follow-up.
- Risks, harms, costs: Time required for education
- 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 that will aid in the family's decision to proceed with surgical intervention and for proper management and care following tympanostomy tube placement
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None
- Implementation considerations: Can enhance adherence with visual aids, customizable patient information sheets, and online resources

Supporting Text. Patient and family education is the process of providing verbal, visual, or written information to the family and addressing any questions or concerns. Information should be provided in understandable terms in a way that is sensitive to the family's language, health literacy level, and cultural needs. While the evidence is mixed, minority families and those of lower socioeconomic status may not share equally in access to high-quality ear care, and clinicians need to be sensitive to these needs.[17,36] Health literacy levels are a key determinant of health outcomes, and patients who possess lower levels are less likely to actively participate in decisions and subsequently have poorer outcomes. Therefore, providers should be sensitive to whether patients and families comprehend and can act on what is being discussed.

Effective communication should improve the family's understanding of the disease, rationale for surgery, and optimal care of the child with tympanostomy tubes. Finding ways to provide education that raises health literacy will lead to a more robust shared decision-making process between provider and family, ultimately improving patient engagement, adherence, and outcomes.[224-227] Failing to engage families, discuss necessary care, or follow up with a patient and family may decrease adherence with follow-up appointments and increase the risk of potentially avoidable sequelae or complications.

Caregiver Understanding of OM and OME Etiology. Caregivers should be counseled on the cause of recurrent AOM and OME and the rationale for inserting tympanostomy tubes. For example, the clinician might explain the following:

1. Middle ear infections (AOM) or fluid buildup (OME) are most often caused by a poorly functioning eustachian tube, a slender passage in the child's skull, made of bone and cartilage, that connects the back of the nose and the middle ear space (behind the eardrum).
2. Normally, the eustachian tube should protect (seal off) the middle ear from germs and mucus in the back of the nose. It must also open briefly at times, usually when swallowing or yawning, to replace air that is absorbed in the middle ear and even out pressures.
3. If the air behind the eardrum is not maintained by regular opening of the eustachian tube, the middle ear develops a negative pressure (vacuum), which can either suck in germs from the back of the nose and cause ear infections or eventually fill the middle ear with mucus or fluid to even out the pressure.
4. Young children have horizontal eustachian tubes that are not fully developed, but the tube gets longer, stiffer, and more vertical as they grow, allowing it to function better.
5. A tympanostomy tube, also called an ear tube or pressure-equalizing tube, works by allowing air to enter the middle ear directly, through the small opening in the tube, which allows any fluid to drain and eliminates the negative pressure (vacuum) that contributed to fluid buildup and ear infections.

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.[212] Generally, the child should be evaluated by the otolaryngologist or designee within 3 months of placement and then periodically by an otolaryngologist or designee while the tympanostomy tubes are in place to detect any complications and provide ongoing education. Learners commonly do not retain all information presented in a single session, and repetition of consistently presented information has long been shown to play a critical role in learning and memory.[228,229] Several months (6-12) after tube extrusion, an additional follow-up appointment with the otolaryngologist or designee should occur to ensure that the ears are healthy and that hearing is optimal, as well as to identify possible recurrent fluid or infections and 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 sequelae or complications, most of which are easily treated once identified and are not associated with long-term morbidity.[24,38,112] *Referral to the otolaryngologist* is appropriate 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, including granuloma, refractory otorrhea, perforation at the tube site, cholesteatoma, retraction pocket, or a retained tube for 3 years or longer.[24,37,230]

Caregivers of children with tympanostomy tubes should be given information regarding longevity of the tympanostomy tubes. This will vary by the type of tube that is placed (short vs long term). Short-term tubes generally last 6 to 18 months, but long-term tubes typically remain in place for several years.[231] 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.[24] Rarely, the tube will displace into the middle ear space and may require surgical removal.[38] The goal is for the tubes to last long enough for the eustachian tube to mature and the child to outgrow his or her middle ear disease. For every 5 or 6 children with tubes, however, about 1 requires reinsertion of a second set of tubes within 3 years.[34,83,84,232,233]

Discussing Risks and Managing Common Tube Problems. Caregivers should be educated regarding the potential complications of tympanostomy tube placement during the consultation visit. Acute TTO (eg, an ear infection with a tube) occurs in up to 50% of children who are closely monitored in RCTs,[54] but in cohort studies 16% of children have postoperative otorrhea (first 30 days), 26% delayed otorrhea, 7% recurrent otorrhea, and 4% chronic otorrhea.[24] Management of TTO is fully discussed in a subsequent recommendation; however, caregivers should be counseled that TTO may occur, could be blood tinged (no cause for concern), responds to topical antibiotic ear drops, does not usually require oral antibiotics, and benefits from water precautions until the discharge is no longer present. Up to 3% of tubes may fail to extrude and require active removal; persistent tympanic membrane perforation occurs with about 2% of short-term tubes and up to 20% of long-term tubes; and localized cholesteatoma may be seen in 0.5% of ears.[24,34,54,59,234]

Families should also be educated concerning water exposure, as discussed in KAS 15. Water precautions with consistent use of ear plugs are unnecessary for most children with tympanostomy tubes.[235-237] However, water precautions may be implemented for children during an episode of acute TTO, if the child is prone to recurrent acute TTO, or if the child has transient discomfort upon exposure to water during swimming, diving, or hair washing.[238]

Importance of Perioperative Education. Caregiver education and efficient communication will improve the family's understanding of how to best and most cost-effectively care for the child with ear tubes, allow for shared care decisions, enhance adherence to routine follow-up care, and facilitate prevention or early identification of complications. This education should be provided in writing (**Figure 9**), using understandable terms in a culturally appropriate manner and enhanced through direct interaction based on the information provided in this guideline section. Additionally, good information provided to caregivers in the medium that they most appreciate may reduce the volume and burden to staff of routine follow-up telephone calls to clinicians' offices.[139,239]

STATEMENT 13. PERIOPERATIVE EAR DROPS: Clinicians should *not* routinely prescribe postoperative antibiotic ear drops after tympanostomy tube placement. *Recommendation against prescribing based on systematic reviews and randomized controlled trials with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Reduce overuse and routine use of antibiotic ear drops after tympanostomy tube surgery (National Quality Strategy Domain: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Promote Effective Prevention/Treatments)
- Aggregate evidence quality: Grade B, based on systematic reviews, randomized controlled trials, and before-and-after studies with a balance between benefit and harm, with a preponderance of benefit over harm
- Level of confidence in evidence: Moderate
- Benefits: Avoidance of unnecessary antibiotics, cost savings, reduced local side effects (skin irritation, allergic reactions, fungal overgrowth), simplification of postoperative care
- Risks, harms, costs: Potential for perioperative TTO or tube occlusion that may need subsequent treatment, no cost in not prescribing
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: The GUG perceived an overuse of perioperative antibiotic drops, which are often administered during surgery and then prescribed routinely for all children after the procedure; in contrast, saline irrigation (washout) during surgery and saline drops after surgery were perceived as underused, despite comparable efficacy in reducing otorrhea
- Intentional vagueness: The word *routinely* is used to acknowledge that there are specific circumstances that might require or would benefit from antibiotic ear drops (refer to text)
- Role of patient preferences: None to small depending on previous patient experience (allergic reaction or any type of adverse side effects)
- Exceptions: Purulent middle ear fluid or AOM at the time of tube placement
- Policy level: Recommendation
- Differences of opinion: None
- Implementation considerations: Describe how to use saline irrigation at the time of tube placement; some electronic medical records may already have tools to ensure routine use of drops that will require change

CLINICAL PRACTICE GUIDELINES

PATIENT INFORMATION

EAR TUBES - A CAREGIVER'S GUIDE

WHY ARE EAR TUBES RECOMMENDED?

Ear tubes are recommended for frequent ear infections or prolonged fluid in the ears. They will:

- Help decrease the number of ear infections
- Allow any future ear infections to be treated with antibiotic ear drops instead of antibiotics that are taken by mouth
- Help prevent fluid from backing up into the area behind the ear drum (middle ear)
- Improve hearing that is decreased because of fluid in the middle ear

HOW LONG WILL MY CHILD'S EAR TUBES LAST?

Most ear tubes last about 6 to 18 months. By the time the tube comes out about 80% of children will have much better ear function and will not need to have the tube replaced.

WHEN DOES MY CHILD NEED TO BE SEEN AGAIN AFTER THE TUBES ARE PLACED?

- After Surgery: We will see your child within 3 months to make sure that the ear tubes are in place and working. We often check your child's hearing at that visit.
- Ongoing Follow-Up: After this first visit, we should see your child regularly, usually every 6 months, while the tubes are in the ears to make sure that the tubes are working and to check for any possible problems, as discussed in the next section. Keep in mind that regular follow-up visits are important, even if your child has no obvious issues with ears or hearing, to prevent problems.
- Final Visit: Once the tubes fall out, your child should return after 6-12 months so your ear, nose, and throat doctor or other health care provider can check the ears to make sure they are healthy.

WHAT ARE THE POSSIBLE COMPLICATIONS, OR PROBLEMS, OF EAR TUBES?

- *Scarring.* A white mark from scarring (sclerosis) or a small depression or pocket may be seen on the eardrum, but this usually does not affect hearing or cause infections and is usually of no concern.
- *Perforation.* About 1-2 out of every 100 children will still have a hole (perforation) in the eardrum after a short-term tube falls out, with up to 1 in every 5 children having a perforation after a long-term tube. The hole will often close on its own, but if it does not, it can be repaired in the operating room as a day surgery procedure.
- *Tubes falling in.* Tubes almost always fall out of the ear drum into the ear canal. Very rarely a tube can fall into the middle ear, but usually does not cause any problem and can be removed, if needed.
- *Tubes not coming out.* Most tubes come out within 12 to 24 months. If the tube is still in after 2 to 3 years, or longer, it can be removed.
- *Tube coming out too early.* In rare cases the tube may fall out before 6 months, but many children will have improved by that time. For those who continue to get ear fluid or frequent ear infections a tube may need to be replaced.

DOES MY CHILD NEED EAR PLUGS WHEN EXPOSED TO WATER?

Your child will not usually need ear plugs for swimming and bathing while the tubes are in place and open. Head bands or other special efforts to keep water from entering the ear canal are also unnecessary, but may be helpful in the following situations:

- Pain or discomfort when water enters the ear canal
- Current fluid or drainage from the ear canal (an ear infection with the tube), or your child has had frequent drainage
- Swimming in lakes or non-chlorinated pools that are not clean
- Dunking head in the bathtub (soapy water passes through the tiny hole in the tube easier than plain water)

There are several types of soft ear plugs or ear putty available, as well as neoprene headbands to cover the ears. NEVER use Play-Doh or Silly Putty as an ear plug—these materials can become trapped in the ear canal and even require surgical removal.

Figure 9. (continued)

EAR TUBES AND EAR INFECTIONS

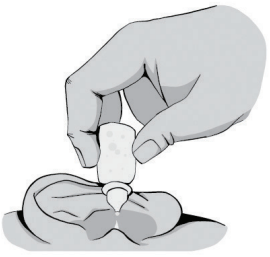
Ear tubes will help decrease the number of ear infections, but your child may still get an ear infection when he or she has ear tubes. When the tube is open and working, you may see drainage at the opening of the ear canal. Before ear tubes, this drainage would stay in the middle ear, trapped behind the eardrum, unless the pressure caused the eardrum to burst or rupture. Now that the tube makes an opening in the ear drum, drainage will come through the ear tube into the ear canal.

Drainage can be thin, thick, cloudy, yellow, or green, and even bloody. Most children do not typically have fever or pain when they have ear drainage with tubes in place.

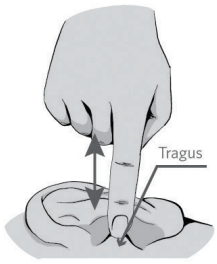
If you see drainage from the ear, we recommend the following:

1. Antibiotic ear drops, without oral antibiotics, are all that is needed in most cases (usually ofloxacin or ciprofloxacin-dexamethasone). Do NOT use over the counter ear drops.
2. Ear drainage may build up or dry at the opening of the ear canal. Remove the crusting with a cotton-tipped swab dipped in hydrogen peroxide or warm water. If the drainage is thick, you can also roll up a piece of tissue or toilet paper to help soak up the drainage out before you use ear drops.
3. Do not swim during infections when there is drainage or discharge coming from the ear. During bathing, use silicone ear plugs, or coat a small cotton ball with petroleum jelly and use it to cover the opening of the ear canal.
4. Use the ear drops only for the amount of time recommended by your doctor, because using them too long could result in a yeast infection.
5. Antibiotics taken by mouth are not needed for most ear drainage with tubes in place. Sometimes they may be needed if your child has another reason to be on an antibiotic, or the infection does not go away after using only ear drops.

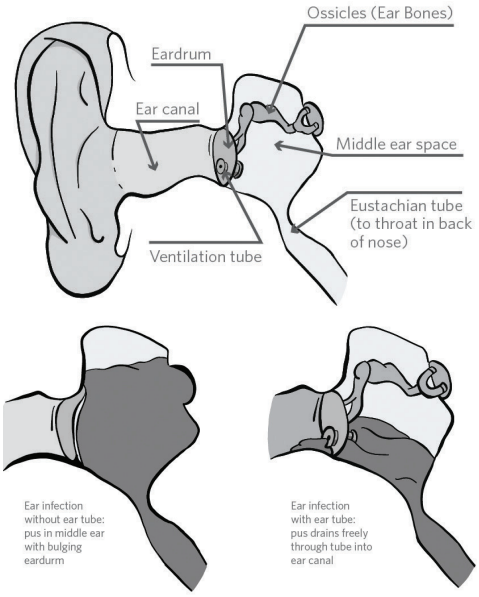
When using ear drops, do the following to help pump the drops in the ear canal and get down to the ear tube:



1. Have your child lay down on their side. Put ear drops into opening of ear canal.



2. Push down on tragus 4-5 times (small piece of cartilage in front of ear canal opening). This will help pump the drops into the canal.



What are possible reasons why my doctor or health care provider may diagnose an ear infection when we haven't seen drainage yet?

1. The tube is open and drainage has started but is not yet seen at the ear canal opening. This suggests an early stage of infection for which antibiotic ear drops will help it go away quickly.
2. The tube is not working or is blocked, so the ear infection is treated as if the tube was not there. This is a time when antibiotics by mouth may be needed. The blocked tube does not do any harm (and will not cause a problem), but it also will not drain the infection. Use acetaminophen or ibuprofen for pain.
3. The tube is open but there is no drainage in the tube opening or ear canal. In this case no special treatment is necessary, even if the eardrum appears red or irritated, which can occur when your child cries or has fever without an ear infection.

When to Call the Ear Doctor (Otolaryngologist):

1. Your child's regular doctor or health care provider can't see the tube in the ear, or the tube is blocked.
2. Your child has a hearing loss, continued ear infections or continued ear pain/discomfort.
3. Ear drainage continues for more than 7-10 days without improvement with treatment.
4. Drainage from the ear occurs frequently or more than you think should happen.
5. There is wax build-up in the ear canal that doesn't allow the tube to be seen.

SOURCE: Rosenfeld RM, Tunkel DE, Schwartz SR, et al. Clinical Practice Guideline: Tympanostomy Tubes in Children (Update). *Otolaryngol Head Neck Surg*. 2022;166(1_suppl):S1-S55.

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The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) represents approximately 12,000 specialists worldwide who treat the ear, nose, throat, and related structures of the head and neck. The AAO-HNS Foundation works to advance the art, science, and ethical practice of otolaryngology–head and neck surgery through education, research, and lifelong learning.

Figure 9. Caregiver information for children with tympanostomy tubes.

Table 9. Saline Washout (Irrigation) to Prevent Postoperative Tube Otorrhea.

1. Fill a 3.0-mL syringe with 1.5 mL of sterile saline solution
2. Attach a No. 3 French otologic suction to the end of the syringe
3. Prepare to irrigate the middle ear space by either
   a. Inserting the tip of suction through the myringotomy incision into the middle ear space *before the tube is inserted* (best when using soft silicone tube)

   OR
   b. Placing the tip of the suction flush against the opening of the tube *after the tube is inserted* (best when using a rigid fluoroplastic-type tube)
4. While occluding the cutoff bypass hole in the suction thumb plate, have an assistant gently push the syringe plunger to irrigate the middle ear space
5. Suction the ear canal to remove the irrigating solution, then repeat, if necessary, until the fluid is clear (may require 2 or 3 washouts)

or the ability for the clinician to override; educational materials to change established perioperative routine use of drops and instruct about intraoperative saline washout

Supporting Text. The purpose of this statement is to reduce unnecessary routine prescribing of antibiotic ear drops after tympanostomy tube insertion in children. Whether to administer a single dose of antibiotic ear drops in the operating room after tube insertion *is not* the subject of this key action statement, as this recommendation against prescribing relates to continuing use of antibiotic ear drops that may be prescribed for up to 10 days after surgery.

Based on a Cochrane systematic review[240] of 15 RCTs assessing the effectiveness of intervention in preventing postoperative otorrhea, multiple saline washouts during surgery and a single application of antibiotic/steroid drops had comparable efficacy in preventing postoperative otorrhea. These findings support saline washouts as a safe, low-cost alternative to antibiotic drops, which the GUG perceived as underutilized by many clinicians. Based on data from 2 low-risk RCTs in the Cochrane review, saline washouts (**Table 9**) reduced otorrhea incidence from 30% to 16% (relative risk, 0.52; 95% CI, 0.27-1.00) for a number needed to treat for benefit (NNTB) of 7 children. Although a single application of antibiotic-steroid ear drops also reduced otorrhea incidence from 9% to 1% (relative risk, 0.13; 95% CI, 0.03-0.57), the NNTB of 13 means that nearly twice as many children would need treatment with antibiotic-steroid ear drops as compared with saline washouts to prevent 1 episode of postoperative otorrhea.

This same Cochrane review also assessed postoperative otorrhea rates when antibiotic ear drops were prescribed for a prolonged period after surgery. Based on data from 4 low-risk RCTs, antibiotic drops did decrease otorrhea with individual studies (data not suitable for pooling) showing NNTBs ranging from 3 to 15, with the highest benefit when antibiotic-steroid ear drops were used. The authors concluded that if a surgeon anticipates a high rate of otorrhea after tube insertion, then either saline irrigation or a single application of antibiotic ear drops would reduce the rate. Although prolonged ear drops were also effective, this approach had added cost and did not necessarily improve outcomes beyond the single intraoperative treatment.

In a clinical trial[241] published after the Cochrane review, 291 children having tube insertion for chronic OME had their ears (N = 560) randomized into 4 groups for interventions to prevent postoperative otorrhea: (1) saline washout (irrigation) of the middle ear cavity, (2) oral amoxicillin for 7 days, (3) oral amoxicillin for 7 days plus ciprofloxacin ear drops for 3 days, or (4) observation (control). No significant differences were found among groups regarding postoperative otorrhea, which ranged from 1.1% to 2.3%. These findings support the Cochrane conclusion of no added benefit from continuing antibiotic ear drops after surgery when compared with saline washout.

A more recent RCT showed no benefit of routine prescribing of antibiotic ear drops as compared with saline solution. Children (N = 174) undergoing tympanostomy tube insertion were randomized to intraoperative ciprofloxacin or normal saline[242] ear drops, which was continued for 5 days after surgery. Twelve children were excluded because of purulent otorrhea at the time of surgery, which was treated with ciprofloxacin drops. Of the remaining 128 children, about 62% had recurrent AOM as their indication for surgery, 21% chronic OME as the indication, and 48% had mucoid effusions. There were no differences at 4 or 6 weeks in the incidence, duration, and QOL impact of early tympanostomy tube otorrhea or tube patency between ciprofloxacin and normal saline.

The generalizability of the evidence cited here is limited by some trials including only children with chronic OME and others excluding children with AOM at the time of tube insertion. Moreover, nearly all RCTs excluded children at high risk for postoperative otorrhea, including those with cleft palate, Down syndrome, immune deficiency, and craniofacial disorders. Postoperative otorrhea is common in children with cleft palate, but whether this would be improved by routine prescribing of antibiotic ear drops is unknown.[9,243] Similarly, although certain baseline factors are associated with a higher

incidence of acute tube otorrhea (eg, young age, recurrent AOM history, recurrent upper respiratory tract infections, and the presence of older siblings), the impact of these factors on immediate postoperative otorrhea has not been studied, nor has the effect of routine prescribing of antibiotic ear drops.

Although intraluminal obstruction of a tympanostomy tube by crust, mucus plug, or dried blood may occur after insertion, routine administration or prescription of antibiotic ear drops at surgery has not significantly reduced its occurrence. A study that examined coating of grommet tubes with antibiotic ointment at the time of surgery found no benefits for decreasing postoperative tube obstruction. Similarly, Gabarain et al also did not see difference in postoperative tube patency between ciprofloxacin and normal saline.[242] A review of nearly 600 patients from 3 RCTs did not find an increase in intraluminal occlusion in patients who did not receive ear drops.[239] Conversely, Poetker et al[244] found that antibiotic drops decreased the rate of postoperative tube obstruction by about 12% (number needed to treat of 8).

Despite some limitations in study generalizability that affect our confidence, there are cost and administration difficulties (and possible harm; eg, fungal, local skin reactions) of prolonged antibiotic drops over intraoperative saline irrigation at the time of tube placement. Children with active AOM or with purulent effusions at the time of tube insertion may derive benefit from antibiotic eardrops, so until further evidence is available, they are excluded from this recommendation. Therefore, the GUG is advising against routine prescribing of antibiotic ear drops following tube insertion, leaving it to clinician preference regarding intraoperative management, which may involve saline washout, a single application of antibiotic ear drops (with or without a steroid), or simply no treatment at all.

STATEMENT 14. ACUTE TYMPANOSTOMY TUBE OTORRHEA: Clinicians should prescribe topical antibiotic ear drops 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

- Quality improvement opportunity: Discourage inappropriate and ineffective overuse of systemic antibiotics, with attendant adverse effects, in treating uncomplicated TTO (National Quality Strategy Domain: Promoting Effective Prevention/Treatments; Patient Safety)
- Aggregate evidence quality: Grade B, based on RCTs demonstrating superior efficacy of topical vs 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), avoiding overuse and adverse effects of systemic antibiotics, including bacterial resistance
- Risks, harms, costs: Additional expense of antibiotic ear drops (if not generic) as compared with systemic 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 ear drops are safer and more effective than oral antibiotics
- Exceptions: Children with complicated otorrhea, cellulitis of adjacent skin, or concurrent bacterial infection requiring antibiotics (eg, bacterial sinusitis, group A strep throat) or those children who are immunocompromised
- Policy level: Strong recommendation
- Differences of opinion: None
- Implementation considerations: Illustrations for caregivers showing proper administration of ear drops for children with TTO (eg, ''pumping'' the tragus) and using tissue spears for home cleaning of obstructing discharge in the ear canal; clarification for clinicians why the typical antibiotic resistance levels for bacterial pathogens, based on serum concentrations, do not apply when topical antibiotic ear drops are administered; education materials aimed at primary care settings where acute TTO is often treated

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. In addition, this recommendation does not apply to prophylactic administration of drops at the time of tube placement or prescription of drops for immediate use after tubes.

Otorrhea is the most common sequela of tympanostomy tubes, with a mean incidence of 26% (range, 4%-68%) in observational studies[27] and up to 83% with prospective surveillance.[245] 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%.[24]

Acute delayed TTO in young children with tympanostomy tubes is usually a manifestation of AOM and is caused by *Pseudomonas aeruginosa* or typical nasopharyngeal pathogens, which include *Streptococcus pneumoniae*, *Hemophilus influenzae* (nontypeable), and *Moraxella catarrhalis*.[246,247] Methicillin-resistant *Staphylococcus aureus* (MRSA) has also been reported in cultures of otorrhea and should be suspected when the otorrhea is recurrent or recalcitrant. Viral coinfection is often present when young children present with acute TTO,[248] leading some clinicians to classify the discharge as the ''runny ear'' equivalent of a ''runny nose'' when counseling parents about the significance of the discharge.

Four RCTs have compared topical antibiotic eardrops (ofloxacin, ciprofloxacin, or ciprofloxacin-dexamethasone) with systemic oral antibiotics (amoxicillin or amoxicillin-clavulanate) for treating acute TTO in children.[249-251] Superior outcomes with topical therapy were achieved in some studies for clinical cure,[249-251] bacterial eradication,[250] and patient satisfaction.[250] One additional RCT assessed topical antibiotics with and without concurrent oral antibiotics but did not find any advantage to combination therapy.[252] 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. A systematic review confirmed the results of individual RCTs, showing superior cure rates with topical antibiotic drops as compared with oral antibiotics[253] for acute TTO in children. Explanations for improved outcomes with topical antibiotic therapy include increased drug concentration at the site of infection and improved coverage of likely pathogens, especially *P aeruginosa*.

Topical antibiotic therapy avoids adverse events associated with systemic antibiotics, including dermatitis,[249,250] allergic reactions, gastrointestinal upset,[249,250] oral thrush,[250] and potential for increased antibiotic resistance.[247] Only topical drops approved for use with tympanostomy tubes should be prescribed (eg, quinolone drops with or without steroid) to avoid potential ototoxicity from aminoglycoside-containing eardrops, which are often used to treat acute otitis externa.[254] Otomycosis has not been reported after topical therapy in RCTs of acute TTO,[249-251] but prolonged or frequent use of quinolone eardrops may be a causative factor.[255,256] 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 are not absorbed systemically.

Acute TTO usually improves rapidly with topical antibiotic therapy, provided that the drops can reach the middle ear space.[37] 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.[257] Tissue spears can be used to assist caregivers in cleaning the external auditory canal and to facilitate entry of topical drops (**Figure 10**).[258] The child's caregiver can be instructed to use tissue spears to clear otorrhea from the canal prior to installation of drops.[259] 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.[260,261] Last, caregivers should be advised to prevent water entry into the ear canal during periods of active TTO.

Any dry crust or adherent discharge at the ear canal entrance or on the surrounding skin can be softened and cleaned with a cotton-tipped swab and hydrogen peroxide, which can be used safely when a tympanostomy tube is present.[262] Regular cleaning is important to minimize local skin irritation, discomfort, and potential cellulitis. Persistent debris despite these measures can often be removed by suctioning through an open otoscope head or by using a binocular microscope for visualization.

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 is present (eg, sinusitis, pneumonia, or streptococcal pharyngitis)
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 nonototoxic topical antibiotic drops

Children who fail topical therapy may require further cleaning of the ear canal or suctioning of the tube lumen to facilitate drug delivery. Culture of persistent drainage from the ear canal may help target future therapy, detecting pathogens such as fungi and methicillin-resistant *Staphylococcus aureus* (MRSA). Culture results of persistent TTO are usually susceptible to quinolone antibiotics, but even if resistance is reported, ototopical treatment will be successful.[263] Antimicrobial sensitivities from otorrhea cultures are assessed for resistance by using 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 times higher. Given that the bactericidal ability of quinolone antibiotics is concentration dependent, these high levels of local concentration will typically overcome resistance[264] levels based on serum level cut points.

About 4% to 8% of children treated with topical quinolone otic drops require oral antibiotic rescue therapy for persistent symptoms,[249,250] with the choice of antibiotic guided by culture results. If the TTO is refractory to aural debridement and topical and oral antibiotic treatment, ear wicks were described to successfully manage these patients in 1 small case series, averting the need for tube removal or intravenous antibiotics.[265] Improved penetration of the drops through the ear

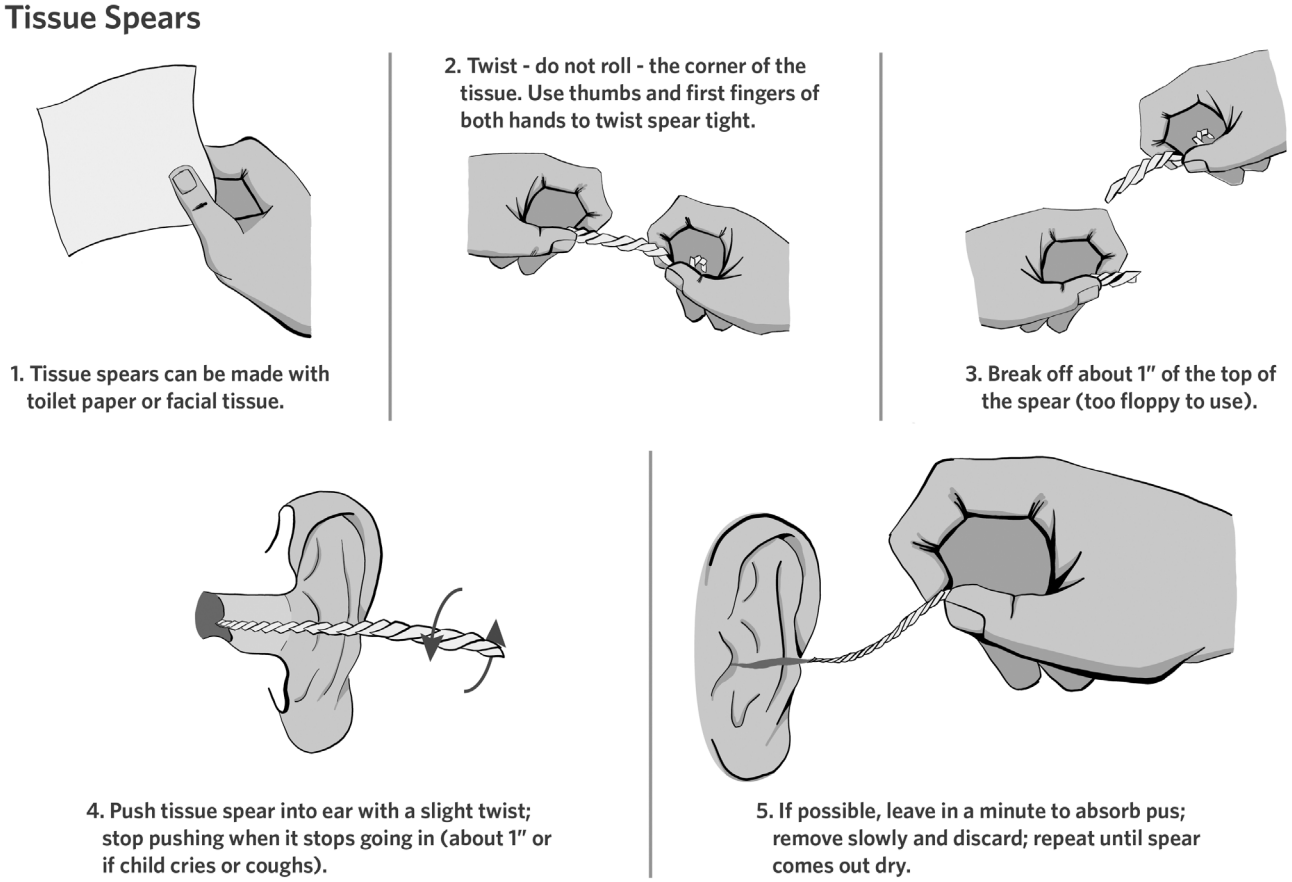

Figure 10. Tissue spears. Adapted from Centre for Remote Health.[286]

canal to the tympanic membrane because of a wick might be the reason for the success with this treatment.

When children present with persistent painless otorrhea that is pink or bloody, the usual cause is granulation tissue or a granuloma at the junction of the tympanostomy tube with the tympanic membrane, which occurs in about 4% of children with tubes.[24] The treatment of choice is a topical quinolone drop, with or without dexamethasone[266]; systemic antibiotics should not be prescribed, and the caregiver should be reassured that the bloody discharge is not a cause for concern, should respond to therapy, and will not damage the ear or hearing.

STATEMENT 15. 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 systematic reviews and randomized controlled trials with consistent effects and a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Avoid unnecessary restrictions on child activity and water avoidance that may decrease quality of life or lead to ongoing concerns by the child beyond the period of intubation (National Quality Strategy Domain: Person- and Family-Centered Care; Care Coordination; Effective Prevention and Treatment)
- Aggregate evidence quality: Grade B, based on systematic reviews, randomized controlled trials, and multiple observational studies with consistent effects
- Level of confidence in evidence: High
- Benefits: Allows for normal activity and swimming, reduced anxiety, cost savings
- Risks, harms, costs: 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 allow water precautions to be advised for subgroups who may benefit from water precautions in specific situations (eg, lake swimming, deep diving, history of recurrent otorrhea, head dunking in the bathtub, or otalgia from water entry into the ear canal)
- Role of patient (caregiver) preferences: Large; significant role in deciding whether to use water

precautions based on the child's specific needs, comfort level, and tolerance of water exposure
- Exceptions: Children with tympanostomy tubes and an active episode of TTO, recurrent or prolonged otorrhea episodes, and those with a history of problems with prior water exposure
- Policy level: Recommendation
- Differences of opinion: None
- Implementation considerations: 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 advised in the past by some otolaryngologists,[267] but evidence led to a recommendation against routine water precautions in the 2013 guideline.

Prior to the 2013 guideline, many providers recommended water precautions for patients with indwelling tympanostomy tubes. A survey of physicians in the northwestern United States reported that 47% of responding otolaryngologists allowed swimming without any water precautions for patients with tympanostomy tubes.[268] Moreover, while 47% of otolaryngologists recommended ear plugs or other barrier devices, 73% of primary care physicians recommended these water precautions. Despite our recommendation against routine water precautions in this prior guideline, a subsequent survey in the United Kingdom found that 90% of clinicians continued to recommend some type of water precaution.[269] Additionally, social media continues to provide inconsistent and sometime erroneous information to patients and caregivers about this aspect of posttympanostomy care.[270]

The most compelling evidence against routine water precautions for tympanostomy tubes comes from a large RCT comparing swimming/bathing with and without routine ear plug use over a period of 9 months.[238] 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 acute 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.

Two additional RCTs have assessed the need for water precautions after tympanostomy tube placement, reinforcing our recommendation against routine use. Subtil et al randomized 244 children with tympanostomy tubes to water precautions (ear plugs, headbands, or both) or no precautions during bathing or swimming and found comparable outcomes, with no benefits attributable to the routine water precautions.[236] Similarly, Miyake et al randomized 80 children with tympanostomy tubes to ''protection'' with ear plugs and advice not to swim versus no ear plugs or swimming restrictions. Despite a small reduction in otorrhea with ear plugs in only the first postoperative month, there were no differences between the groups during months 2 to 13 after surgery.[235]

Two systematic reviews published after the 2013 guideline found no benefits for routine water precautions in children with tympanostomy tubes, but these were conducted prior to the RCTs cited in the prior paragraph. The first, a Cochrane review published in 2016, found no benefit for ear plugs after tympanostomy tube placement and suggested that additional research would best focus on identifying groups of children who might benefit from such intervention.[237] Similarly, Steele and colleagues found no compelling evidence for water precautions in their meta-analysis.[253]

The available clinical evidence continues to find no clinically significant reduction in otorrhea with routine water precaution. 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.[271] Even with deeper diving, the increase in ear canal pressure is accompanied by a corresponding rise in nasopharyngeal pressure, which can prevent passive opening of the eustachian tube and water entry into the middle ear space.[272] Moreover, water contamination in the middle ear does not invariably cause infection, and if it should occur, the TTO is usually painless and readily managed with antibiotic ear drops.

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 highly contaminated water, for deep diving, or for children who experience ear discomfort during swimming. For all these circumstances, however, an acceptable approach would be to first avoid water precautions and instead reserve them for children with recurrent or persistent TTO.

STATEMENT 16. FOLLOW-UP: The surgeon or designee should examine the ears of a child within 3 months of tympanostomy tube insertion AND should educate families regarding the need for routine, periodic follow-up to examine the ears until the tubes extrude. *Strong recommendation based on randomized controlled trials, a systematic review, and observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Encourage timely documentation of tube outcomes; promote adherence to routine, follow-up care to optimize tube function and care; reduce incidence of unrecognized tympanostomy tube complications (National Quality Strategy Domain: Effective Communication and Care Coordination; Person- and Family-Centered Care; Promoting Patient Safety by Reducing Harm)
- Aggregate evidence quality: Grade B, based on RCTs with limitations of tube outcomes, systematic review of consensus of opinion on recommended tube follow-up, and observational studies on tube complication rates
- Level of confidence in evidence: Medium; there is good evidence and strong consensus on the value of follow-up, based on observational studies and RCTs exploring differences among tube types; however, evidence on timing of first follow-up and subsequent visits is largely driven by consensus opinion and may be affected by access to care, insurance restrictions, and proximity to office
- Benefits: Identify and manage tube obstruction, early extrusion, granulation tissue, perforation, or failure to extrude (retained tube); ensure that tubes are functional; opportunity to reassess hearing; opportunity to educate caregivers on otorrhea, unnecessary water precautions, and the importance of regular follow-up visits until the tubes extrude
- Risks, harms, costs: Direct cost of care; indirect costs of time, travel, and work absence
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: There is a perception that timely follow-up after surgery, to document outcomes, and during intubation may not be routinely occurring in children with tympanostomy tubes; assumption that regular follow-up visits, even for asymptomatic children, can reduce tube sequelae or complications
- Intentional vagueness: ''Within 3 months of tympanostomy tube insertion'' is intended to set an upper limit for initial follow-up, but earlier assessment is permitted; the intervals for subsequent follow-up are at the discretion of the clinician but should continue until the tubes have extruded
- Role of patient (caregiver) preferences: Limited, although a caregiver may decline follow-up visits, which should be documented in the medical record
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None
- Implementation considerations: Supporting materials to facilitate documentation of follow-up findings, as well as to educate caregivers and patients

Supporting Text. The purpose of this statement is to emphasize the need for outcome assessment within 3 months of tympanostomy tube placement and the need for regular follow-up visits until the tubes have extruded. This recommendation offers quality improvement opportunities in recognizing early extrusions, tube obstruction, tube medialization, otorrhea, delay in diagnosis of retained tubes, perforation, or other complications. The follow-up schedule should be determined at the time of tube placement, and the first follow-up appointment should generally be scheduled at the time of scheduling for tube placement.

Follow-up schedules after tympanostomy tube placement are largely driven by consensus opinion, with initial follow-up at 1 to 3 months after tube insertion and considerable variation on subsequent office visits, for which most US clinicians advocate 6-month intervals until tube extrusion.[273] We recommend that the surgeon or designee examine the ears of a child within 3 months of tympanostomy tube insertion. This first visit provides an opportunity to document in the medical record whether the tube is intact and patent, as well as any changes in clinical outcomes (eg, hearing, QOL, AOM frequency). The discussion should reinforce that routine water precautions are unnecessary but regular follow-up visits are important until the tube extrudes. This is also an opportunity to further educate families on the potential for TTO, its significance, the role of antibiotic eardrops in management, and the lack of efficacy or appropriateness for treating with oral antibiotics.

Between 5% and 11% of children may develop obstruction of one or both tubes in the first few months after surgery, so a visit within that time frame offers an opportunity for early detection and management.[55,274,275] An obstructing mucus plug in the tube lumen can often be displaced into the middle ear by using the binocular microscope with an otologic pick or, less often, lifted out of the tube with the pick into the ear canal. Alternatively, ear drops (saline or antibiotic) can be prescribed to soften and potentially dissolve the obstructing debris. In one study,[276] a 50% success rate in opening obstructed tubes was achieved by using hydrogen peroxide or sodium bicarbonate drops, as compared with 100% failure with observation. Although there are no data in the literature relating the success in opening the tube to the duration of intubation, clinical experience suggests that the sooner obstruction is detected and managed (ideally within a few months of surgery), the more likely persistent patency can be achieved.

Clinicians should ideally assess a child's hearing before surgery and at the first postoperative visit, but when resources or access to audiometry is limited, a single postoperative assessment may be the best approach to document normal hearing. In a single-institution case series[91] of nearly 2300 children, 80% had hearing loss before tube insertion, with hearing improvement noted in most, but not all, children after surgery. Postoperative audiometry revealed a 3.9% prevalence of sensorineural hearing loss and a 0.6% prevalence of persistent conductive hearing loss, despite resolution of MEE.

This finding has been corroborated by other case series,[277] demonstrating improved hearing in most children after tympanostomy tube placement but with a small percentage having persistent hearing loss. These studies support obtaining a postoperative hearing evaluation after tympanostomy tube placement to document hearing status. This evaluation should be performed at least 6 weeks after tube placement, as progressive hearing improvement can be expected over the first postoperative month in most patients (as middle ear edema and inflammation subside), and earlier audiometry may underestimate the degree of hearing improvement.[277]

A cohort study[278] of nearly 1500 children after tympanostomy tubes found that only 26% were followed until after tube extrusion, 22% were lost to follow-up within 2 years, and 52% were lost to follow-up after 2 years or longer after placement. Risk factors for loss to follow-up included older patient age, public insurance, and greater travel distance to the practice. Adherence to an office visit in the postoperative period was correlated with likelihood of completing follow-up visits until tube extrusion.

Periodic follow-up for all children with tubes is essential to detect and manage complications, which may vary by the type of tube use and its composition. For example, in 1 trial,[279] thermoplastic elastomer tympanostomy tubes had higher rates of occlusion than silicone tympanostomy tubes, with an overall rate of about 11%. In another trial,[280] long-shafted tubes, especially the Armstrong design, were less likely to extrude early as compared with tubes with a short shaft. Similar to the prior trial, rate of occlusion was about 11% of all tubes, with no significant difference found regarding time to first event of tube occlusion by tube shape or material. After the tube extruded, only 1.3% of ears had persistent perforation of the tympanic membrane for more than 90 days. These studies highlight a clinically significant incidence of early and delayed issues with tympanostomy tube performance, underscoring the importance of ongoing monitoring of patients after tympanostomy tube placement.

There is no consensus on the optimal duration of intubation or what constitutes a ''retained'' tube, but most studies recommend removing a tympanostomy tube after 2 to 3 years to reduce the incidence of persistent perforation and other tube-related complications.[281,282] One chart review[283] showed low rates of otorrhea, granulation tissue, and persistent perforation when tubes were removed after 2 to 3 years, but rates increased to >50% for all complications with intubation for 5 years or longer. A retained T-tube or other silicone tube can be easily removed in the office setting,[284] but a rigid grommet-type tube may require general anesthesia in an operative setting for removal.

Repeated follow-up with a specialist can in some instances be resource intensive. As such, once adequate postoperative tympanostomy tube function and hearing improvement are established within 3 months by the surgeon or designee, some follow-up care may occur in primary care offices. If this approach is chosen, the specialist should ideally be informed of the visit, with referral to otolaryngology implemented upon any complication, such as early extrusion, tube obstruction, tube medialization, otorrhea, retained tube, or tympanic membrane perforation. Whether routine follow-up should occur with the otolaryngologist, primary care clinician, or both is based on shared decision making with the caregiver as well as collaboration with the medical team. Telemedicine with video-otoscopy for ongoing remote monitoring may play a future role in follow-up of tympanostomy tubes.

Implementation Considerations

The complete guideline update is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. An executive summary of the recommendations will also be published to summarize the key action statements for clinicians and offer a concise overview of essential text, tables, and figures. The guideline will be presented to AAO-HNSF members and other clinicians, including an international audience, as a Panel Presentation at the AAO-HNSF 2021 Annual Meeting & OTO Experience prior to publication. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations. A full-text version of the guideline will also be accessible free of charge at www.entnet.org. A plain language summary will be available as well, aimed at parents and caregivers of children who are being considered for tympanostomy tubes or have tubes in place. The implementation needs for each KAS are detailed in the corresponding action statement profile.

Implementation challenges are numerous when trying to reduce variation in practices—some long established—about decisions to place tympanostomy tubes, the use of adjuvant therapies and surgery, and care after the tubes are placed. To facilitate change and clarify expectations, the guideline update provides tables and figures that (1) help clinicians identify at-risk children who need to be considered differently when assessing need for tympanostomy tubes; (2) list validated questions to assess for hearing difficulty when formal audiologic testing is unavailable or impractical; (3) compare the indications, advantages, and complications of long- and short-term tube designs; (4) describe the steps for saline irrigation at the time of tympanostomy tube insertion; and (5) explain how to prepare and use tissue spears to clean the ear canal prior to antibiotic ear drop therapy. The guideline update contains an information sheet about decision making against surgery for recurrent AOM when no effusion is present and an information sheet designed for caregivers and parents but equally informative to referring physicians. Finally, a short guide for the care of children after tubes is provided to facilitate education about expected outcomes, follow-up needs, and avoidance of complications.

Given the importance of caregiver engagement and education in promoting optimal tube outcomes, the GUG developed a plain language summary of this guideline, published concurrently with the full guideline, available for download at https://www.entnet.org/content/clinical-practice-guidelines. We will also explore foreign language versions of the guideline and supporting materials to facilitate communication with diverse families and stakeholders. Last, the GUG invites

clinicians who use the guideline to inform the AAO-HNSF of any free, noncommercial web-based resources that are relevant to the guideline topics that could be added to the guideline webpage to promote access.

Implementation of the proposed recommendations contained in the guideline update will need additional written and online resources, ideally integrated within electronic medical records and decision support tools. These tools, which include performance measures derived from guideline recommendation statements, will need to educate primary care providers about the use of ototopical therapy as monotherapy for TTO, a concept that is still not widely adopted outside the otolaryngology realm. Additionally, decision making about the appropriate use of adenoidectomy as a surgery adjunct will need distillation of the evidence base contained here into practical algorithms for surgeons. The routine use of antibiotic drops after tympanostomy tube surgery is commonplace now, and the recommendation against this practice will need to be disseminated, with analysis of outcomes as practices change. A ''blueprint'' for follow-up of children after tympanostomy tubes would be helpful, detailing the roles of primary care providers, otolaryngologists, and audiologists as well as the frequency of visits to each.

The updated guideline now includes a flowchart of the guideline key action statements in **Figure 3**. The flowchart facilitates more rapid understanding of the guideline logic, the sequence of the action statements, and the interrelationship of key recommendations and options for tube insertion. The flowchart can be adopted as a quick reference guide to support the implementation of the guideline's recommendations.

Research Needs

1. Can we identify clinical factors that predict persistence of MEE in children who present with effusions of short duration?
2. What is the ideal timing of audiologic testing for a child being considered for tubes—before surgery, after surgery, or both?
3. If resources are limited and audiologic testing is done only after tube placement, how will this affect surgical decision making or counseling about ''permanent'' hearing loss diagnosed only after surgery?
4. Are there any caregiver questions, in addition to the two proposed in this CPG, that can predict hearing difficulties and quantify severity, without formal audiologic testing, in patients considered for tubes?
5. Can we identify the children with OME and speech and language delays who will benefit from tympanostomy tube placement?
6. What is the relationship of MEE and balance abnormalities, and how do these balance abnormalities change after tympanostomy tube placement?
7. Are there behavioral problems that correlate with the presence and duration of middle ear fluid problems, and can we screen for these problems in children who have OME?
8. What is the best time to evaluate children referred for possible surgical treatment of recurrent AOM with relation to the last episode of AOM?
9. Can we quantify the predictive value of the presence of middle ear fluid in one or both ears for likelihood of more episodes of AOM in children with a history of recurrent AOM?
10. What are the benefits of tympanostomy tube placement on frequency of AOM, prevalence of OME, and speech and language development for children in specific at-risk populations?
11. Does tympanostomy tube surgery present unique risks or greater complications in some of the at-risk groups?
12. What is the actual frequency of AOM and prevalence of OME in specific at-risk groups?
13. Is there the potential for underdiagnosis of OME because of attention to other conditions or overdiagnosis of OME because of greater clinical exposure for some of the at-risk populations?
14. How strongly is abnormal tympanometry at the initial clinical encounter associated with persistence of OME?
15. What are the clinical indicators that best predict the need for repeated tympanostomy tube placement?
16. What is the role of allergy testing in children with recurrent tube otorrhea or a need for repeated tympanostomy tube placement, and can managing allergy, if present, result in beneficial outcomes?
17. Are there certain types of long-term tubes that are more often associated with complications such as granulation or otorrhea?
18. Which subgroups of children should be considered for adenoidectomy at the time of the first set of tubes or when younger than age 4 years?
19. How do ''face-to face'' counseling, written materials, and online resources best inform parents and caregivers and facilitate shared surgical decision making?
20. What are the indications to prescribe postoperative ototopical antibiotics at the time of surgery?
21. Will the incidence of postoperative otorrhea and the causative microbiology change with adoption of the recommendation to limit routine drop use after surgery?
22. Are there predictors for failure of ototopical therapy as initial treatment for TTO?
23. Can we identify the children at risk for otorrhea, as well as other clinical indicators for posttympanostomy water precautions?
24. To what extent can recommendations regarding water precautions for children with tympanostomy tubes be generalized to adults with tympanostomy tubes?
25. What is the ideal follow-up schedule for examining patients with tubes?
26. How often should children be assessed in primary care settings, and how often should children be

assessed by otolaryngologists, after tympanostomy tubes are placed?
27. How often should hearing be formally assessed after tympanostomy tubes are placed?
28. What is the duration of intubation that is associated with eardrum complications if the tube is not removed?
29. If a child has a retained tympanostomy tube for more than 3 years and has normal hearing, an otherwise normal eardrum, and no symptoms, should the tube be removed, or is additional observation a preferred option?
30. If the decision is made to remove a retained tympanostomy tube, when should a myringoplasty be performed?
31. If a myringoplasty is performed at the time of tube removal, is there a preferred artificial or autograft material for this repair?
32. What is the best management for an asymptomatic child with normal hearing who on examination has a tympanostomy tube that is medialized into the middle ear behind an intact eardrum?
33. Are there differences in access to surgical treatment of otitis media, as well as differences in surgical decision making, across socioeconomic, ethnic, and racial groups?

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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 American Academy of Otolaryngology–Head and Neck Surgery Foundation 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.

Supplemental Material

Additional supporting information is available in the online version of the article.

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