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Otolaryngology -- Head and Neck Surgery 2013 149: 8

DOI: 10.1177/0194599813490141

The online version of this article can be found at:

<http://oto.sagepub.com/content/149/1/8>

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Clinical Practice Guideline: Tympanostomy Tubes in Children—Executive Summary

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Otolaryngology—
Head and Neck Surgery
149(1) 8–16
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DOI: 10.1177/0194599813490141
http://otojournal.org



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Abstract

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) has published a supplement to this issue featuring the new Clinical Practice Guideline: Tympanostomy Tubes in Children. To assist in implementing the guideline recommendations, this article summarizes the rationale, purpose, and key action statements. The 12 recommendations developed address patient selection, surgical indications for and management of tympanostomy tubes in children. The development group broadly discussed indications for tube placement, perioperative management, care of children with indwelling tubes, and outcomes of tympanostomy tube surgery. Given the lack of current published guidance on surgical indications, the group focused on situations in which tube insertion would be optional, recommended, or not recommended. Additional emphasis was placed on opportunities for quality improvement, particularly regarding shared decision making and care of children with existing tubes.

Keywords

guideline, otitis media, tympanostomy tubes, grommets, pediatric otolaryngology

Received April 15, 2013; accepted April 23, 2013.

The Clinical Practice Guideline: Tympanostomy Tubes in Children 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. The guideline's target audience includes specialists, primary care clinicians, and allied health professionals, as represented by this multidisciplinary guideline development group. Recommendations were developed to address patient selection and surgical indications for and management of tympanostomy tubes in children. Recommendations in a guideline can be implemented only if they are clear and identifiable. This goal is best achieved by structuring the guideline around a series of key action statements, which are supported by amplifying text and action statement profile. For ease of reference, only the statements and profiles are included in this brief summary. Please refer to the complete guideline for important information in the amplifying text that further explains the supporting evidence and details of implementation for each key action statement.¹

Background

Insertion of tympanostomy tubes is the most common ambulatory surgery performed on children in the United States. Each year, 667,000 children younger than 15 years receive tympanostomy tubes, accounting for more than 20% of all ambulatory surgery in this group.² By age 3 years, nearly 1 of every 15 children (6.8%) will have tympanostomy tubes, increasing by more than 2-fold with day care attendance.³

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

Table 1. Abbreviations and definitions of common terms.

Term	Definition
Otitis media with effusion (OME) Chronic OME	The presence of fluid in the middle ear without signs or symptoms of acute ear infection OME persisting for 3 months or longer from the date of onset (if known) or from the date of diagnosis (if known)
Acute otitis media (AOM) Recurrent AOM	The rapid onset of signs and symptoms of inflammation of the middle ear Three or more well-documented and separate AOM episodes in the past 6 months OR at least 4 well-documented and separate AOM episodes in the past 12 months with at least 1 in the past 6 months ⁹
Middle ear effusion	Fluid in the middle ear from any cause but most often from OME and during, or after, an episode of AOM
Tympanostomy tube otorrhea	Discharge from the middle ear through the tube, usually caused by AOM or external contamination of the middle ear from water entry (swimming, bathing, or hair washing)

of the eustachian tube, a slender connection between the middle ear and back of the nose that normally ventilates the middle ear space and equalizes pressure with the external environment.⁵

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

Risks and potential adverse events of tympanostomy tube insertion are related to general anesthesia usually required for the procedure and the effect of the tympanostomy tube on the tympanic membrane and middle ear.¹⁰ Tympanostomy tube sequelae are common but generally transient (otorrhea) or do not affect function (tympanosclerosis, focal atrophy, or

shallow retraction pocket). Tympanic membrane perforations, which may require repair, are seen in about 2% of children after placement of short-term tympanostomy tubes.¹⁰

When making clinical decisions, the risks of tube insertion must be balanced against the risks of prolonged or recurrent otitis media, which include suppurative complications, damage to the tympanic membrane, adverse effects of antibiotics, and potential developmental sequelae of hearing loss. The frequency of tympanostomy tube insertion combined with variations in accepted indications for surgery create a pressing need for evidence-based guidelines to aid clinicians in identifying the best surgical candidates and optimizing subsequent care.

Purpose

The primary purpose of this clinical practice guideline is to provide clinicians with evidence-based recommendations on patient selection, surgical indications for tympanostomy tubes, and management of tympanostomy tubes in children. 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. The target audience includes specialists, primary care clinicians, and allied health professionals, as represented by this multidisciplinary guideline development group.

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Table 2. Risk factors for developmental difficulties.^a

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

^aSensory, physical, cognitive, or behavioral factors that place children who have OME at increased risk for developmental difficulties (delay or disorder).⁶

Although children considered at risk for developmental delays or disorders (**Table 2**) are often excluded for ethical reasons from clinical research involving tympanostomy tubes, the guideline development group decided to include them in the scope because these patients may derive enhanced benefit from tympanostomy tubes.¹¹ This decision was based on clinical experience of the guideline development group and a recommendation from a multidisciplinary guideline on OME that “clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME, and should more promptly evaluate hearing, speech, language, and need for intervention,” including tympanostomy tubes.⁶

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

Methods

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm.¹² Members of the panel included a pediatric and adult otolaryngologist, otologist/neurotologist, anesthesiologist, audiologist, family physician, behavioral pediatrician, pediatrician, speech/language pathologist, advanced nurse practitioner, physician assistant, resident physician, and consumer advocates. For additional details on methodology, please refer to the complete text of the guideline.¹ The 12 guideline recommendations are summarized in **Table 3**, with the corresponding action statements and profiles reproduced below. Supporting text and complete citations can be found in the guideline proper.¹

Key Action Statements

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 (RCTs) on efficacy of tubes for children with OME of less than 2 to 3 months’ duration and a preponderance of benefit over harm.*

Action Statement Profile

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

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

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

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational and cross-sectional studies assessing the prevalence of conductive hearing loss with OME
- Level of confidence in evidence: High
- Benefits: Documentation of hearing status, improved decision making regarding the need for surgery in chronic OME, establishment of baseline hearing prior to surgery, detection of coexisting sensorineural hearing loss
- Risks, harms, costs: Cost of the audiologic assessment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The words *age-appropriate* audiologic testing are used to recognize that the specific methods will vary with the age of the child, but a full discussion of the specifics of testing is beyond the scope of this guideline
- Role of patient (caregiver) preferences: Some caregivers may decline testing
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

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

Action Statement Profile

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

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

STATEMENT 4. CHRONIC OME WITH SYMPTOMS: Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced QOL. *Option based on RCTs and before-and-after studies with a balance between benefit and harm.*

Action Statement Profile

- Aggregate evidence quality: Grade C, based on before-and-after studies on vestibular function and QOL, RCTs on reduced MEE after tubes for chronic OME, and observational studies regarding the impact of MEE on children as related, but not limited to, school performance, behavioral issues, and speech delay
- Level of confidence in evidence: High for vestibular problems and QOL; medium for poor school performance, behavioral problems, and ear discomfort, because of study limitations and the multifactorial nature of these issues
- Benefits: Reduced prevalence of MEE, possible relief of symptoms attributed to chronic OME, elimination of MEE as a confounding factor from efforts to understand the reason or cause of a vestibular problem, poor school performance, behavioral problem, or ear discomfort
- Risks, harms, costs: None related to offering surgery, but if performed, tympanostomy tube insertion includes risks from anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation

tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), premature tympanostomy tube extrusion, retained tympanostomy tube, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs

- Benefit-harm assessment: Equilibrium
- Value judgments: Chronic MEE has been associated with problems other than hearing loss; intervening when MEE is identified can reduce symptoms. The group's confidence in the evidence of a child benefiting from intervention was insufficient to conclude a preponderance of benefit over harm and instead found at equilibrium
- Intentional vagueness: The words *likely attributable* are used to reflect the understanding that the symptoms listed may have multifactorial causes, of which OME may be only one factor, and resolution of OME may not necessarily resolve the problem
- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

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

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High
- Benefits: Detection of structural changes in the tympanic membrane that may require intervention, detection of new hearing difficulties or symptoms that would lead to reassessing the need for tympanostomy tube insertion, discussion of strategies for optimizing the listening-learning environment for children with OME, as well as ongoing counseling and education of parents/caregiver
- Risks, harms, costs: Cost of examination(s)
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although it is uncommon, untreated OME can cause progressive changes in the tympanic membrane that require surgical intervention. There was an implicit assumption that surveillance

and early detection/intervention could prevent complications and would also provide opportunities for ongoing education and counseling of caregivers

- Intentional vagueness: The surveillance interval is broadly defined at 3 to 6 months to accommodate provider and patient preference; "significant" hearing loss is broadly defined as one that is noticed by the caregiver, reported by the child, or interferes in school performance or quality of life
- Role of patient (caregiver) preferences: Opportunity for shared decision making regarding the surveillance interval
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

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 RCTs with a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade A, based on a meta-analysis of RCTs, a systematic review of RCT control groups regarding the natural history of recurrent AOM, and other RCTs
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary surgery and its risks, avoid surgery in children for whom RCTs have not demonstrated any benefit for reducing AOM incidence or in children with a condition that has reasonable likelihood of spontaneous resolution, cost savings
- Risks, harms, costs: Delay in intervention for children who eventually require tympanostomy tubes, need for systemic antibiotics among children who continue to have episodes of recurrent AOM
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Implicit in this recommendation is the ability to reassess children who continue to have AOM despite observation and to perform tympanostomy tube insertion if MEE is present (Statement 7); risk of complications or poor outcomes from delayed tube insertion for children who continue to have recurrent AOM is minimal
- Intentional vagueness: The method of confirming the absence of MEE should be based on clinician experience and may include tympanometry, simple otoscopy, and/or pneumatic otoscopy
- Role of patient (caregiver) preferences: Limited, because of favorable natural history and good evidence that otherwise healthy children with recurrent

Table 3. Summary of guideline action statements.

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

AOM without MEE do not have a reduced incidence of AOM after tympanostomy tube insertion

- Exceptions: At-risk children; children with histories of severe or persistent AOM or immunosuppression; prior complication of otitis media (mastoiditis, meningitis, facial nerve paralysis); multiple antibiotic allergy or intolerance
- Policy level: Recommendation
- Differences of opinion: None

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 RCTs with minimal limitations and a preponderance of benefit over harm.*

Action Statement Profile

- Aggregate evidence quality: Grade B, based on RCTs with minor limitations
- Level of confidence in evidence: Medium; some uncertainty regarding the magnitude of clinical benefit and importance, because of heterogeneity in the design and outcomes of clinical trials.
- Benefits: Mean decrease of approximately 3 episodes of AOM per year, ability to treat future episodes of

AOM with topical antibiotics instead of systemic antibiotics, reduced pain with future AOM episodes, improved hearing during AOM episodes

- Risks, harms, costs: Risks from anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), premature tympanostomy tube extrusion, retained tympanostomy tube tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: In addition to the benefits seen in RCTs, the presence of effusion at the time of assessment served as a marker of diagnostic accuracy for AOM
- Intentional vagueness: The method of confirming the presence of 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 to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

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

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High for Down syndrome, cleft palate, and permanent hearing loss; medium for other risk factors
- Benefits: Facilitation of future decisions about tube candidacy, identification of children who might benefit from early intervention (including tympanostomy tubes), identification of children who might benefit from more active and accurate surveillance of middle ear status as well as those who require more prompt evaluation of hearing, speech, and language
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Despite the limited high-quality evidence about the impact of tubes on this population (nearly all RCTs exclude children who are at risk), the panel considered it important to use at-risk status

as a factor in decision making about tube candidacy, building on recommendations made in the OME guideline.⁵ The panel assumed that at-risk children would be less likely to tolerate OME or recurrent AOM than would the otherwise healthy child

- Intentional vagueness: None
- Role of patient (caregiver) preferences: None, since this recommendation deals only with acquiring information to assist in decision making
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 9. TYMPANOSTOMY TUBES AND AT-RISK CHILDREN: Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly, as reflected by a type B (flat) tympanogram or persistence of effusion for 3 months or longer. *Option based on a systematic review and observational studies with a balance between benefit and harm.*

Action Statement Profile

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

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

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

Action Statement Profile

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

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

Action Statement Profile

- Aggregate evidence quality: Grade B, based on RCTs demonstrating equal efficacy of topical versus oral

antibiotic therapy for otorrhea as well as improved outcomes with topical antibiotic therapy when different topical preparations are compared

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

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

Action Statement Profile

- Aggregate evidence quality: Grade B, based on 1 RCT and multiple observational studies with consistent effects
- Level of confidence in evidence: High
- Benefits: Allows for normal activity and swimming, reduced anxiety, cost savings
- Risk, harm, cost: Potential for slight increase in otorrhea rates in some children
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of not restricting or limiting children's water activity in the absence of proven, clinically significant benefits of routine water precautions

- Intentional vagueness: The word *routine* is used to soften the recommendation since individual children may benefit from water precautions in specific situations (eg, lake swimming, deep diving, recurrent otorrhea, head dunking in the bathtub, or otalgia from water entry into the ear canal)
- Role of patient (caregiver) preferences: Significant role in deciding whether or not to use water precautions based on the child's specific needs, comfort level, and tolerance of water exposure
- Exceptions: Children with tympanostomy tubes and (1) an active episode of otorrhea or (2) recurrent or prolonged otorrhea episodes, as well as those with a history of problems with prior water exposure
- Policy level: Recommendation
- Differences of opinion: None

Disclaimer

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

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Disclosures

Competing interests: Seth R. Schwartz, research funding from Cochlear Corporation, instructor for temporal bone course with Medtronic ENT; Melissa A. Pynnonen, consultant for K. Storz; David E. Tunkel, consultant for Medtronic ENT; Heather M. Hussey, salaried employee of AAO-HNSF; Alison M. Grimes, husband is an employee

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Sponsorships: American Academy of Otolaryngology—Head and Neck Surgery Foundation.

Funding source: American Academy of Otolaryngology—Head and Neck Surgery Foundation.

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