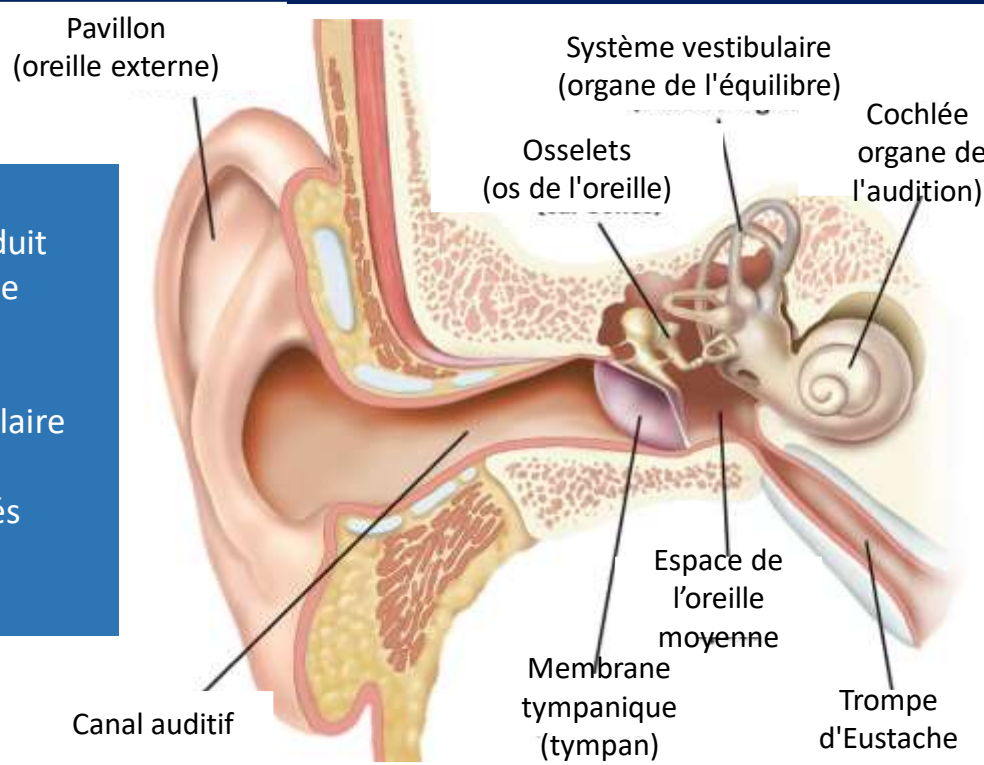
Résumé exécutif des lignes directrices de la pratique clinique sur les aérateurs trans tympaniques chez les enfants (mise à jour)

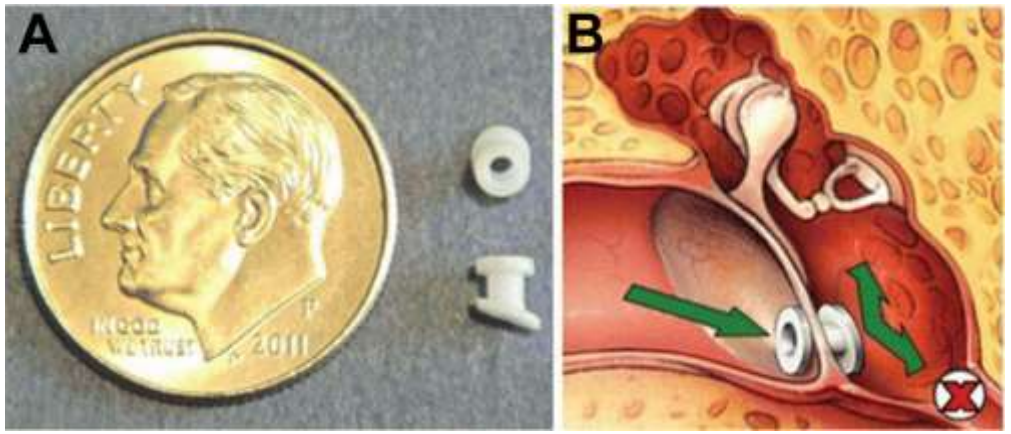
Résumé exécutif des lignes directrices de la pratique clinique sur les aérateurs transtympaniques chez les enfants (mise à jour)

- L'aérateur transtympanique, qui mesure environ 1/20ème de pouce de large, est placé dans le tympan de l'enfant (membrane tympanique) pour ventiler l'espace de l'oreille moyenne

- Les aérateurs transtympaniques sont le plus souvent insérés en raison d'un liquide persistant dans l'oreille moyenne, d'infections auriculaires fréquentes ou d'infections auriculaires qui persistent après un traitement antibiotique. Toutes ces conditions sont regroupées sous le terme d'otite moyenne (inflammation de l'oreille moyenne), qui est, après l'infection aiguë des voies respiratoires supérieures, la maladie la plus fréquemment diagnostiquée chez les enfants par les professionnels de la santé

- Relations entre l'oreille externe (pavillon et conduit auditif), l'oreille moyenne (osselets et membrane tympanique) et l'oreille interne (système vestibulaire de la cochlée)
- Les aérateurs sont insérés dans la membrane tympanique (tympan)





- (A) Taille de l'aérateur transtympanique par rapport à une pièce de 10 centimes
- (B) Les aérateurs transtympaniques sont également appelés tubes de ventilation parce que l'ouverture permet à l'air de pénétrer dans l'oreille moyenne directement à partir du canal auditif (flèches), s'ajoutant à la ventilation par la trompe d'Eustache de l'enfant qui fonctionne mal (X).

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Résumé exécutif des lignes directrices de la pratique clinique sur les aérateurs Trans tympaniques chez les enfants (mise à jour)

Déclaration	Action	Puissance
1. OME de courte durée	Les médecins ne doivent pas procéder à l'insertion d'un aérateur transtympanique chez les enfants n'ayant eu qu'un seul épisode d'OME d'une durée inférieure à 3 mois, à partir de la date d'apparition (si elle est connue) ou de la date du diagnostic (si l'apparition est inconnue)	Recommendation (contre)
2. Évaluation de l'audition	Les médecins doivent obtenir une évaluation de l'audition si l'OME persiste pendant 3 mois ou plus OU avant une opération lorsqu'un enfant devient candidat à l'insertion d'un aérateur trans tympanique.	Recommendation
3. OME chronique bilatérale avec difficulté d'audition	Les médecins devraient proposer l'insertion d'un aérateur transtympanique bilatéral aux enfants présentant une OME bilatérale depuis 3 mois ou plus ET des difficultés d'audition documentées.	Recommendation
4. OME chronique avec symptômes	Les médecins peuvent procéder à l'insertion d'un aérateur transtympanique chez les enfants présentant une OME unilatérale ou bilatérale depuis 3 mois ou plus (OME chronique) ET des symptômes qui sont probablement attribuables, en tout ou en partie, à l'OME qui incluent, sans s'y limiter, des problèmes d'équilibre (vestibulaire), un mauvais rendement scolaire, des problèmes de comportement, une gêne auditive ou une qualité de vie réduite..	Option

Rosenfeld RM, et al. Otolaryngology–Head and Neck Surgery. 2022; 166(2): 189-206. OME, otite moyenne avec épanchement.

Résumé exécutif des lignes directrices de la pratique clinique sur les aérateurs transtympaniques chez les enfants (mise à jour)

Déclaration	Action	Puissance
5. Surveillance de l'OME chronique	Les médecins doivent réévaluer, à des intervalles de 3 à 6 mois, les enfants présentant une OME chronique qui ne reçoivent pas d'aérateurs transtympaniques, jusqu'à ce que l'épanchement ait disparu, qu'une perte auditive significative soit détectée ou que des anomalies structurelles de la membrane tympanique ou de l'oreille moyenne soient suspectées	Recommendation
6. OMA récurrente sans EOM	Les médecins ne doivent pas procéder à l'insertion d'un aérateur transtympanique chez les enfants présentant une OMA récurrente qui ne présentent pas d'EOM dans l'une ou l'autre des oreilles au moment de l'évaluation de la candidature pour l'insertion d'un aérateur.	Recommendation (against)
7. OMA récurrente avec EOM	Les médecins ne doivent pas offrir de procéder à l'insertion d'un aérateur transtympanique bilatéral chez les enfants présentant une OMA récurrente et qui ont une EOM unilatérale ou bilatérale au moment de l'évaluation de la candidature pour l'insertion d'un aérateur.	Recommendation
8. Enfants à risque	Les médecins doivent déterminer si un enfant présentant une OMA récurrente ou une OME quelconque durée présente un risque accru de problèmes d'élocution, de langage ou d'apprentissage dus à l'otite moyenne en raison de facteurs de base sensoriels, physiques, cognitifs ou comportementaux (tableau 2)	Recommendation
9. Aérateurs trans tympaniques et enfants à risque	Les médecins peuvent procéder à l'insertion d'un aérateur transtympanique chez les enfants à risque présentant une OME unilatérale ou bilatérale qui est susceptible de persister, comme en témoigne un tympanogramme de type B (plat) ou un épanchement documenté pendant 3 mois ou plus.	Option

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eille moyenne.

Résumé exécutif des lignes directrices de la pratique clinique sur les aérateurs trans tympaniques chez les enfants (mise à jour)

Déclaration	Action	Puissance
10. Aérateurs à long terme	Le médecin ne doit pas placer d'aérateurs à long terme comme opération initiale pour les enfants qui répondent aux critères d'insertion d'aérateur, à moins qu'il n'y ait une raison spécifique basée sur un besoin anticipé de ventilation prolongée de l'oreille moyenne au-delà de celle d'un aérateur à court terme	Recommendation (contre)
11. Adénoïdectomie adjuvante	Les médecins peuvent pratiquer une adénoïdectomie en complément de l'insertion d'un aérateur transtympanique chez les enfants présentant des symptômes directement liés aux adénoïdes (infection des adénoïdes ou obstruction nasale) OU chez les enfants âgés de 4 ans ou plus afin de réduire potentiellement l'incidence future d'otites moyennes récurrentes ou la nécessité de réinsérer un aérateur	Recommendation
12. Éducation périopératoire	Au cours de la période périopératoire, les médecins doivent informer les soignants des enfants porteurs d'aérateurs transtympaniques de la durée prévue du fonctionnement de l'aérateur, du calendrier de suivi recommandé et de la détection des complications	Recommendation

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Résumé exécutif des lignes directrices de la pratique clinique sur les aérateurs trans tympaniques chez les enfants (mise à jour)

Déclaration	Action	Puissance
13. Gouttes auriculaires périopératoires	Les médecins ne doivent pas prescrire systématiquement des gouttes auriculaires antibiotiques postopératoires après l'insertion d'un aérateur trans tympanique.	Recommendation (contre)
14. Acute tympanostomy tube otorrhea	Les médecins doivent prescrire des gouttes auriculaires à base d'antibiotiques topiques uniquement, sans antibiotiques oraux, pour les enfants présentant une otorrhée aiguë non compliquée due à l'aérateur transtympanique	Strong recommendation
15. Water precautions	Les médecins ne doivent pas encourager les précautions prophylactiques de routine contre l'eau (utilisation de protection auditive ou de bandeaux, évitement de la natation ou des sports aquatiques) pour les enfants porteurs d'aérateurs transtympaniques.	Recommendation (contre)
16. Follow-up	Le chirurgien ou la personne désignée doit examiner les oreilles de l'enfant dans les 3 mois suivant l'insertion de l'aérateur transtympanique ET doit informer les familles de la nécessité d'un suivi régulier et périodique pour examiner les oreilles jusqu'à l'extrusion des aérateurs	Forte recommendation

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Executive Summary of Clinical Practice Guideline on Tympanostomy Tubes in Children (Update)

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Abstract

Objective. This executive summary of the guideline update provides evidence-based recommendations for patient selection and surgical indications for managing tympanostomy tubes in children. The summary and guideline are 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 executive summary is to provide a succinct overview for clinicians of the key action statements (recommendations), summary tables, and patient decision aids from the update of the American Academy of Otolaryngology–Head and Neck Surgery Foundation's "Clinical Practice Guideline: Tympanostomy Tubes in Children (Update)." The new guideline updates recommendations in the prior guideline from 2013 and provides clinicians with trustworthy, evidence-based recommendations on patient selection and surgical indications for managing tympanostomy tubes in children. This summary is not intended to substitute for the full guideline, and clinicians are encouraged to read the full guideline before implementing the recommended actions.

Methods. The guideline on which this summary is based was developed using 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," which were followed explicitly. The guideline update group represented 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. *Strong recommendations* were made for the following key action statements: (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.

Recommendations were made for the following key action statements: (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 (AOM) who do not have middle ear effusion (MEE) in either ear at the time of assessment for tube candidacy. (7) 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. (8) 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. (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.

Options were offered from the following key action statements: (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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This executive summary is a companion to the full updated clinical practice guideline on tympanostomy tubes in children published by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) as a journal supplement.[1] The purpose is to provide quick reference for clinicians to the key action statements (KASs), guideline recommendations, and supporting materials. The summary is not intended as a substitute for the full guideline, which clinicians should read before implementing the recommendations that follow. The full guideline contains additional patient-oriented materials, including handouts and frequently asked questions, that can facilitate implementation. There is also a plain language summary of the full guideline, to which patients and families can be referred as a resource for shared decision making.[2]

Update Rationale and Scope

This executive summary is an update and replacement for the earlier executive summary that accompanied the original guideline, ''Tympanostomy Tubes in Children,'' published in 2013 by the AAO-HNSF.[3] 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 clinical practice guidelines, 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 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[3] offered the first trustworthy recommendations[4] on tympanostomy tube indications and was prompted, in part, by overuse concerns from the Joint Commission and American Medical Association.[5] Subsequent research showed excellent adherence by clinicians to guideline recommendations for tube insertion and for watchful waiting to reduce unnecessary surgery.[6-8] These recommendations have been adopted, in part, by other countries publishing guidelines on OME that secondarily discuss tympanostomy tubes.[9-13] 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),[14] declining to 413,000 procedures in 2010,[15] most likely because of universal immunization with pneumococcal conjugate vaccine.[16,17] Despite this decline, in 2014 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.[18,19]

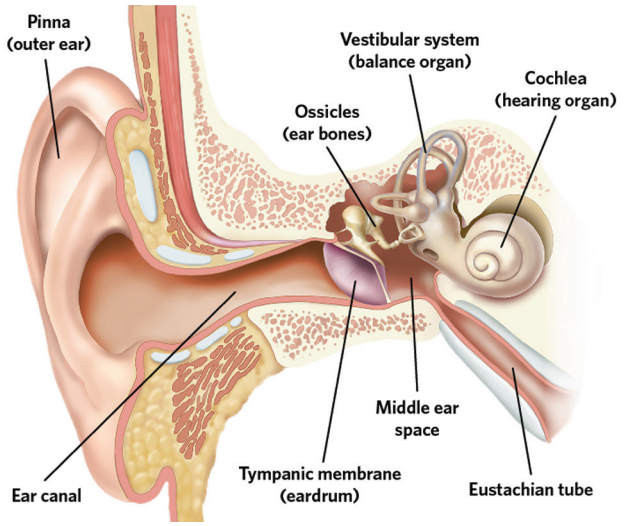


Figure 1. Relationship of the outer ear (pinna and ear canal), middle ear (ossicles and tympanic membrane), and inner ear (cochlea vestibular system). Tubes are inserted into the tympanic membrane (eardrum).

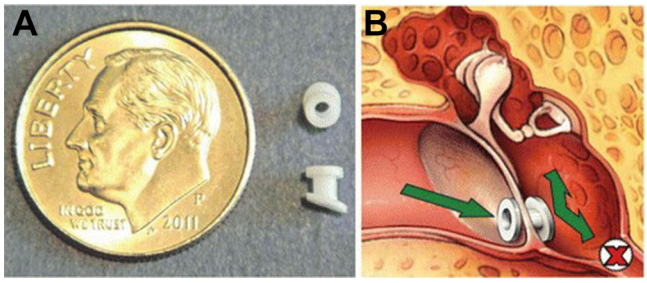


Figure 2. (A) Size of tympanostomy tube as compared with a dime. (B) Tympanostomy tubes are also called ventilation tubes because the opening allows air to enter the middle ear directly from the ear canal (arrows), which supplements ventilation through the child's poorly functioning eustachian tube (X).[33]

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.[20] 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.[21]

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.[22] Placement of tympanostomy tubes significantly reduces middle ear effusion prevalence, resolves hearing loss caused by middle ear effusion, reduces the incidence of recurrent acute otitis media (AOM), and provides a mechanism for drainage and

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; this may include caregiver report, audiologic assessment by an audiologist, or hearing testing by a physician or allied health professional using screening or standard equipment, which may be automated or manual. Does not include use of noisemakers or other 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[32]	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).

administration of topical antibiotic therapy should acute tube otorrhea occur.[23,24] Tympanostomy tubes also can improve disease-specific quality of life (QOL) for children with chronic OME, recurrent AOM, or both.[25]

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.[26] 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.[27] 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.[23]

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 mild to moderate hearing loss that is often associated with middle ear effusion. Additional information on the potential benefits and risks of tympanostomy tubes is detailed in the Health Care Burden section of the 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.[3] Clinicians interested in a more detailed discussion of the health care burden of tympanostomy tubes can refer to the appropriate section in the full guideline update.

Guideline Purpose

The purpose of the full clinical practice guideline update is to reassess and update recommendations in our prior guideline[3] and to provide clinicians with trustworthy, evidence-based recommendations on patient selection and surgical indications for managing tympanostomy tubes in children. A clinical practice guideline is defined, as suggested by the Institute of Medicine, as ''statements that include recommendations intended to optimize patient care that are informed by systematic review of the evidence and an assessment of the benefits and harms of alternative care options.''[28]

The 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.[24]

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.[29] This builds on a similar decision for the original tube guideline[3] 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.[22]

Table 2. Risk Factors for Developmental Difficulties.[a]

Permanent hearing loss independent of otitis media with effusion (OME)
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 OME at increased risk for developmental difficulties (delay or disorder).[22]
[b]The conditions in this row are a new addition to the list.

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.

The updated guideline 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.[27] 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[30] published as a companion to the clinical practice guideline update.

Methods

In developing the guideline 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.[4] 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. For additional details on methodology, please refer to the complete text of the updated 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 3**, 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.

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.[31] The role of patient/caregiver preferences in making decisions deserves 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.[31] 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.[31] 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 Priorities: 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 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

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)

Table 3. 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 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	KAS unchanged; new text on cochlear implantation
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

(continued)

Table 3. (continued)

Statement	Action	Strength	Comment
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

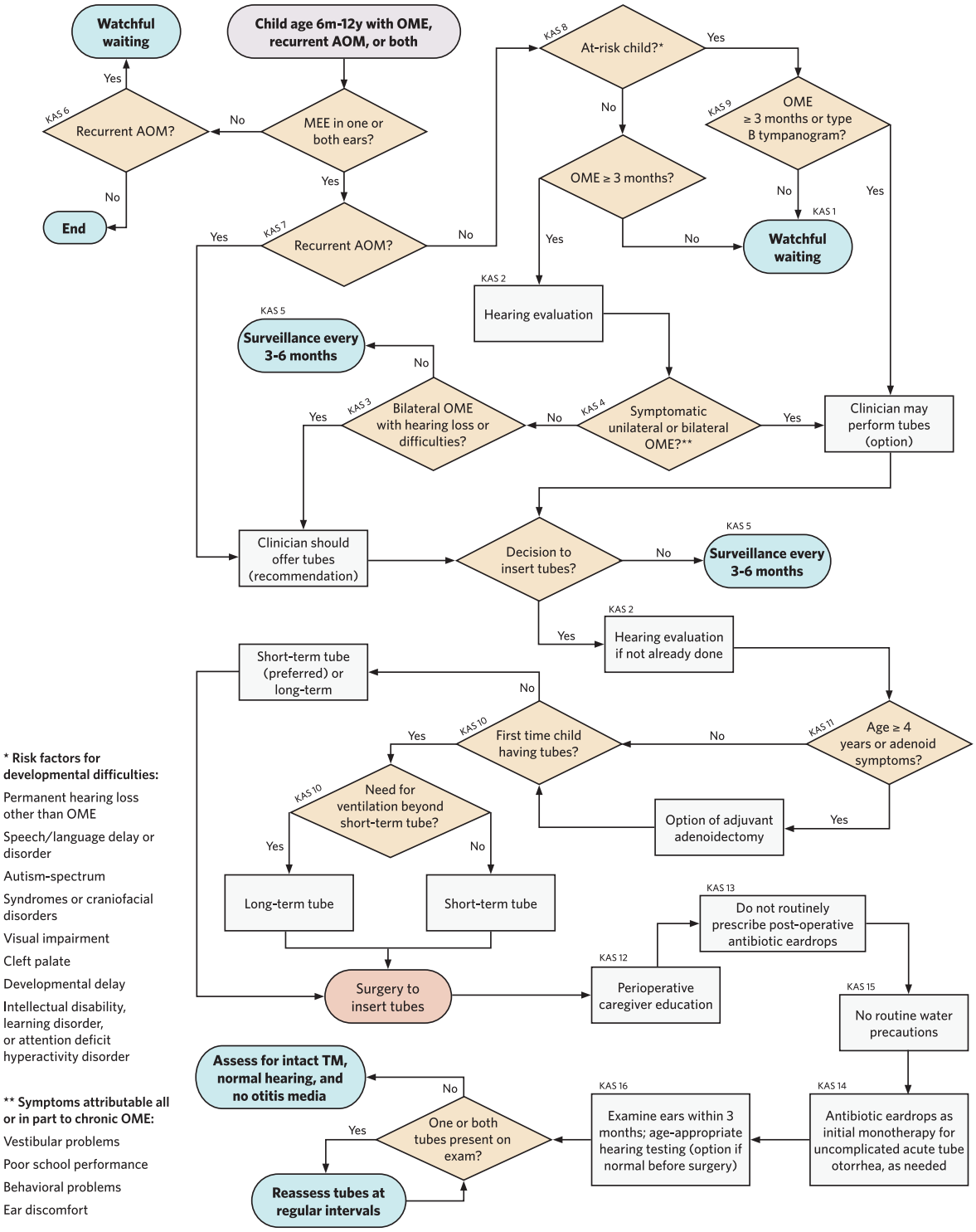
Abbreviations: AOM, acute otitis media; KAS, key action statement; MEE, middle ear effusion; OME, otitis media with effusion.

- 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

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,



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.

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 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

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 1 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 comments above)

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, is 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

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 the child and (2) what role patient preference and future infections might have in altering this decision
- 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

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

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 (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
- 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.[22] 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

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 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, 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

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 on 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

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 Domains: 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 for 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

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

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

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 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

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 Priorities: 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 or 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

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 Domains: 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

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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.

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