



Effective Health Care

Tympanostomy Tubes in Children

Nomination Summary Document

Results of Topic Selection Process & Next Steps

- The topic, *Tympanostomy Tubes in Children*, will go forward for refinement as a systematic review. The scope of this topic, including populations, interventions, comparators, and outcomes, will be further developed in the refinement phase.
- When key questions have been drafted, they will be posted on the AHRQ Web site and open for public comment. To sign up for notification when this and other Effective Health Care (EHC) Program topics are posted for public comment, please go to <http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

Topic Description

Nominator(s): Health care professional association

Nomination Summary: The nominator asserts that there is clinical uncertainty regarding indications for tympanostomy in children as well as the prescription of antibiotics for children with tube otorrhea. There is also uncertainty regarding prophylactic water precaution devices.

Key Question #1: What is the comparative effectiveness of tympanostomy tubes in children with chronic otitis media with effusion (OME) at different thresholds of frequency of clinical indication?

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Population(s): Children, aged 6 mo. – 12 years, with chronic OME

Intervention(s): Insertion of tympanostomy tubes

Comparator(s): Antibiotic or other non-surgical treatments or no intervention

Outcome(s): Reduction in the prevalence of middle ear effusion; improvement of hearing levels (HLs); speech and language improvement; health-related quality of life (HRQoL)

Key Question #2: What is the comparative effectiveness of tympanostomy tubes in children with recurrent acute otitis media (AOM) at different thresholds of frequency of clinical indication?

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Population(s): Children, aged 6 mo. – 12 years, with recurrent AOM

Intervention(s): Insertion of tympanostomy tubes

Comparator(s): Antibiotic or other non-surgical treatments or no intervention

Outcome(s): Prevention of recurrent AOM; prevention of AOM complications; school absenteeism; HRQoL

Key Question #3: What is the comparative effectiveness of obtaining a hearing test prior to inserting tympanostomy tubes to improve certainty of indications for tympanostomy and patient satisfaction?

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Population(s): Children, aged 6 mo. – 12 years, being considered for tympanostomy tubes

Intervention(s): Hearing testing

Comparator(s): No test

Outcome(s): Improvement in indications for tympanostomy; patient satisfaction with the change in hearing following surgery

Key Question #4: What is the comparative effectiveness of topical antibiotic drops and/or systemic antibiotics for children with tympanostomy tube otorrhea (TTO)?

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Population(s): Children, aged 6 mo. – 12 years with tympanostomy tubes and with TTO

Intervention(s): Topical antibiotic drops or systemic antibiotic administration

Comparator(s): Systemic antibiotic administration or topical antibiotic drops or no intervention

Outcome(s): Reduction of TTO duration or recurrence; prevention of other complications; school absenteeism; HRQoL

Key Question #5: Does the use of prophylactic water precautions (ear plugs, headbands, etc.) following tympanostomy tube insertion reduce infections, TTO or other complications?

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Population(s): Children, aged 6 mo. – 12 years with tympanostomy tubes

Intervention(s): Use of ear plugs or headbands or avoidance of water

Comparator(s): No prophylactic water precautions

Outcome(s): Infections; TTO; other complications; HRQoL

**Key Questions
from Nominator:**

1. What are the indications for inserting tympanostomy tubes (how many otitis media w/ effusion or acute otitis media episodes in what time frame)?
2. Should clinicians obtain a hearing test prior to inserting tympanostomy tubes?
3. Should clinicians prescribe topical antibiotic eardrops and/or antibiotics for children with uncomplicated acute tympanostomy tube otorrhea?
4. Do children with tubes need to wear prophylactic water precautions (earplugs or headbands)?

In consultation with a clinical reviewer, the Key Questions were revised in order to examine the comparative effectiveness of tympanostomy in OME and the comparative effectiveness of tympanostomy in AOM separately.

Considerations

- The topic meets all EHC Program selection criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Tympanostomy tubes are used to treat different indications, including recurrent acute otitis media (AOM), and chronic otitis media with effusion (OME). Between 84% and 93% of all children experience at least one episode of AOM. AOM occurs when infection leads to the accumulation of pus and mucus behind the eardrum, blocking the Eustachian tube. This causes earache and swelling. AOM is considered recurrent when children have had at least three episodes within six months or four episodes within one year.¹ Approximately 80% of children younger than 10 years old have had an episode of OME. Effusion indicates that fluid builds up in the ear after an infection. OME is considered chronic when it persists beyond three months.¹ At any given time, 5% of children aged 2-4 years have hearing loss due to middle ear effusion.²
- The most common adverse event following the insertion of tympanostomy tubes is tympanostomy tube otorrhea (TTO), or drainage which results from tube insertion, affecting approximately 16% of children within four weeks of surgery and 26% of children while tubes are in place.³ Antibiotics are not recommended for the treatment of TTO, and current guidelines also advise against the use of prophylactic water precautions for children with tubes in order to avoid TTO or bacterial infection.
- Tympanostomy tube insertion is the most common ambulatory surgery performed in children in the US. However, the appropriateness and efficacy of tympanostomy tube surgery has been questioned due to limited evidence. Most criticism has centered on surgery in children with OME of less than three months duration determined by extrapolation of findings at discrete office visits. There are also concerns regarding the efficacy of tympanostomy tubes for recurrent AOM; the nominator notes that systematic reviews report insufficient evidence, small short-term benefits, or moderate benefits of similar magnitude to antibiotic prophylaxis.
- We identified a clinical practice guideline published in 2013 by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF), which covers the entire scope of the nomination.
- We identified several systematic reviews published since the search date of the AAO-HNSF guideline that addressed portions of the scope of this nomination. However these reviews did not fully address the entire scope of the nomination. A systematic review that assesses the evidence across the full scope of the nomination could inform future efforts for guideline development by the AAO-HNSF.

References

1. American Academy of Otolaryngology – Head and Neck Surgery. Retrieved from www.entnet.org
2. Kay DJ, Nelson M, Rosenfeld RM. Meta-analysis of tympanostomy tube sequelae. *Otolaryngol Head Neck Surg.* 2001;124(4):374-380.
3. Kogan MD, Overpeck MD, Hoffman HJ, Casselbrant ML. Factors associated with tympanostomy tube insertion among preschool-aged children in the United States. *Am J Public Health.* 2000;90(2):245-250.