

Key Questions and Background

Tympanostomy Tubes in Children

Background

Middle ear inflammation (otitis media) is one of the most common ailments of childhood, with a diagnostic frequency second only to upper respiratory infection. Otitis media can present as an ear infection (acute otitis media (AOM)) or as fluid in the middle ear in the absence of an infection (otitis media with effusion (OME)). In some children, ear infections do not respond to antibiotic therapy or recur within a month of completing antibiotics (persistent otitis media) or continue to recur within six to twelve months (recurrent otitis media). Persistent or recurrent otitis media as well as chronic otitis media with effusion can lead to long-term hearing problems, frequent doctor visits, decreased quality of life for both the child and parent, as well as missed school and work. Further, hearing loss can lead to a number of developmental delays, including speech, language, and cognitive problems, the impact of which are likely even greater in children already at risk for developmental difficulties or delays (including those with conditions such as autism spectrum disorders, Down syndrome, among others).

Tympanostomy tube insertion is the primary surgical treatment for chronic OME and persistent AOM, and is performed in approximately 667,000 children each year. Tympanostomy tubes are small tubes that are inserted into the eardrum in order to allow the flow of both air and fluid between the middle and outer ear. Tube placement is performed under general anesthesia, and tubes typically fall out within 12 to 14 months. Tympanostomy tubes may decrease the occurrence of otitis media, and may improve hearing and quality of life. Risks of tympanostomy tube insertion may include otorrhea, blockage of the tube lumen, granulation tissue formation, premature tube extrusion, and tube displacement. In addition, there are risks associated with use of general anesthesia. In the longer term, tympanostomy tubes may lead to changes in the eardrum as well as possible long-term hearing loss. Other treatment options include antibiotics or other medications such as steroids or mucolytics, myringotomy (eardrum incision), adenoidectomy, or autoinflation of the Eustachian tube. In addition, because otitis media often resolves spontaneously, especially within the first six months, and may not cause long-term hearing or developmental problems, watchful waiting or delayed tube placement may be considered.

Policy Context

There are significant questions related to the use of tympanostomy tubes for the treatment of otitis media with effusion in children under the age of 16 regarding efficacy, safety, differential efficacy and safety in subgroups, and cost.

Objectives

To systematically review, critically appraise, analyze and synthesize research evidence evaluating the comparative efficacy, effectiveness, and safety of tympanostomy tubes in children for treating otitis media with or without effusion. The differential effectiveness and safety of tympanostomy tubes for subpopulations will be evaluated, as will the cost effectiveness.

Key Questions

In children aged 16 years and younger with either (a) chronic otitis media with effusion (OME) or (b) recurrent or persistent acute otitis media (AOM) (evaluated separately):

1. What is the evidence of the short- and long-term efficacy and effectiveness of tympanostomy tube insertion compared with alternative treatment options or watchful waiting? Under what circumstances are tympanostomy tubes indicated?
2. What is the evidence regarding short- and long-term harms and complications of placement of tympanostomy tubes compared with alternative treatment options or watchful waiting?
3. Is there evidence of differential efficacy, effectiveness, or safety of tympanostomy tubes compared with alternative treatment options or watchful waiting? Include consideration of age, sex, race, ethnicity, socioeconomic status, risk for developmental delay, underlying sensorineural hearing loss, repeated exposure to large groups of children, duration of otitis media, and recurrent acute versus chronic otitis media.
4. What is the evidence of cost-effectiveness of tympanostomy tubes compared with alternative treatment options?

Scope

Population: Children age 16 and younger with either: (a) Chronic otitis media with effusion (OME), or (b) Recurrent or persistent acute otitis media (AOM) (evaluated separately)

Intervention: Tympanostomy tube insertion

Comparator: Watchful waiting with or without delayed tympanostomy tube insertion, or Alternative disease-appropriate treatments, including:

- Antibiotic therapy (systemic or topical antibiotics)
- Other medications (mucolytics, oral or intranasal steroids)
- Myringotomy alone
- Adenoidectomy
- Autoinflation of the Eustachian tube
- Complementary and alternative medicine treatments

Outcomes:

- **Efficacy/effectiveness** (*indicates primary outcome)

OME:

Clinical outcomes: Hearing loss*, otorrhea*, recurrent AOM*, balance and coordination (vestibular function), recurrent OME, cholesteatoma

Functional and quality of life outcomes: Attention and behavioral outcomes*, academic achievement*, auditory processing*, speech and language development*, parent satisfaction with treatment/outcomes*, patient quality of life*, pain, parental quality of life, patient satisfaction with treatment/outcomes

Healthcare utilization: Surgery*, medication usage, number of office visits

AOM:

Clinical outcomes: Hearing loss*, recurrent AOM*, balance and coordination (vestibular function), otorrhea, recurrent OME, cholesteatoma

Functional and quality of life outcomes: Parent satisfaction with treatment/outcomes*, patient quality of life*, attention and behavioral outcomes, academic achievement, auditory processing, speech and language development, pain, parental quality of life, patient satisfaction with treatment/outcomes

Healthcare utilization: Surgery*, medication usage, number of office visits

- **Harms**

Treatment related harms, including: Harms of tympanostomy tubes (e.g., otorrhea, blockage of the tympanostomy tube lumen, premature tube extrusion, tube displacement into middle ear, tympanosclerosis/ myringosclerosis; or tympanic membrane atrophy, atelectasis, retraction pocket formation, or perforation), harms of general anesthesia (e.g., death, laryngospasm, bronchospasm), and harms of alternative treatment options (e.g., adverse effects of antibiotics, suppurative complications, etc.)

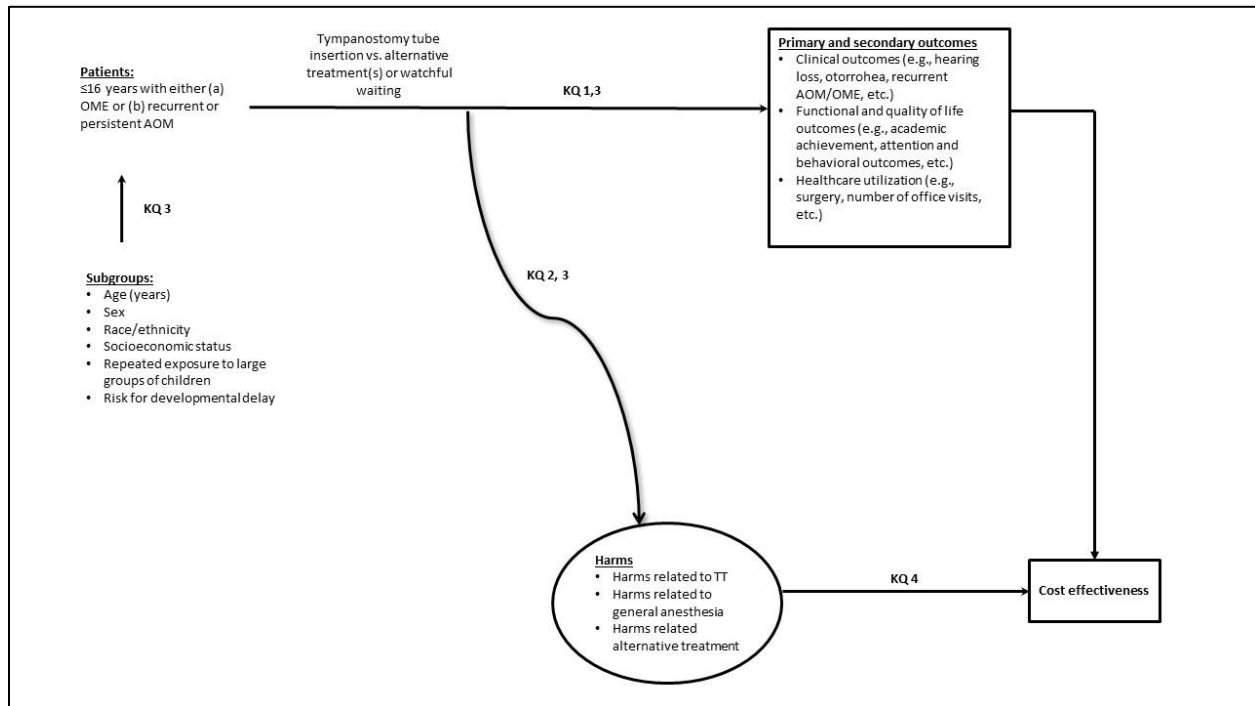
- **Cost-Effectiveness**

Cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER)) outcomes

Study Design

The focus will be on studies with the least potential for bias. For Key Questions 1-3, high-quality systematic reviews will be considered if available, randomized controlled trials (RCTs) and non-randomized comparative prospective studies will be sought, and nonrandomized comparative retrospective studies will be considered only if there are insufficient prospective studies. For Key Question 2, high-quality non-comparative studies (case series) designed specifically to evaluate harms/adverse events will be considered. For Key Question 3, studies which stratify on patient or other characteristics and formally evaluate statistical interaction (effect modification) will be sought. For Key Question 4, only full, formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies) will be considered.

Analytic Framework



For more information about this technology review and the Washington State Health Technology Assessment program, Visit www.hca.wa.gov/hta .