Washington State Health Care Authority

Agency Medical Director Comments

Tympanostomy Tubes in Children

November 20, 2015

Robert Mootz, DC
Associate Medical Director,
WA - Department of Labor & Industries

Agency Medical Director Concerns

- **Safety = Medium**
- **Efficacy = High**
- **Cost = Medium**

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Background

Used for ventilation and draining of fluid accumulation in the middle ear

Recurrent acute otitis media (AOM)

- 3 infections in 6 months or 4 in 1 year
- Usually painful

Chronic otitis media with persistent effusion (OME)

- 6 months unilateral; 3 months bilateral
- Usually minimally symptomatic

Other (eustachian tube dysfunction, barotrauma)

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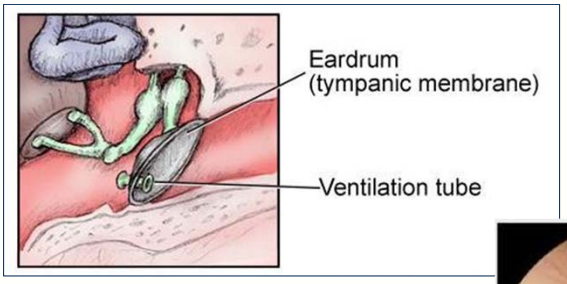

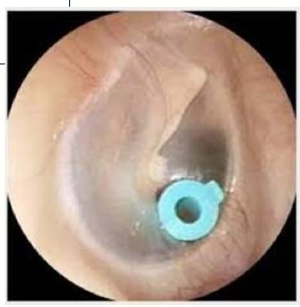

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Tympanostomy Tubes in Children

Otitis Media

1. Extremely common
   - Most children have at least 1 episode
   - 20% of OM in preschoolers becomes chronic
   - In US > $ 0.5 Billion in Medicaid costs
2. Usually self-limiting, however
   - Large proportion become recurrent or chronic
3. Etiology
   - Viral or bacterial
   - Eustachian tube dysfunction

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Tympanostomy Tubes in Children

Impacts

From OM

- Short term: pain, fever, sleep, eating
- Long term: hearing loss with resultant secondary language, learning, development concerns
- Impacts on QOL, missed school/work

From tube insertion

- General anesthesia risks (younger)
- Tubes frequently fall out, repeats

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Tympanostomy Tubes in Children

PEB/UMP Utilization

	Unique Members	Procs	Submitted	Allowed	Paid	Average Paid/ Proc
2011	164	172	$1,489,000	$837,000	$710,000	$4,131
2012	122	123	$1,224,000	$628,000	$540,000	$4,398
2013	144	147	$1,645,000	$801,000	$689,000	$4,688
2014	170	172	$1,643,000	$746,000	$635,000	$3,697

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Tympanostomy Tubes in Children

Medicaid Utilization

	Unique Mbrs FFS	FFS Procs	Paid FFS (Rounded)	Average FFS Paid/ Proc	Unique Members Managed	Managed Procs	Managed Care Paid Equivalent	Average Managed Paid/Proc Equivalent
2012	664	674	$1,174,000	*$1,743*	2,851	2,922	$4,722,000	$1,599
2013	531	545	$816,000	*$1,497*	3,123	3,212	$5,176,000	$1,595
2014	497	509	$724,000	*$1,424*	2,915	3,030	$4,892,000	$1,615

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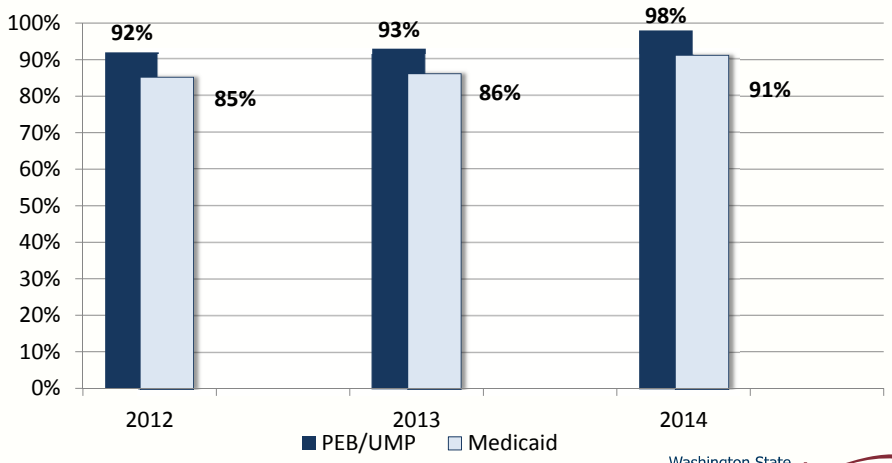
Tympanostomy Tubes in Children

Percent of Population with Bilateral Procedures, 2011-2014



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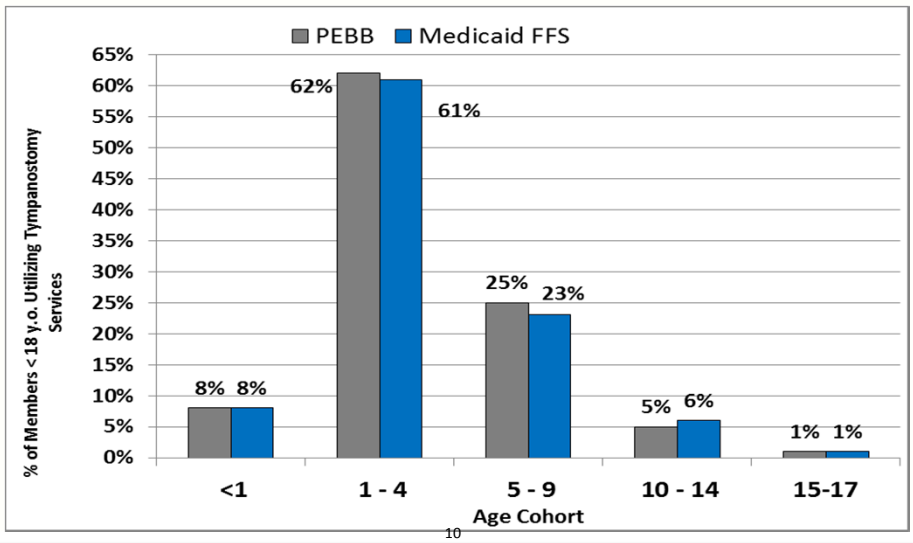
Members < 18 Years
Utilizing Tympanostomy Services: Age Cohort



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Current State Agency Policy

Medicaid – Covered (no conditions)

PEBB – Covered (no conditions)

Labor & Industries – n/a

Dept. of Corrections – n/a

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Is Tympanostomy Effective?

Hearing Levels (Audiometry)

- **Between 3 & 9 months follow-up:** 3 - 7 dB less hearing loss in ears with tubes vs. those without *(all patients had bilateral OME and hearing loss at baseline)*
- **6 – 12 months follow-up:** No differences

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Examples of Decibel Levels

10 dB	Normal breathing
20 dB	Rustling leaves, mosquito
30 dB	Whisper
40 dB	Stream, refrigerator humming
50-65 dB	Quiet office, normal conversation, laughter
70 dB	Vacuum cleaner, hair dryer
75-80 dB	Dishwasher, washing machine, traffic noise
85-90 dB	Diesel truck, motorcycle, lawnmower
100 dB	Train, garbage truck
110 dB	Jackhammer, power saw, symphony orchestra
110-125 dB	Stereo
110-140 dB	Rock concerts

Is Tympanostomy Effective?

Patient quality of life:

- One small RCT of obstructive sleep apnea patients with otitis media with persistent effusion (OME) reported greater improvement in disease-specific patient quality of life at 6 months, not sustained at 12 months.
- Otherwise no differences between groups in disease-specific patient quality of life at 6 or 12 months.
- A sub-analysis of one RCT comparing tube placement to no treatment for acute otitis media (AOM) found no differences between groups at 4 or 12 months.

Tympanostomy Tubes in Children

Is Tympanostomy Effective?

No differences in:

- Speech and language outcomes compared to watchful waiting for otitis media with persistent effusion (OME) at any time point evaluated.
- Incidence of complications from OME:
  - *Persistent perforation*
  - *Cholesteatoma*
  - *Persistent chronic otorrhea*

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Tympanostomy Tubes in Children

Agency Medical Director Concerns

1. Ear fluid of short duration is likely to resolve spontaneously
2. We may be placing more tubes than necessary
3. Is bilateral tube placement always necessary if only one ear is impacted? (may not matter – little cost difference and the anesthesia is already given)
4. General anesthesia has risks in young children
5. Concerns about long term risks to language development or learning disabilities may be unfounded
6. In children with comorbid conditions or speech delay, earlier tube placement may be appropriate
7. Short term benefits vs. risks should be made clear (shared decision-making opportunities)

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Agency Medical Director Recommendations

In otherwise healthy children with ***recurrent acute otitis media***:

Potentially consider coverage with conditions:

- **More than 3 episodes in 6 months, OR**
- **More than 4 episodes in 12 months**

Discussion: Guidelines from the American Academy of Pediatrics (2013); other society guidelines differ (e.g., only if effusion present at time of placement)

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Agency Medical Director Recommendations

In otherwise healthy children with ***otitis media with persistent effusion***:

Consider coverage with conditions:

- **At least 3 months chronic effusion[1] AND**
- **Demonstrated persistent hearing loss**
  (NICE recommends 25 – 30 db)

1 Follows recommendations from: National Institute for Health and Care Excellence (NICE) 2008, American Academy of Otolaryngology HNS, and Choosing Wisely

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Agency Medical Director Summary

Exclude from conditional coverage:

1. Special populations
   - e.g., Downs syndrome, cleft palate, and developmental delay
2. OM with complications
   - e.g., meningitis, facial nerve paralysis, coalescent mastoiditis, or brain abscess

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Questions?

More Information

www.hca.wa.gov/hta/Pages/Tympan_tubes.aspx

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Health Technology Assessment

Order of Scheduled Presentations:

Tympanostomy Tubes in Children

	Name
1	
2	
3	
4	
5	
6	

No requests to provide public comment on the technology review were received.

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Health Technology Assessment

Tympanostomy Tubes in Children

Clinical Expert

Carol J. MacArthur, MD

Professor, Otolaryngology, Head and Neck Surgery
Oregon Health and Science University

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.	✓	
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

13 Therapeutics

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 12/10/14 C. MacArthur

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

CURRICULUM VITAE
OREGON HEALTH & SCIENCE UNIVERSITY

NAME **Carol Jeanne MacArthur, M.D.** **October 24, 2014**

I. PRESENT POSITION AND ADDRESS

Academic Rank: **Professor**

Department/Division: **Otolaryngology, Head and Neck Surgery**

Professional Address: **OHSU**

E-Mail Address: **macarthc@ohsu.edu**

II. EDUCATION

Undergraduate and Graduate:

1979 B.A., Chemistry
Occidental College, LosAngeles, California

1984 M.D.
University of California, LosAngeles

Postgraduate:

Internship and Residencies:

1984-1985 Intern, General Surgery
University of California, Davis

1985-1986 Resident, General Surgery
University of California, Davis

1986-1990 Resident, Otolaryngology
University of California, Davis

Fellowship:

1990-1991 Fellow, Pediatric Otolaryngology
Boston Children's Hospital
Harvard Medical School

Certification:

1990	American Board of Otolaryngology

Licenses:

1986 - present	California
1990 - 1991	Massachusetts
2002 – present	Oregon

III. PROFESSIONAL EXPERIENCE

Academic:

1989-1990	Clinical Instructor, Department of Otolaryngology, University of California, Davis
1990-1991	Clinical Fellow, Otology and Laryngology (Pediatric Otolaryngology), Boston Children's Hospital, Harvard Medical School
1991-1996	Assistant Professor In-Residence, Department of Otolaryngology - Head and Neck Surgery, University of California, Irvine
1993-1996	Assistant Professor In-Residence, Department of Pediatrics University of California, Irvine
1996-2002	Assistant Clinical Professor, Department of Otolaryngology - Head and Neck Surgery, University of California, Irvine
2002 – 2007	Assistant Professor, Department of Otolaryngology – Head and Neck Surgery, Oregon Health and Sciences University
2007- 2014	Associate Professor, Department of Otolaryngology – Head and Neck Surgery, Oregon Health and Sciences University
2014-present	Professor, Department of Otolaryngology – Head and Neck Surgery, Oregon Health and Sciences University

IV. SCHOLARSHIP

Area(s) of Research/Scholarly Interest:

Inner Ear Impact of Chronic Middle ear Inflammation (mouse model)
Steroid Responsive Mechanisms in the Ear (mouse model)
Genetic Susceptibility to Otitis Media – candidate genes

Hemangiomas and Vascular Birthmarks
Pediatric Dysphagia
Otitis Media and Down Syndrome

Grants and Contracts:

Federal

2R44 DC 005882 NIH-NIDCD SBIR Phase II McCoy (PI) 1/05 - 12/06
Title: New Treatment for Inflammation in Middle Ear Infections
Goal: to determine anti-inflammation efficacy of novel peptide P13 in otitis media mouse model
Role: **Investigator** – 20% effort.

PA-04-126: Suppl. to 3 R01 DC005593-04S1 Trune (PI) 7/1/06-8/31/08
Title: Steroid Responsive Mechanisms in the Ear
Goal: Promote Reentry into Biomedical and Behavioral Research Careers", NIH-NIDCD
Role: **Principal Investigator of Supplement**– 50% effort.

2R44 DC 005882-04 NIH-NIDCD SBIR Phase IIB McCoy (PI) 8/1/07-7/31/11
Title: New Treatment for Inflammation in Middle Ear Infections
Goal: to determine anti-inflammation efficacy of novel peptide P13 in otitis media mouse model
Role: **Investigator** – 10% effort.

R01 DC009455-01, NIH-NIDCD Trune (PI) 04/09 – 04/14
Title: Inner Ear Impact of Chronic Middle Ear Inflammation
Goal: to evaluate inner ear gene expression during acute and chronic otitis media
Role: **Co-Investigator**: 40% effort.

Other Support

G1. Investigator Development Award, "Prospective Evaluation of Cleft-Related Velopharyngeal Insufficiency Comparing Accelerometric, Aerodynamic, and Perceptual Measures", American Academy of Facial Plastic and Reconstructive Surgery, PI Carol MacArthur, M.D., $15,000 7/1/93 – 7/1/94, 10% effort.

G2. Recipient $2000 Fellowship to attend the Advanced Clinical Research Conference, Deafness Research Foundation, July 30 – August 2, 2003.

G3. American Academy of Otolaryngology-sponsored multi-institutional research effort: "Laryngomalacia: Prospective Study of Treatment of Gastroesophageal Reflux on Outcomes". Co-PIs: Carol MacArthur, Joseph Kerschner, Dana Thompson, $10,000, 2007- 2009.

G4. CORE Grant ASPO: "Innate Immune Response Gene Polymorphisms in Otitis Media". Philip Zald (PI), Dennis Trune, Carol MacArthur. 2008-2009.

G5. National Organization for Hearing Research Foundation Award, "Innate immune response gene polymorphisms in otitis media", **PI Carol MacArthur**. 1/24/11 – 1/24/13.

G6. Oregon Center for Translational Research Institute (OCTRI) – Strategic Investment Grant. "Genetic Susceptibility to Chronic Otitis Media with Effusion – candidate genes."
PI: Carol MacArthur, 2013-2014
5% effort.

Pending Support
None

Publications/Creative Work:

Peer-reviewed
DeHaan FP, Delker GL, Covey WD, Bellomo AF, Brown JA, Ferrara DM, Haubrich RH, Lander EB, **MacArthur CJ**, Meinhold RW, Neddenriep D, Schubert DM, Stewart RG: Electrophilic aromatic substitution, 6: A kinetic study of the formylation of aromatics with 1, 1-dichloromethyl ether in nitromethane. *Journal of Organic Chemistry* 1984;49:3936.

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MacArthur CJ and Doyle KA. Sensorineural hearing loss in children. **Slide Lecture Series** for the Academy of Otolaryngology, Head and Neck Surgery, 2006.

MacArthur CJ, Hefeneider SH, McCoy SL and Trune DR. Evaluation of the mouse model for acute otitis media. Hearing Research 219:12-23, 2006.

MacArthur CJ, Hefeneider SH, Kempton JB, Trune DR. C3H/HeJ Mouse Model for spontaneous chronic otitis media. Triologic Thesis, Laryngoscope 116:1071-1079, 2006.

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Sie KCY, Starr JR, Bloom DC, Cunningham M, de Serres LM, Drake AF, Elluru R, Haddad J, Hartnick C, **MacArthur CJ,** Milczuk HA, Muntz HR, Perkins JA, Senders C, Smith ME, Tollefson T, Willging JP, Zdanski CJ. Multicenter interrater and intrarater reliability in the endoscopic evaluation of velopharyngeal insufficiency. Arch Otolaryngology Head Neck Surg 134(7):757-763, 2008.

Smith LK, Gubbels SP, **MacArthur CJ**, Milczuk HA. The effect of the palatoplasty method on the frequency of ear tube placement. Arch Otolaryngology Head Neck Surgery 134(10):1085-1089, 2008.

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Paulson LM, **MacArthur CJ**, Beaulieu KB, Brockman JH, Milczuk HA. Speech outcomes after tonsillectomy in patients with known velopharyngeal insufficiency. Int J Otolaryngol. 2012;2012:912767. Epub 2011 Nov 22. **M5**

Carroll SR, Zald PB, Soler ZM, Milczuk HA, Trune DR, **MacArthur CJ**. Innate immunity gene single nucleotide polymorphisms and otitis media. Int J Pediatr Otorhinolaryngol. 2012 Jul;76(7):976-9. doi: 10.1016/j.ijporl.2012.03.011. Epub 2012 Apr 9. **M6**

MacArthur CJ. Prenatal diagnosis of fetal cervicofacial anomalies. Curr Opin Otolaryngol Head Neck Surg. 2012 Dec;20(6):482-90. doi: 10.1097/MOO.0b013e3283582e21.

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Laryngoscope 2012 Dec;122(S4):S59-S60. doi: 10.1002/lary.23818.

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MacArthur CJ, Wilmot B, Wang Y, Schuller M, Lighthall J, Trune DR. Genetic Susceptibility to Chronic Otitis Media with Effusion: Candidate Genes. . Laryngoscope. 2013 Aug 8. doi: 10.1002/lary.24349. [Epub ahead of print] PMID:23929584. **M7**

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Lighthall JG, Kempton JB, Hausman F, **MacArthur CJ**, Trune DR. Control of Middle Ear Inflammatory and Ion Homeostasis Genes by Transtympanic Steroid Treatment. PLOS ONE (submitted). **M8**

Paulson, LM, Weaver TS, MacArthur CJ. Outcomes of tympanostomy tube placement in children with Down syndrome – a retrospective review. In print. **M9**

Gerecci D, Flatley E, Weissman JL, **MacArthur CJ.** Lipofibromatosis in the submental region of a pediatric patient: A case report. In preparation.

Non-peer-reviewed

MacArthur CJ, Richon J, Allen, RM: QRS Alterations with upright exercise. *Clinical Research* 1979;27(1):8A.

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MacArthur CJ, Recent advances in pediatric otolaryngology. American Academy of Pediatrics (Section IV, District IX), Orange County Pediatric Society, Fall 1992 Newsletter.

MacArthur CJ, Oregon Academy of Pediatrics Fall Newsletter 2003, "Use of Ototopical Drops for the Draining Ear".

MacArthur CJ, Letter to the editor: *Otolaryngology Head and Neck Surgery,"* Hemangiomas and Vascular Malformations: Terminology and Classification", 2003

Al-Mazrou K, **MacArthur C**, Hashash M, Richardson M. Tympanic Membrane Epidermal Inclusion Cysts. Reprinted from Proceedings of the 5th European Congress of Oto-Rhino-Laryngology Head and Neck Surgery, Rodos (Greece), September 11-16, 2004, p. 167-172.

MacArthur CJ. "Hemangioma and Vascular Birthmarks", Consult News, 12/01/04.

Trune DR, Hausman FA, Kempton JB, **MacArthur CJ.** Susceptibility of inner ear ion

homeostasis genes to chronic otitis media. **Extended Abstracts**, 10th International Symposium on Recent Advances in Otitis Media. August 2011.

Book Chapters

MacArthur CJ, Healy GB: Acquired voice disorders in the pediatric population. In Rubin JS, et al (eds.), Diagnosis and Treatment of Voice Disorders, Igaku-Shoin, New York, 1995, pp. 189-202.

MacArthur CJ: Vasoproliferative tumors in children. In Gates GA (ed), Current Therapy in Otolaryngology - Head and Neck Surgery, sixth edition, Mosby, St. Louis, 1998, pp. 496-500.

MacArthur CJ: Embryology and anatomy of the neck. In Wetmore R, et al (eds), Pediatric Otolaryngology: Principles and Practice Pathways, Thieme, New York, 2000, pp. 917-930.

MacArthur CJ, Smith RJH: Pediatric Head and Neck Malignancies. In Cummings CW, et al (eds), Otolaryngology Head and Neck Surgery, 4th edition, 2005.

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MacArthur CJ: Embryology and anatomy of the neck. In Wetmore R, et al (eds), Pediatric Otolaryngology: Principles and Practice Pathways, Thieme, second edition, New York, 2012, pp. 829-840.

MacArthur CJ and Lam DJ: "Evaluation of the Child with Rhinologic Disease". In Sataloff et al (eds), Comprehensive Textbook of Otolaryngology, 2013.

Reviews

MacArthur CJ: Review of Pediatric Laryngology and Bronchoesophagology, Holinger LD, et al (eds), Lippincott-Raven, Philadelphia, 1997; *Laryngoscope* 1998; 108:947-948.

Invited Lectures, Conference Presentations or Professorships:

International and National

January 2004 Moderator of Vascular Anomalies Panel at the Western Section of the Society for Pediatric Otolaryngology, Denver, CO.

May 2004 Al-Mazrou, K, **MacArthur C**, Richardson M. Partial Glossectomy in Children, American Society for Pediatric Otolaryngology (ASPO).

May 2004 Ghaheri B, Milczuk H, **MacArthur CJ** and Richardson MA. Comparison of Tonsillectomy Techniques and Effects on Post-operative Morbidity, ASPO.

May 2004 Moderator, Obstructive Sleep Apnea Section, ASPO 19th Annual Meeting, Podium presentations

February 2005 **MacArthur CJ** and Trune DR. Development of the C3H/HeJ Mouse Model for the Study of Spontaneous Chronic Otitis Media and Its Impact on the Inner Ear", Association for Research in Otolaryngology (ARO).

February 2005 Hefeneider S, Kurtz S, McCoy S, **MacArthur C**, Trune D. A new treatment strategy for otitis media with effusion, ARO.

May 2005 Bloom DC, Starr JR, Davis T, **MacArthur CJ**, Milczuk HA, Perkins JA, Willging JP, Sie KCY. Multicenter inter-rater and intra-rater reliability in the evaluation of velopharyngeal insufficiency. **Podium Presentation** ASPO.

May 2005 Grosz AH, Milczuk HA, **MacArthur CJ**, Brockman JH. Effects of tonsillectomy on speech in pediatric patients with velopharyngeal insufficiency. **Podium presentation**, ASPO.

May 2005 **Moderator**, Tonsils and Adenoids – Outcomes Section, ASPO 20th Annual Meeting, **Podium presentation.**

February 2006 Trune DR, Kempton B, **MacArthur CJ**. Prednisolone Improvement of Cochlear Function in Mice with Chronic Otitis Media, ARO.

May 2006 Smith LK, Gubbels SP, **MacArthur CJ**, Milczuk HA. Does the type of initial palatoplasty affect the frequency of ear tube placement in children with cleft palate? **Podium presentation**, ASPO.

February 2007 Trune DR, Kempton B, DeGagne J, Ghaheri B, Pillars D, **MacArthur C**J. Tissue Remodeling Cytokines in the Middle and Inner Ear During Acute and Chronic Otitis Media, ARO.

February 2007 **MacArthur CJ**, Kempton B, Pillars D, DeGagne J, Trune D. Bacteriology of Chronic Otitis Media in C3H/HeJ mice, ARO.

May 2007 **MacArthur CJ, Wang TD.** Early Surgical Intervention in Hemangiomas of Infancy, ASPO, San Diego, CA.

May 2007 **MacArthur CJ,** Monroe M. Pediatric MRSA Infections in the Head and Neck, ASPO, San Diego, CA.

June 2007 **MacArthur CJ,** Kempton B, Trune D. Impact of Various Therapeutic Steroids on C3H/HeJ Mouse Chronic Otitis Media , 9th International Symposium on Recent Advances in Otitis Media, St. Pete Beach, Florida, June 3-7, 2007.

June 2007 **MacArthur CJ,** Kempton B, Trune D. Glucocorticoid and Mineralocorticoid Suppression of Acute Otitis Media in the Mouse, 9th International Symposium on Recent Advances in Otitis Media, St. Pete Beach, Florida, June 3-7, 2007.

June 2007 McCoy SL, Trune DR, **MacArthur CJ**, Hefeneider SH. A novel peptide inhibitor of middle ear inflammation in experimental otitis media, 9th International Symposium on Recent Advances in Otitis Media, St. Pete Beach, Florida, June 3-7, 2007.

June 2007 Hefeneider SH, Trune DR, **MacArthur CJ**, McCoy SL. Characterization of a novel peptide that inhibits TLR-signaling and limits bacterial-induced inflammation. 8th World Congress on Inflammation, Copenhagen, June 16-22, 2007.

February 2008 **MacArthur CJ**, Kempton B, DeGagne JM, Trune DR. Glucocorticoid and mineralocorticoid suppression of acute and chronic otitis media in mice. ARO, Phoenix, Feb 16-21, 2008.

February 2008 Trune DR, Pang J, Kempton JB, **MacArthur CJ**, Pillers DM. Correlation of middle and inner ear cytokine gene expression in mouse otitis media models suggests inflammatory factors contribute to sensorineural hearing loss. ARO, Phoenix, Feb 16-21, 2008.

May 2008 Dennis R Trune, De-Ann M Pillers, J B Kempton, **Carol J MacArthur**. Steroid Treatments Protect the Mouse Inner Ear During Chronic Otitis Media. Pediatric Academic Societies & Asian Society for Pediatric Research Joint Meeting, Hawaii, May 2 – 6, 2008.

May 2008 De-Ann M Pillers, Jiaqing Pang, J B Kempton, **Carol J MacArthur**, MD, Dennis R Trune. Inner Ear Inflammatory Gene Expression During Acute and Chronic Otitis Media in the Mouse. Pediatric Academic Societies & Asian Society for Pediatric research Joint Meeting, Hawaii, May 2 – 6, 2008.

May 2008 Slough C, **MacArthur CJ.** Mediastinal nontuberculous mycobacteria as a cause of pediatric airway obstruction. ASPO, May 2-4, 2008, Orlando, FL.

May 2008 Angelos P, **MacArthur CM.** Pediatric plastic bronchitis: a case report and literature review. ASPO, May 2-4, 2008, Orlando, FL.

May 2009 **MacArthur CJ**. ASPO Vascular Anomalies Task Force Seminar on Venous Malformations: Etiology, Evaluation, Treatment. Organized 4 hour seminar at the ASPO National Meeting.

May 2009 Slough C, **MacArthur CJ**, Use of preoperative sclerotherapy in the surgical management of venous malformation in the head and neck. ASPO, May 22 – 24, 2009, Seattle, WA

May 2009 Pilkington J, **MacArthur CJ.** Treatment patterns for pediatric nontuberculous mycobacterial (NTM) infections. ASPO, May 22 – 24, 2009, Seattle, WA

May 2009 **MacArthur CJ.** Surgical excision of venous malformations with pre-op sclerotherapy. Vascular Anomalies Task Force Meeting, ASPO, May 21, 2009.

February 2010 **MacArthur C**, Hausman F, Kempton B, Trune D. Impact of middle ear inflammation on ion homeostasis gene expression. ARO, Anaheim. Feb 6-10, 2010.

February 2010 Trune D, Kempton B, Hausman F, Larrain B, **MacArthur C**. Inner Ear Inflammatory Cytokines during Acute Otitis Media in the Mouse. ARO, Anaheim. Feb 6-10, 2010.

February 2010 Hausman F, Kempton B, **MacArthur C**, Trune D. Enhanced Inner Ear Ion Homeostasis Gene Expression with Intratympanic Steroid Delivery. ARO, Anaheim. Feb 6-10, 2010.

February 2010 Larrain B, Hausman F, Kempton B, **MacArthur C**, Trune D. Measurement of Mouse Middle Ear Inflammatory Cytokines with Multiplex ELISA Assays. ARO, Anaheim. Feb 6-10, 2010.

April 2010 Mann J, Krol A, Siegel D, Milczuk HA, Recht M, Richardson M, Powers M, **MacArthur CJ**. Pneumocystis jirovecii pneumonia in two infants treated with oral prednisone for hemangiomas. International Society for the Study of Vascular Anomalies, Apr 21-24, 2010, Brussels, Belgium

April 2010 Mann L, Siegel D, Krol A, **MacArthur CJ**. Diffuse lymphangiectasia in a 14-year old girl with congenital lymphedema. International Society for the Study of Vascular Anomalies, Apr 21-24, 2010, Brussels, Belgium

May 2010 Carroll SR, Zald PB, Soler ZM, Trune DR, **MacArthur CJ**. Innate Immunity Gene Single Nucleotide Polymorphisms and Otitis Media. ASPO **Podium Presentation**, April 30 – May 2, 2010.

February 2011 **MacArthur CJ**, Hausman F, Kempton JB, Trune DR. Impact of murine chronic middle ear inflammation on ion homeostasis gene expression. ARO, Baltimore. Feb 19-23, 2011.

April 2011 Clayburgh D, Milczuk H, Gorsek S, Sinden N, Bowman K, **MacArthur CJ.** Tonsillectomy Is an Effective Treatment for Pediatric Patients with Dysphagia and Tonsillar Hypertrophy, ASPO **Podium Presentation**, April 30, 2011.
Received second place Charles Ferguson Clinical Science Award from ASPO.

June 2011 Trune DR, Hausman F**,** Kempton B**, MacArthur CJ**. Susceptibility of inner ear ion homeostasis genes to chronic otitis media. 10th International Symposium on Recent Advances in Otitis Media. June 6 – 9, 2011

June 2011 Hefeneider S, McCoy S, **MacArthur CJ,** Trune DR, A Novel Treatment for

Middle Ear Fluid and Associated Hearing Impairment in Otitis Media. 10th International Symposium on Recent Advances in Otitis Media. June 6 – 9, 2011.

June 2011 **MacArthur CJ,** Hausman F, Kempton JB, Trune DR, Middle ear cytokine gene production in response to bacterial and steroid challenges. 10th International Symposium on Recent Advances in Otitis Media. **Podium Presentation**. June 6, 2011

January 2012 **Invited Panel member**, "Hemangiomas and vascular malformations update", Combined Triologic Section meeting, Miami Beach, January 26, 2012.

February 2012 **MacArthur CJ,** Hausman F, Kempton JB, Trune DR. Effect of vasopressin on aquaporin and inflammatory gene expression in otitis media. ARO, San Diego, CA Feb 25-29, 2012.

February 2012 Trune DR, Delaney K, Hausman F, Kempton B, **MacArthur CJ,** Choi D. Transtympanically Delivered Steroids Impact Thousands of Inner Ear Genes over Conventional Systemic Delivery. ARO, San Diego, CA Feb 29, 2012. Podium Presentation.

February 2012 Lighthall J, Kempton B, Hausman F, **MacArthur CJ**, Trune DR. Control of middle ear inflammatory and ion homeostasis genes by trans-tympanic steroid treatment after inoculation with heat-killed Haemophilus influenza. ARO, San Diego, CA Feb 25-29, 2012.

February 2012 Hausman F, Wilson T, Kempton B, **MacArthur CJ,** Trune DR. Variability in RT-PCR housekeeping gene quantification is reduced by improved RNA extraction. ARO, San Diego, CA Feb 25-29, 2012.

February 2012 Kempton B, Hausman F, Larrain B, **MacArthur CJ**, Trune DR. Inner ear inflammation ipsilateral to clear middle ears suggests sensorineural hearing loss in chronic otitis media may also result from circulating immune factors. ARO, San Diego, CA Feb 25-29, 2012.

February 2012 Larrain B, Hausman F, Kempton B, **MacArthur CJ**, Trune DR. Serum inflammatory cytokines potentially underlie hearing loss in immune disorders. ARO, San Diego, CA Feb 25-29, 2012.

April 2012 **Mini-Seminar Course Director,** American Society of Pediatric Otolaryngology (ASPO) meeting, "Update on Management of infantile hemangiomas with debate on treatment protocols for propranolol use", April 20-22, 2012.

February 2013 MacArthur CJ, Kempton B, Hausman F, Trune DR. Otitis Media Impacts Hundreds of Middle and Inner Ear Genes.RO, Baltimore, MD Feb 17, 2013.

April 2013 Wang Y, Wilmot B, Schuller M, **MacArthur CJ.** Genetic Susceptibility to Chronic Otitis Media with Effusion: Candidate Genes. Triologic Meeting **Podium presentation.** April 11-2, 2013.

April 2013 Liao S, Martin W, **MacArthur CJ**, Lubianski T, Coopersmith N, Wood A-M, Durham H, Mace J, Steyger P. "Factors Affecting Decibel Levels in an Open-Ward Neonatal Intensive Care Unit (NICU): A Prospective Study in Premature Infants". ASPO **Podium presentation**. April 26-27, 2013.

June 2013 **MacArthur CJ,** Wang YL, Schuller M, Lighthall J, Trune DR. Genetic susceptibility to chronic otitis media with effusion (COME): candidate gene SNPs. **Podium presentation,** 7th Extraordinary International Symposium on Recent Advances in Otitis Media June 13-16 2013, Stockholm, Sweden.

June 2013 **MacArthur CJ**, Hausman F, Kempton JB, Trune DR. Ginsenoside Rg1, a glucocorticoid receptor agonist, has anti-inflammatory effects in murine otitis media. 7th Extraordinary International Symposium on Recent Advances in Otitis Media June 13-16 2013, in Stockholm, Sweden.

June 2013 Paulson L, Weaver T, **MacArthur CJ**. Otologic outcomes in Down syndrome children receiving tympanostomy tubes for chronic or recurrent acute otitis media. 7th Extraordinary International Symposium on Recent Advances in Otitis Media June 13-16 2013, in Stockholm, Sweden.

June 2013 Trune DR, Lighthall J, Kempton B, Hausman F, **MacArthur CJ.** Mineralocorticoids clear middle ear inflammation. 7th Extraordinary International Symposium on Recent Advances in Otitis Media June 13-16 2013, in Stockholm, Sweden.

June 2013 Hefeneider S, **MacArthur CJ,** Trune DR, McCoy S. Inhibition of Toll-like receptor signaling as a treatment for middle ear fluid and hearing impairment in Otitis media with effusion. 7th Extraordinary International Symposium on Recent Advances in Otitis Media June 13-16 2013, in Stockholm, Sweden.

February 2014 Trune DR, Hausman F, Kempton B, **MacArthur CJ.** Reduced Expression of Critical Inner Ear Genes with Aging. ARO, San Diego, CA Feb 23, 2014.

February 2014 Kempton JB, Hausman F, Wilson K, **MacArthur CJ**, Trune DR. Improved Inner Ear RNA Extraction and Quantification. ARO, San Diego, CA Feb 23, 2014.

February 2014 **MacArthur CJ**, Kempton JB, Hausman F, Choi, D, Trune DR. Correlation of Affymetrix and RT-PCR for assessment of treatment impact in middle and inner ear genes. ARO, San Diego, CA Feb 23, 2014.

February 2014 **MacArthur CJ**, Kempton JB, Hausman F, Trune DR. Ginsenoside (Rg1) has anti-inflammatory properties in the inflamed murine middle ear. ARO, San Diego,

CA Feb 23, 2014.

April 2014 Yarbrough K, Krol A, Mann J, Leitenberger S, **MacArthur CJ.** Is Routine ECG Necessary Prior to Initiation of Propranolol for Treatment of Infantile Hemangiomas? **Podium Presentation.** ISSVA, Melbourne, Australia, April 3, 2014.

April 2014 Nesbit G, **MacArthur CJ,** Krol A**.** MRI Differentiation of Venous and Lymphatic Malformations of the Head and Neck: the Hematocrit versus Debris Level Sign. ISSVA, Melbourne, Australia, April 4, 2014.

May 2014 Quintanilla-Dieck L, Weaver T, **MacArthur CJ.** Efficacy of injection laryngoplasty for pediatric patients with dysphagia and type 1 laryngeal cleft. ASPO May 16-18, 2014, LasVegas, NV. **Honoraria Third Place Award for best Clinical Poster.**

May 2014 Hamilton N, Azarow K, **MacArthur CJ**, Hendrickson M. Novel Technique for Removal of a Chronically Retained Esophageal Foreign Body. Pacific Association of Pediatric Surgeons. May 24-29, 2014

May 2015 Liao S, **MacArthur CJ**, et al. Effect of decibel levels and gentamicin exposure on hearing outcomes in premature infants in the neonatal intensive care unit (NICU). **Podium presentation** ASPO April 24-26, 2015/

Regional and Local (Since October 2002)

10/30/02 **Speaker**, OHSU Pediatric Hematology/Oncology Tumor Board, "Pediatric Head and Neck Rhabdomyosarcoma"

02/11/03 **Speaker**, "Pediatric Otolaryngologic Emergencies", 34th OHSU Annual Family Practice Review, Marriot Hotel, Portland, Oregon, February 10 – 14, 2003.

11/7/03 **Panelist** at the Oregon Academy of Otolaryngology Meeting "Vascular Anomalies"

12/04/03 **Speaker**, OHSU Pediatric Grand Rounds – "Otitis Media Update"

1/05/04 **Speaker**, OHSU Otolaryngology Grand Rounds, "Otitis Media Update"

02/3/04 **Speaker**, 35th OHSU Annual Family Medicine Review, "Pediatric Otolaryngology Emergencies"

10/9/04 Oregon Hearing Research Center Hearing Fair 2004, "Sensorineural Hearing Loss in Children"

12/7/04 **Grand Rounds Speaker** (Salem Hospital Pediatric Grand Rounds) – "Sensorineural Hearing Loss in Children"

01/3/05 **Speaker**, OHSU Department of Otolaryngology Grand Rounds, "Sensorineural Hearing Loss Evaluation and Management in Children"

02/17/05 **Invited Speaker**, 36th Annual OHSU Family Medicine Review, "Pediatric ENT Emergencies"

03/19/05 **Speaker**, Grand Rounds, Vascular Surgery Department at OHSU, "Hemangiomas and Vascular Birthmarks"

09/19/05 **Speaker**, OHSU Department of Otolaryngology Grand Rounds, "C3H/HeJ Mouse Model for Spontaneous Chronic Otitis Media",

11/11/05 **Speaker**, Oregon Academy of Otolaryngology Fall Meeting, "C3H/HeJ Mouse Model for Otitis Media"

02/16/06 **Invited Speaker**, 37th Annual OHSU Family Medicine Review, "Pediatric ENT Emergencies"

02/27/06 **Invited Speaker**, Department of Pediatrics Grand Rounds, Peace Health Hospital, Salem, OR. "Sensorineural Hearing Loss in Children – Evaluation and Rehabilitation"

12/04/06 **Speaker**, OHSU Department of Otolaryngology Grand Rounds, "Early Excision of Hemangiomas of Infancy"

01/15/07 **Podium Presentation,** Northwest and Oregon Academies of Otolaryngology Annual Winter Conference, "Early Excision of Hemangiomas of Infancy".

06/02/07 **Invited Speaker,** CF Parent Education Day, OHSU, Doernbecher Children's Hospital, Portland, OR, "Sinus Problems in Cystic Fibrosis Patients"

12/17/07 **Speaker**, OHSU Department of Otolaryngology Grand Rounds, "Excision vs. Sclerotherapy for Treatment of Venous Malformations of the Head and Neck"

11/03/08 McCoy, S., Trune, D., **MacArthur, C.,** Gold J., Hefeneider, S. A novel therapeutic peptide for treatment of inflammatory disease. "Innovation Showcase: Spotlight on Infectious Disease", OHSU, Portland, Nov 3, 2008.

03/06/09 **Invited Speaker and Panel Member**, 4th Annual Pediatric Review & Update, "Otitis Media Update".

04/27/09 **Speaker**, OHSU Department of Otolaryngology Grand Rounds, "Steroid Control of Otitis Media in the Mouse Model"

11/14/09 **Panelist**, Oregon Academy of Otolaryngology-Head and Neck Surgery Meeting,

November 6, 2009, "Coblation vs. Electrocautery Tonsillectomy"

04/26/10 **Speaker**, OHSU Department of Otolaryngology Grand Rounds, "Part I: Murine middle ear inflammation and ion homeostasis gene expression; Part II: Propranolol use for infantile hemangiomas"

10/25/10 **Speaker**, Maternal Fetal Medicine Conference, OHSU, "EXIT Procedure for Giant Fetal Neck Masses"

02/24-26/12 **Meeting Scientific Director; Panel Moderator**, Oregon Academy of Otolaryngology, "Pediatric Hemangioma and Vascular Malformations Management".

02/2012 **Speaker,** OHSU Department of Otolaryngology Grand Rounds, **"**Current Management of Hemangiomas and Vascular Anomalies".

05/14/2012 **Invited Speaker,** Department of Pediatrics Grand Rounds, Peace Health Hospital, Eugene, OR. "Update on Pediatric Hemangiomas and Vascular Anomalies – What's new".

11/1/2013 **Invited Speaker,** Oregon Academy of Otolaryngology Meeting, Portland, OR; "Post Tonsillectomy Pain Control Update: Use of narcotics in children"

3/10/14 **Invited Speaker**, OHSU Department of Otolaryngology Grand Rounds, "Professionalism. What does it mean and what does it mean for us as surgeons.?"

5/31/14 **Invited Keynote Speaker,** "Management of the Child with Sinusitis and Nasal Polyps", Pediatric Ear, Nose and Throat Disorders: What the Primary Care Clinician should know today, CHOC Children's Hospital, Orange, California.

V. SERVICE

Membership in Professional Societies:

1983-2005 Member, American Medical Association

1983-2002 Member, California Medical Association

1986-present Member, American Academy of Otolaryngology - Head and Neck Surgery

1987-1996 Member, American Academy of Facial Plastic and Reconstructive Surgery

1989-1997 Member, American Cleft Palate-Craniofacial Association

1990-present Member, Society for Ear, Nose, and Throat Advances in Children

1990-present Fellow, American Academy of Otolaryngology - Head and Neck Surgery

1991-1995	Member, Women Faculty Steering Committee, University of California, Irvine
1991-present	Fellow, American College of Surgeons
1992-1995	Member, Association of Women Surgeons
1992-1997	Member, Orange County Society of Otolaryngology - Head and Neck Surgery
1992-2002	Member, Orange County Medical Association
1992-present	Member, American Academy of Pediatrics, Otolaryngology Section
1995-present	Member, American Society of Pediatric Otolaryngology
2002-present	Member, Oregon Academy of Otolaryngology, Head & Neck Surgery
2005-present	Elected to the prestigious Triologic Society. Election to this society is by nomination only, with subsequent submission of a thesis of original research with peer review.
2011-2012	President, Oregon Academy of Otolaryngology, Head & Neck Surgery
2013-present	Member, Society of University Otolaryngologists

Granting Agency Review Work:

03/21/2009	CORE (Centralized Otolaryngology Research) grant reviewer, Dallas, TX. ASPO Research Committee representative.
2010, 2011, 2013	Deafness Research Foundation (DRF)
2012	Medical Research Council (MRC). MRC/Astra Zeneca Mechanisms of Disease, Molecular & Cellular Medicine Board, Genetics/Genomics, June 2012
2013	Hearing Health Foundation (HHF – Formerly DRF)
2013	Action on Hearing Loss (Formerly The Royal National Institute for Deaf People)

Editorial Review Activities:

2004-present	Otolaryngology Head and Neck Surgery I have performed 35 reviews for *Otolaryngology Head and Neck Surgery* from 2007 to the present
2006-2008	Western Section Triologic Society, Resident Research Awards Selection Committee

2008 – 2011 Editorial Board, Otolaryngology Head and Neck Surgery

2004-present Head and Neck
I have reviewed 10 manuscripts from 2004-present

2006-present The Laryngoscope I have performed 20 reviews for *The Laryngoscope* from 2009 to the present

2007 – present Archives of Otolaryngology, Head and Neck Surgery I have reviewed 7 manuscripts for *Archives of Otolaryngology, Head and Neck Surgery* from 2007 - present

2009 – present International Journal of Pediatric Otorhinolaryngology. I have completed 14 reviews for the *International Journal of Pediatric Otorhinolaryngology* from 2007 to the present

Ad Hoc Review Activities:

2012 - present American Journal of Pathology
I have reviewed 1 manuscript for the *American Journal of Pathology* from 2012 - present

2012 - present PLOS Journal
I have reviewed 2 manuscripts for *PLOS journal* from 2012-present

2013 – present BMC Medical Genetics
I have reviewed 1 manuscript for *BMC Medical Genetics* from 2013-present

Committees:

International/National

1998-2001 Member, Audit Committee, American Society of Pediatric Otolaryngology

1995-present Member, Recurrent Respiratory Papillomas Task Force, American Society
of Pediatric Otolaryngology

2003 - 2005 Member, Program Committee, American Society of Pediatric
Otolaryngology

2003-present Member, Task Force, Vascular Anomalies, American Society of Pediatric Otolaryngology

2003 – present Member, Velopharyngeal Insufficiency Study Group, American Society of Pediatric Otolaryngology

2003-present Member, Task Force, Vascular Anomalies, American Society of Pediatric Otolaryngology

2005-2006 Member, Ad Hoc Research Priorities Committee, American Society of Pediatric Otolaryngology

2007-2009 Member, Research Committee, American Society of Pediatric Otolaryngology

2009 – present CORE Study Section Member (Centralized Otolaryngology Research) for the Academy of Otolaryngology Head & Neck Surgery

2010 - 2011 Alternate Guest Examiner American Board of Otolaryngology

2011 - present Guest Examiner American Board of Otolaryngology

2012 – 2015 Member, Long Range/Strategic Planning Committee, American Society of Pediatric Otolaryngology

2013 - 2014 Member Working Group, Pediatric Otolaryngology Milestone Project, jointly sponsored by the American Board of Otolaryngology and ACGME

Institutional

1980-1984 Member, Medical School Admissions Committee
University of California, Los Angeles

1988-1990 Member, Resident Medical Staff Committee
University of California, Davis Medical School

1992-1995 Member, Medical School Admissions Committee
University of California, Irvine

1992-2002 Member, Cleft/Craniofacial Panel
Children's Hospital Orange County

1992-1996 Physician Liaison, Quality Resource Management
University of California, Irvine Medical Center

1992-1996 Alternate Member, Human Subjects Review Committee
University of California, Irvine, Medical Center

1993-1996 Member, Operating Room Committee
University of California, Irvine Medical Center

1995-2000 Member, Credentials Committee, Children's Hospital of Orange County

1995-1997	Member, Medical Executive Committee, Children's Hospital of Orange County
2002-present	Founder and Co-Director Hemangioma and Vascular Birthmarks Clinic, Doernbecher Children's Hospital, Oregon Health & Science University
2003-present	Member, Craniofacial Disorders Team, Doernbecher Children's Hospital, Oregon Health & Science University
2003-present	Member, Velopharyngeal Insufficiency Team, Doernbecher Children's Hospital, Oregon Health & Science University
2003-present	Member, Pediatric Sleep Disorders Team, Doernbecher Children's Hospital, Oregon Health & Science University
2009 – 2016	School of Medicine Faculty Council Elected member, unit 6.
2012 – present	Member and Otolaryngology Department representative, Maternal Fetal Medicine team, Doernbecher Children's Hospital, Oregon Health & Science University
2012-present	OHSU FPP E-Visit Workgroup
2012 – present	Search Committee, Chief Pediatric Hospitalist
2012- present	Committee on Committees Member, Unit 5, elected position
2013 - present	FPP Quality Incentives Committee
2013 – 2016	School of Medicine Faculty Council Elected member, unit 6.
2014-2016	Committee on Committee Co-Chair
2014 – present	Safe Opioid Use Oversight Committee Member
2014 – present	Committee on Professionalism, member
2014 – 2015	College of Medicine Portfolio Coach (0.1 FTE position)

Departmental

1989-1990	Member, Cleft Lip/Palate, Craniofacial Anomalies Panel, University of California, Davis

1990-1991	Member, Cleft Lip/Palate, Craniofacial Anomalies Panel Harvard Medical School, Children's Hospital, Boston
1991-2002	Member, Cleft/Lip/Palate, Craniofacial Anomalies Panel, Children's Hospital, Orange County
1991-1993	Chair, Committee for Medical Student Education University of California, Irvine
1992-1994	Co-Director, Southern California Otolaryngology Basic Science Symposium, University of California, Irvine
1993-1995	Director, Residency Training Program, Department of Otolaryngology, University of California, Irvine
2004-2005	Co-Director Colloquia/Continuity Curriculum Series (Otolaryngology Section), Third Year OHSU Medical Students
2005-2010	Director Colloquia/Continuity Curriculum Series (Otolaryngology Section), Third Year OHSU Medical Students
2010 – present	Director, 3rd year Medical Student Rotation with Otolaryngology Head & Neck Surgery Department, OTOL 709C
2007 – present	Member, Promotion and Tenure Committee
2012 – present	Clinical Operations Group

Community Service:

-Habitat for Humanity, occasional volunteer
-2009-2013: Lakeridge High School Concessions stand volunteer, 25 hours/year
-2010-2011: Lakeridge High School Track Team volunteer, refresh track and athletic stadium, 3 hrs/year.

Clinical Responsibilities:

Pediatric Otolaryngology Clinic: Three sessions per week seeing pediatric otolaryngology patients at DCH, and, at Bethany sites (12 hours).

Monthly multidisciplinary Hemangioma and Vascular Birthmarks clinic (4 hours monthly with additional 8 hours prep time and data entry). Maintain database of all clinic patients seen through this multidisciplinary clinic. Screen all patient referrals for this clinic.

Operating Room: Two sessions per week (14-20 hours).

On call one week every 4 weeks for Pediatric Otolaryngology division (all pediatric otolaryngology emergency in-house consultations, surgeries)

Craniofacial Disorders Team Member, seeing 1 velopharyngeal insufficiency (VPI) patient per week coordinated with VPI speech pathologist

Pediatric Sleep Disorders Team Member, seeing approximately 20 patients per month

Active collaboration with CDRC Feeding Clinic for care of their dysphagia patients.

Active collaboration with Cystic Fibrosis (CF) Clinic for care of the CF patient with sinonasal polyposis and chronic rhinosinusitis.

VI. TEACHING (OHSU Educator's Portfolio):

Overview of your Role as an Educator:

National:

I am involved in teaching on a national level in the following ways:

I. Meeting Presentations (See "Invited Lectures" and "Educational Conference Presentations")

II. Task Force Presentations and Participation (ASPO Vascular Anomalies, Research Priorities and Respiratory Papillomas). Via these Task Forces within our Pediatric Otolaryngology Society (ASPO), we set priorities for research and disseminate information.

III. Publication of Slide Lecture Series on "Sensorineural Hearing Loss in Children" for the Academy of Otolaryngology Head and Neck Surgery (2006). This comprehensive didactic series is an up-to-date lengthy 84-slide lecture complete with annotations and references. This slide series was the result of a year-long effort. Extensive review of the current literature on evaluation and management of sensorineural hearing loss in children was carried out and 84 educational slides were created in Power Point. Each slide required its own reference list and an explanatory paragraph. These presentations are by invitation only and are peer-reviewed. The lecture series are of great educational value to the Academy of Otolaryngology, Head & Neck Surgery.

Local/Regional:

At OHSU, I teach in four areas: in the clinic, in the operating room, in formal lectures and by mentoring students.

Clinic Setting: In the pediatric otolaryngology clinic, I teach the otolaryngology resident (four hours weekly) and a pediatric resident (eight hours monthly) as we see patients together.

Sometimes an informal lecture ensues, sometimes we learn by the patient situation. I often use this time with the pediatric resident to teach how to properly examine the ear. I also teach fourth year medical students (eight hours monthly) in clinic. This serves as an opportunity to expose medical students to our specialty.

A special teaching interest of mine is the teaching involved during the Hemangioma and Vascular Anomalies Clinic. This multispecialty clinic was established by me and Dr. Alfons Krol to improve the care of patients with complex vascular anomalies. I spend four hours a month teaching in the setting of this clinic. During each clinic, I teach directly to the residents in attendance (pediatric, dermatology, radiology and otolaryngology). The teaching effort involved in this clinic will increase the attendant's knowledge of types of vascular lesions and management of such lesions.

Operating Room: In the operating room, I teach the otolaryngology resident in a hands-on manner, one-on-one, to perform pediatric otolaryngology procedures, eight hours a week. As well, we often have a pediatric resident, anesthesia resident and nursing student who participate in this teaching opportunity as part of their education.

Formal Lectures: I give regular formal lectures to the pediatric residents (4-5 per year), family medicine residents (1 per year), tumor board (1 per year), Speech and Audiology Department (1 per year), Grand Rounds (Otolaryngology, Pediatrics – 1 each per year). I give regular lectures to the otolaryngology residents at their Quiz sessions (3 per year).

Mentoring: I have also mentored both medical students and residents (numerous) and college students in the clinic, operating room and research lab (see Educator's Portfolio for details). I teach Head and Neck Anatomy each year in the Gross Anatomy Lab to the first year medical students (3 hours per year).

Scholarship of Teaching:

Curriculum Development

MacArthur CJ: Otolaryngology - Head and Neck Surgery Syllabus, 1992, for University of California, Irvine, Medical School medical students.

Development of Hemangioma and Vascular Birthmarks Multispecialty Clinic 2003.

Development Colloquia/Continuity Curriculum Series, (Otolaryngology Section), Third Year OHSU Medical Students 2005.

Development of Airway Hemangioma Database for ASPO Vascular Anomalies Task Force Members (2003 – present).

Development of Protocol for Referral of Cystic Fibrosis Patients for Sinus Surgery 03/02/04.

Development and maintenance of Database for Hemangioma and Vascular Birthmarks Clinic – 2003-present. File Maker Pro 2003-2013. RedCap 2013-present.

Educational Publications

MacArthur CJ and Doyle KA. Sensorineural hearing loss in children. **Slide Lecture Series** for the Academy of Otolaryngology, Head and Neck Surgery, 2006.

MacArthur CJ: Recent advances in pediatric otolaryngology. American Academy of Pediatrics (Section IV, District IX), Orange County Pediatric Society, Fall 1992 Newsletter.

MacArthur CJ, Oregon Academy of Pediatrics Fall Newsletter 2003, "Use of Ototopical Drops for the Draining Ear".

Creation OHSU Pediatric Otolaryngology Division Webpage with links to medically informative sites for patients and physicians, 2003.

Update and Revision of Otolaryngology site on the OHSU Doernbecher.com website (Child Health A-Z). 2005.

Al-Mazrou K, **MacArthur C**J, Hashash M, Richardson M. Tympanic Membrane Epidermal Inclusion Cysts. Reprinted from Proceedings of the 5th European Congress of Oto-Rhino-Laryngology Head and Neck Surgery, Rodos (Greece), September 11-16, 2004, p. 167-172.

MacArthur CJ. "Hemangioma and Vascular Birthmarks", Consult News, 12/01/04.

Educational Conference Presentations (preparation 5 hours for each new lecture;1 hour for each repeat lecture, updates to information)

12/03/02	OHSU Otolaryngology Resident Quiz Session, "Pediatric Sinusitis"
09/09/03	OHSU Pediatric M & M Conference, "Intracranial Complications of Sinusitis"
09/11/03	OHSU Pediatric Resident Lecture Series, "Pediatric Nasal Obstruction and Sinusitis"
10/21/03	OHSU Otolaryngology Resident Quiz Session, "Malignant Head and Neck Masses in Children"
11/06/03	OHSU PA Student /Family Practice resident Lectures, "Otitis Media"
11/12/03	HEENT Exam to the 1st year medical students at OHSU (3:00 – 3:30 pm) -small group hands on teaching of the HEENT exam, 1st year OHSU medical students (3:30 – 5:00 pm)
1/26/04	Doernbecher Children's Hospital Operating Room In-Service "Pediatric Sinusitis"
1/27/04	OHSU Pediatric Resident Lecture "Deep neck infections and tonsillitis"

02/24/04 OHSU Pediatric Resident Lecture, "Neck Masses in Pediatric Patients"

03/09/04 OHSU Pediatric Department M & M Conference: "Pediatric Airway Foreign Bodies"

03/30/04 OHSU Pediatric Resident Lecture: "Vascular Lesions in Pediatric Patients: Terminology and Classification"

05/17/04 Doernbecher Operating Room In Service, "Vascular Malformations: Terminology and Treatment"

07/20/04 OHSU Pediatric Resident Noon Conference Lecture, "Otitis Media"

10/26/04 OHSU Pediatric Resident Lecture Series – "Tonsillitis and Deep Neck Infections"

12/04/04 OHSU Pediatric Grand Rounds, "Otitis Media Update"

12/07/04 Quiz Session for OHSU Otolaryngology Residents, "Vascular Malformations and Hemangiomas"

01/04/05 Quiz Session for OHSU Otolaryngology Residents, "Pediatric Sinusitis"

01/18/05 OHSU Pediatric Residency Noon Lectures series, "Vascular Lesions in Children"

02/15/05 OHSU Pediatric Residency Noon Lecture series, "Pediatric Otolaryngology Emergencies"

04/12/05 Journal club *Archives of Otolaryngology Head & Neck Surgery, March 2005 issue,* OHSU Dept. Otolaryngology residents.

08/25/05 OHSU Pediatric Residency Noon Lecture Series, "Otitis Media"

10/20/05 OHSU Pediatric Residency Noon Lecture Series, "Tonsillitis/Adenoids/Neck Infections"

11/29/05 OHSU Pediatric Residency Noon Lecture Series, "Pediatric Sinusitis"

12/20/05 OHSU Pediatric Residency Noon Lecture Series, "Vascular Lesions: Hemangiomas vs. Malformations"

1/10/06 OHSU Department of Pediatrics Morbidity & Mortality Conference, "Intracranial Complications of Sinusitis"

02/06/06 Medical Colloquia Lecture for OHSU Third Year Medical Students, "Evaluation of the Pediatric Airway"

06/14/06 PANDA Lecture. "Pediatric Otolaryngology Emergencies"

09/14/06 OHSU Pediatric Residency Noon Lecture Series, "Otitis Media"

11/28/06 OHSU Pediatric Residency Noon Lecture Series, "Noisy Breathing"

12/05/06 Quiz Session for OHSU Otolaryngology Residents, "Vascular Malformations and Hemangiomas"

12/12/06 Quiz Session for OHSU Otolaryngology Residents, "Benign Pediatric Head and Neck Masses"

01/11/07 OHSU Pediatric Residency Noon Lecture Series, "Pediatric Neck Masses"

02/05/07 Medical Colloquia lecture for OHSU Third Year Medical Students, "Hemangiomas and Vascular Anomalies of the Head and Neck"

03/06/07 OHSU Pediatric Residency Noon Lecture Series, "Pediatric Otolaryngology Emergencies"

04/03/07 OHSU Pediatric Residency Noon Lectures series, "Vascular Lesions in Children"

04/04/07 Department of Pediatrics Noon Lecture, St. Vincent's Hospital, Portland, OR. "Pediatric Deep Neck Infections"

09/25/07 OHSU Pediatric Residency Noon Lecture Series, "Otitis Media"

11/06/07 OHSU Pediatric Residency Noon Lectures series, "Stridor and Noisy Breathing"

11/13/07 Quiz Session for OHSU Otolaryngology Residents, "Acquired Airway Lesions"

11/27/07 Quiz Session for OHSU Otolaryngology Residents, "Otitis Media"

12/04/07 OHSU Pediatric Residency Noon Lecture Series, "Pediatric Neck Masses"

02/08/08 Medical Colloquia lecture for OHSU Third Year Medical Students, "Hemangiomas and Vascular Anomalies of the Head and Neck"

07/29/08 OHSU Pediatric Residency Noon Lecture Series, "Otitis Media"

10/14/08 OHSU Department of Pediatrics, Morbidity & Mortality Conference, "Intracranial Complications of Cholesteatomas and Mastoiditis"

11/11/08 Quiz Session for OHSU Otolaryngology Residents, "Congenital sensorineural hearing loss" (preparation 3 hours)

11/25/08 Quiz Session for OHSU Otolaryngology Residents, "Vascular Anomalies: Terminology, Pathophysiology and Management" (preparation 3 hours)

12/02/08 OHSU Pediatric Residency Noon Lecture Series, “Deep Neck Infections and Tonsillitis”

09/22/09 OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”

10/28/09 OHSU Pediatric Residency Noon Lecture Series, “Pediatric Neck Masses”

12/01/09 OHSU Pediatric Residency Noon Lecture Series, “Deep Neck Infections and Tonsillitis”

01/05/10 OHSU Pediatric Residency Noon Lectures series, “Vascular Lesions in Children”

09/07/2010 OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”

11/30/10 Quiz Session for OHSU Otolaryngology Residents, “Vascular Anomalies: Terminology, Pathophysiology and Management”

12/7/10 Quiz Session for OHSU Otolaryngology Residents, “Congenital sensorineural hearing loss”

9/20/11 OHSU Pediatric Residency Noon Lecture Series, “Pediatric nasal and sinus problems”

11/29/11 OHSU Pediatric Residency Noon Lectures series, “Hemangiomas and Vascular Malformations in Children” (preparation 1 hour)

12/19/2011 OHSU Pediatric Residency Noon Lecture Series, “Pediatric Neck Masses” (preparation 1 hour)

08/08/2012 OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”

09/17/13 OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”

October 2012 DCH Operating Room In service: “Image guidance Sinonasal Surgery & Endoscopic Endonasal Approach to Intracranial Masses”

11/12/13 Quiz Session for OHSU Otolaryngology Residents, “Congenital Airway Problems"

12/3/13 Quiz Session for OHSU Otolaryngology Residents, “Otitis Media”

Educational Activity

Teaching Activity:

My teaching activity is divided into teaching faculty (Otolaryngology, Pediatric), otolaryngology residents, pediatric residents and medical students. *Faculty* teaching is via Grand Rounds

lectures, given once yearly to Otolaryngology, Pediatrics and Vascular Surgery. *Resident teaching*: I devote 12 hours a week to the otolaryngology resident on the pediatric otolaryngology service. I devote 3 hours a week to a pediatric resident that spends one clinic session a week with us. I devote approximately 2 hours of preparation per each of 10 lectures I give yearly to residents and students.

Medical Student teaching:

I have been elected as a **College of Medicine Portfolio Coach** for 2014-2015. This 0.1 FTE position involves 4-5 hours a week mentoring 4 medical students in academic advising.

I spend 3 hours a year in the Anatomy Lab with the first year medical students. I also spend 8-20 hours a month teaching 4th year medical students that rotate through the Pediatric Otolaryngology clinic.

I sponsor a second year medical student through the Principles of Clinical Medicine (PCM) quarterly.

Advising:

I am advisor to one otolaryngology resident for the duration of their residency. This involves meeting twice yearly (total 3 hours) to advise them on the progress of their residency and future plans.

Mentoring:

I mentored our international fellow, ***Khalid Al-Mazrou, MD***, for 10 hours a week from October 2002 through June 2004.

I mentored Antonius Rabsch, an international medical student from Germany for 10 hours a week for 3 months from September 2003 – November 2003.

I mentored Lynelle Smith, a second year medical student for 4 months in 2005, devoting 2 hours a week for 16 weeks (PCM).

I mentored a college student (Allie Gruner) for 6 weeks from July through August 2004, devoting 2 hours a week to her.

I advised ***Anna Grosz, MD,*** an otolaryngology resident as her faculty mentor from 2003 – 2006.

I mentored a foreign medical graduate, ***Sagila George, MD*** meeting weekly in the lab, supervising writing a paper together from 2008 – 2010. She was accepted into a pediatric residency program in 2010.

I mentored a pre-med student, ***Jed Pilkington***, and met monthly to work on a publication and poster from 2008 – 2009. He was accepted into medical school in 2009.

I advised ***Matthew Miller, MD,*** otolaryngology resident, as his faculty mentor from 2009 – 2012.

I mentored ***Sarah Carroll, MD,*** an otolaryngology resident during her 6 month research rotation (Jan – June 2009). This resulted in a publication (M6).

I mentored a 1st year medical student, ***Morgan O'Connor***. We worked on a clinical paper getting it ready for submission and revising data January – April 2010.

I mentored a 4th year medical student, ***Megan Lundeburg***, with research projects and writing a paper prior to her applying to Otolaryngology residency in 2011. April 2010 – April 2011.

I mentored ***Daniel Clayburgh, MD***, otolaryngology resident, collaborated on Tonsillectomy Is an effective treatment for pediatric patients with dysphagia and tonsillar hypertrophy, ASPO **Podium Presentation**, April 30, 2011. **Received second place Charles Ferguson Clinical Science Award from ASPO. This resulted in a publication (M4).**

I mentored ***Jessyka Lighthall, MD,*** an otolaryngology resident during her 6 month research rotation (Jan – June 2011). We received a National Organization for Hearing Research Foundation $20,000 grant for our project "Innate immune response gene polymorphisms in otitis media". This resulted in a publication (M7) and a submitted manuscript in revision (M8).

I mentored **Laurel Murphy**, MS 2, as a Principles of Clinical Medicine (PCM) student Spring term, 2011.

I mentored **Ricky Tavangari,** MS 3, who worked on the "Innate immune response gene polymorphisms in otitis media" project with Dr. Lighthall and I. March 2011 – Sept 2011.

I mentored **Yue Linda Wang**, MS 2 who worked on the "Innate immune response gene polymorphisms in otitis media" project. She worked 0.5 FTE summer 2011, working both in the clinic recruiting patients to the study, collecting saliva as well as extracting DNA in the lab. 2011 – 2012. This resulted in a publication (M7).

I am mentoring **Lourdes Quintanilla-Dieck, MD,** otolaryngology resident, July 2011 – present. Collaborating on "Pediatric dysphagia outcomes after injection laryngoplasty for type I laryngeal cleft" project.

I am mentored **Casey Ward**, MS 2, as a Principles of Clinical Medicine (PCM) student Spring term, 2012.

I mentored **Michael Schuller,** a pre-Physician's assistant student. He worked as a research assistant on the National Organization for Hearing Research Foundation Award Grant, "Innate immune response gene polymorphisms in otitis media", PI Carol MacArthur, $20,000, 1/24/11 – 1/24/12. He was subsequently accepted to a Physician's Assistant training program Fall, 2013.

I mentored a college student, **Emily Walker**, Summer 2012

I mentored **Hans Han**, MS1, Fall 2012 via the Principles of Clinical Medicine course.

I mentored **Derek Lam**, MD in establishing the Doernbecher Airway Center, 2013 – 2014.

I am mentoring **Alex Labby**, MS1, Winter 2012 – present. He is working on the prospective study regarding outcomes of PE tube insertion in Down Syndrome patients.

I am mentoring **Tyler Weaver,** MS IV, Winter 2013-present. He is working on two projects in clinical research with me in anticipation of applying to an Otolaryngology residency for 2014. This resulted in a publication (M9).

I am mentoring **Nicole Bowman,** PSU, Summer 2013 - present. She is working with me in redesigning our database for the Vascular Birthmarks clinic into RedCap.

Administration of Teaching:

I administrate the multispecialty clinic (Hemangioma and Vascular Birthmarks clinic), spending 8 hours monthly preparing medical information, coordinating specialists and arranging follow up evaluation and treatments.

I also administrate the third year medical student rotation with the department.

Effectiveness of Educational Activity:

Reviews of my teaching effectiveness have been universally positive. I am available, approachable and interested in teaching at all levels. Pediatric residents who rotate with our service have been especially positive about how applicable the information I teach them is to their future profession and skills. It has been expressed that I am able to direct the teaching in a manner that will benefit them in their future careers.

Administration of Educational Programs and Committees

I have been the Director of the third year medical student course "Continuity Curriculum" for the years 2004 - 2010. As such, I revised and expanded our Department's exposure to the third year medical students. We added more lecture time and we revamped the clinic practical exam to include exposure to more aspects of our field's subspecialties. In 2010 we changed the medical student exposure to Otolaryngology and founded a course that any third year medical students can enroll in, OTOL 709C. Prior to establishing this course, there was no way for a third year medical student to rotate through Otolaryngology.

Service and Membership of Educational Committees:

2002-present	OHSU Department of Otolaryngology Residency Selection Committee
2003-present	Member, Cleft Craniofacial Disorders Team

2003-present	Member, Velopharyngeal Insufficiency Evaluation Clinic/Team
2003-present	Member, Pediatric Sleep Disorders Multispecialty Clinic, Doernbecher Hospital

Honors and Awards for Education:

Elected to "Portland's Best Doctors" list 2005 - 2006, *Portland Monthly, Magazine*

Best Doctor's in America list – 2005-2013

Collaborative Skills:

Our research team on otitis media models in mice is an example of collaborative research: I provide clinical expertise as well as research skills, Dennis Trune, PhD provides extensive experience and research skills in mouse research and histology, and, Steven Hefeneider, PhD, provides extensive skills in *in vitro* research for modulators of inflammation in otitis media.

The research team for the genetics of chronic otitis media is collaborative with Dr. Beth Wilmot and Dr. Shannon McWeeney in OCTRI, Dennis Trune PhD and I. We have collaborated with the International Consortium, OTIGEN, for replication studies, working with research teams in Australia, Finland and England.

Professional Development in Education:

2003	Advanced Clinical Research Conference, Deafness Research Foundation
2008	AAMC Mid-Career Women Faculty Professional Development Seminar
2009-2010	Lead Mentor Program, OHSU
2011	Paths to Leadership Faculty course (selected for this six month course offered at the OHSU School of Medicine)
2012	Endoscopic Endonasal Surgery of the Cranial Base and Pituitary Fossa, 9/26/12-9/29/12

Tympanostomy Tubes in Children

November 20, 2015

HEALTH TECHNOLOGY ASSESSMENT
prepared by:

Robin Hashimoto, PhD
Joseph R. Dettori, PhD, MPH
Erika Brodt, BS
Krystle Pagarigan, BS

Spectrum Research, Inc., Tacoma, WA

Tympanostomy Tubes (TT)

2

- **TT insertion is the most common outpatient surgery performed in children in the US:**
  - Performed in ~667,000 children age <15 per year
  - 1:15 children will undergo TT insertion by age 3
- Inserted into eardrum to equalize middle ear pressure and allow fluid drainage
- Inserted primarily to treat chronic otitis media with effusion (OME) or recurrent (or persistent) ear infection (AOM)

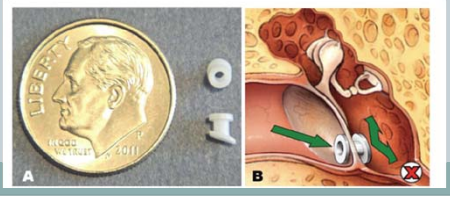

Image from Rosenfeld et al. 2013. Clinical Practice Guideline: Tympanostomy Tubes in Children. Otolaryngology-Head and Neck Surgery. 149:S1-S35.

Otitis Media with Effusion (OME)

3

- **Characterized by fluid in the middle ear without symptoms of acute ear infection** (e.g., fever, pain)
  - Can result from upper respiratory infections, allergies, ~~or~~ Eustachian tube dysfunction
- Common in children due to immature Eustachian tube function combined with propensity to get frequent colds
  - By age 10, 90% of children will have ≥1 episode of OME
  - The majority resolve spontaneously
  - 30%-40% of cases develop into chronic OME (i.e., ≥3 months)

Otitis Media with Effusion (OME)

4

- Often asymptomatic aside from sensation of fullness in ear, which may be accompanied by hearing loss
  - OME associated with conductive hearing level of 28 dB (8 worse than normal hearing threshold)
  - When OME becomes chronic, there is a concern that this impaired hearing may result in developmental delays related to:
    - Language and speech
    - Behavior
    - Academic achievement
  - Chronic OME may reduce QoL for both child and parent

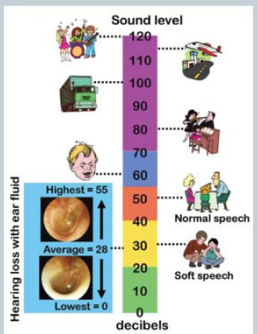

Image from Rosenfeld et al. 2013. Clinical Practice Guideline: Tympanostomy Tubes in Children. Otolaryngology-Head and Neck Surgery. 149:S1-S35.

Otitis Media with Effusion (OME)

5

- Chronic OME is also associated with an increased risk of:
  - Cholesteatoma (accumulated keratinizing epithelium)
  - Retraction pockets
  - Atelectasis (weakened portions of eardrum that collapsed)
  - AOM
  - Middle ear cysts
  - Tympanic scarring
- Risk factor:
  - Patients with cleft palate, Down syndrome, craniofacial disorders at very high risk due to impaired Eustachian tube function

Acute Otitis Media (AOM)

6

- **Ear infection**
  - Sudden onset of inflammation in middle ear
  - Associated with ear pain, irritability, loss of balance, fever, impaired hearing
- Common in children
  - By age 1, 50% of children will have ≥1 episode of AOM
  - By age 3, 70% of children will have ≥1 episode of AOM
  - AOM is considerably less common after age 7
- Recurrent AOM: ≥3 episodes in 6 months OR ≥4 episodes in 12 months with ≥1 in past 6 months
- Persistent AOM: persistence or recurrence of AOM within 1 month of antibiotic therapy

Acute Otitis Media (AOM)

7

- In recurrent AOM, impaired hearing may lead to developmental delays
- Reduced quality of life for both child and parent
- Risk factors:
  - Patients with cleft palate, Down syndrome, craniofacial disorders at very high risk due to impaired Eustachian tube function
  - Upper respiratory infection
  - Daycare
  - Exposure to cigarette smoke

TT insertion

8

- Outpatient procedure
- Inserted under general anesthesia
- Small incision made in eardrum (myringotomy)
- Fluid may be aspirated from middle ear
- Tube inserted into myringotomy incision
- Tubes typically fall out on their own within 15 months (if not designed to stay in long-term) due to accumulation of keratin between the tube flange and the surface of the eardrum
- Check-ups performed at 4- to 6-month intervals to evaluate tube function and middle ear status
- 100+ FDA-approved tubes used for OM
  - Made of plastic, metal, or ceramic
  - Shape and size varies

Anticipated outcomes

9

- Improvement in hearing levels by 5-12 dB
  - Greatest benefit early on
- Reduction in middle ear effusion by 32%
- Improvement in quality of life for child and parent
- Decrease in AOM incidence

Adverse events

10

- Otorrhea (usually transient)
- Persistent perforation after tube falls out (may require repair)
- Blockage of tube lumen by secretions (treated by drops and/or tube replacement)
- Granulation tissue forming around tube (treated by drops)
- Premature extrusion (i.e., ≤6 months) (often re-inserted)
- Tympanosclerosis (plaques of calcium and phosphate crystals, can be asymptomatic but lead to minor hearing loss)
- Atelectasis (atrophy or collapse of eardrum, can result from TT re-insertion)
- Retraction pockets (collapse of eardrum into middle ear following tube extrusion, results from weakened eardrum, can collect debris and lead to cholesteatoma formation)
- Harms of anesthesia

Comparators

11

- Watchful waiting (WW)
  - Child is monitored
  - Many cases resolve spontaneously
  - Surgery performed if condition deteriorates or continues to persist
- Myringotomy
  - Relieves severe otalgia and drains middle ear
  - Cold knife: brief ventilation (~72 hours)
  - Laser: ventilation for 1-7 weeks
- Adenoidectomy (± tonsillectomy)
  - May be indicated when frequent throat infections disrupt Eustachian tube function which can lead to chronic OME or recurrent AOM
  - Also indicated for obstructive sleep apnea
- Antibiotics
- Other medications
- Autoinflation of the Eustachian tube
- Complementary and alternative procedures

Guidelines

12

- **Chronic OME**
  - American Academy of Otolaryngology-Head and Neck Surgery Foundation, 2013 (Rosenfeld et al.):
    - TT recommended in children with chronic bilateral OME and documented hearing difficulties
    - TT an option in children with chronic unilateral or bilateral OME and symptoms attributable to OME (e.g., impaired balance, poor school performance, behavioral problems, ear discomfort, reduced quality of life)
    - TT an option in children at risk for developmental disorders (e.g., cleft palate) with unilateral or bilateral OME that is unlikely to resolve quickly.
    - TT not recommended in children with a single episode of OME <3 months duration

Guidelines

13

- **Recurrent AOM**
  - American Academy of Otolaryngology-Head and Neck Surgery Foundation (2013 guideline) :
    - TT recommended in children with recurrent AOM with unilateral or bilateral middle ear effusion
    - TT not recommended in children with recurrent AOM but without middle ear effusion
  - The American Academy of Pediatrics (2013 guideline):
    - TT recommended in children with recurrent AOM

Key Questions

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In children aged 16 years and younger with either (a) chronic OME or (b) recurrent or persistent AOM (evaluated separately), what is the evidence of:

1. The short-and long-term **efficacy and effectiveness** of TT compared with watchful waiting or alternative treatment options?
2. Short- and long-term **harms and complications** of TT compared with watchful waiting or alternative treatment options?
3. **Differential efficacy or safety** of TT compared with watchful waiting or alternative treatment options in subpopulations?
4. The **cost-effectiveness** of TT compared with watchful waiting or alternative treatment options?

Inclusion criteria (PICO)

15

- **Participants.** Children age ≤16 with either chronic OME or recurrent AOM
- **Intervention.** Tympanostomy tube (TT) insertion
- **Comparators**. Watchful waiting (WW), myringotomy, adenoidectomy (Ad), antibiotic therapy, mucolytics, steroids, Eustachian tube autoinflation, complementary and alternative medicine treatments

Inclusion criteria (PICO)

16

- **Outcomes.**
  - **Clinical outcomes.**
    - **Hearing**
    - **Cholesteatoma**
    - Otorrhea, balance and coordination, recurrent AOM or OME
  - **Functional and quality of life outcomes.**
    - **Speech and language development**
    - **Parent satisfaction**
    - **Patient quality of life**
    - Attention and behavioral outcomes, academic achievement, auditory processing, pain, parent quality of life, patient satisfaction

Inclusion criteria (PICO)

17

- **Outcomes.**
  - **Healthcare utilization.**
    - Surgery, medication usage, number of office visits
  - **Harms.**
    - **Perforation**
    - **Chronic otorrhea**
    - Tube blockage, premature extrusion, tube displacement, tympanosclerosis/Myringosclerosis, tympanic membrane atrophy, atelectasis, retraction pocket formation
    - Harms of general anesthesia
  - **Cost-effectiveness.**

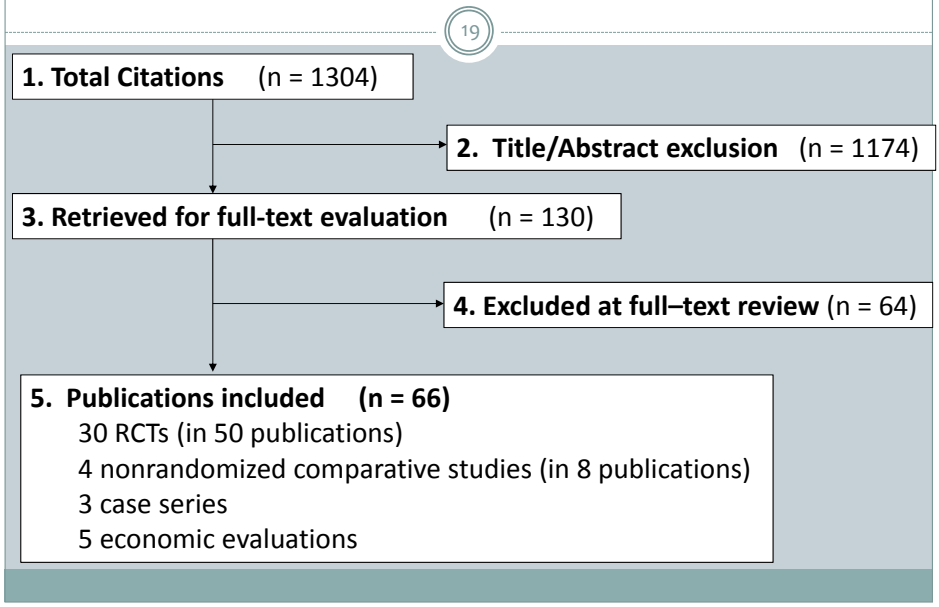
Inclusion criteria (PICO)

18

- **Studies**
  - **Randomized controlled trials (RCTs) (KQ1-2)**
  - **Nonrandomized comparative (cohort) studies (KQ1-2):**
    - N ≥ 100 patients
    - Follow-up ≥ 80%
  - **Case series designed to evaluated harms (KQ2):**
    - N ≥ 500 patients
    - Follow-up ≥ 70%
  - **RCTs stratified on characteristics of interest and formally evaluated statistical interaction (effect modification) (KQ3)**
  - **Formal economic studies (KQ4)**

Literature search

19



Overall strength of evidence (GRADE)

20

Quality rating	Interpretation
High	High confidence that the evidence reflects the true effect.
Moderate	Moderate confidence in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Insufficient	Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.

Results: KQ1

21

What is the evidence of the short- and long-term efficacy and effectiveness of TT insertion compared with WW or alternative treatment options?

KQ1: Overview of evidence base

22

OME:

- TT vs. WW: 7 RCTs (N=52-429) (Table 7)
  - Only comparator providing MODERATE or HIGH SoE
  - Publication: 1989-2012
  - Location: US (3), UK (2), The Netherlands (2)
  - Age: 0.6-12 years
  - Bilateral OME: 4 RCTs
  - Bilateral or unilateral OME: 3 RCTs
  - Hearing loss (≥20-25 dB) required in 3 RCTs, another reported that 71.5% had hearing loss (≥ 20 dB) at baseline, 3 RCTs provided no details
  - Disrupted speech, language, or behavior required in 1 RCT
- TT (unilateral) vs. no procedure (contralateral): 5 RCTs (N=35-185) (1983-1994)
- TT vs. myringotomy: 7 RCTs (N=30-227) (1987-2006)
- TT + Ad vs. myringotomy + Ad: 8 RCTs (N=52-578) (1987-2011) & 3 cohort studies
- TT + Ad vs. Ad: 4 RCTs (N=60-228) (1978-1994) & 1 cohort study
- TT vs. myringotomy + Ad: 2 RCTs (N=99-578) (1987-2009)
- TT (unilateral) vs. no procedure (unilateral) + Ad: 2 RCTs (N=78-228) (1993-1994)
- TT vs. antibiotics: 1 RCT (N=139) (1991-2005)

KQ1: Overview of evidence base

23

Recurrent AOM:

- TT vs. prophylactic antibiotics: 4 RCTs (N=65-264) (1981-1996)
- TT vs. placebo or no treatment: 3 RCTs (N=65-264) (1986-2014)

OME or recurrent AOM:

- TT (unilateral) vs. myringotomy or no procedure (contralateral): 1 RCT (N=57) (1991)

KQ1: Hearing levels

24

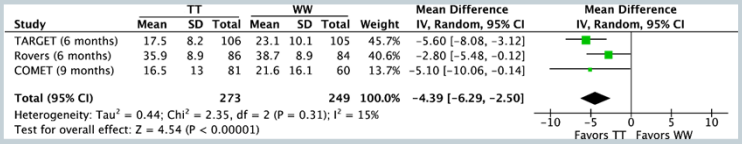
Summary:

- Hearing levels were reported for all comparators identified.
- Results suggested that hearing levels were significantly better (i.e., 3-7 dB lower) in ears with tubes versus those without tubes between 3 and 9 months (varies with comparator) follow-up (f/u).
- This difference was not observed at later follow-up time points (ranging from 6-120 months).

KQ1: Mean Hearing Levels- TT vs. WW for OME

25

6-9 months (Fig. 3) (mean age 1.6-5.2 years)

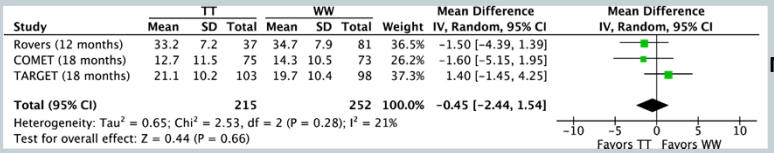


Study	TT Mean	TT SD	TT Total	WW Mean	WW SD	WW Total	Weight	Mean Difference IV, Random, 95% CI
TARGET (6 months)	17.5	8.2	106	23.1	10.1	105	45.7%	-5.60 [-8.08, -3.12]
Rovers (6 months)	35.9	8.9	86	38.7	8.9	84	40.6%	-2.80 [-5.48, -0.12]
COMET (9 months)	16.5	13	81	21.6	16.1	60	13.7%	-5.10 [-10.06, -0.14]
Total (95% CI)			**273**			**249**	**100.0%**	**-4.39 [-6.29, -2.50]**

Heterogeneity: Tau² = 0.44; Chi² = 2.35, df = 2 (P = 0.31); I² = 15%
Test for overall effect: Z = 4.54 (P < 0.00001)

MODERATE SoE

12-18 months (Figure 4) (mean age 1.6-5.2 years)



Study	TT Mean	TT SD	TT Total	WW Mean	WW SD	WW Total	Weight	Mean Difference IV, Random, 95% CI
Rovers (12 months)	33.2	7.2	37	34.7	7.9	81	36.5%	-1.50 [-4.39, 1.39]
COMET (18 months)	12.7	11.5	75	14.3	10.5	73	26.2%	-1.60 [-5.15, 1.95]
TARGET (18 months)	21.1	10.2	103	19.7	10.4	98	37.3%	1.40 [-1.45, 4.25]
Total (95% CI)			**215**			**252**	**100.0%**	**-0.45 [-2.44, 1.54]**

Heterogeneity: Tau² = 0.65; Chi² = 2.53, df = 2 (P = 0.28); I² = 21%
Test for overall effect: Z = 0.44 (P = 0.66)

MODERATE SoE

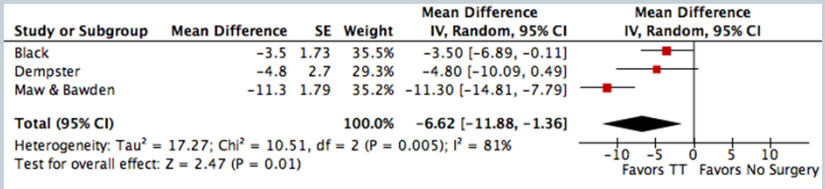
Age 6: Mean hearing levels were similar between TT and WW groups (1 RCT, N=281)

HIGH SoE

KQ1: Mean Hearing Levels- TT vs. no procedure (by-ear analysis) for OME

26

6 months (Fig. 10) (age 2-9 years)



Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Black	-3.5	1.73	35.5%	-3.50 [-6.89, -0.11]
Dempster	-4.8	2.7	29.3%	-4.80 [-10.09, 0.49]
Maw & Bawden	-11.3	1.79	35.2%	-11.30 [-14.81, -7.79]
Total (95% CI)			**100.0%**	**-6.62 [-11.88, -1.36]**

Heterogeneity: Tau² = 17.27; Chi² = 10.51, df = 2 (P = 0.005); I² = 81%
Test for overall effect: Z = 2.47 (P = 0.01)

LOW SoE

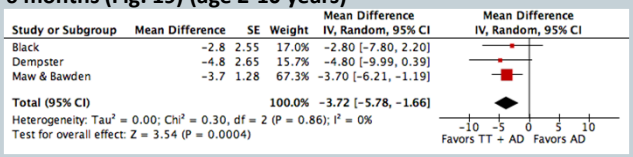
48 months: Mean hearing levels were similar between groups.
(2 RCTs, N=81-89 (170 ears)) (age 2-9 years)

60, 84, 120 months: Mean hearing levels were similar between groups.
(1 RCT, N=15-56 (35-103 ears)) (age 2-9 years)

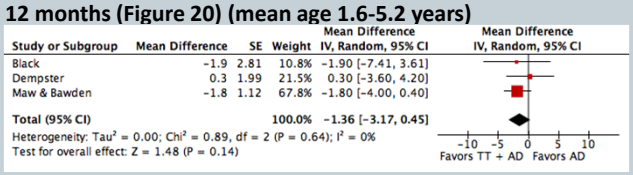
KQ1: Mean Hearing Levels- TT+Ad vs. Ad (by-ear analysis) for OME

27

6 months (Fig. 19) (age 2-10 years)



12 months (Figure 20) (mean age 1.6-5.2 years)



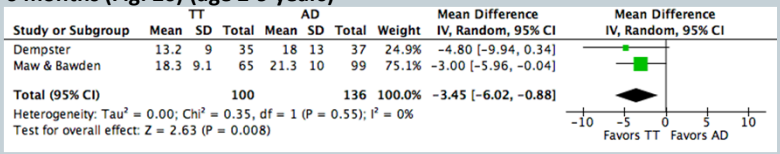
36, 48, 84, 120 months: Mean hearing levels were similar between groups.
(1 RCT, N=42-112 (85-222 ears)) (age 2-9 years)

LOW SoE

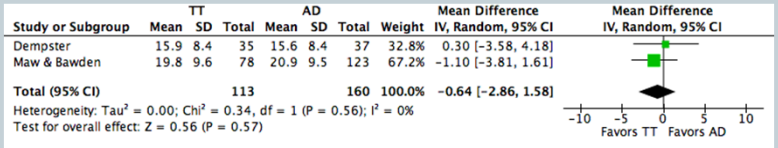
KQ1: Mean Hearing Levels- TT (unilateral) vs. no procedure (unilateral) + Ad for OME

28

6 months (Fig. 26) (age 2-9 years)



12 months (Figure 27) (age 2-9years)



Longer f/u from 1 RCT, mean age 5.9 years:

24 months: Mean hearing levels were similar between groups (N=169)

36 & 48 months: Mean hearing levels were 2.1-2.8 dB worse in the TT ear. (N=155-169)

84 & 120 months: Mean hearing levels were similar between groups. (N=58-102)

LOW SoE

KQ1: Hearing- additional comparators for OME

29

- **TT vs. myringotomy: LOW SoE for all**
  - **6 months**: mean hearing better in the TT ear (2 RCTs, total N=67) (LOW SoE)
  - **12, 24 months**: no difference between groups (1-2 RCTs, N=76=277)
  - **0-24 months**: TT patients had 7% to 8.5% fewer evaluations with hearing levels ≥20 dB vs. control group (1 RCT, N=277)
- **TT + Ad vs. myringotomy + Ad: LOW SoE for all**
  - **3 months**: hearing 4.3 dB better in TT ear (1 RCT, N=108, 216 ears)
  - **6, 12, 24 months**: no difference between groups, with a total of 6 RCTs reporting (1-2 RCTs & N=37-155 per outcome)
- **TT vs. myringotomy + Ad:**
  - **0-24 months**: in worse ear, TT patients had 8.4% *more* evaluations with hearing levels ≥20 dB vs. control group; in better ear, no difference between groups. (1 RCT, N=180)
- **TT vs. antibiotics:**
  - **2 & 4 months:** hearing ~5-9 dB better in TT group (1 RCT, N=125)
  - **6, 12, 18 months:** hearing levels similar between groups (1 RCT, N=125)

KQ1: Hearing – OME or recurrent AOM

30

OME or recurrent AOM

- **TT (unilateral) vs. myringotomy or no procedure (contralateral) (1 RCT, N=37, 74 ears) LOW SoE for all**
  - **3, 6, 9 months**: mean hearing 3.4-3.7 dB better in the TT ear
  - **9 months**: 32% of patients had hearing levels ≥5 dB lower in TT ear (p=0.04)
  - **12, 15, 18, 24, >24 months**: no difference between groups

Recurrent AOM

- **TT vs. prophylactic antibiotics**
  - **0-24 months**: no difference between groups in percentage of time with hearing levels >15 dB (1 RCT, N=163) (LOW SoE)

KQ1: Speech & Language

31

Summary:

- Speech and language outcomes were only evaluated for TT compared with watchful waiting for OME.
- Results suggest no difference between groups at any time point evaluated.

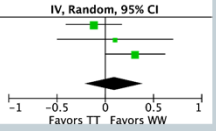
KQ1: Speech & Language - TT vs. WW for OME

32

Verbal comprehension (Reynell test) at 6-9 months (Fig. 5) (mean age 1.2-4.7 years)

	TT			WW				Std. Mean Difference	Std. Mean Difference
Study	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Rovers (6 months)	-0.06	0.95	93	0.06	1.05	94	42.0%	-0.12 [-0.41, 0.17]	
Rach (6 months)	0.17	0.61	22	0.11	0.55	21	18.3%	0.10 [-0.50, 0.70]	
COMET (9 months)	-0.04	1.02	87	-0.35	0.98	77	39.6%	0.31 [-0.00, 0.62]	
Total (95% CI)			**202**			**192**	**100.0%**	**0.09 [-0.21, 0.39]**	

Heterogeneity: $Tau^2 = 0.03$; $Chi^2 = 3.96$, df = 2 (P = 0.14); $I^2 = 49\%$
Test for overall effect: Z = 0.59 (P = 0.55)

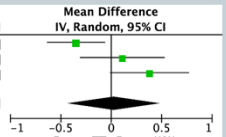


MODERATE SoE

Expressive language (Reynell, Schlichting tests) at 6-9 months (Fig. 6) (mean age 1.2-4.7 yrs.)

	TT			WW				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Rovers (6 months)	-0.18	1.19	93	0.17	0.74	94	36.3%	-0.35 [-0.63, -0.07]	
Rach (6 months)	0.29	0.75	22	0.18	0.64	21	31.3%	0.11 [-0.31, 0.53]	
COMET (9 months)	-0.62	1.27	87	-1	1.25	76	32.4%	0.38 [-0.01, 0.77]	
Total (95% CI)			**202**			**191**	**100.0%**	**0.03 [-0.42, 0.49]**	

Heterogeneity: $Tau^2 = 0.13$; $Chi^2 = 9.57$, df = 2 (P = 0.008); $I^2 = 79\%$
Test for overall effect: Z = 0.13 (P = 0.90)



MODERATE SoE

KQ1: Speech & Language

33

F/U	Studies, N	Comparative Impact	Quality
TT vs. WW for OME (Age 1.2-4.7 years)			
6-9 mos.	3 RCTs N=393	No difference in verbal comprehension (Reynell test) or expressive language (Reynell and/or Schlichting tests) between groups.	⊕⊕⊕○ MODERATE
12-18 mos.	1-2 RCTs N=152-388	No difference in verbal comprehension (Reynell test (2 RCTs, N=388) or expressive language (Reynell test, 1 RCT, N=152) between groups	⊕⊕⊕○ MODERATE
Age 3, 4, 6, 9-11 yrs.	1 RCT N=304-401	No differences between groups (various measures of language development).	⊕⊕⊕⊕ HIGH
Age 7-8 yrs.	1 RCT N=67	No differences between groups (various measures of language development).	⊕⊕○○ LOW

KQ1: Parent Satisfaction

34

Summary:

- Parent satisfaction was reported in a subanalysis of one RCT that compared TT to antibiotics for OME.
- Evidence was insufficient and thus no firm conclusions can be made.

KQ1: Patient Quality of Life

35

Summary:

- Results were mixed.
- One trial of OME patients found no differences between groups in disease-specific patient quality of life at 6 and 12 months (MODERATE SoE).
- Another small RCT of obstructive sleep apnea patients with OME reported greater improvement in disease-specific patient quality of life at 6 months though the difference was not sustained at 12 months (LOW SoE).
- A subanalysis of one RCT comparing TT to no treatment for recurrent AOM found no differences between groups at 4 or 12 months (LOW SoE).

KQ1: Patient QoL

36

F/U	Studies, N	Comparative Impact	Quality
TT vs. WW for OME (Age 1.6 years)			
6 & 12 mos.	1 RCT N=165-176	No differences between groups (TAIQOL subdomains)	⊕⊕⊕o MODERATE
TT+Ad vs. Myringotomy+Ad for OME (Age 4.5 years)			
6 mos.	1 RCT N=44	TT+Ad-Tons patients had greater improvement in OM-6 scores than control group (-0.38 vs. 0.00, MD -0.38, 95% CI -0.64 to -0.12, p=0.0050).	⊕⊕oo LOW
12 mos.	1 RCT N=41	No differences between groups (improvement in OM-6 scores).	⊕⊕oo LOW
TT vs. No procedure for recurrent AOM (Age 3.6 years)			
4 & 12 mos.	1 RCT N=81-85	No differences between groups (ear-related QoL).	⊕⊕oo LOW

KQ1: Cholesteatoma

37

Summary:

- There was no difference between groups in the incidence of cholesteatoma at any time point measured (LOW SoE).

KQ1: Cholesteatoma

38

OME	F/U	Studies, N	Comparative Impact	Quality	Age
TT vs. WW	≤36 mos. & At age 5	2 RCTs N=275	No differences between groups.	⊕⊕oo LOW	0.6-12 yrs.
TT vs. Myr.	≤24-36 mos.	2 RCTs N=353	No differences between groups (rare).	⊕⊕oo LOW	0.6-12 yrs.
TT+Ad vs. Myr+Ad	≤24 mos.	1 RCT N=301	No cases	⊕⊕oo LOW	4-8 yrs.
TT+Ad vs. Ad	60 mos.	1 RCT N=55 (110 ears)	No cases	⊕⊕oo LOW	4-10 yrs.
TT vs. Myr+Ad	≤24 mos.	1 RCT N=301	No cases	⊕⊕oo LOW	4-8 yrs.

KQ1: Cholesteatoma

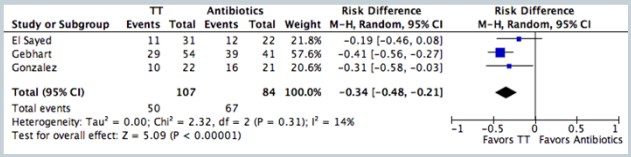
39

Recurrent AOM	F/U	Studies, N	Comparative Impact	Quality	Age
TT vs. antibiotics	≤24-30 mos.	2 RCTs N=258	No cases	⊕⊕OO LOW	0.6-2.9 yrs.
TT vs. placebo	≤24 mos.	1 RCT N=163	No cases	⊕⊕OO LOW	0.6-2.9 yrs.
OME or Recurrent AOM					
TT (unilateral) vs. Myr. or no procedure (contralateral)	≤24 mos.	1 RCTs N=57 (114 ears)	No cases	⊕⊕OO LOW	2.3 yrs.

KQ1: AOM recurrence (in patients treated for recurrent AOM)

40

TT vs. Antibiotics for recurrent AOM: AOM recurrence through 6 months



TT vs. Placebo or No Treatment for recurrent AOM: AOM recurrence through 6-12 months

- **Both trials reported that AOM recurrence occurred in significantly fewer TT vs. no treatment patients**
  - **TT vs. Placebo, 6 months (1 RCT, N=42):** 45% vs. 85%, RD -40%, 95% CI -66% to -14%, p=0.0083
  - **TT vs. No Treatment, 12 months (1 RCT, N=200):** 52% vs. 66%, RD -14%, 95% CI -14% to -0.5%, p=0.0447

Results: KQ2

41

What is the evidence of the short- and long-term harms of TT insertion compared with WW or alternative treatment options?

KQ2: Overview of evidence base

42

OME:

- TT vs. WW: 5 RCTs
- TT (unilateral) vs. no procedure (contralateral): 4 RCTs
- TT vs. myringotomy: 6 RCTs
- TT + Ad vs. myringotomy + Ad: 7 RCTs & 3 cohort studies
- TT + Ad vs. Ad: 3 RCTs
- TT vs. myringotomy + Ad: 2 RCTs
- TT (unilateral) vs. no procedure (unilateral) + Ad: 2 RCTs
- TT vs. antibiotics: 1 RCT

Recurrent AOM:

- TT vs. prophylactic antibiotics: 4 RCTs
- TT vs. placebo or no treatment: 3 RCTs

OME or recurrent AOM:

- TT (unilateral) vs. myringotomy or no procedure (contralat.): 1 RCT
- TT: 3 case series

KQ2: Perforation

43

Summary:

- There was no difference between groups in the formation of persistent perforation (LOW SoE).

KQ2: Perforation

OME	F/U	Studies, N	Comparative Impact	Quality	Age
TT (unilat.) vs. No procedure (contralat.)	6-60 mos.	2 RCTs N=169 (204 ears)	No differences between groups (perforation).	⊕⊕oo LOW	3.9-5.7 yrs.
TT+Ad vs. Myr+Ad	≤24-36 mos.	3 RCTs N=591	No differences between groups (perisistent perforation).	⊕⊕oo LOW	2.9-8 yrs.
TT+Ad vs. Ad	60 mos.	1 RCT N=55 (110 ears)	No cases (perforation).	⊕⊕oo LOW	4-10 yrs.
TT vs. Myr+Ad	≤24 & 36 mos.	2 RCTs N=557	No differences between groups (perisistent perforation or perforation).	⊕⊕oo LOW	4-8 yrs.
TT vs. Ad	6 & 12 mos.	1 RCT N=72	No differences between groups (perforation).	⊕⊕oo LOW	5.9 yrs.
TT vs. Antibiotics	≤18 mos.	1 RCT N=60	No cases in TT group (chronic perforation).	⊕⊕oo LOW	4.9 yrs.

KQ2: Perforation

45

Recurrent AOM	F/U	Studies, N	Comparative Impact	Quality	Age
TT vs. antibiotics	≤21 mos.	2 RCTs N=130	TT: 3.7%-13.2% (perforation or persistent perforation) Control: NR	⊕⊕oo LOW	0.6-2.9 yrs.
TT vs. placebo	≤21 mos.	1 RCT N=76	TT: 13.2% (perforation or persistent perforation) Control: NR	⊕⊕oo LOW	0.6-2.9 yrs.
OME or Recurrent AOM					
TT (unilateral) vs. Myr. or no procedure (contralateral)	≤24 mos.	1 RCTs N=57 (114 ears)	TT ears: 4% (permanent perforation) Control ears: 0%	⊕⊕oo LOW	2.3 yrs.

KQ2: Chronic Otorrhea

46

Summary:

- Results were mixed.
- Chronic otorrhea (occurring three or more times a year) was more common following TT compared with WW through 12 months (LOW SoE).
- Chronic otorrhea (occurring three or more times a year) occurred similarly between TT + Ad and Myr + Ad groups through 12 months (LOW SoE).
- There was no difference between TT and WW groups in the development of persistent otorrhea requiring hospitalization (LOW SoE).

KQ2: Chronic otorrhea

47

OME	F/U	Studies, N	Comparative Impact	Quality	Age
TT vs. WW	≤12 mos.	1 RCT N=187	Chronic otorrhea (3X/year) was more common in the TT versus WW group (25% vs. 5%, RD 19%, 95% CI 10% to 29%, p<0.01).	⊕⊕oo LOW	1.6 yrs.
TT vs. WW; TT vs. Myr	≤36 mos.	2 RCTs N=89	Persistent otorrhea requiring hospitalization, intravenous antibiotics, and daily suctioning occurred similarly between groups in one trial and in 2.2% of all patients who ultimately underwent TT insertion in another trial.	⊕⊕oo LOW	0.6-12 yrs.
TT+Ad vs. Myr+Ad	≤12 mos.	1 RCT N=78	Chronic otorrhea (≥3 episodes per year) occurred similarly between groups through 12 months.	⊕⊕oo LOW	0.6-12 yrs.

Results: KQ3

48

Is there evidence of differential efficacy or safety of TT insertion compared with WW or alternative treatment options? Include consideration of age, sex, race, ethnicity, socioeconomic status, risk for developmental delay, repeated exposure to large groups of children, duration of OM, and recurrent acute OM versus chronic OM.

All evidence was insufficient quality in SoE evaluation.

Results: KQ4

49

What is the evidence of cost-effectiveness of TT compared with WW or alternative treatment options?

KQ4: TT vs. WW for OME

50

- **Evidence base**: 1 cost utility analysis (QHES 80/100)
- **Population**: 1 RCT (included in HTA) comparing TT vs. WW
  - N=187 children with persistent bilateral OME
- **Perspective**: societal
- **Costs**: both direct and indirect actual costs included (1998 USD)
  - Results: TT more expensive than WW ($454 vs. $120, p<0.001)
- **Outcome used to calculate QALY**: language development as measured by Reynell test & Schlichting test
  - Results: No difference between groups at 12 months
- **Cost/QALY:**
  - ICER could not be calculated since there was no difference in language development between groups
  - Estimated ICERs calculated, results suggest higher costs for TT with no differences in effect
  - Similar results from sensitivity analysis (varies cost)
- **Conclusion**: TT insertion should not be a standard treatment in children with persistent OME

OME: Summary and Gaps in Evidence

51

Outcome	Summary	Gaps in evidence
Hearing	Hearing levels were 3-7 dB lower in TT group between 3-9 months (LOW to MODERATE SoE) (all comparators). Hearing levels were similar between groups at later time points (6-120 months) (LOW to MODERATE SoE) (all comparators).	Most evidence related to mean hearing levels rather than achievement of normal hearing levels.
Speech & Language	No differences between groups at any time point (6-18 months and various ages up to 9-11 years) (LOW to HIGH SoE) (TT vs. WW only).	Evidence available for one comparator only.
Parent satisfaction	Insufficient SoE	No evidence.
Patient QoL	No differences between groups at any time point (6-12 months) (LOW to MODERATE SoE).	Limited evidence base (2 RCTs); no long-term evidence.
Cholesteatoma	No difference between groups (LOW SoE).	Rare outcome; studies underpowered to detect potential differences between groups.
Persistent perforation	No difference between groups (LOW SoE).	Rare outcome; studies underpowered.
Chronic otorrhea	Mixed results; may be more common following TT insertion (LOW SoE)	Limited evidence base (4 trials).

Recurrent AOM: Summary and Gaps in Evidence

52

Outcome	Summary	Gaps in evidence
Hearing	Hearing levels were 3-9 dB lower in TT group between 2-9 months (LOW SoE). Hearing levels were similar between groups at later time points (6-120 months) (LOW SoE).	Limited evidence base (2 RCTs)
Speech & Language	No evidence.	No evidence.
Parent satisfaction	No evidence.	No evidence.
Patient QoL	No differences between groups (4 & 12 months) (LOW SoE).	Limited evidence base (subanalysis of 1 RCT); no long-term evidence.
Cholesteatoma	No cases (LOW SoE)	Rare outcome; studies underpowered to detect potential differences between groups.
Persistent perforation	No evidence.	No evidence.
Chronic otorrhea	No evidence.	No evidence.


Thank you.
53
Questions?

Washington State Health Care Authority
Health Technology Assessment

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*, otorrohea*, 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), otorrohea, 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., otorrhoea, 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.)

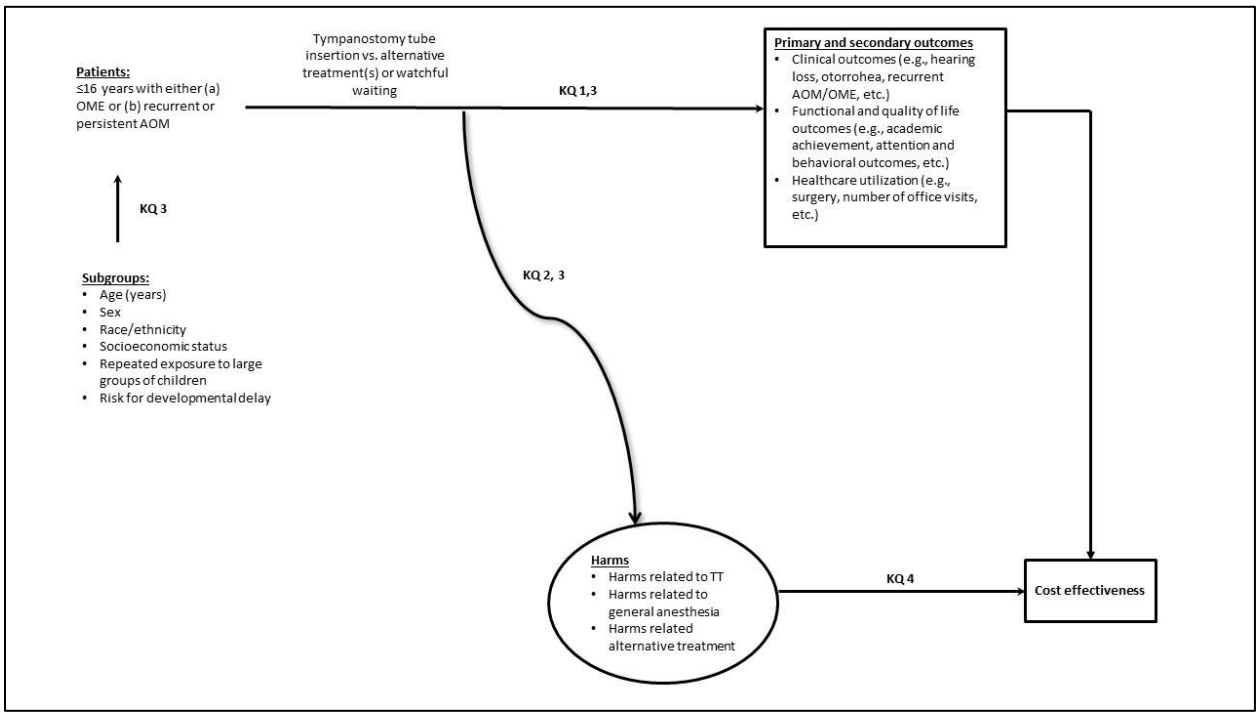
- **Cost-Effectiveness**

  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 .

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Health Technology Evidence Identification

Discussion Document:

What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Ottorhea chronic	
Persistent perforation	
Blockage of lumen	
Granulation tissue	
Premature extrusion	
Tympansclerosis	
Atelectasis	
Retraction pockets	
Anesthesia harms	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Improved hearing levels	
Reduction in middle ear effusion	
QOL for parent and/or child	
Decrease Acute OM indidence	
Special Population / Considerations Outcomes	**Special Populations/ Considerations Evidence**

Cost Outcomes	Cost Evidence
Costs	
Cost-effectiveness	

Medicare Coverage and Guidelines

[From Page 82 of evidence report]

Centers for Medicare and Medicaid Services:
There are currently no National Coverage Decisions published from the Centers for Medicare and Medicaid services.

Table 2. Clinical Guidelines [From page 47 of Final Report]

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
OME						
The American Academy of Otolaryngology-Head and Neck Surgery Foundation[141] *Clinical Practice Guideline: Tympanostomy Tubes in Children (2013)*	2005 through February 2012	Children 6 months to 12 years of age, with tympanostomy tubes or being considered for TT in any case setting, as an intervention of OM of any time.	Tympanostomy tube insertion, including indications for tube placement, preoperative care, and postoperative care	4 guidelines, 15 systematic reviews or meta-analyses	1. Clinicians should not perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months' duration. (Recommendation (against)*) 2. Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer (chronic OME) OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion. (Recommendation*) 3. Clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer (chronic OME) AND documented hearing difficulties. (Recommendation*) 4. Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable to OME that include, but are not limited to, vestibular problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life. (Option*) 5. Clinicians should reevaluate, at 3- to 6 month intervals, children with chronic OME who did not receive tympanostomy tubes, until the effusion is no longer present, significant hearing	Grade C† Grade C† Grade B† Grade C† Grade C†

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
					loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected. (Recommendation*)	
					6. Clinicians should determine if a child with… OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors. (Recommendation*)	Grade C†
					7. Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly as reflected by a type B (flat) tympanogram or persistence of effusion for 3 months or longer (chronic OME). (Option*)	Grade C†
					8. 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*)	Grade C†
					9. Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics for children with uncomplicated acute TT otorrhea. (Strong Recommendation*)	Grade B†
					10. Water precautions: Clinicians should not encourage routine, prophylactic water precautions (use of earplugs, headbands; avoidance of swimming or water sports) for children with tympanostomy tubes. (Recommendation (against) *)	Grade B†

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
The Darwin Otitis Guidelines Group in collaboration with the Office for Aboriginal and Torres Strait Islander Health Otitis Media Technical Advisory Group[37] *Recommendations for clinical care guidelines on the management of otitis media in Aboriginal and Torres Strait Islander populations (2010)*	2001 – April 1, 2010	Children (specifically in the Aboriginal and Torres Strait Islander populations)	Tympanostomy tubes	8 SRs, 1 guideline	**Management of Persistent Otitis Media with Effusion (OME):** 1. Refer the child (who is not at high risk for chronic suppurative OM) for grommet insertion if: • the child has a persistent hearing loss >20dB, • the parents understand that the operation will provide a modest improvement in hearing for 6-9 months, and • surgery is consistent with the parents' preferences. The likelihood of benefit from grommets increases with greater levels of hearing loss.	Grade A‡
				1 non-systematic review	2. Refer the child (who is not at high risk for chronic suppurative OM) for grommet insertion if: • the child has a persistent hearing loss >20dB, • the parents understand that the operation will provide a modest improvement in hearing for 6-9 months, and • surgery is consistent with the parents' preferences. The likelihood of benefit from grommets increases.	Good practice point (GPP)‡
				3 SRs, 3 clinical guidelines	3. Consider referral for adenoidectomy if bilateral OME has occurred despite previous grommet (tympanostomy tube) insertion or if the child is at high risk of chronic suppurative OM.	Grade B‡

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
				1 clinical guideline	4. Grommets plus adenoidectomy can be an option for children >3 years who have recurrent persistent OME and hearing loss after previous grommet insertion, severe nasal obstruction, or chronic adenoiditis.	Grade B‡
British Columbia Medical Association, British Columbia Ministry of Health Services, Guidelines and Protocols Advisory Committee[103] *Otitis Media: Acute Otitis Media (AOM) and Otitis Media with Effusions (OME) (2010)*	NR	Otherwise healthy children over the age of 6 months presenting with AOM or OME. Does not include children with craniofacial abnormalities, immune deficiencies, and complications of AOM (e.g. mastoiditis, facial paralysis, etc.) or serious underlying disease.	Tympanostomy tubes	NR	• If a child with OME does become a candidate for surgery, tympanostomy tube insertion is the preferred initial procedure. • Surgical treatment of OME may prevent middle ear complications, including: atelectatic tympanic membrane, permanent conductive hearing loss, cholesteatoma, etc.	NR
National Institute for Health and Care Excellence (NICE)[108] *Surgical management of otitis media with effusion in children, NICE clinical guideline 60 (2008)*	NR	Children under the age of 12 years presenting with OME. Special populations: Children with cleft palate, Down's syndrome	Tympanostomy tubes	NR	**Appropriate time for intervention:** • The persistence of bilateral OME and hearing loss should be confirmed over a period of 3 months before intervention is considered. The child's hearing should be re-tested at the end of this time. • During the active observation period, advice on educational and behavioral strategies to minimize the effects of the hearing loss should be offered. **Children who will benefit from surgical intervention:** • Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dB HL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dB HL not available) should be considered for surgical intervention.	NR

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
					• Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25–30 dB HL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. **Surgical interventions:** • Once a decision has been taken to offer surgical intervention for OME in children, the insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms. • Children who have undergone insertion of ventilation tubes for OME should be followed up and their hearing should be re-assessed. **Management of OME in children with Down's syndrome** • The care of children with Down's syndrome who are suspected of having OME should be undertaken by a multidisciplinary team with expertise in assessing and treating these children. • Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss. • Before ventilation tubes are offered as an alternative to hearing aids for treating OME in children with Down's syndrome, the following factors should be considered:	

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
					• the severity of hearing loss • the age of the child • the practicality of ventilation tube insertion • the risks associated with ventilation tubes • the likelihood of early extrusion of ventilation tubes **Management of OME in children with cleft palate:** • The care of children with cleft palate who are suspected of having OME should be undertaken by the local otological and audiological services with expertise in assessing and treating these children in liaison with the regional multidisciplinary cleft lip and palate team. • Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment. • Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.	
Korean Society of Otology[80] *Korean Clinical Practice Guidelines: Otitis Media In Children (2012)*	2004 - 2009	Otherwise healthy Korean children under 15 years old presenting with OME.	Tympanostomy Tubes	1 systematic review, 5 studies (study type NR)	• Ventilation tube insertion is the preferred initial procedure when a child becomes a surgical candidate. (Recommendation§) • Surgical intervention is necessary when a child shows hearing loss of a moderate degree or worse, and when the tympanic membrane is anticipated to develop irreversible changes. • When OME persists over the 3-month	Grade B§

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
					observation but the hearing threshold in the better ear is lower than the criterion demanding surgical intervention, the duration of disease is considered as the most crucial factor to determine whether surgical intervention should be performed.	
Tsilis 2013[163] *Chronic Otitis Media in Children: An Evidence-Based Guide for Diagnosis and Management (2013)*	NR	Children presenting with chronic OM.	Tympanostomy Tubes	NR	• For those presenting with chronic otitis media and a retracted tympanic membrane, tympanostomy tube placement and regular follow-up should be attempted when the fundus of the retraction pocket is visible and clean.	NR
AOM						
American Academy of Pediatrics[82] *Clinical Practice Guideline: The Diagnosis and Management of Acute Otitis Media (2013)*	NR - October 2011	Otherwise healthy children without underlying conditions that may alter the natural course of AOM, aged 6 months to 12 years or age.	Tympanostomy Tubes	3 RCTs, 1 SR, 1 multicenter nonrandomized observational study	• Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year, with 1 episode in the preceding 6 months). (Option**) • Benefits: Decreased frequency of AOM. Ability to treat AOM with topical antibiotic therapy. • Risks, harms, cost: Risks of anesthesia or surgery. Cost. Scarring of TM, chronic perforation, cholesteatoma, otorrhea. • Benefits-harms assessment: Equilibrium of benefit and harm. • Value judgments: None • Intentional vagueness: Option based on limited evidence. • Role of patient preferences: Joint decision of parent and clinician. • Exclusions: Any contraindication to anesthesia and surgery.	Grade B†
The American Academy of Otolaryngology-Head and	2005 through	Children 6 months to 12 years of age, with tympanostomy	Tympanostomy tube insertion, including	4 guidelines, 15 systematic reviews	• Clinicians should not perform	Grade A†

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
Neck Surgery Foundation[141] *Clinical Practice Guideline: Tympanostomy Tubes in Children (2013)*	February 2012	tubes or being considered for TT in any case setting, as an intervention of OM of any time.	indications for tube placement, preoperative care, and postoperative care	or meta-analyses	tympanostomy tube insertion in children with recurrent AOM who do not have middle ear effusion in either ear at the time of assessment for tube candidacy. (Recommendation (against) *) • Clinicians should offer bilateral tympanostomy tube insertion to children with recurrent AOM who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy. (Recommendation*) • Clinicians should determine if a child with recurrent AOM… is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors. (Recommendation*) • In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up complications. (Recommendation*) • Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics for children with uncomplicated acute TTO. (Strong Recommendation*) • Water precautions: Clinicians should not encourage routine, prophylactic water precautions (use of earplugs, headbands; avoidance of swimming or water sports) for children with tympanostomy tubes. (Recommendation (against)*)	Grade B† Grade C† Grade C† Grade B† Grade B†

Organization(s) Title (Year)	Search Dates	Population Investigated	Intervention	Evidence Base Available	Recommendations	Level of Evidence
The Darwin Otitis Guidelines Group in collaboration with the Office for Aboriginal and Torres Strait Islander Health Otitis Media Technical Advisory Group[37] *Recommendations for clinical care guidelines on the management of otitis media in Aboriginal and Torres Strait Islander populations (2010)*	2001 – April 1, 2010	Children (specifically in the Aboriginal and Torres Strait Islander populations)	Tympanostomy tubes	4 SRs, 3 clinical guidelines	**Management of recurrent AOM (rAOM)** (defined as 3 episodes of AOM within a 6 months period or 4 episodes within 12 months): Refer for consideration of grommet surgery if: • The child is at low risk of developing chronic suppurative OM, and • rAOM fails to improve on antibiotic prophylaxis (>3 episodes in 6 months or >4 episodes in 1 year).	Grade B‡
Kitamura 2014[75] *Clinical Practice Guidelines for the Diagnosis and Management of AOM in Children in Japan—2013 update (2014)*	2006 - 2009	AOM patients aged <15 years who were free from AOM or OME within one month prior to onset, who do not have a TT inserted, who have no craniofacial abnormality, and who do not suffer from immunodeficiency.	Tympanostomy Tubes	NR	• Insertion of a tympanostomy tube for one year and short-term insertion for one month significantly reduce the frequency of occurrence of recurring otitis media (ROM) (defined as three or more occurrences of AOM within the previous six months, or four or more within the previous 12 months).	NR

Clinical Committee Findings and Decisions

Efficacy Considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
    - Refer to evidence identification document and discussion.
    - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
    - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

(2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
    - What are the known conditions/criteria and evidence state
    - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered ____ Covered Unconditionally ____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination

Following review of the proposed findings and decision document and public comments:

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.