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
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)
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

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
## Medicaid Utilization

<table>
<thead>
<tr>
<th></th>
<th>Unique Mbrs FFS</th>
<th>FFS Procs</th>
<th>Paid FFS (Rounded)</th>
<th>Average FFS Paid/Proc</th>
<th>Unique Members Managed</th>
<th>Managed Procs</th>
<th>Managed Care Paid Equivalent</th>
<th>Average Managed Paid/Proc Equivalent</th>
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<tbody>
<tr>
<td>2012</td>
<td>664</td>
<td>674</td>
<td>$1,174,000</td>
<td>$1,743</td>
<td>2,851</td>
<td>2,922</td>
<td>$4,722,000</td>
<td>$1,599</td>
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<tr>
<td>2013</td>
<td>531</td>
<td>545</td>
<td>$816,000</td>
<td>$1,497</td>
<td>3,123</td>
<td>3,212</td>
<td>$5,176,000</td>
<td>$1,595</td>
</tr>
<tr>
<td>2014</td>
<td>497</td>
<td>509</td>
<td>$724,000</td>
<td>$1,424</td>
<td>2,915</td>
<td>3,030</td>
<td>$4,892,000</td>
<td>$1,615</td>
</tr>
</tbody>
</table>
Percent of Population with Bilateral Procedures, 2011-2014

Members < 18 Years Utilizing Tympanostomy Services: Age Cohort
Current State Agency Policy

Medicaid – Covered (no conditions)
PEBB – Covered (no conditions)
Labor & Industries – n/a
Dept. of Corrections – n/a

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
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.
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

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)
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)*

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

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

Questions?

More Information

www.hca.wa.gov/hta/Pages/Tympan_tubes.aspx
Order of Scheduled Presentations:

_Tympanostomy Tubes in Children_

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<th>Name</th>
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<tr>
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No requests to provide public comment on the technology review were received.
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”

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1. Salary or payments such as consulting fees or honoraria in excess of $10,000.</td>
<td>✓</td>
<td></td>
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<tr>
<td>2. Equity interests such as stocks, stock options or other ownership interests.</td>
<td>✓</td>
<td></td>
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<tr>
<td>3. Status or position as an officer, board member, trustee, owner.</td>
<td>✓</td>
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<tr>
<td>4. Loan or intellectual property rights.</td>
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<tr>
<td>5. Research funding.</td>
<td>✓</td>
<td></td>
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<tr>
<td>6. Any other relationship, including travel arrangements.</td>
<td>✓</td>
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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

13 Therapeutics

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<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>7. Representation: if representing a person or organization, include the name and</td>
<td></td>
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<tr>
<td>funding sources (e.g. member dues, governmental/faith, commercial products or</td>
<td></td>
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<tr>
<td>services, grants from industry or government).</td>
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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 [Signature]
12/10/14 [Date]
C. Masters [Print Name]

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5128

Participant_disclosure Page 2 of 2
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


PI: Carol MacArthur, 2013-2014
5% effort.

Pending Support
None

Publications/Creative Work:

Peer-reviewed


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


Non-peer-reviewed


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


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

**Book Chapters**


**Reviews**


**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


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


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 CJ. Tissue Remodeling Cytokines in the Middle and Inner Ear During Acute and Chronic Otitis Media, ARO.


April 2011 Clayburgh D, Milczuk H, Gorsek S, Sinden N, Bowman K, **MacArthur C.J.** 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 C.J.** 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 C.J**, 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.


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.


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.

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.


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


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.


Regional and Local (Since October 2002)
10/30/02  Speaker, OHSU Pediatric Hematology/Oncology Tumor Board, “Pediatric Head and Neck Rhabdomyosarcoma”


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”


12/7/04  Grand Rounds Speaker (Salem Hospital Pediatric Grand Rounds) – “Sensorineural Hearing Loss in Children”
01/05 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”


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

            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)

1989-1990 | Departmental 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


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


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

Educational Publications


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


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.


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”
OHSU Pediatric Resident Lecture, “Neck Masses in Pediatric Patients”

OHSU Pediatric Department M & M Conference: “Pediatric Airway Foreign Bodies”

OHSU Pediatric Resident Lecture: “Vascular Lesions in Pediatric Patients: Terminology and Classification”

Doernbecher Operating Room In Service, “Vascular Malformations: Terminology and Treatment”

OHSU Pediatric Resident Noon Conference Lecture, “Otitis Media”

OHSU Pediatric Resident Lecture Series – “Tonsillitis and Deep Neck Infections”

OHSU Pediatric Grand Rounds, “Otitis Media Update”

Quiz Session for OHSU Otolaryngology Residents, “Vascular Malformations and Hemangiomas”

Quiz Session for OHSU Otolaryngology Residents, “Pediatric Sinusitis”

OHSU Pediatric Residency Noon Lectures series, “Vascular Lesions in Children”

OHSU Pediatric Residency Noon Lecture series, “Pediatric Otolaryngology Emergencies”


OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”

OHSU Pediatric Residency Noon Lecture Series, “Tonsillitis/Adenoids/Neck Infections”

OHSU Pediatric Residency Noon Lecture Series, “Pediatric Sinusitis”

OHSU Pediatric Residency Noon Lecture Series, “Vascular Lesions: Hemangiomas vs. Malformations”

OHSU Department of Pediatrics Morbidity & Mortality Conference, “Intracranial Complications of Sinusitis”

Medical Colloquia Lecture for OHSU Third Year Medical Students, “Evaluation of the Pediatric Airway”

PANDA Lecture. “Pediatric Otolaryngology Emergencies”
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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</thead>
<tbody>
<tr>
<td>09/14/06</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”</td>
</tr>
<tr>
<td>11/28/06</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Noisy Breathing”</td>
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<tr>
<td>12/05/06</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Vascular Malformations and Hemangiomas”</td>
</tr>
<tr>
<td>12/12/06</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Benign Pediatric Head and Neck Masses”</td>
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<tr>
<td>01/11/07</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Pediatric Neck Masses”</td>
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<tr>
<td>02/05/07</td>
<td>Medical Colloquia lecture for OHSU Third Year Medical Students, “Hemangiomas and Vascular Anomalies of the Head and Neck”</td>
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<tr>
<td>03/06/07</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Pediatric Otolaryngology Emergencies”</td>
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<tr>
<td>04/03/07</td>
<td>OHSU Pediatric Residency Noon Lectures series, “Vascular Lesions in Children”</td>
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<tr>
<td>04/04/07</td>
<td>Department of Pediatrics Noon Lecture, St. Vincent’s Hospital, Portland, OR. “Pediatric Deep Neck Infections”</td>
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<tr>
<td>09/25/07</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”</td>
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<tr>
<td>11/06/07</td>
<td>OHSU Pediatric Residency Noon Lectures series, “Stridor and Noisy Breathing”</td>
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<tr>
<td>11/13/07</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Acquired Airway Lesions”</td>
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<td>11/27/07</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Otitis Media”</td>
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<td>12/04/07</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Pediatric Neck Masses”</td>
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<td>02/08/08</td>
<td>Medical Colloquia lecture for OHSU Third Year Medical Students, “Hemangiomas and Vascular Anomalies of the Head and Neck”</td>
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<td>07/29/08</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”</td>
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<td>10/14/08</td>
<td>OHSU Department of Pediatrics, Morbidity &amp; Mortality Conference, “Intracranial Complications of Cholesteatomas and Mastoiditis”</td>
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<td>11/11/08</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Congenital sensorineural hearing loss” (preparation 3 hours)</td>
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<tr>
<td>11/25/08</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Vascular Anomalies: Terminology, Pathophysiology and Management” (preparation 3 hours)</td>
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<tr>
<td>Date</td>
<td>Event Description</td>
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<td>12/02/08</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Deep Neck Infections and Tonsillitis”</td>
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<td>09/22/09</td>
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<td>09/07/2010</td>
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<td>11/30/10</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Vascular Anomalies: Terminology, Pathophysiology and Management”</td>
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<td>12/7/10</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Congenital sensorineural hearing loss”</td>
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<tr>
<td>11/29/10</td>
<td>OHSU Pediatric Residency Noon Lectures series, “Hemangiomas and Vascular Malformations in Children” (preparation 1 hour)</td>
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<td>12/19/2011</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Pediatric Neck Masses”             (preparation 1 hour)</td>
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<tr>
<td>08/08/2012</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”</td>
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<td>09/17/13</td>
<td>OHSU Pediatric Residency Noon Lecture Series, “Otitis Media”</td>
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<td>October 2012</td>
<td>DCH Operating Room In service: “Image guidance Sinonasal Surgery &amp; Endoscopic Endonasal Approach to Intracranial Masses”</td>
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<td>11/12/13</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Congenital Airway Problems”</td>
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<tr>
<td>12/3/13</td>
<td>Quiz Session for OHSU Otolaryngology Residents, “Otitis Media”</td>
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**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 Quinteranilla-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 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:**

<table>
<thead>
<tr>
<th>Year</th>
<th>Position</th>
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<tbody>
<tr>
<td>2002-present</td>
<td>OHSU Department of Otolaryngology Residency Selection Committee</td>
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<tr>
<td>2003-present</td>
<td>Member, Cleft Craniofacial Disorders Team</td>
</tr>
</tbody>
</table>
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)

- 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)

Otitis Media with Effusion (OME)

- 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)

- 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

Otitis Media with Effusion (OME)

- 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)

- 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)

- 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

- 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

- 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

- 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

- **Watchful waiting (WW)**
  - Child is monitored
  - Many cases resolve spontaneously
  - Surgery performed if condition deteriorates or continues to persist
- **Mycringotomy**
  - 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

- **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

- Recurrent AOM
    - 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
    - TT recommended in children with recurrent AOM

Key Questions

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)

- **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.

- **Studies**
  - Randomized controlled trials (RCTs) (KQ1-2)
  - Nonrandomized comparative (cohort) studies (KQ1-2):
    - N ≥ 100 patients
    - Follow-up ≥ 80%
  - Case series designed to evaluate 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

1. Total Citations  \( (n = 1304) \)

2. Title/Abstract exclusion  \( (n = 1174) \)

3. Retrieved for full-text evaluation  \( (n = 130) \)

4. Excluded at full-text review  \( (n = 64) \)

5. Publications included  \( (n = 66) \)
   - 30 RCTs (in 50 publications)
   - 4 nonrandomized comparative studies (in 8 publications)
   - 3 case series
   - 5 economic evaluations

Overall strength of evidence (GRADE)

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<tr>
<th>Quality rating</th>
<th>Interpretation</th>
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<tbody>
<tr>
<td>High</td>
<td>High confidence that the evidence reflects the true effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>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.</td>
</tr>
<tr>
<td>Low</td>
<td>Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.</td>
</tr>
<tr>
<td>Insufficient</td>
<td>Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.</td>
</tr>
</tbody>
</table>
What is the evidence of the short- and long-term efficacy and effectiveness of TT insertion compared with WW or alternative treatment options?

**Results: KQ1**

**KQ1: Overview of evidence base**

**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 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

**Recurrent AOM:**
- 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

**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**

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

<table>
<thead>
<tr>
<th>Study</th>
<th>TT</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>WW</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rovers (6 months)</td>
<td>17.5</td>
<td>8.2</td>
<td>100</td>
<td>23.1</td>
<td>15.3</td>
<td>100</td>
<td>105</td>
<td>10%</td>
<td>49.7%</td>
<td>-3.40 (-6.89, -0.11)</td>
<td>-3.40 (-6.89, -0.11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMET (9 months)</td>
<td>18.5</td>
<td>11.2</td>
<td>81</td>
<td>21.4</td>
<td>16.3</td>
<td>80</td>
<td>85</td>
<td>10%</td>
<td>49.7%</td>
<td>-1.80 (-3.14, -0.46)</td>
<td>-1.80 (-3.14, -0.46)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>279</td>
<td>249</td>
<td>100.0%</td>
<td>-4.39 [-6.29, -2.50]</td>
<td>-4.39 [-6.29, -2.50]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for overall effect: Z = 0.04 (P = 0.96)

**MODERATE SoE**

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

<table>
<thead>
<tr>
<th>Study</th>
<th>TT</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>WW</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rovers (12 months)</td>
<td>33.2</td>
<td>7.2</td>
<td>37</td>
<td>34.7</td>
<td>7.9</td>
<td>37</td>
<td>36.5%</td>
<td>-1.90 (-4.39, 1.59)</td>
<td>-1.90 (-4.39, 1.59)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMET (18 months)</td>
<td>32.7</td>
<td>11.5</td>
<td>75</td>
<td>24.3</td>
<td>16.5</td>
<td>72</td>
<td>26.2%</td>
<td>-1.80 (-5.15, 1.55)</td>
<td>-1.80 (-5.15, 1.55)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TARGET (18 months)</td>
<td>21.1</td>
<td>10.2</td>
<td>103</td>
<td>19.7</td>
<td>10.4</td>
<td>98</td>
<td>37.3%</td>
<td>1.40 (-1.45, 4.25)</td>
<td>1.40 (-1.45, 4.25)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>215</td>
<td>252</td>
<td>100.0%</td>
<td>-0.45 [-2.44, 1.54]</td>
<td>-0.45 [-2.44, 1.54]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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**

60, 84, 120 months: Mean hearing levels were similar between groups.

(1 RCT, N=15-56 (35-103 ears)) (age 2-9 years)

**LOW SoE**

---

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

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

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Difference</th>
<th>SE</th>
<th>Weight</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>-3.5</td>
<td>1.1</td>
<td>35.5%</td>
<td>-3.50 (-6.89, -0.11)</td>
<td>-3.50 (-6.89, -0.11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dempster</td>
<td>-4.8</td>
<td>2.7</td>
<td>29.3%</td>
<td>-4.80 (-10.09, 0.49)</td>
<td>-4.80 (-10.09, 0.49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maw &amp; Bawden</td>
<td>-11.3</td>
<td>1.79</td>
<td>35.2%</td>
<td>-11.30 (-14.81, -7.79)</td>
<td>-11.30 (-14.81, -7.79)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>100.0%</td>
<td>-6.62 [-11.88, -1.36]</td>
<td>-6.62 [-11.88, -1.36]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

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)
KQ1: Hearing - additional comparators for OME

- **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

**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)
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

<p>| Verbal comprehension (Reynell test) at 6-9 months (Fig. 5) (mean age 1.2-4.7 years) |
|-----------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Mean (SD)</th>
<th>Weight</th>
<th>Mean (SD)</th>
<th>Weight</th>
<th>Mean (SD)</th>
<th>Weight</th>
<th>Mean (SD)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal comprehension (Reynell test) at 6-9 months (Fig. 5) (mean age 1.2-4.7 yrs.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Mean (SD)</td>
<td>Weight</td>
<td>Mean (SD)</td>
<td>Weight</td>
<td>Mean (SD)</td>
<td>Weight</td>
<td>Mean (SD)</td>
<td>Weight</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------------</td>
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</tr>
</tbody>
</table>

MODERATE SoE

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

<p>| Expressive language (Reynell, Schlichting tests) at 6-9 months (Fig. 6) (mean age 1.2-4.7 yrs.) |
|-----------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Mean (SD)</th>
<th>Weight</th>
<th>Mean (SD)</th>
<th>Weight</th>
<th>Mean (SD)</th>
<th>Weight</th>
<th>Mean (SD)</th>
<th>Weight</th>
</tr>
</thead>
</table>

MODERATE SoE
### KQ1: Speech & Language

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

### 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

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).

<table>
<thead>
<tr>
<th>F/U</th>
<th>Studies, N</th>
<th>Comparative Impact</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>TT vs. WW for OME (Age 1.6 years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 &amp; 12 mos.</td>
<td>1 RCT N=165-176</td>
<td>No differences between groups (TAIQOL subdomains)</td>
<td>☋☺☺ Low</td>
</tr>
<tr>
<td>TT+Ad vs. Myringotomy+Ad for OME (Age 4.5 years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 mos.</td>
<td>1 RCT N=44</td>
<td>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).</td>
<td>☋☺☺ LOW</td>
</tr>
<tr>
<td>12 mos.</td>
<td>1 RCT N=41</td>
<td>No differences between groups (improvement in OM-6 scores).</td>
<td>☋☺☺ LOW</td>
</tr>
<tr>
<td>TT vs. No procedure for recurrent AOM (Age 3.6 years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 &amp; 12 mos.</td>
<td>1 RCT N=81-85</td>
<td>No differences between groups (ear-related QoL).</td>
<td>☋☺☺ LOW</td>
</tr>
</tbody>
</table>
**KQ1: Cholesteatoma**

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

<table>
<thead>
<tr>
<th>OME</th>
<th>F/U</th>
<th>Studies, N</th>
<th>Comparative Impact</th>
<th>Quality</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>TT vs. WW</td>
<td>≤36 mos. &amp; At age 5</td>
<td>2 RCTs N=275</td>
<td>No differences between groups.</td>
<td>⨁⨁○○</td>
<td>LOW 0.6-12 yrs.</td>
</tr>
<tr>
<td>TT vs. Myr.</td>
<td>≤24-36 mos.</td>
<td>2 RCTs N=353</td>
<td>No differences between groups (rare).</td>
<td>⨁⨁○○</td>
<td>LOW 0.6-12 yrs.</td>
</tr>
<tr>
<td>TT+Ad vs. Myr+Ad</td>
<td>≤24 mos.</td>
<td>1 RCT N=301</td>
<td>No cases</td>
<td>⨁⨁○○</td>
<td>LOW 4-8 yrs.</td>
</tr>
<tr>
<td>TT+Ad vs. Ad</td>
<td>60 mos.</td>
<td>1 RCT N=55 (110 ears)</td>
<td>No cases</td>
<td>⨁⨁○○</td>
<td>LOW 4-10 yrs.</td>
</tr>
<tr>
<td>TT vs. Myr+Ad</td>
<td>≤24 mos.</td>
<td>1 RCT N=301</td>
<td>No cases</td>
<td>⨁⨁○○</td>
<td>LOW 4-8 yrs.</td>
</tr>
</tbody>
</table>
**KQ1: Cholesteatoma**

<table>
<thead>
<tr>
<th>Recurrent AOM</th>
<th>F/U</th>
<th>Studies, N</th>
<th>Comparative Impact</th>
<th>Quality</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>TT vs. antibiotics</td>
<td>≤24-30 mos.</td>
<td>2 RCTs N=258</td>
<td>No cases</td>
<td>☐ ☐ ☐ ☐</td>
<td>LOW 0.6-2.9 yrs.</td>
</tr>
<tr>
<td>TT vs. placebo</td>
<td>≤24 mos.</td>
<td>1 RCT N=163</td>
<td>No cases</td>
<td>☐ ☐ ☐ ☐</td>
<td>LOW 0.6-2.9 yrs.</td>
</tr>
<tr>
<td>OME or Recurrent AOM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT (unilateral) vs. Myr. or no procedure (contralateral)</td>
<td>≤24 mos.</td>
<td>1 RCTs N=57</td>
<td>No cases</td>
<td>☐ ☐ ☐ ☐</td>
<td>LOW 2.3 yrs.</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Total Events</th>
<th>Total Weight</th>
<th>M-H Random, 95% CI</th>
<th>M-H Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. heed</td>
<td>11</td>
<td>12</td>
<td>23.88 -0.19 (-0.46, 0.11)</td>
<td></td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>29</td>
<td>34</td>
<td>57.42 -0.41 (-0.68, -0.27)</td>
<td></td>
</tr>
<tr>
<td>Cotrimoxazol</td>
<td>10</td>
<td>34</td>
<td>20.84 -0.21 (-0.38, -0.05)</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>50</td>
<td>64</td>
<td>5.03 0.00 (-0.18, 0.21)</td>
<td></td>
</tr>
</tbody>
</table>

**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**

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**

**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**

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

<table>
<thead>
<tr>
<th>OME</th>
<th>F/U</th>
<th>Studies, N</th>
<th>Comparative Impact</th>
<th>Quality</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>TT (unilat.) vs. No procedure (contralat.)</td>
<td>6-60 mos.</td>
<td>2 RCTs N=169 (204 ears)</td>
<td>No differences between groups (perforation).</td>
<td>✭✭✭✭✭</td>
<td>3.9-5.7 yrs.</td>
</tr>
<tr>
<td>TT+Ad vs. Myr+Ad</td>
<td>≤24-36 mos.</td>
<td>3 RCTs N=591</td>
<td>No differences between groups (persistent perforation).</td>
<td>✭✭✭✭✭</td>
<td>2.9-8 yrs.</td>
</tr>
<tr>
<td>TT+Ad vs. Ad</td>
<td>60 mos.</td>
<td>1 RCT N=55 (110 ears)</td>
<td>No cases (perforation).</td>
<td>✭✭✭✭✭</td>
<td>4-10 yrs.</td>
</tr>
<tr>
<td>TT vs. Myr+Ad</td>
<td>≤24 &amp; 36 mos.</td>
<td>2 RCTs N=557</td>
<td>No differences between groups (persistent perforation or perforation).</td>
<td>✭✭✭✭✭</td>
<td>4-8 yrs.</td>
</tr>
<tr>
<td>TT vs. Ad</td>
<td>6 &amp; 12 mos.</td>
<td>1 RCT N=72</td>
<td>No differences between groups (perforation).</td>
<td>✭✭✭✭✭</td>
<td>5.9 yrs.</td>
</tr>
<tr>
<td>TT vs. Antibiotics</td>
<td>≤18 mos.</td>
<td>1 RCT N=60</td>
<td>No cases in TT group (chronic perforation).</td>
<td>✭✭✭✭✭</td>
<td>4.9 yrs.</td>
</tr>
</tbody>
</table>
## KQ2: Perforation

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

## KQ2: Chronic Otorrhea

**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

<table>
<thead>
<tr>
<th>OME</th>
<th>F/U</th>
<th>Studies , N</th>
<th>Comparative Impact</th>
<th>Quality</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>TT vs. WW ≤12 mos.</td>
<td>1</td>
<td>RCT N=187</td>
<td>Chronic otorrhea (3X/year) was more common in the TT versus WW group (25% vs. 5%, RD 19%, 95% CI 10% to 29%, p&lt;0.01).</td>
<td>☀️☀️∞</td>
<td>LOW</td>
</tr>
<tr>
<td>TT vs. WW; TT vs. Myr</td>
<td>≤36</td>
<td>RCTs N=89</td>
<td>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.</td>
<td>☀️☀️∞</td>
<td>LOW</td>
</tr>
<tr>
<td>TT+Ad vs. Myr+Ad</td>
<td>≤12</td>
<td>RCT N=78</td>
<td>Chronic otorrhea (≥3 episodes per year) occurred similarly between groups through 12 months.</td>
<td>☀️☀️∞</td>
<td>LOW</td>
</tr>
</tbody>
</table>

Results: KQ3

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

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

KQ4: TT vs. WW for OME

- **Evidence base:** 1 cost utility analysis (CUES 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**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Summary</th>
<th>Gaps in evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing</td>
<td>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).</td>
<td>Most evidence related to mean hearing levels rather than achievement of normal hearing levels.</td>
</tr>
<tr>
<td>Speech &amp; Language</td>
<td>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).</td>
<td>Evidence available for one comparator only.</td>
</tr>
<tr>
<td>Parent satisfaction</td>
<td>Insufficient SoE</td>
<td>No evidence.</td>
</tr>
<tr>
<td>Patient QoL</td>
<td>No differences between groups at any time point (6-12 months) (LOW to MODERATE SoE).</td>
<td>Limited evidence base (2 RCTs); no long-term evidence.</td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td>No difference between groups (LOW SoE).</td>
<td>Rare outcome; studies underpowered to detect potential differences between groups.</td>
</tr>
<tr>
<td>Persistent perforation</td>
<td>No difference between groups (LOW SoE).</td>
<td>Rare outcome; studies underpowered.</td>
</tr>
<tr>
<td>Chronic otorrhea</td>
<td>Mixed results; may be more common following TT insertion (LOW SoE)</td>
<td>Limited evidence base (4 trials).</td>
</tr>
</tbody>
</table>

**Recurrent AOM: Summary and Gaps in Evidence**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Summary</th>
<th>Gaps in evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing</td>
<td>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).</td>
<td>Limited evidence base (2 RCTs)</td>
</tr>
<tr>
<td>Speech &amp; Language</td>
<td>No evidence.</td>
<td>No evidence.</td>
</tr>
<tr>
<td>Parent satisfaction</td>
<td>No evidence.</td>
<td>No evidence.</td>
</tr>
<tr>
<td>Patient QoL</td>
<td>No differences between groups (4 &amp; 12 months) (LOW SoE).</td>
<td>Limited evidence base (subanalysis of 1 RCT); no long-term evidence.</td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td>No cases (LOW SoE)</td>
<td>Rare outcome; studies underpowered to detect potential differences between groups.</td>
</tr>
<tr>
<td>Persistent perforation</td>
<td>No evidence.</td>
<td>No evidence.</td>
</tr>
<tr>
<td>Chronic otorrhea</td>
<td>No evidence.</td>
<td>No evidence.</td>
</tr>
</tbody>
</table>
Thank you.

Questions?
Key Questions and Background

Tympanostomy Tubes in Children

Background

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

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

Policy Context

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

Objectives

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

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

1. What is the evidence of the short- and long-term efficacy and effectiveness of tympanostomy tube insertion compared with alternative treatment options or watchful waiting? Under what circumstances are tympanostomy tubes indicated?

2. What is the evidence regarding short- and long-term harms and complications of placement of tympanostomy tubes compared with alternative treatment options or watchful waiting?

3. Is there evidence of differential efficacy, effectiveness, or safety of tympanostomy tubes compared with alternative treatment options or watchful waiting? Include consideration of age, sex, race, ethnicity, socioeconomic status, risk for developmental delay, underlying sensorineural hearing loss, repeated exposure to large groups of children, duration of otitis media, and recurrent acute versus chronic otitis media.

4. What is the evidence of cost-effectiveness of tympanostomy tubes compared with alternative treatment options?

Scope

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

Intervention: Tympanostomy tube insertion

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

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

Outcomes:

- Efficacy/effectiveness (*indicates primary outcome)

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


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

Clinical outcomes: Hearing loss*, recurrent AOM*, balance and coordination (vestibular function), otorrhoea, 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.
For more information about this technology review and the Washington State Health Technology Assessment program, Visit [www.hca.wa.gov/hta](http://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.

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\(^1\) 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](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](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 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.

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

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;

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

<table>
<thead>
<tr>
<th>Safety Outcomes</th>
<th>Safety Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ototorhea chronic</td>
<td></td>
</tr>
<tr>
<td>Persistent perforation</td>
<td></td>
</tr>
<tr>
<td>Blockage of lumen</td>
<td></td>
</tr>
<tr>
<td>Granulation tissue</td>
<td></td>
</tr>
<tr>
<td>Premature extrusion</td>
<td></td>
</tr>
<tr>
<td>Tympanosclerosis</td>
<td></td>
</tr>
<tr>
<td>Atelectasis</td>
<td></td>
</tr>
<tr>
<td>Retraction pockets</td>
<td></td>
</tr>
<tr>
<td>Anesthesia harms</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy – Effectiveness Outcomes</th>
<th>Efficacy / Effectiveness Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved hearing levels</td>
<td></td>
</tr>
<tr>
<td>Reduction in middle ear effusion</td>
<td></td>
</tr>
<tr>
<td>QOL for parent and/or child</td>
<td></td>
</tr>
<tr>
<td>Decrease Acute OM incidence</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special Population / Considerations Outcomes</th>
<th>Special Populations / Considerations Evidence</th>
</tr>
</thead>
</table>
## 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]

<table>
<thead>
<tr>
<th>Organization(s) Title (Year)</th>
<th>Search Dates</th>
<th>Population Investigated</th>
<th>Intervention</th>
<th>Evidence Base Available</th>
<th>Recommendations</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>The American Academy of Otolaryngology-Head and Neck Surgery Foundation¹⁴¹</td>
<td>2005 through February 2012</td>
<td>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.</td>
<td>Tympanostomy tube insertion, including indications for tube placement, preoperative care, and postoperative care</td>
<td>4 guidelines, 15 systematic reviews or meta-analyses</td>
<td>1. Clinicians should not perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months’ duration. (Recommendation (against)*)</td>
<td>Grade C†</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>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*)</td>
<td>Grade C†</td>
</tr>
<tr>
<td>Clinical Practice Guideline: Tympanostomy Tubes in Children (2013)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>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*)</td>
<td>Grade B†</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>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*)</td>
<td>Grade C†</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>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</td>
<td>Grade C†</td>
</tr>
<tr>
<td>Organization(s) Title (Year)</td>
<td>Search Dates</td>
<td>Population Investigated</td>
<td>Intervention</td>
<td>Evidence Base Available</td>
<td>Recommendations</td>
<td>Level of Evidence</td>
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<td></td>
<td>loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected. (Recommendation*)</td>
<td>Grade C†</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>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*)</td>
<td>Grade C†</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>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*)</td>
<td>Grade C†</td>
</tr>
<tr>
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<td></td>
<td>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*)</td>
<td>Grade B†</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>9. Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics for children with uncomplicated acute TT otorrhea. (Strong Recommendation*)</td>
<td>Grade B†</td>
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<td></td>
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<td>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) *)</td>
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| The Darwin Otitis Guidelines Group in collaboration with the Office for Aboriginal and Torres Strait Islander Health Otitis Media Technical Advisory Group | 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)‡ |
<p>| | | | | 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‡ |</p>
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| British Columbia Medical Association, British Columbia Ministry of Health Services, Guidelines and Protocols Advisory Committee | 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) | 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 |

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‡
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- 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:
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</table>
| ^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 period. | Grade B§ |
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| *Tsilis 2013*[^1] [^2]  
*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*[^2]  
*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† |
<p>| The American Academy of Otolaryngology-Head and Neck Surgery | 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† |</p>
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<td>Neck Surgery Foundation 141</td>
<td>February 2012</td>
<td>tubes or being considered for TT in any case setting, as an intervention of OM of any time.</td>
<td>indications for tube placement, preoperative care, and postoperative care</td>
<td>or meta-analyses</td>
<td>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) *)</td>
<td>Grade B†</td>
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<td><em>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</em>)</td>
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<td><em>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</em>)</td>
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<td><em>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</em>)</td>
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<td><em>Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics for children with uncomplicated acute TTO. (Strong Recommendation</em>)</td>
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Grade C†
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| The Darwin Otitis Guidelines Group in collaboration with the Office for Aboriginal and Torres Strait Islander Health Otitis Media Technical Advisory Group<sup>37</sup>  
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<sup>75</sup>  
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:

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<th>Unproven (no)</th>
<th>Equivalent (yes)</th>
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<th>More (yes)</th>
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**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.