

March 21, 2025 Meeting Materials

Health Technology Clinical Committee

Hyperbaric oxygen therapy (HBOT) for Sudden Sensorineural Hearing Loss (SSNHL)

Contents

- HBOT HTCC clinical expert information
- Agency Medical Director presentation
- Scheduled public comments presenters and presentations
- HBOT evidence presentation
- HTCC decision aid
- HBOT final key questions

Health Technology Clinical Committee

Application for Membership



1

Contact information

First name:

Middle initial:

Last name:

Address:

Phone number:

Best method, time to reach you:

Email:

Today's date

2

Personal information (optional)

Gender:

Male

Female

X/non-binary¹

Pronouns (select all that apply)

She/her

He/him

They/them

Other (subj./obj.):

Race or Ethnicity

American Indian or Alaska Native

Asian or Pacific Islander American

Black/ African American

Latino, Hispanic, Spanish

White/ Caucasian

Other:

3

Professional training

Education (list degrees):

Health care practitioner licenses:

Professional affiliations:

Board certifications, formal training, or other designations:

Current position (title and employer):

Current practice type and years in practice:

Total years as an active practitioner:

Location of practice (city):

¹ Non-binary (X) is an umbrella term used to describe those who do not identify as exclusively male or female. This includes but is not limited to people who identify as genderqueer, gender fluid, agender, or bigender.

1) Why you would like to serve on the clinical committee;

3) How your training and experience will inform your role on the committee

5

Ability to serve

Are you able to participate in all-day meetings, an estimated six times per year?	Yes	No
Are you willing to commit to the responsibilities of a committee member, including:		
• Attending meetings prepared for the topics of the day;		
• Actively participating in discussions;		
• Making decisions based on the evidence presented and the public interest ¹ ?	Yes	No
Could you, or any relative, benefit financially from the decisions made by the HTCC?	Yes	No

6

References

Provide three professional references:

1. First name: Last name:

Relationship: Title:

Contact email: Phone number:
2. First name: Last name:

Relationship: Title:

Contact email: Phone number:
3. First name: Last name:

Relationship: Title:

Contact email: Phone number:

For your application to be reviewed, please include:

Completed application

curriculum vitae

[conflict of interest disclosure](#) 

Download this form and send the completed version to shtap@hca.wa.gov

OR mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

¹ Detailed in Washington Administrative Code (WAC) and committee bylaws

Health Technology Clinical Committee

Conflict of Interest Disclosure

Instructions

This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.

Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1

Applicant information

First name:

Middle initial:

Last name:

Phone number:

Email:

2

Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling \$1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

- | | | |
|--|--|---|
| A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity. | C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected. | D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees. |
| B. Employment including work as an independent contractor, consultant, whether written or unwritten. | | E. Participating on a company's proprietary governing boards. |
| | | F. Participating in a speakers bureau. |
| | | G. Receiving honoraria. |

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3

Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

4

Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Date

Download this form and send the completed version to shatap@hca.wa.gov.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

COLLEGE OF MEDICINE CURRICULUM VITAE

Jay T. Rubinstein, M.D., Ph.D.

October 20, 2024

I. EDUCATION AND PROFESSIONAL HISTORY

Education

1981	Sc.B. with Honors	Brown University	(Engineering)
1983	Sc.M.	Brown University	(Engineering)
1987	M.D. with Honors	University of Washington	
1988	Ph.D.	University of Washington	(Bioengineering)

Internships and Residencies

1988-89	Intern (Surgery), Beth Israel Hospital, Boston MA
1990-94	Resident (Otolaryngology), Massachusetts Eye & Ear Infirmary, Boston, MA

Clinical and Research Fellowships

1988	Research Fellow, Department of Physiology and Biophysics, University of Washington, Seattle WA
1989-90	Research Fellow, Department of Otology and Laryngology, Harvard Medical School
1994-95	Clinical Fellow in Otology/Neurotology, Department of Otolaryngology, The University of Iowa Hospitals and Clinics, Iowa City IA

Academic Appointments

1989-95	Research Affiliate, Research Laboratory of Electronics, Massachusetts Institute of Technology
1994-95	Fellow Associate, The University of Iowa Hospitals and Clinics, Iowa City IA
1995-00	Assistant Professor, Department of Otolaryngology-Head and Neck Surgery, The University of Iowa Hospitals and Clinics
1997-04	Faculty Appointment, Interdisciplinary Neuroscience PhD Program, The University of Iowa
1996-00	Assistant Professor, Department of Physiology & Biophysics, The University of Iowa
2000-04	Associate Professor with Tenure, Department of Otolaryngology-Head and Neck Surgery, The University of Iowa
2000-04	Associate Professor, Department of Physiology & Biophysics, The University of Iowa
2000-04	Associate Professor, Department of Biomedical Engineering, The University of Iowa
2003-04	Boerhaave Professor, Leiden University, The Netherlands
2004-	Virginia Merrill Bloedel Professor and Director, Virginia Merrill Bloedel Hearing Research Center, University of Washington
2004-	Professor of Otolaryngology-Head and Neck Surgery, University of Washington
2004-05	Adjunct Professor of Bioengineering, University of Washington
2005-	Professor of Bioengineering, University of Washington
2012-	Research Affiliate, Washington National Primate Research Center

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Other Employment Pertaining to Current Professional Appointments

1975-77 Software Developer, Telmar Communications Corp., New York NY
1979 Research Assistant, Geoelectromagnetics Laboratory, Department of Geological Sciences, Brown University, Providence RI
1980-81 Research Assistant, Visual Physiology Laboratory, Division of Engineering and Center for Neural Science, Brown University, Providence RI
1980-82 Teaching Assistant, Digital Electronics Laboratory, Division of Engineering, Brown University, Providence RI
1981-82 Research Assistant, Laboratory for Engineering Man/Machine Systems, Division of Engineering, Brown University, Providence RI
1996-04 Attending Surgeon, VA Medical Center, Iowa City, Iowa
2005- Board of Trustees, Listen & Talk School, Seattle, WA
2006-08 Board of Trustees, Executive Committee, Northwest Lions Foundation for Sight and Hearing, Seattle, WA
2006-12 Chairman, Board of Trustees, Audient, LLC, Seattle, WA
2008-12 Board of Directors, SightLife, LLC, Seattle, WA
2010- Medical Advisory Board, National Organization for Hearing Research

Certification and Licensure

Certification

1995 Diplomate, American Board of Otolaryngology--Head and Neck Surgery
2005 Neurotology Certificate of Added Qualifications
2013 Neurotology Certificate renewal

Licensure

1994 Iowa License #29758 (expired)
1994 California License (expired)
1994 Massachusetts License (expired)
2004 Washington License MD00044088 (active)

Honors and Awards

1981 Honorary Undergraduate Teaching Assistantship
1981 Sigma Xi
1984-86 Poncin Scholarship Award
1987 Alpha Omega Alpha
1992 American Academy of Otolaryngology Resident Research Grant
2003-04 Boerhaave Professor, Leiden University, the Netherlands
2005-06 Best Doctors in America
2006 Elected Senior Member of the IEEE
2006 Elected to the Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum
2007-08 President-elect, American Auditory Society

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- 2007-08 Best Doctors in America
- 2009 Presidential Citation, American Otologic Society
- 2009-10 President, American Auditory Society
- 2009 Honor Award, American Academy of Otolaryngology – HNS
- 2009-10 Best Doctors in America
- 2010-11 Best Doctors in America
- 2012-13 President-elect, Association for Research in Otolaryngology
- 2012 Seattle Top Doctors
- 2013-14 President, Association for Research in Otolaryngology
- 2014-15 Past-President, Association for Research in Otolaryngology
- 2015 Americas Top Doctors
- 2016 Seattle Top Doctors
- 2017 Seattle Top Doctors
- 2018-21 President-Elect, The Politzer Society
- 2018 America's Top Doctors 5 years
- 2019 Elected Fellow, American Institute of Medical and Biological Engineering

II. TEACHING

Classroom, Seminar, or Teaching Laboratory

- 1980-82 Teaching Assistant, Digital Electronics Laboratory, Brown University
- 1994-03 Weekly Neurotology Conference - lectures to otolaryngology residents and supervision of temporal bone dissection.
- 1994-03 Otolaryngology Basic Science Course
- 1995-03 Lectures to first & third year medical students on physiology & pathophysiology of the ear.
- 1997-03 Lectures to neuroscience graduate students on auditory physiology
- 2000-03 Lectures to primary care physicians on management of tinnitus, dizziness and hearing loss

Clinical Teaching (in ward, clinic, or operating room)

Otolaryngology Residents, Fellows and Medical Students

Teaching Activities Other Than Classroom or Clinical

- 1991-92 Assisted in undergraduate thesis supervision for Konstantina M. Trbovic, "Modeling of Auditory Nerve Responses to Electrical Stimulation," Department of Physics, Massachusetts Institute of Technology
- 1994 External thesis reader for Johan Frijns, MD, PhD. "Cochlear Implants, A Modeling Approach", Department of ENT, Leiden, Netherlands.
- 2000 PhD Committee for Leonid Litvak, Harvard/MIT Speech & Hearing Science Program.

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- 2000 PhD Committee for Karen Chi, Department of Speech Pathology and Audiology, University of Iowa
- 2001 PhD Committee for Christina Runge, Department of Speech Pathology and Audiology, University of Iowa
- 2001-03 Mentor, Doris Duke Clinical Research Fellowship Program, University of Iowa
- 2003 PhD Committee for Tiffany Johnson, Department of Speech Pathology and Audiology, University of Iowa
- 2005-07 Research mentor Chad Ruffin, visiting Howard Hughes Fellow.
- 2005-06 Research mentor Grace Liu, MD visiting medical student.
- 2005-06 PhD Committee for Lendra Friesen, Department of Speech and Hearing Sciences, University of Washington
- 2007 PhD Committee for Olivier Macherey, University of Leuven, Belgium, "Effects of Stimulus Waveform on Hearing with Cochlear Implants"
- 2007 External Thesis Reader for JE Smit, University of Pretoria, "Modeled Response of the Electrically Stimulated Nerve Fiber"
- 2008- PhD Committee for Katie Faulkner, Department of Speech and Hearing Sciences, University of Washington

Clinical Activities

A. Inpatient

Surgery performed 1.5 day per week in operating rooms of UW Medical Center and Seattle Childrens

B. Outpatient

Patient appointments 1.5 days per week

Master's and Ph.D. Theses Directed and Postdoctoral Fellows Supervised

- 1992-93 Committee Member and Thesis Reader for Masters Degree Candidate Eric R. Stutman, Thesis Titled "A Model for Temporal Sensitivity of Neurons in the Auditory Brainstem: The Role of a Slow, Low-Threshold Potassium Conductance," Department of Biomedical Engineering, Boston University
- 1995-96 Charles Miller, PhD - Postdoctoral Fellow. Physiology of electrically stimulated spiral ganglion cells, University of Iowa.
- 1995-96 Akihiro Matsuoka, MD, PhD. Response of auditory nerve to pulse trains. Dept of Speech Pathology & Audiology, University of Iowa.
- 1999-02 Nahla Hussein, MD. Doctoral Thesis, Suez Canal University, Egypt
- 2001-03 Gang Chen, MSE student, Dept. of Electrical Engineering, U. of I.
- 2001-03 Haiming Chen, MSE thesis, Dept. of Electrical Engineering, Radial-longitudinal impedance model for human cochlear implants.
- 2002-03 Ron Andreatta, MSE student, Dept of Biomedical Engineering, U. of I.
- 2002-03 Robert Hong, MD, Doris Duke Fellow, University of Iowa.
- 2005-07 Jeff Longnion, MD/PhD student in bioengineering, UW
- 2005-11 Jong Ho Won, PhD student in bioengineering, UW

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2005-09 Vasant Dasika, PhD. Postdoctoral fellow, UW.
2005-06 Steven Bierer, PhD. Postdoctoral fellow, UW.
2005-06 Robert Kang, MD, Otolaryngology-HNS resident, UW.
2007-08 Seeyoun Kwon, Visiting bioengineering graduate student, Hanyang University, Seoul.
2007-11 Nikita Imennov, PhD student in bioengineering, UW.
2009-10 Kyu Hwan Jung, MD, Visiting Fellow, Samsung Medical Center, Seoul.
2010-11 Minhyun Park, MD, Seoul National University, Seoul.
2010-11 Akinori Kashio, MD, Tokyo University, Tokyo
2011-12 Hyun-Joon Shim, MD, Seoul National University
2012-14 Il-Joon Moon, MD, Samsung Medical Center, Seoul
2009-12 Gary Jones, PhD, Postdoctoral fellow, UW
2014-16 Elle O'Brien, PhD student in neurobiology, UW
2016-19 Jesse Resnick, MD, PhD student in neurobiology, UW
2021-22 Charlotte Benoit, MD, Postdoctoral fellow, UW
2019-23 Ryan Carlson, PhD, MSTP student, UW

Clinical Fellows Supervised

1996-98 Paul Gidley, MD. Currently Professor, Department of Head and Neck Surgery, University of Texas MD Anderson Cancer Center,
1998-00 Brian Perry, MD. Currently in private practice, San Antonio, TX
2000-02 Ravi Samy, MD. Currently Associate Professor, Department of Otolaryngology, University of Cincinnati
2002-04 Ted Meyer, MD, PhD. Currently Associate Professor, Medical University of South Carolina
2011-12 Michal Preis, MD. Currently an otolaryngologist at Maimonides Medical Center, Brooklyn, NY
2014-15 Kavita Dedhia, MD. Currently Assistant Professor, Department of Otolaryngology, Emory University, Atlanta GA

III.SCHOLARSHIP

Papers Published

1. **Rubinstein J.T.** and Silverman, H.F. Some Comments on the Design and Implementation of FIR Filterbanks for Speech Recognition. In: Proceedings of the IEEE International Conference on Acoustics, Speech and Signal Processing. IEEE Speech and Signal Processing Society 812-815, 1983.
2. Soma, M., Spelman, F.A. and **Rubinstein, J.T.** Fields Produced by the Cochlear Prosthesis: The Ear as a Multilayered Medium. In: Frontiers of Engineering and

Computing in Health Care. Boston: IEEE Engineering in Medicine and Biology Society 401-405, 1984.

3. **Rubinstein, J.T.**, Spelman, F.A. and Soma, M. Mixed Boundary Value Problems in the Implanted Cochlea. In: Frontiers of Engineering and Computing in Health Care. IEEE Engineering in Medicine and Biology Society 1120-1123, 1985.
4. **Rubinstein, J.T.**, Suesserman, M.F. and Spelman, F.A. Measurements and Models of Recessed Electrodes. Proceedings of the Ninth Annual Conference of the IEEE Engineering in Medicine and Biology Society. Boston: IEEE Engineering in Medicine and Biology Society 913-914, 1987.
5. **Rubinstein, J.T.**, Spelman, F.A., Soma, M. and Suesserman, M.F. Current Density Profiles of Surface Mounted and Recessed Electrodes for Neural Prostheses. IEEE Transactions Biomedical Engineering BME 34:864-874, 1987.
6. **Rubinstein, J.T.** and Spelman, F.A. Analytical Theory for Extracellular Electrical Stimulation of Nerve with Focal Electrodes 1: Passive Unmyelinated Axon. Biophysical Journal 54:975-981, 1988.
7. Suesserman, M.F., Spelman, F.A. and **Rubinstein, J.T.** In-Vitro Measurement and Characterization of Current Density Profiles Produced by Nonrecessed, Simple Recessed, and Radially Varying Recessed Stimulating Electrodes. IEEE Transactions on Biomedical Engineering 38(5):401-408, 1991.
8. **Rubinstein, J.T.** Analytical Theory for Extracellular Electrical Stimulation of Nerve with Focal Electrodes 2: Passive Myelinated Axon. Biophysical Journal 60: 538-555, 1991.
9. **Rubinstein, J.T.** Axon Termination Conditions for Electrical Stimulation. IEEE Transactions on Biomedical Engineering 40(7):654-663, 1993.
10. **Rubinstein, J.T.** Threshold Fluctuations in an N Sodium Channel Model of the Node of Ranvier. Biophysical Journal 68:779-785, 1995.
11. Zbar RIS, Megerian CA, Khan A, **Rubinstein JT.** Invisible Culprit: Intralabyrinthine Schwannomas that do not appear on Enhanced Magnetic Resonance Imaging. Annals of Otolaryngology, Rhinology & Laryngology, 106(9):739-742, September 1997.
12. Arcuri MR and **Rubinstein JT.** Facial Implants. Dental Clinics of North America, Vol 42, Number 1, January 1998

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13. Miller CA, Abbas PJ, **Rubinstein JT**, Robinson BK, Matsuoka AJ, Woodworth G. Electrically evoked compound action potentials of Guinea pig and cat: responses to monopolar, monophasic stimulation. *Hear. Research* 119(1-2):142-154, 1998.
14. **Rubinstein JT**, Parkinson WS, Lowder MW, Gantz BJ, Tyler RS. Single-channel to multichannel conversions in adult cochlear implant subjects. *American Journal of Otology*, 19 (4): 461-466, July, 1998.
15. **Rubinstein JT**, Gantz BJ, Parkinson WS. Management of cochlear implant infections. *American Journal of Otology*, 20 (1) 46-49, 1999.
16. **Rubinstein JT**, Wilson BS, Finley CC, Abbas PJ. Pseudospontaneous activity: stochastic independence with electrical stimulation of the auditory nerve. *Hearing Research*, 127, 108-118, 1999.
17. Miller CA, Abbas PJ, Robinson BK, **Rubinstein JT**, Matsuoka AJ. Electrically evoked single-fiber action potentials from cat: responses to monopolar, monophasic stimulation. *Hearing Research*, 130 (1-2) 197-218, 1999.
18. **Rubinstein JT**, Parkinson WS, Tyler RS, Gantz BJ. Residual speech recognition and cochlear implant performance: effects of implantation criteria. *American Journal of Otology*, 20 (3)445-452, 1999.
19. Gantz, BJ, **Rubinstein JT**, Gidley P, Woodworth G. Surgical management of Bell's Palsy. *Laryngoscope* 109:1177-1188,1999
20. **Rubinstein JT**, Miller CA. How do cochlear prostheses work? *Current Opinion in Neurobiology* 9:399-404,1999.
21. Miller CA, Abbas PJ, **Rubinstein JT**. An empirically based model of the electrically evoked compound action potential. *Hearing Research*, 135 (1-2)1-18,1999.
22. Gidley PW, Gantz BJ, **Rubinstein JT**. Facial nerve grafts - from cerebellopontine angle and beyond. *American Journal of Otology* 20:781-788, 1999.
23. **Rubinstein JT**, Bauman NM. Management of Meniere's Disease in Children. *Meniere's Disease* 1999--Update, 409-418, 1999.

24. Vannier MW, Wang G, Skinner MW, **Rubinstein JT**. New X-ray imaging strategies – Implications for cochlear implantation. Review of Progress in Qualitative Nondestructive Evaluation 18(B): 1569-1574, 1999.
25. Ali T, **Rubinstein, JT**. Rheumatoid arthritis of the temporomandibular joint with herniation into the external auditory canal. Annals of Otology, Rhinology, and Laryngology 109 (2) 177-179, 2000.
26. White JA, **Rubinstein JT**, Kay AR. Intrinsic noise in neurons. Trends in Neuroscience 23:131-137, 2000.
27. Tyler RS, **Rubinstein JT**, Teagle H, Kelsay D, Gantz BJ. Pre-lingually deaf children can perform as well as post-lingually deaf adults using cochlear implants. Cochlear Implants International 1 (1), 39-44, 2000.
28. Yoo SK, Wang G, **Rubinstein JT**, Skinner M, Vannier M. Three-dimensional modeling and visualization of the cochlea on the internet. IEEE Transactions on Information Technology in Biomedicine 412, 144-151, 2000.
29. Yang S, Wang G, Skinner MW, **Rubinstein JT**, Vannier MW. Localization of dense markers in radiographs. Medical Physics 27 (4), 775-777, 2000.
30. Wang G, Skinner MW, **Rubinstein JT**, Howard MA, Vannier MW: Digital X-ray stereophotogrammetry for cochlear implantation. IEEE Transactions on Biomedical Engineering, 47 (8) 1120-1130, 2000.
31. Matsuoka AJ, Abbas PJ, **Rubinstein JT**, Miller CA. The neuronal response to electrical constant-amplitude pulse train stimulation: evoked compound action potential recordings. Hearing Research, 149, 115-128, 2000.
32. Matsuoka AJ, Abbas PJ, Miller CA, **Rubinstein JT**. The neuronal response to electrical constant-amplitude pulse train stimulation: additive Gaussian noise. Hearing Research, 149 , 129-137, 2000.
33. Gantz B, **Rubinstein J**, Tyler R, Teagle HFB, Cohen N, Waltzman S.Miyamoto R, Kirk K. Long-term results of cochlear implants in children with residual hearing. Ann Otol Rhinol Laryngol, 109 (12), 33-36, 2000.
34. Tyler RS, Kelsay DMR, Teagle HFB, **Rubinstein JT**, Gantz BJ, Christ AM. Seven year speech perception results and the effects of age, residual hearing and preimplant speech perception in prelingually deaf children using the nucleus and clarion cochlear implants. Adv Oto-Rhino-Laryngology 57, 305-310, 2000.

35. Tyler RS, Parkinson A, Wilson B, Parkinson W, Lowder M, Witt S, **Rubinstein J**, Gantz B. Evaluation of different choices of n in an n -of- m processor for cochlear implants. *Adv Oto-Rhino- Laryn* 57, 311-315, 2000.
36. Yoo SK, Wang G, **Rubinstein JT**, Vannier MW. Three-dimensional geometric modeling of the cochlea using helico-spiral approximation. *IEEE Transactions on Biomedical Engineering* 47 (10) 1392-1402, 2000
37. Perry BP, **Rubinstein JT**. Imaging case study of the month: meningitis due to acute otitis media and arachnoid granulations. *Annals of Otology, Rhinology & Laryngology*, 109, 877-879, 2000
38. Miller CA, Robinson BK, **Rubinstein JT**, Abbas PJ, Samuelson CR Auditory nerve response to monophasic and biphasic electric stimuli. *Hearing Research* 151, 79-94, 2001.
39. Matsuoka AJ, **Rubinstein JT**, Abbas PJ, Miller CA. The effects of interpulse interval on stochastic properties of electrical stimulation models and measurements. *IEEE Transactions on Biomedical Engineering*, Vol 48, No 4, 416-424, April 2001.
40. Perry BP, Gantz BJ, **Rubinstein JT**. Acoustic neuromas in the elderly. *Otology & Neurotology* Vol 22, No 3, 389-391, May, 2001.
41. Lustig, LR, Arts HA, Brackmann DE, Francis HF, Molony T, Megerian CA, Moore GF, Moore KM, Morrow T, Postic W, **Rubinstein JT**, Sireddy S, Syms III, CA, Takahashi G, Vernick D, Wackym PA, Niparko JK. Hearing rehabilitation using the Baha bone anchored hearing aid: results in 40 patients. *Otology & Neurotology* Vol 22, No 3, 328-334, May 2001.
42. **Rubinstein JT**, Miller CA, Mino H, Abbas PJ. Analysis of monophasic and biphasic electrical stimulation. *IEEE Transactions on Biomedical Engineering* 48(10): 1065-1070, 2001.
43. Gantz, BJ, **Rubinstein JT**, Gidley P, Woodworth G. Results of Surgical Decompression for Bell's Palsy. *Update on Facial Nerve Disorders, AAOHNS Monograph*, Alexandria, VA, pp. 181-193, 2001.
44. Yoo SK, Wang G, **Rubinstein JT**, Vannier MW. Semi-automatic segmentation of the cochlea using real-time volume rendering and regional adaptive snake modeling. *Journal of Digital Imaging* 14(4): 173-181, 2001

45. Tyler RS, Gantz GJ, **Rubinstein JT**, Wilson BS, Parkinson AJ, Wolaver A, Preece JP, Witt S, Lowder MW. Three-month results with bilateral cochlear implants. *Ear & Hearing* 23 (supplement): 80-89, 2002.
46. Gantz BJ, Tyler RS, **Rubinstein JT**, Wolaver A, Lowder M, Abbas P, Brown C, Hughes M, Preece JP. Binaural cochlear implants: results of subjects implanted bilaterally during the same operation. *Otology & Neurotology* 23(2): 169-180, 2002.
47. Jiang M, Wang G, Skinner MW, **Rubinstein JT**, Vannier MW. Blind deblurring of spiral CT image: comparative studies on edge to noise ratios. *Medical Physics* 29(5): 821-829, 2002.
48. Tyler RS, Preece JP, Wilson BS, **Rubinstein JT**, Parkinson AJ, Wolaver AA, Gantz BJ. Distance, localization and speech perception pilot studies with bilateral cochlear implants. *Cochlear Implants – An Update*, 517-522, 2002.
49. Mino H, **Rubinstein JT**, White JA. Comparison of algorithms for the simulation of action potentials with stochastic sodium channels. *Annals of Biomedical Engineering* 30(4): 578-587, 2002.
50. **Rubinstein JT**. Pediatric cochlear implants: prosthetic hearing and language development. by invitation to *The Lancet* 360: 483-85, 2002.
51. **Rubinstein JT** and Turner CW. A novel acoustic simulation of cochlear implant hearing: effects of temporal fine structure. First International IEEE EMBS Conference on Neural Engineering, IEEE press, 142-145, 2003.
52. Chen AF, Samy RF, Kirby P, Gantz BJ and **Rubinstein JT**. Neuroepithelial Cysts of the Middle Ear. *Annals of Otology, Rhinology and Laryngology* 112: 356-360, 2003.
53. **Rubinstein JT**, Tyler RS, Wolaver A and Brown CJ. Electrical suppression of tinnitus with high-rate pulse trains. *Otology & Neurotology*, 24: 478-485, 2003.
54. Hong RS, **Rubinstein JT**, Wehner D, Horn D. Dynamic range enhancement for cochlear implants. *Otology & Neurotology*, 24: 590-595, 2003.
55. **Rubinstein JT** and Della Santina CC. Analysis of a biophysical model for vestibular prosthesis research. *Journal of Vestibular Research* 12(2-3): 69-76, 2003.
56. Jiang M, Wang G, Skinner MW, **Rubinstein JT**, Vannier MW. Blind deblurring of spiral CT images. *IEEE Transactions on Medical Imaging* 22(7): 837-845, 2003.

57. **Rubinstein JT**, Hong RS. Signal coding in cochlear implants: Exploiting stochastic effects of electrical stimulation. *Annals of Otology, Rhinology and Laryngology* 112(suppl 191): 14-19, 2003.
58. Gomaa NA, **Rubinstein JT**, Lowder MW, Tyler RS, Gantz BJ. Residual speech perception and cochlear implant performance in postlingually deafened adults. *Ear & Hearing* 24(6): 539-544, 2003.
59. Hong RS and **Rubinstein JT**. High-rate conditioning pulse trains in cochlear implants: Dynamic range measures with sinusoidal stimuli. *Journal of the Acoustical Society of America* 114(6): 3327-3342, 2003.
60. Christensen GE, He J, Dill JA, **Rubinstein JT**, Vannier M, and Wang G. Automatic Measurement of the Labyrinth Using Image Registration and a Deformable Inner Ear Atlas. *Academic Radiology* 10(9): 988-99, 2003.
61. Mino H, **Rubinstein JT**, Miller CA, Abbas PJ. Effects of electrode-to-fiber distance on temporal jitter with electrical stimulation. *IEEE Transactions on Biomedical Engineering* 51(1): 13-20, 2004.
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32. **Rubinstein JT**, Wilson BS, Abbas PJ. Restoration of acoustic-like patterns of auditory nerve activity with electrical stimulation. 4th European Symposium on a Cochlear Implantation, s=Hertongenbosch, The Netherlands, 1998.
33. Miller CA, Abbas PJ, **Rubinstein JT**, Matsuoka AJ, Robinson BK. Ongoing research at the University of Iowa Auditory Electrophysiology Lab: Efforts to improve implant performance. 7th Symposium on Cochlear Implants in Children, Iowa City, Iowa, 1998.
34. **Rubinstein JT**, Miller CM, Abbas PJ, Matsuoka AJ. Computational dissection of the electrically evoked compound action potential. 1st International Symposium & Workshop on Objective Measures in Cochlear Implantation, Nottingham, UK, 1998.
35. Miller CA, Abbas PJ, **Rubinstein JT**, Robinson BK, Matsuoka AJ. Relationship between the gross electrically evoked auditory nerve response and single-fiber action potentials. First International Symposium & Workshop on Objective Measures in Cochlear Implantation. Nottingham, UK, 1998.
36. Matsuoka AJ, Abbas PJ, **Rubinstein JT**, Miller CA. Compound action potential responses to electrical constant-amplitude pulse trains. Association for Research in Otolaryngology Midwinter Meeting, St Petersburg Beach, FL, 1999.
37. Miller CA, Abbas PJ, **Rubinstein JT**, Robinson BK, Matsuoka AJ. Intracochlear electrical excitation of single auditory nerve fibers: Insights into modes of neural excitation and recruitment. Association for Research in Otolaryngology Midwinter Meeting, St Petersburg Beach, FL 1999.

38. **Rubinstein JT**, Miller CA, Abbas PJ, Wilson BS. Emulating physiologic firing patterns of auditory neurons with electrical stimulation. Association for Research in Otolaryngology Midwinter Meeting. St Petersburg, Beach, FL, 1999.
39. Miller CA, Abbas PJ, **Rubinstein JT**, Matsuoka AJ, Robinson BK. Relationships between single fiber and compound action potentials evoked electrically from the auditory nerve. Conference on Implantable Auditory Prostheses, Pacific Grove, California, 1999.
40. Dasika VK, Werner LA, Nie K, Norton SJ, **Rubinstein JT**. Application of the observer-based psychoacoustic procedure to infants and toddlers with cochlear implants. 11th International Conference on Cochlear Implants in Children, Charlotte, NC, 2007.
41. **Rubinstein JT**, Drennan WR, Corkrum K, Sie K, Norton SJ. Monaural benefits of second-side cochlear implants in “older” children. 11th International Conference on Cochlear Implants in Children, Charlotte, NC, 2007.

Selected NIH Contract Progress Reports

P.J. Abbas, **J.T. Rubinstein**, C.A. Miller and A.J. Matsuoka, First Quarterly Progress Report NO1-DC-6-2111, The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1997.

J.T. Rubinstein, A.J. Matsuoka, P.J. Abbas, and C.A. Miller, Second Quarterly Progress Report NO1-DC-6-2111, The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation" 1997.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, and A.J. Matsuoka, Third Quarterly Progress Report NO1-DC-6-2111, The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1997.

P.J. Abbas, C.A. Miller, A.J. Matsuoka, **J.T. Rubinstein**. Fourth Quarterly Progress Report NO1-DC-6-2111, The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1997.

J.T. Rubinstein, P.J. Abbas, C.A. Miller, A.J. Matsuoka. Fifth Quarterly Progress Report NO1-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1998.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, B.K. Robinson, A.J. Matsuoka. Sixth Quarterly Progress Report NO1-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1998.

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A.J. Matsuoka, P.J. Abbas, **J.T. Rubinstein**, C.A. Miller. Seventh Quarterly Progress Report N01-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1998.

J.T. Rubinstein, P.J. Abbas, C.A. Miller. Eighth Quarterly Progress Report N01-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1998.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, B.K. Robinson, A.J. Matsuoka. Ninth Quarterly Progress Report N01-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1999.

P.J. Abbas, C.A. Miller, **J.T. Rubinstein**, A.J. Matsuoka. Tenth Quarterly Progress Report N01-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1999.

J.T. Rubinstein, P.J. Abbas, C.A. Miller. Eleventh Quarterly Progress Report N01-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1999.

P.J. Abbas, **J.T. Rubinstein**, C.A. Miller, A.J. Matsuoka, B.K. Robinson. Final Progress Report N01-DC-6-2111. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1999.

P.J. Abbas, C.A. Miller, **J.T. Rubinstein**, B.K. Robinson. First Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 1999.

J.T. Rubinstein, P.J. Abbas, C.A. Miller. Second Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, C.J. Brown. First Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

P.J. Abbas, C.A. Miller, **J.T. Rubinstein**, B.K. Robinson, B.A. Abkes, C. Runge-Samuelson. Third Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

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C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, C. Runge-Samuelson. Second Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

H. Mino, **J.T. Rubinstein**, C.A. Miller, P.J. Abbas. Fourth Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

J.T. Rubinstein, C.A. Miller, H. Mino, P.J. Abbas. Third Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, C. Runge-Samuelson, B.K. Robinson, Fifth Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

C. Runge-Samuelson, **J.T. Rubinstein**, P.J. Abbas, C.A. Miller, G.J. Smith, B.K. Robinson, B.A. Abkes. Fourth Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

J.T. Rubinstein, C.A. Miller, P.J. Abbas, H. Mino. Sixth Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2001.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, B.K. Robinson. Fifth Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2001.

P.J. Abbas, C.A. Miller, **J.T. Rubinstein**, B.K. Robinson. Seventh Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2001.

C.A. Miller, P.J. Abbas, **J.T. Rubinstein**, J.F. Hetke. Sixth Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2001.

Other Special Presentations

Theses

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1. **Rubinstein, J.T.** A Microprocessor-Based Bone Mineral Analyzer [Undergraduate Thesis]. Providence RI: Brown University, 1981.
2. **Rubinstein, J.T.** Some Analysis and a Program for the Design of FIR Digital Filterbanks for Speech Recognition [Masters Thesis]. Providence RI: Brown University, 1982.
3. **Rubinstein, J.T.** Quasi-static Analytical Models for Electrical Stimulation of the Auditory Nervous System [Dissertation]. Seattle WA: University of Washington, 1988.

Invited Presentations

- 1991 Invited Speaker; Asilomar Conference on Implantable Auditory Prostheses
- 1993 Invited Speaker; Bryant College Conference on Cochlear Implants
- 1995 Invited Speaker; Asilomar Conference on Implantable Auditory Prostheses
- 1995 Chairman, Neural Modeling Session, Biomedical Engineering Society
- 1996 Moderator, Cochlear Implant Session, Association for Research in Otolaryngology
- 1996 Invited speaker, Bloedel Hearing Research Center, University of Washington
- 1997 Invited speaker, 5th International Cochlear Implant Conference, New York, NY
- 1997 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
- 1998 International Faculty, First International Symposium & Workshop on Objective Measures in Cochlear Implants, Nottingham, U.K.
- 1999 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
- 2000 Invited speaker, CI 2000, 6th International Cochlear Implant Conference, Miami Beach, Florida
- 2000 Invited speaker, 5th European Symposium on Paediatric Cochlear Implantation, Antwerp, Belgium
- 2000 Invited speaker, World Congress on Medical Physics & Biomedical Engineering, Chicago, IL
- 2000 Invited Speaker, 45th Japan Audiological Society Meeting, Nagoya, Japan
- 2001 Moderator, 8th Symposium on Cochlear Implants in Children, Los Angeles, CA
- 2001 Moderator, Second International Symposium & Workshop on Objective Measures in Cochlear Implants, Lyon, France
- 2001 Visiting Professor, Hospital of the University of Geneva, Geneva Switzerland
- 2001 Co-Chair, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
- 2001 Visiting Professor, Department of Otolaryngology, Johns Hopkins School of Medicine, Baltimore, MD
- 2002 Outreach Faculty, Wireless Integrated MicroSystems Engineering Research Center, University of Michigan, Ann Arbor, MI
- 2002 Visiting Professor, First International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul, Korea
- 2002 Panel on the Future of Cochlear Implants in Children. Triological Society Annual Meeting, Boca Raton, FL

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- 2002 Invited Speaker, Prentice Bloedel Day, Department of Otolaryngology, University of Washington, Seattle, WA
- 2002 Visiting Professor, Department of Otolaryngology, Mount Sinai School of Medicine, New York, NY
- 2002 Invited Speaker, Symposium on frontiers of organ and tissue replacement, American Society for Artificial Internal Organs, New York, NY
- 2002 International Advisory Member, 7th International Cochlear Implant Conference, Manchester, UK
- 2002 Visiting Professor, Department of Otolaryngology, University of Cincinnati, Cincinnati, OH
- 2002 Featured Speaker, Research Study Club, Los Angeles County Otolaryngology Society
- 2003 Keynote Speaker, NYU Cochlear Implant Course, Department of Otolaryngology, New York University, NY
- 2002 Invited panel on artificial organs, Third Annual Conference on Regenerative Medicine & DNA Therapies, Washington, D.C.
- 2003 Faculty Board, 4th International Symposium on Electronic Implants in Otology & Conventional Hearing Aids, Toulouse, France
- 2003 Guest speaker, American Auditory Society, Scottsdale, AZ
- 2003 Visiting Professor, Second International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul.
- 2003 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
- 2003 Invited speaker, Research Plenary Session, Annual meeting of Self-Help for Hard of Hearing People, Atlanta, GA
- 2003 Invited Faculty, 9th Symposium on Cochlear Implants in Children, Washington, DC
- 2003 Invited speaker, Workshop on Cochlear Implants: Perception, Physiology, Models, Association for Research in Otolaryngology, Daytona Beach, FL
- 2003 Invited speaker, Symposium on Tinnitus: Mechanisms, Models, Therapy, Association for Research in Otolaryngology, Daytona Beach, FL
- 2003 Visiting Professor, Saint Louis University / Washington University combined grand rounds, Saint Louis, MO.
- 2003 Visiting Professor, Department of Otolaryngology, University of Texas, Houston, Guest Speaker, Houston Society of Otolaryngology.
- 2003 Guest Faculty, Third International Symposium on Objective Measures in Cochlear Implantation, Department of Otolaryngology, University of Michigan, Ann Arbor, MI.
- 2003 Invited Lecturer, Department of Phonetics and Linguistics, University College London, UK.
- 2003 Twilight Lecture, The Ear Foundation, University of Nottingham, UK.
- 2003 Keynote Speaker, Asia-Pacific Symposium on Cochlear Implants, Taipei, Taiwan.
- 2004 International Advisory Panel, VIII International Cochlear Implant Conference, Indianapolis, IN.

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- 2004 International Faculty, 7th European Symposium on Paediatric Cochlear Implantation, Geneva, Switzerland
- 2004 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2004 Invited Lecturer, MRC Cognition and Brain Sciences Unit, University of Cambridge, UK
- 2004 Visiting Professor, Laboratory of Experimental ORL, University of Leuven, Belgium
- 2004 Guest Speaker, 204th General Meeting of the Netherlands Union of Otolaryngology, Nieuwegein, Netherlands
- 2004 Moderator, Research Forum, American Academy of Otolaryngology – Head and Neck Surgery, New York, NY
- 2004 Visiting Professor, Third International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul
- 2004 Guest Speaker, 2nd International Symposium on Advanced Technology for Recovery of Human Sensibility, Kyungpook University, Daegu, Korea.
- 2004 Guest Professor, University of Michigan Temporal Bone Dissection Course, Ann Arbor, MI
- 2004 Guest Speaker, Hearing, Balance and Chemical Senses Seminar, Kresge Hearing Research Institute, Ann Arbor, MI
- 2005 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2005 Keynote Speaker, Frontiers in Hearing, Breckenridge, CO
- 2005 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
- 2005 International Faculty, 5th Asia Pacific Symposium on Cochlear Implant and Related Sciences, Hong Kong.
- 2006 Visiting Professor, Department of Otolaryngology, University of Florida, Gainesville.
- 2006 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2006 Visiting Professor, Department of Otolaryngology, University of Pennsylvania, Philadelphia.
- 2006 Guest Speaker, Neuroengineering Now, Department of Bioengineering, University of Texas, Dallas, TX
- 2006 Visiting Professor, Osaka University Department of Otolaryngology, Osaka, Japan
- 2006 Guest Speaker, Second Annual Cochlear Implant Centres Group Education Day, Sunnybrook Health Sciences Centre, Toronto, Canada
- 2007 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
- 2007 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2007 Howard P House Memorial Lecture, Pacific Coast Oto-Ophthalmologic Society, Oahu, HI
- 2007 Visiting Professor, Fourth International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul
- 2007 Guest Professor, Updates in Otology & Neurotology, Cesme, Turkey
- 2007 International Faculty, Asia Pacific Symposium on Cochlear Implant and Related Sciences, Sydney, Australia
- 2008 Keynote Speaker, 2nd International Music and Cochlear Implant Symposium, University Hospital of Zurich, Switzerland
- 2008 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands

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- 2008 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2008 Visiting Professor, Fifth International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul, Korea
- 2008 Keynote Speaker, 6th Inner Ear Disease and Cochlear Implant Symposium, Izmir Teaching and Research Hospital, Kusadasi, Turkey
- 2009 Guest Translational Research Lecture, American Auditory Society, Scottsdale, AZ
- 2009 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
- 2009 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2009 Invited Speaker, Nemours Cochlear Implant Symposium, AI duPont Hospital for Children, Wilmington, DE
- 2009 Invited Speaker, Conference on Implanted Auditory Prostheses, Lake Tahoe, CA
- 2009 International Faculty, Asia Pacific Symposium on Cochlear Implant and Related Sciences, Singapore
- 2010 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2010 International Otologist, Frontiers of Otolaryngology, University of Melbourne, Australia
- 2010 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
- 2010 Distinguished speaker, House Ear Institute, Los Angeles
- 2010 Consulting speaker, IESLab, Ltd, Jinan, China
- 2010 Guest Professor, Dept of Otolaryngology, Miyazaki University, Japan
- 2010 Invited Speaker, Sixth International Symposium on Meniere's disease, Kyoto, Japan
- 2010 International Faculty, 7th Inner Ear and Cochlear Implantation Symposium, Bodrum, Turkey
- 2011 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
- 2011 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
- 2011 Holy Hour Speaker, Dept ExpORL, Katholieke Universiteit Leuven, Belgium
- 2011 Willard Fee Lecture, Dept of Otolaryngology, Stanford University, Stanford, CA
- 2011 Keynote speaker, Korean Otological Society, Jeong-Sun, Korea
- 2011 Plenary speaker, 8th Asia-Pacific Symposium on Cochlear Implant, Daegu, Korea
- 2011 Visiting professor, Samsung Medical Center, Seoul, Korea
- 2012 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
- 2012 Guest surgeon, Xijing Hospital, Xi'an, China
- 2012 Keynote address, 7th International Symposium on Objective Measures in Auditory Implants, Amsterdam, Netherlands
- 2012 International Faculty, 8th Inner Ear and Cochlear Implantation Symposium, Cappadoccia, Turkey
- 2012 Guest speaker, 16th International Symposium on Audiological Medicine, Beijing
- 2012 Seminar speaker, Weldon School of Biomedical Engineering, Purdue University, West Lafayette, IN
- 2013 Visiting Professor, Department of Otolaryngology, Bnai Zion Medical Center, Technion, Haifa, Israel
- 2013 Keynote speaker, Leiden University Cochlear Implant Course, The Netherlands.
- 2013 Schindler Lecture, UC San Francisco Department of Otolaryngology-HNS.

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- 2014 Visiting Surgeon, Global Foundation for Children with Hearing Loss, Childrens' Hospital #1, Ho Chi Minh City, Hanoi Nat'l Childrens' Hospital, Vietnam
- 2014 Keynote speaker, Leiden University Cochlear Implant Course, The Netherlands.
- 2014 Guest Faculty, Cochlear Colloquium, Mumbai, India
- 2015 Keynote speaker, Asia Pacific Symposium on Cochlear Implants, Beijing, China
- 2015 Invited speaker, Acoustical Society of America, Pittsburgh, PA
- 2016 Wilson TS Wang Visiting Professor, Department of Otolaryngology, Chinese University of Hong Kong
- 2016 Invited Speaker, Barany Society, Seoul, Korea
- 2016 Visiting Professor, Department of Otolaryngology, UT Southwestern, Dallas, TX.
- 2017 Robert H Mathog MD Memorial Lectureship, Department of Otolaryngology - HNS, Wayne State University, Detroit
- 2017 Schuknecht Lecture, Massachusetts Eye & Ear, Harvard Medical School, Boston
- 2017 John Niparko Lecture, Department of Otolaryngology, University of Southern California, Los Angeles
- 2018 Invited speaker, Crossroads of Music and Technology, Berklee School of Music, Boston, MA
- 2018 Guest speaker, The Politzer Society, Las Palmas de Gran Canaria, Spain
- 2018 Guest faculty, Cochlear China surgeons advisory board, Beijing, China
- 2019 John Daly Lecture, Department of Otolaryngology, New York University
- 2019 Guest Faculty, Ibero-American Conference on Cochlear Implants, Pamplona
- 2019 Keynote speaker, Asia-Pacific Conference on Cochlear Implants, Tokyo
- 2021 Residency graduation speaker, University of Utah Otolaryngology, Salt Lake City
- 2022 Graduation speaker, Department of Bioengineering, UC San Diego, San Diego
- 2022 Invited speaker, Great Debates, American Academy of Otolaryngology, Philadelphia
- 2023 Keynote lecture, Current Trends in Implantation Otology, Dublin
- 2024 Keynote Lecture, Politzer Society Meeting, Rome
- 2024 Senturia Lecture, Department of Otolaryngology, Washington University St Louis
- 2025 Grand Rounds & Sensory Neuroscience and Engineering Lecturer, Stanford University

Patents Received

1. **Jay T Rubinstein.** Pseudospontaneous Neural Stimulation System and Method. U.S. Patent No. 6,078,838. 6/20/00.
2. **Jay T Rubinstein,** Carolyn J Brown, Richard S Tyler, Paul J Abbas. System and Method for Application of Pseudospontaneous Neural Stimulation. U.S. Patent No. 6,295,472, 9/25/01.
3. **Jay T Rubinstein,** Carolyn J Brown, Richard S Tyler. System and Method for Diagnosing and/or Reducing Tinnitus. U.S. Patent No. 6,631,295, 10/7/03.
4. **Jay T Rubinstein,** Blake S Wilson. Speech Processing System and Method using Pseudospontaneous Stimulation. U.S. Patent No. 6,907,130, 6/14/05.
5. Kaibao Nie, Les Atlas, **Jay Rubinstein,** Xing Li, Charles Clark. Enhanced Signal Processing for Cochlear Implants. U.S. Patent No. 8,019,431, 9/13/11

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6. Frank Risi, Colin Irwin, **Jay T Rubinstein**, Felipe Santos and James O Phillips.
Vestibular stimulation Device. U.S. Patent No. 9,089,692, 7/28/15

Patents Applied For

1. **Jay Rubinstein**, Kaibao Nie, Steven Bierer, James Phillips, Leo Ling
Electrically-evoked Vestibular Compound Action Potentials to Guide Placement and
Programming of a Vestibular Neural Stimulator, 2009
2. **Jay Rubinstein**, James Phillips, Albert Fuchs, Leo Ling, Kaibao Nie, Steven Bierer,
Vestibular Implant Stimuli for the Treatment of Meniere's Disease, 2009
3. **Jay Rubinstein**, William Harrison. Electrodes for the Treatment of Tinnitus, 2008
4. **Jay Rubinstein**, William Harrison. Systems and Methods for the Treatment of Tinnitus,
2008

Areas of Research

Functional electrical stimulation of the inner ear

Treatment of hearing loss, tinnitus and vestibular dysfunction

High performance computing for neural modeling

Grants and Contracts

- | | | |
|---------|--|--------------------------|
| 1995-97 | San Diego Supercomputer Center.
Biophysical Model of Spiral Ganglion Cell and Auditory Nerve
Principal Investigator | 200 Cray hours quarterly |
| 1996-99 | The Whitaker Foundation.
Biophysical Model of Type - I Spiral Ganglion Cells
Principal Investigator | \$210,000 |
| 1996-98 | NIH, Shannon Award, NO1-R55 DC/ODO2948-01.
Comparative Biophysical Model of Spiral Ganglion Cells
Principal Investigator | \$100,000 |
| 1996-99 | National Institutes of Health, Contract No. N01-DC-6-2111.
The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation
Co-Principal Investigator | \$852,000 |
| 1997 | National Institutes of Health, SBIR R43DC03505
Cochlear Electrode with High Channel Selectivity
Subcontract PI | \$99,550 |
| 1998 | National Institutes of Health
Cochlear Implant Conference
Co-Investigator (Shannon, PI) | \$25,000 |
| 1999-00 | Braintronics, Inc. | |

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	Tinnitus Suppression with Electrical Stimulation	
	Principal Investigator	\$150,000
1999-04	National Institutes of Health 1 R01 DC03590	
	Spiral CT for Cochlear Implantation	
	Investigator (Wang, PI)	\$1,159,301
1999-02	National Institutes of Health Contract No. NIH-DC-98-14	
	The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation	
	Co-Principal Investigator	\$1,116,095
1999-02	National Institutes of Health Contract No. NIH-DC-98-11	
	Effects of Remaining Hair Cells on Cochlear Implant Function	
	Co-Investigator (Abbas, PI)	\$879,110
2000-03	Tinnitus Research Consortium	
	Electrical Suppression of Tinnitus	
	Principal Investigator	\$300,000
2001	National Institutes of Health 1 R13 DC005041-01	
	2001 Conference on Implantable Auditory Prostheses	
	Conference Co-Chair (Shannon, PI)	\$30,000
2001-06	National Institutes of Health P50	
	Iowa Cochlear Implant Center IV	
	Co-Director (Gantz, PI)	\$10,823,000
2002-06	National Institutes of Health Contract No. NIH-DC-98-11	
	Effects of Remaining Hair Cells on Cochlear Implant Function	
	Co-Investigator (Abbas, PI)	\$1,522,412
2002-03	Braintronics, Inc	
	Ear Implant for Tinnitus Suppression	
	Principal Investigator	\$250,000
2002	Advanced Bionics Inc.	
	Dynamic range with high-rate conditioning stimuli	
	Principal Investigator	\$30,000
2003	Advanced Bionics Inc.	
	Frequency discrimination with high-rate conditioning stimuli	
	Principal Investigator	\$30,000
2004-08	National Institutes of Health R01 DC05972	
	Randomized Trial of Tinnitus Retraining Therapy	
	Investigator (Tyler, PI)	\$1,768,575
2006	National Organization for Hearing Research Foundation	
	Measuring and improving hearing in infants with cochlear implants	
	Role: Mentor (Dasika, PI)	\$20,000
2005-10	National Institutes of Health R01 DC007525	
	Optimized Conditioned Processing for Cochlear Implants	
	Principal Investigator	\$1,905,126
2006-11	National Institutes of Health R13 DC006616	

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	Building the Next Generation of Clinical Researchers - American Auditory Society	
	Role: Co-Investigator (Gorga, PI)	\$133,579
2006-11	National Institutes of Health DC-05-0011 (Phillips, PI)	
	Neurophysiological Studies of Electrical Stimulation for the Vestibular Nerve	
	Investigator	\$2,831,646
2006-07	Cochlear Corporation	
	Validation of the UW CAMP music test for cochlear implant recipients.	
	Role: PI	\$30,000
2007-08	Advanced Bionics Corporation	
	Validation of the UW CAMP music test for cochlear implant recipients	
	Role: PI	\$15,000
2006-08	Cochlear Corporation	
	Clinical Trial of the Nucleus Hybrid Cochlear Implant	
	Role: PI	\$7,500
2008	National Institutes of Health F32 DC008238 (Dasika, PI)	
	The development of sensitivity to electrical stimulation with cochlear implants.	
	Role: Mentor	\$58,898
2009-11	National Institutes of Health F31 DC009755 (Won, PI)	
	Psychophysics of speech processor modifications in cochlear implants.	
	Role: Mentor	\$68,836
2008-09	Cochlear Corporation	
	Clinical Trial of the Nucleus Hybrid S12 Cochlear Implant	
	Role: PI	\$7,500
2009-11	Wallace Coulter Foundation	
	Clinical Feasibility of a Vestibular Neurostimulator	
	Role: PI	\$212,000
2009-11	National Institutes of Health F31 DC010306	
	A model-based approach for optimizing cochlear implant stimulation	
	Role: Co-mentor (Goldwyn, PI)	\$68,836
2010	University of Washington Technology Gap Innovation Fund	
	Improving speech and music perception with cochlear implants	
	Role: Investigator (Nie, PI)	\$50,000
2009-11	National Institutes of Health F31 DC010309 (Faulkner, PI)	
	Auditory Training to Improve Spectral Resolution in Cochlear Implant Listeners	
	Role: Co-mentor	\$41,000
2010-12	National Institutes of Health F32 DC011431 (Jones, PI)	
	Modeling spectral-ripple discrimination by cochlear implant users	
	Role: Mentor	\$80,000
2010-15	National Institutes of Health R01 DC010148 (Drennan, PI)	
	Improved analysis of cochlear implant sound processing	
	Role: Investigator	\$1,875,000
2011	ITHS/National Primate Research Center (Phillips, PI)	

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	Vestibular Prosthesis for Bilateral and Uncompensated Unilateral Loss	
	Role: Co-investigator	\$75,000
2011-14	Kranwinkle Family	
	Clinical Feasibility of a Vestibular Implant for Meniere's disease	
	Role: PI	\$1,004,000
2013-14	American Otologic Society (Horn, PI)	
	Spectral and Temporal Resolution in Children with Cochlear Implants	
	Role: Co-mentor	\$80,000
2014-15	Wallace Coulter Foundation (Atlas, PI)	
	Tonality in Cochlear Implants	
	Role: Investigator	\$100,000
2014-19	National Institutes of Health R01 DC014002	
	Optimization of a human vestibular implant	
	Role: PI	\$2,961,610
2014-19	National Institutes of Health K23 DC013055 (Horn, PI)	
	Spectral and Temporal Resolution in Children with Cochlear Implants	
	Role: Co-Mentor	\$1,151,530
2014	Anderson Family	
	Operating support for the Bloedel Center	
	Role: PI	\$100,000
2014-	Bill and Melinda Gates Foundation	
	Bloedel Minigrant Endowment	
	Role: PI	\$500,000
2015-16	Wallace Coulter Foundation (Atlas, PI)	
	Tonality in Cochlear Implants	
	Role: Investigator	\$100,000
2018-19	National Institutes of Health F31DC017349-01 (Resnick, PI)	
	Peripheral Limitations in Cochlear Implant Performance: Computational Exploration of how Demyelination and Degeneration Impact Neural Electrophysiology and Coding	
	Role: Mentor	\$77,000
2018-21	Department of Defense DM170556OD (Drennan, PI)	
	Early Detection of Noise-induced Hearing Loss	
	Role: Investigator	\$1,568,560
2018-19	Cheney Foundation (Horn, PI)	
	Psychophysics of infants with cochlear implants	
	Role: Mentor	\$10,000
2019-20	Cheney Foundation (Carlson, PI)	
	Genetics of pediatric hearing loss	
	Role: Mentor	\$5,000
2021-26	National Institutes of Health R01-DC018531 (Horn PI)	

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	Development of Sensitivity to Acoustic Modulation in Infants who use Cochlear Implants	
	Role: Investigator	\$3,488,270
2021-22	Decibel Therapeutics (Rubinstein PI)	
	Gene therapy for sensorineural hearing loss	
	Role: PI	\$732,872
2023-	Regeneron (Rubinstein PI)	
	Clinical trial agreement	
	Gene therapy for sensorineural hearing loss	
	Role: PI	\$285,243 (estimated)
2023-	National Institutes of Health R13-DC020895 (Rubinstein PI)	
	Conference on Implantable Auditory Prostheses	
	Role: PI	\$120,000

IV. SERVICE

Professional Affiliations

1980-	IEEE Engineering in Medicine and Biology Society
1986-	Association for Research in Otolaryngology
1990-	American Academy of Otolaryngology-Head and Neck Surgery
1992-94	Triological Society Resident Fellow
1996-	American Neurotology Society - Associate Member
1999-	American Auditory Society
2002-	American Otological Society
2006-	IEEE Senior Member
2006-	Collegium ORLAS
2007-09	President-elect and Program Chair, American Auditory Society
2008-11	Council, Association for Research in Otolaryngology
2009-10	President, American Auditory Society
2009-16	Vice-President, CORLAS-US group
2012-13	President-elect, Association for Research in Otolaryngology
2013-14	President, Association for Research in Otolaryngology
2014-15	Past-President, Association for Research in Otolaryngology
2016-	Treasurer, CORLAS-US group
2019-	College of Fellows, American Institute of Medical and Biological Engineering
2018-22	President-Elect, The Pulitzer Society
2023-	President, The Pulitzer Society

Collegiate, University and National Committees

1992-94	Graduate Medical Education Committee, Massachusetts Eye and Ear Infirmary
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- 1994-00 Committee on Implantable Hearing Devices, American Academy of Otolaryngology-
-Head and Neck Surgery
- 1995- Scientific Advisory Council, NIDCD National Temporal Bone, Hearing and Balance
Pathology Resource Registry
- 1996 Steering Committee, 1997 Asilomar Conference on Implantable Auditory Prostheses
- 1996 Ad Hoc NIH Site Visitor
- 1997 IAIMS Task Force, The University of Iowa
- 1997- American Neurotology Society Research Committee
- 1997- College of Medicine Research Committee
- 1997 Ad Hoc member NIH Hearing Research Study Section
- 1997 Ad Hoc member NIH Sensory Disorders SBIR Study Section
- 1998 Ad Hoc member NIH Hearing SBIR Study Section
- 1999 Ad Hoc member NIH IFCN Study Section
- 2000 Ad Hoc Member, NIH IFCN6 SBIR Study Section
- 2000 Peer reviewer, Conference of Rectors of the Austrian Universities
- 2000 NIH NINDS Special Emphasis Panel ZNS1 SRB-H(04)
- 2001 NIH NIDCD Special Emphasis Panel ZDC1 SRB-O
- 2001 Conference co-chair, Asilomar Conference on Implantable Auditory Prostheses
- 2001 Steering Committee, NIH/VA International Hearing Aid Conference
- 2001 Task Force on New Materials, American Board of Otolaryngology
- 2001 Nominating Committee, Association for Research in Otolaryngology
- 2001 Peer Reviewer, Hearing Loss Guideline Panel, New York State Department of Health
- 2002 Steering Committee, 2003 Asilomar Conference on Implantable Auditory Prostheses
- 2002 Outreach Faculty, Wireless Integrated MicroSystems Engineering Research Center,
University of Michigan, Ann Arbor, MI
- 2002 NIH NIDCD Special Emphasis Panel, ZRG1 IFCN-4(06)
- 2002 Prosthetic Clinical Management National Workgroup on Cochlear Implants,
Department of Veteran Affairs
- 2002 Ad Hoc Reviewer, Swiss National Science Foundation
- 2003 NIH NIDCD Special Emphasis Panel ZDC1 SRB-O
- 2003 Ad Hoc Reviewer, Royal National Institute for the Deaf, UK
- 2003 NIH NIDCD Special Emphasis Panel ZDC1 SRB-R (42)
- 2004 Ad hoc member, NIH AUD study section
- 2005 Ad hoc member, NIH R03 study section
- 2005-09 Permanent member NIH AUD study section
- 2005-08 Government Relations Committee, ARO
- 2006 Guest examiner, American Board of Otolaryngology
- 2006-07 Program Advisory Committee, American Otologic Society
- 2007 Guest examiner, American Board of Otolaryngology
- 2007 Steering committee, Conference on Implantable Auditory Prostheses
- 2007 Ad Hoc Reviewer, US Department of Energy Retinal Prosthesis Program
- 2008 Neurotology Examiner, American Board of Otolaryngology

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2008-09 Scientific Advisory Panel, NIH Roadmap Nanomedicine Initiative
2009 Guest Examiner, American Board of Otolaryngology
2010 Neurotology Examiner, American Board of Otolaryngology
2010 Chair, nominating committee, American Otologic Society
2010 Program Committee, American Otologic Society
2012 Program Committee, American Otologic Society
2012-13 President-elect, Association for Research in Otolaryngology
2013-14 President, Association for Research in Otolaryngology
2014-15 Past President, Association for Research in Otolaryngology
2018-22 President-Elect, The Politzer Society
2018 Chair, NIDCD Special Emphasis Panel
2019 Chair, NIDCD Special Emphasis Panel
2019-23 Guest Examiner, American Board of Otolaryngology
2023- President, The Politzer Society
2024- Chair, NIDCD Special Emphasis Panel

Board Memberships

2001- Scientific Advisory Board, American Tinnitus Association
2002- Surgical Advisory Board, Cochlear Corporation
2003- Editorial Board, Otology and Neurotology
2003- Editorial Board, Hearing Research
2005-08 Associate Editor, Journal of the Association for Research in Otolaryngology
2004-08 Executive Board, American Auditory Society
2005- Board of Trustees, Listen & Talk School, Seattle, WA
2005- Surgical Advisory Board, Advanced Bionics Corporation
2006-08 Board of Trustees, Executive Committee, Northwest Lions Foundation for Sight and Hearing, Seattle, WA
2006-12 Chairman, Board of Trustees, Audient, LLC, Seattle, WA
2008-11 Council-at-large, Association for Research in Otolaryngology
2008-13 Board of Directors, SightLife, LLC, Seattle, WA
2010-13 Board of Directors, Otology & Neurotology
2010-18 Research Advisory Board, American Otologic Society
2012-17 Board of Scientific Counselors, NIDCD
2015 2017-21 NIDCD Strategic Plan Working Group
2017 Chair, Scientific Advisory Board, American Otologic Society

Ad Hoc Reviewer

Annals of Biomedical Engineering
Annals of Neurology
Annals of Otology, Rhinology & Laryngology
American Journal of Otology
Archives of Otolaryngology

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Audiology and Neuro-otology
Ear and Hearing
Hearing Research
Hospital Physician
IEEE Transactions on Biomedical Engineering
Journal of Biomechanics
Journal of Neurophysiology
Journal of Neuroscience
Journal of the Acoustical Society of America
Journal of the Association for Research in Otolaryngology
Laryngoscope
Medical & Biological Engineering & Computing
Nature Medicine
Otology and Neurotology
Science Translational Medicine
The Lancet



Hyperbaric Oxygen Therapy (HBOT) for Sudden Sensorineural Hearing Loss (SSNHL)

Judy Zerzan-Thul, MD, MPH

Chief Medical Officer

Health Care Authority

Background

- ▶ SSNHL is rapid loss of hearing with onset over a period of less than 72 hours. It involves a decrease in hearing of ≥ 30 decibels (dB) affecting at least 3 consecutive frequencies.
 - ▶ More than 90% of cases are idiopathic
 - ▶ 32% to 62% of cases of SSNHL recover spontaneously, which complicates the evaluation of treatments
- ▶ Acute acoustic trauma (AAT) is a less common cause of SSNHL
- ▶ Rationale for the treatment with HBOT is that the hearing loss may be caused by a hypoxic event in the cochlear apparatus; therefore, HBOT may reverse the oxygen deficit, increase oxygen pressures in the cochlea, and improve microcirculation.
- ▶ Administering oxygen at pressures greater than 1 ATA requires environmental compression. This is achieved by placing the patient in an airtight chamber and slowly increasing the environmental pressure while administering 100% oxygen. This results in increased oxygen delivery to the lungs, blood, and other body tissues.
- ▶ Fifteen HBOT centers in WA

Current State Agency Policies

- ▶ Non-covered by 2013 HTCC decision
 - ▶ PEBB/SEBB
 - ▶ Apple Health Managed Care and Fee For Service
 - ▶ Labor and Industries
- ▶ Found low certainty evidence (COE) due to mixed results from 8 randomized controlled all within 2 weeks onset hearing loss.
- ▶ Findings were inconclusive as to whether there is a benefit of HBOT in the acute phase and there was moderate COE from 2 RCTs, suggesting no benefit of HBOT

Why Re-review

- ▶ New studies

- ▶ Note 2 of the studies reviewed before 2013

- ▶ U.S. Food and Drug Administration (FDA) approval

- ▶ FDA regulates both the oxygen and the hyperbaric chambers
 - ▶ July 2021, the FDA has cleared hyperbaric chambers for sudden idiopathic hearing loss

Agency Medical Director Concerns

Safety = Medium

Efficacy = High

Cost = Medium

Diagnosis and Procedure Codes

Bilateral sensorineural hearing loss

- **H90.3:** Bilateral sensorineural hearing loss, meaning hearing loss in both ears

Unilateral sensorineural hearing loss

- **H90.4**

Sensorineural hearing loss in one ear, with normal hearing in the other ear

- **H90.71**

Mixed conductive and sensorineural hearing loss in one ear, with normal hearing in the other ear

- **H90.72**

Mixed conductive and sensorineural hearing loss in one ear, with normal hearing in the other ear

Unspecified sensorineural hearing loss

- **H90.5:** Unspecified sensorineural hearing loss

Mixed conductive and sensorineural hearing loss

- **H90.6:** Mixed conductive and sensorineural hearing loss in both ears

- **H90.8:** Mixed conductive and sensorineural hearing loss, unspecified

Agency Utilization and Cost: 2020-2023

Agency Cost (over 4 years)	
Encounters	252
Total Paid	\$66,617
Individuals	13
Average Paid	\$5,124

Other Payers

Payer	Coverage
Humana	Covered
Premiera Blue Cross	Covered
United	Covered
Aetna	Covered within 3 months of onset
Cigna	Covered within 4 weeks of onset
Kaiser	Covered for severe to profound within 2 weeks if possible; 6 weeks most
Regence Blue Shield	Covered for >40 decibels and within 14 days of onset
TRICARE	No policy
Center for Medicare and Medicaid Services (CMS)	No policy

Guidelines

- ▶ 4 organizations with treatment guidelines
- ▶ The American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF) and the European Committee for Hyperbaric Medicine (ECHM)
 - ▶ Recommend HBOT as an option for the treatment of SSNHL when combined with medical therapy in patients who present within 2 weeks of hearing loss and no later than 1 month of SSNHL onset.
- ▶ The Underseas and Hyperbaric Medical Society (UHMS)
 - ▶ Consider HBOT for patients with moderate to profound idiopathic SSNHL (≥ 41 dB) who present within 14 days of symptom onset

Key Questions

- ▶ 1. Is HBOT effective in improving patient-centered outcomes?
 - ▶ 1a. What is the optimal frequency, dose, and duration of HBOT treatment?
- ▶ 2. What is the differential effectiveness and safety of HBOT according to factors such as age, sex, race or ethnicity, disability, comorbidities, treatment setting, hearing loss duration, severity, or type of hearing loss (e.g., idiopathic vs noise-induced or acute vs. chronic)?
- ▶ 3. What are the harms associated with HBOT?
- ▶ 4. What is the cost effectiveness of HBOT?

Limitations of studies

- ▶ Studies were generally small, with sample sizes ranging from 25 to 121 participants
- ▶ None of the identified trials were in the United States
- ▶ Specific steroid treatments used as cointerventions or comparators varied
- ▶ The timing of HBOT treatment after onset of symptoms varied
- ▶ Definitions of hearing recovery varied across studies and most did not define what degree of hearing recovery was clinically meaningful

HBOT Effectiveness

- ▶ Absolute risk difference of 180 more people per 1,000 (ranging from 14 to 396) achieving complete or partial hearing recovery with HBOT compared with steroids alone
- ▶ All 10 studies HBOT plus steroids about 40% more likely to achieve complete or partial recovery compared with those treated with steroids
- ▶ Among the 7 RCTs that compared HBOT with steroids with steroids alone, 4 RCTs reported differential effectiveness outcomes
 - ▶ One RCT found participants treated with HBOT plus steroids within 7 days had statistically significant hearing recovery; after 7 days did not have statistically significant hearing recovery.
 - ▶ One RCT found mean hearing improvements were significantly better among those with greater hearing loss at baseline; however, a second RCT found no difference by hearing loss at baseline,
 - ▶ Treatment after 14 days not effective

Timing, Duration and Subgroups

- ▶ One RCT comparing 2 HBOT sessions per day for 5 days with 1 HBOT session per day over 10 days found no significant differences
- ▶ One study compared early HBOT treatment (within 10 days) versus late HBOT treatment (11 to 30 days)
 - ▶ At 6 weeks no statistically significant difference in complete, partial, and no hearing recovery between early and late HBOT treatment groups
- ▶ One RCT found that higher pressure (2.5 ATA vs. 1.5 ATA) provided significantly better hearing and WDS improvement
 - ▶ Increasing the time (2 hours vs. 1 hour) for 1.5 ATA did not result in a significant difference
- ▶ Very limited evidence for differential efficacy by subpopulations

Acute Acoustic Trauma (AAT)

- ▶ 7 studies mostly conducted in Europe among male military participants
 - ▶ 1 study was an RCT and 6 were NRSIs
 - ▶ 2 from before 2013, the 1 RCT from 1985
- ▶ The RCT was high RoB
 - ▶ Lack of information about baseline differences and allocation concealment
 - ▶ Concerns regarding outcome selection and lack of blinding for outcome
- ▶ NRSI serious RoB or critical RoB
 - ▶ No attempt or poor attempts to control for confounding

Harms and Cost Effectiveness

- ▶ Very few minor harms
 - ▶ Ear pain
- ▶ No studies on cost-effectiveness

Agency Medical Directors Recommendations

- ▶ Recommend cover HBOT with conditions for idiopathic SSNHL with
 - ▶ Moderate to severe hearing loss
 - ▶ Start treatment within 14 days of onset
 - ▶ Also treat with steroids
- ▶ Do not cover for AAT



Questions?

Hyperbaric oxygen therapy for sudden sensorineural hearing loss

Order of scheduled presentations:

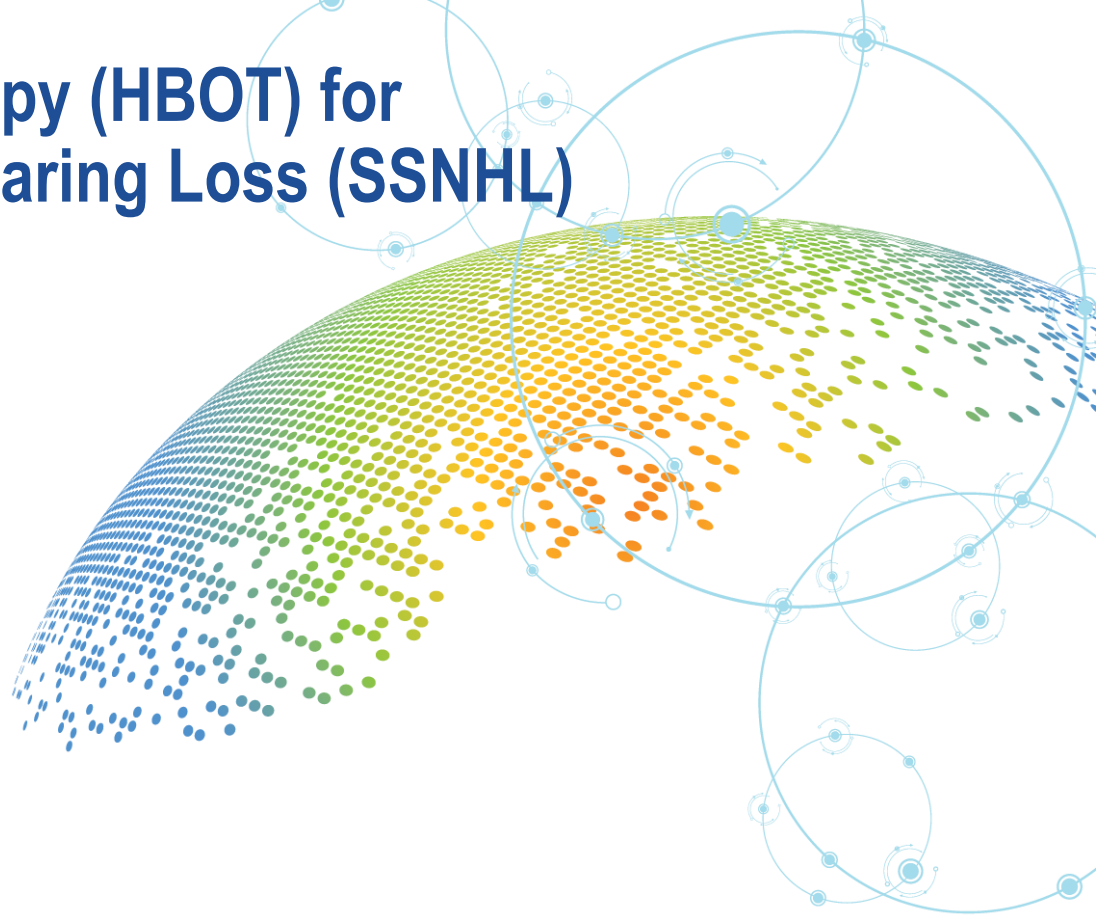
Name	
1	
2	
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Hyperbaric Oxygen Therapy (HBOT) for Sudden Sensorineural Hearing Loss (SSNHL)

Health Technology Assessment
Washington State Health Care Authority

March 21, 2025

Sara Kennedy, MPH
RTI-UNC Evidence-based Practice Center



Project Team

Name

Sara Kennedy, MPH

Karen Crotty, PhD, MPH

Valerie Ng, BS

Mark Howell, MLS

Leila Kahwati, MD MPH

Role

Lead Investigator/ Project Coordinator

Co-Investigator

Research Analyst

Librarian

Scientific Reviewer

Abbreviations

- AAT = Acute acoustic trauma
- ATA = atmosphere absolute (measure of pressure)
- COE = Certainty of evidence
- dB = decibels
- HBOT = Hyperbaric Oxygen Therapy
- NRSI = Nonrandomized studies of interventions
- PTA = Pure-tone average (measure of hearing)
- RCT = Randomized controlled trials
- RoB = Risk of bias
- SSNHL = Sudden sensorineural hearing loss
- WDS = Word discrimination score

Presentation Overview

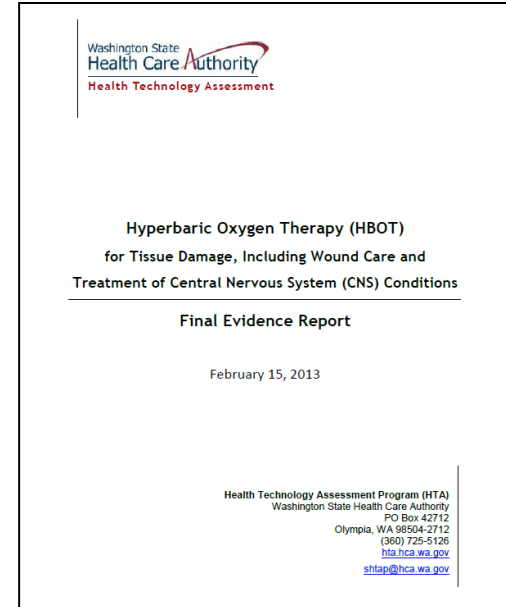
- Policy context
- Background
- Methods
- Findings
- Conclusions
- Questions



Policy Context

Previous Evidence Report

- A review of HBOT for several indications was completed in 2013
 - This report was a review of systematic reviews
- **Conclusions**
 - Acute phase (treatment within 2-weeks): Low-quality evidence due to mixed results from 8 RCTs, inconclusive as to whether there is a benefit of HBOT
 - Chronic phase: Moderate-quality evidence from 2 RCTs suggested no added benefit
- **Coverage Decision**
 - HBOT was not covered for acute or chronic SSNHL



Current Evidence Report Selection

- This topic was selected for an update because of:
 - Medium concerns for safety
 - High concerns for efficacy
 - High concerns for cost
- New evidence that could change the previous determination



Background

Background Hearing Loss

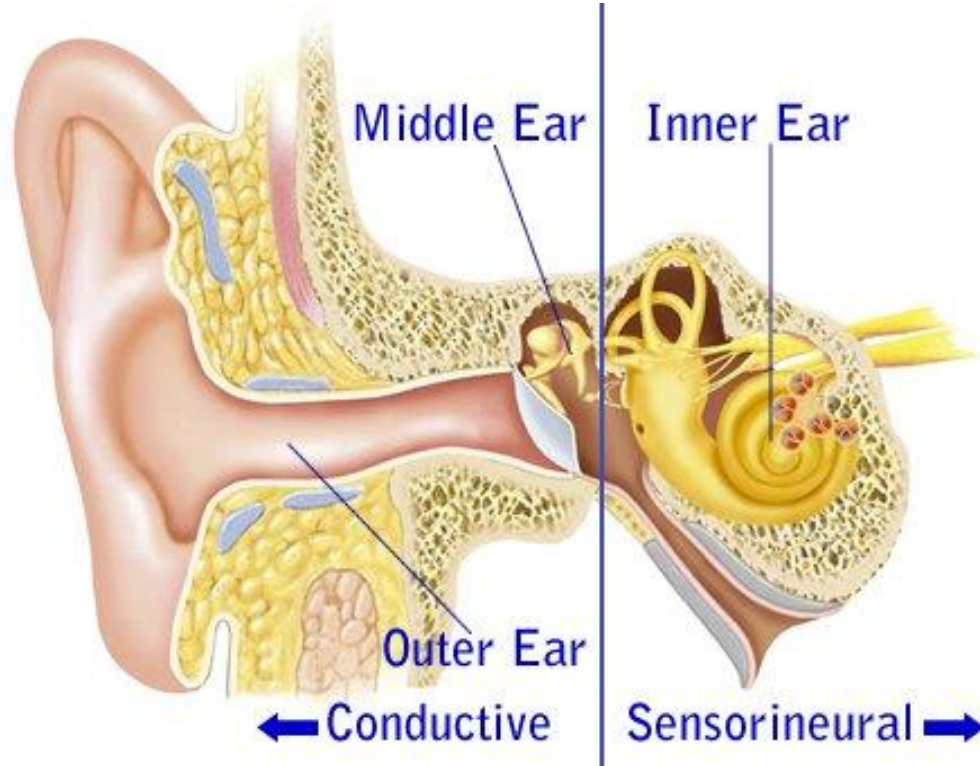


Image Source: Hearingchoices.com

Sudden sensorineural hearing loss (SSNHL)

- Sudden sensorineural hearing loss (SSNHL) is a subset of sensorineural hearing loss, that is:
 1. Sensorineural in nature
 2. Occurs within a 72-hour window
 3. Involves a decrease in hearing of ≥ 30 decibels affecting at least 3 consecutive frequencies.

Note: As a clarification in their 2019 guideline on SSNHL, The American Academy of Otolaryngology specified that they mean idiopathic SSNHL when they use the term SSNHL since >90% of cases are idiopathic.

Source: [American Academy of Otolaryngology \(2019\)](#)

Epidemiology of SSNHL

- 5 to 27 per 100,000 people annually have SSNHL or about 66,000 new cases per year in the US
 - > 90% of SSNHL is idiopathic
 - Dizziness or vertigo co-occur in 30% to 60% of cases
 - Tinnitus is nearly universal in SSNHL and can be a very troubling symptom
- 32% to 65% of cases of SSNHL recover spontaneously
- A suspected cause is some hypoxic event in the cochlear apparatus

Source: [American Academy of Otolaryngology \(2019\)](#)

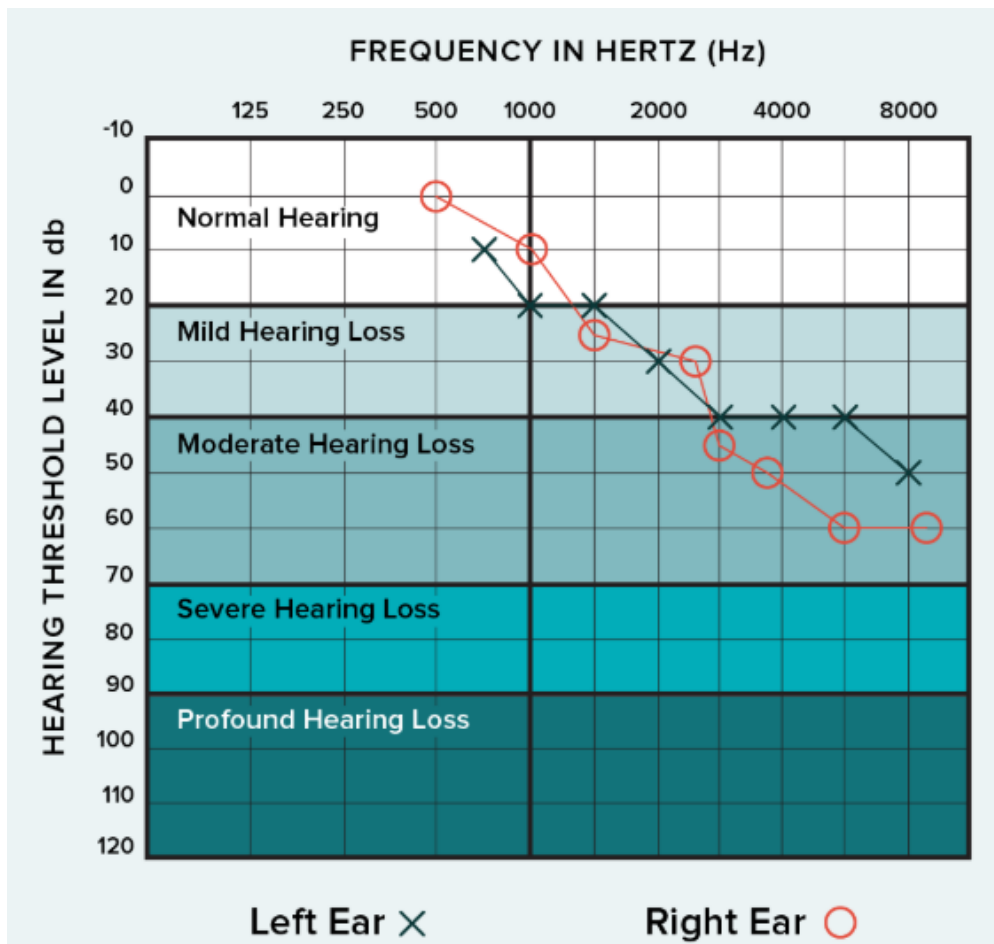
Acute Acoustic Trauma

- Acute acoustic trauma (AAT) or acute noise-induced hearing loss is sensorineural hearing impairment due to exposure to an intense impulse noise
 - Inner ear becomes mechanically damaged, after a short-impact acoustic impulse (intensity of 90–130 dB for a duration of 1 ms).
 - Vasospasm of microcirculation and hypoxia of sensory cells occur
- Symptoms include high-frequency sensorineural hearing loss (4 kHz and higher, while 1–2 kHz influenced minimally) and tinnitus
 - Common in military or law enforcement personnel, who are at an increased exposure to impulse noises from firearm discharges

Source: [Holy et al. \(2021\)](#)

Measurement of Hearing Loss

- Pure-tone average (PTA) is the measurement of an individual's hearing sensitivity
- PTA results are plotted on an audiogram
 - Data from the right and left ears are plotted separately
 - The y axis is the hearing threshold in decibels (or how loud a sound was to be heard)
 - The x axis is the frequency with low tones to the left and high-pitched tones to the right



Source: <https://www.healthline.com/health/audiogram#graph-explained>

Measurement of Hearing Loss

- Context of PTA:
 - PTA of 30 dB: difficulty understanding whispering; words with “p,” “h,” and “g”; birds chirping
 - PTA of 80 dB: difficult to hear a dog barking or a baby crying; normal conversation very challenging without hearing assistance

Degree of Hearing Loss	PTA Range (in dB)
Normal	–10 to 15
Slight	16 to 25
Mild	26 to 40
Moderate	41 to 55
Moderately severe	56 to 70
Severe	71 to 90
Profound	91+

Abbreviations: dB = decibels

Hyperbaric oxygen therapy (HBOT)

- Emerged in the 1660s, widely used beginning in the 1960s
- Air pressure inside is raised to a level that is higher than normal air pressure (> 1.4 ATA)
- Patients breath 100% (pure) oxygen in a chamber
- Increased air pressure helps lungs collect more oxygen
- Getting more oxygen to the tissues that need it can help the body heal
- However, too much oxygen can cause harm

Source: [U.S. Food and Drug Administration \(2021\)](#)



Why HBOT for SSNHL?

- Vascular compromise, and associated cochlear ischemia, is a potential etiology of idiopathic SSNHL and AAT
- The cochlea and the structures within it require a high oxygen supply but the direct vascular supply is minimal
- The increased partial pressure of oxygen from HBOT allows for more delivery of oxygen to the tissues—in this case, the cochlea, which is very sensitive to ischemia.

Source: [American Academy of Otolaryngology \(2019\)](#) and [Undersea & Hyperbaric Medical Society](#)

Regulatory context

The FDA regulates both the oxygen used in HBOT and the hyperbaric chambers.

As of July 2021, the FDA cleared hyperbaric chambers for hearing loss, specifically for complete hearing loss that occurs suddenly and without any known cause.

Source: [Hyperbaric Oxygen Therapy: Get the Facts | FDA](#)

Clinical practice guidelines

AAO-HNS (2019)

Clinicians may offer, or refer to a clinician who can offer, HBOT combined with steroid therapy within 2 weeks of onset of idiopathic SSNHL or as salvage therapy within 1 month of onset of SSNHL.

ECHM (2017)

Recommends HBOT combined with medical therapy within two weeks of disease onset.

IECS (2016)

HBOT with drug therapy could have a small benefit of questionable clinical relevance.

UHMS (2011)

Recommends HBOT for patients with moderate to profound idiopathic SSNHL within 14 days.

AAO-HNSF = American Academy of Otolaryngology - Head and Neck Surgery Foundation; ECHM = European Committee for Hyperbaric Medicine; IECS = Institute for Clinical Effectiveness and Health Policy; UHMS = Underseas and Hyperbaric Medical Society.

Payor context

✓ = covered; ✕ = not covered; — = no policy identified

Medicare	Aetna	Cigna	Humana	Kaiser Permanente	Premera Blue Cross	Regence Blue Shield	TRICARE	United Health Care
—	✓	✓	✓	✓	✓	✓	—	✓

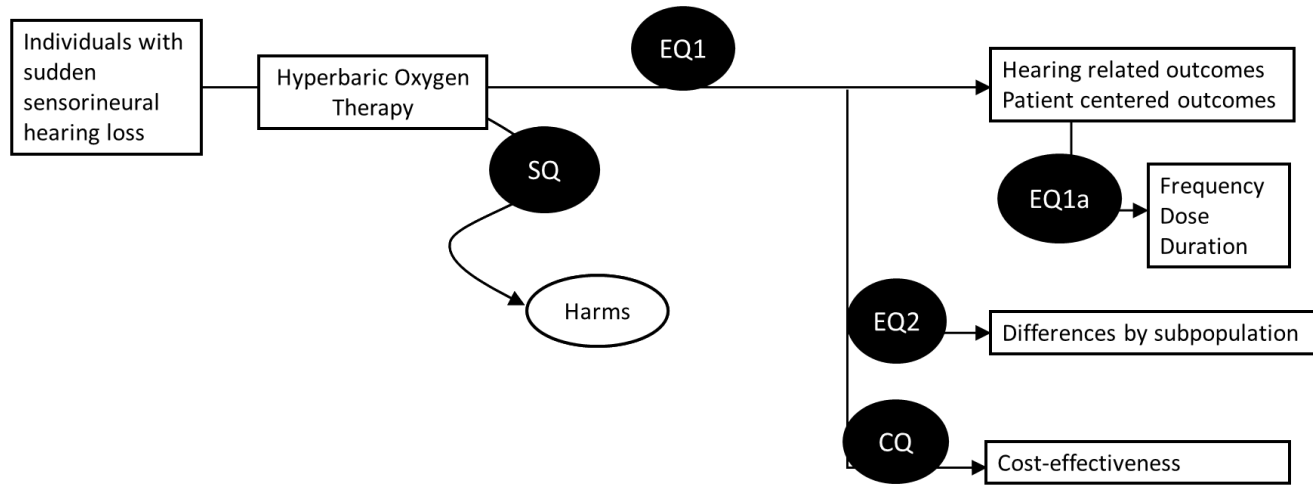
Notes: ✓ = covered with conditions; ✕ = not covered; — = no policy identified.

Conditions generally related to defining thresholds for hearing loss (e.g., decrease in hearing of greater than or equal to 30 decibels) and time since symptom onset (e.g., treatment initiated within 4 weeks or within 3 months of symptom onset).



Methods

Draft key questions and analytic framework



Efficacy Question 1 (EQ1): Is HBOT effective in improving patient-centered outcomes for individuals with SSNHL?

EQ1a. Efficacy: What is the optimal frequency, dose, and duration of HBOT treatment for SSNHL?

EQ 2. Subpopulations: What is the differential effectiveness and safety of HBOT according to factors such as age, sex, race or ethnicity, disability, comorbidities, treatment setting, hearing loss duration, time to treatment, severity or type (e.g., idiopathic or noise-induced or acute vs. chronic)?

Safety Question (SQ): What are the harms associated with HBOT for use in treating SSNHL?

Cost Question (CQ): What is the cost effectiveness of HBOT for SSNHL?

Inclusion criteria (summary)

Population	Children or adults with acute or chronic, idiopathic or noise-induced SSNHL	
Intervention	HBOT, with or without steroids or other medical management	
Comparator	Other treatments or sham HBOT treatments	
Outcomes	• Hearing related or patient centered outcomes • Harms • Cost-effectiveness (U.S. based only)	
Setting	Very high HDI countries	
Study designs	<u>Idiopathic SSNHL</u> EQ1, EQ1a, EQ2, SQ: RCTs CQ: cost utility or effectiveness	<u>AAT</u> KQ1, KQ2, and KQ3: RCTs or NRSIs KQ4: cost utility or effectiveness
Timing	Inception to date	

AAT = acute acoustic trauma; NRSI = nonrandomized study of intervention; HBOT = hyperbaric oxygen therapy; HDI = human development index; RCT = randomized controlled trial; SSNHL = sudden sensorineural hearing loss.

Outcomes of interest (more detail)

Patient-centered outcomes

- Hearing recovery (categorical measures)
- Hearing improvement (continuous measured based on PTA)
- Word discrimination score (WDS)
- Tinnitus
- Depression
- Functional status
- Quality of life

Harms

Ear pain, barotrauma, temporary visual disturbances, oxygen toxicity, serious adverse events, adverse events

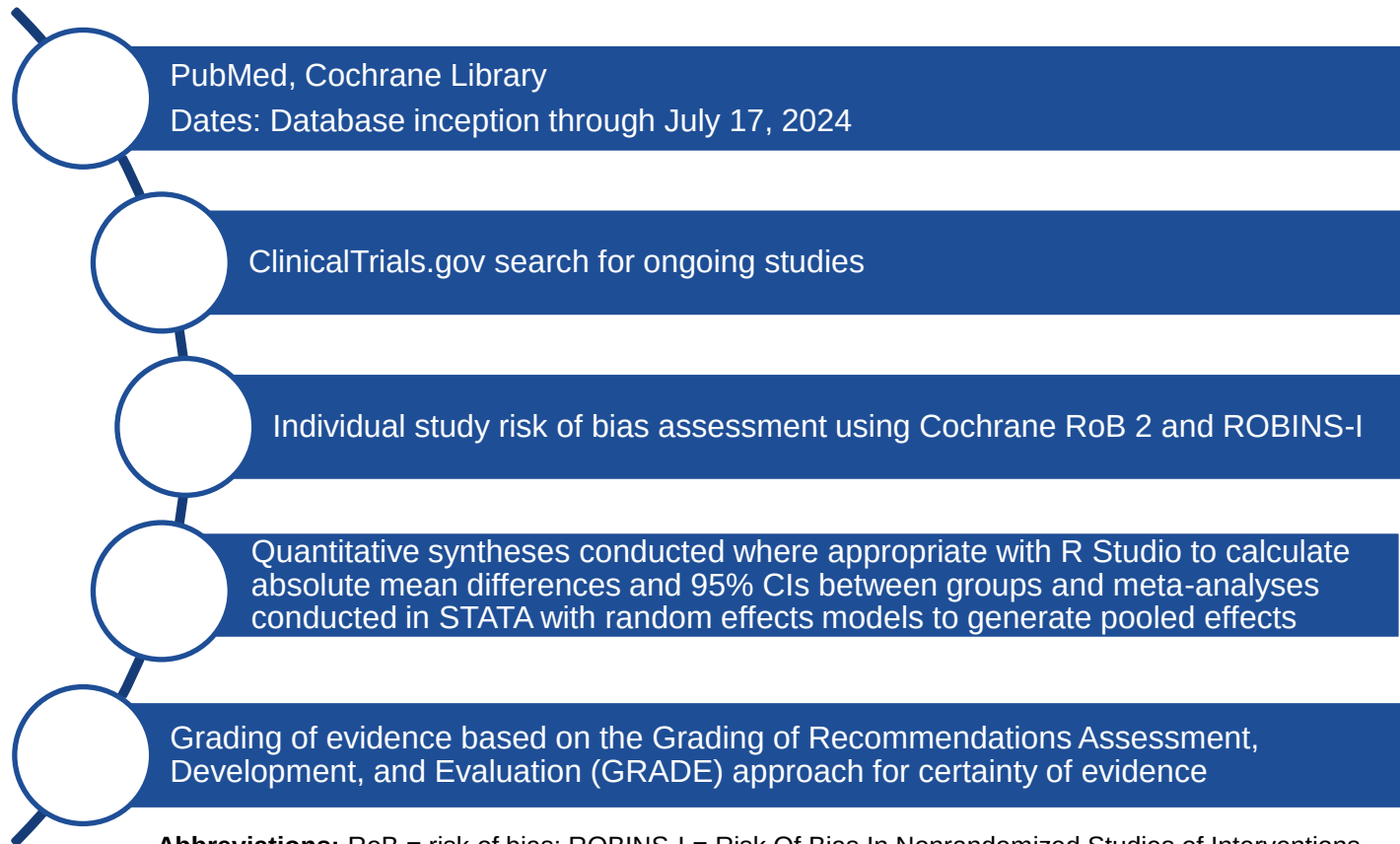
Subpopulations

Differences by age, sex, race or ethnicity, disability, comorbidities, severity of hearing loss, treatment setting, time to treatment

Cost

Cost-effectiveness (U.S. based) from societal or payor perspective

Search and Assessment Methods



Certainty of Evidence Grades and Definitions

Outcomes assessed: Complete/partial hearing recovery, no hearing recovery, mean or median hearing improvement as measured by PTA, residual hearing loss, tinnitus, Word discrimination scores, AEs, SAEs

High

We are **very confident** that the true effect lies close to the estimate of the effect.

Moderate

We are **moderately confident** in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low

Our **confidence** in the effect estimate **is limited**: The true effect may be substantially different from the estimate of the effect

Very Low

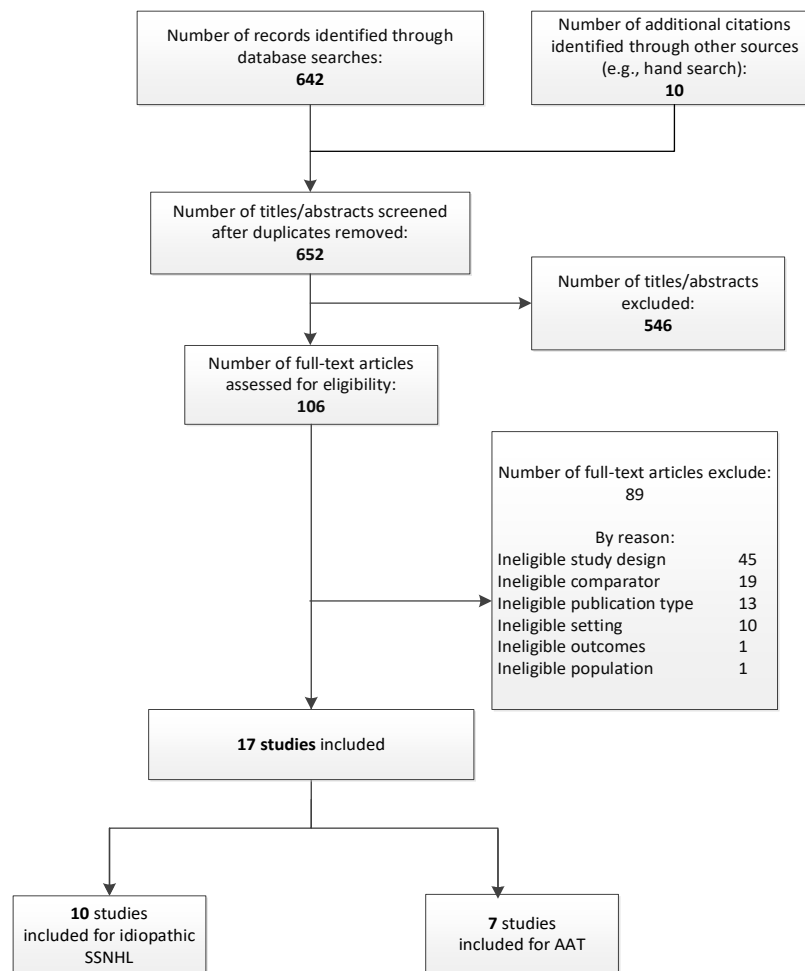
We have **very little confidence** in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.



Summary of Findings

Literature Search Yield

- Screened 652 unique citations
- Included 17 Studies
 - 10 on idiopathic SSNHL
 - 7 on AAT



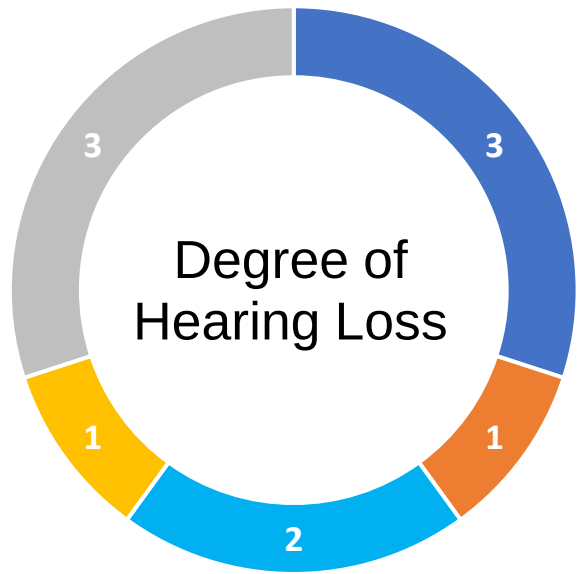


Idiopathic SSNHL

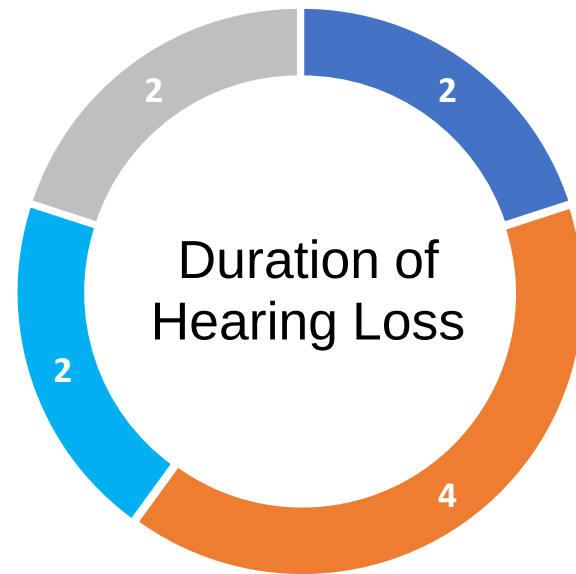
Study and Population Characteristics

- Predominately conducted in Europe, Asia, or Turkey
 - There were no U.S. based studies
- Mostly enrolled adults
 - Two studies included a small number of older children and had age ranges of 13 to 75 years
- Most (6 of 10) only enrolled participants with unilateral hearing loss
 - 3 permitted unilateral or bilateral hearing loss
 - 1 study did not report a related inclusion/exclusion criteria
- All included medical grade HBOT
 - ATA > 2.0

Hearing Loss Inclusion Criteria (Number of studies)



- Mild (at least 30 dB)
- Moderate (41 to 60 dB)
- Severe (> 70 dB)
- Salvage Therapy
- No hearing loss inclusion criteria



- < 7 days
- <10 to 15 days
- <28 or 30 days
- No related inclusion criteria

Comparisons by key question

Comparison	EQ1	EQ1a	EQ2	SQ	CQ	Total
HBOT with Steroids vs. Steroids Only	7	0	4	4	0	7
HBOT Only vs. Steroids Only	1	0	1	1	0	1
Salvage Therapy	1	0	1	1	0	1
Alternative HBOT Therapies	0	2	0	0	0	2

Legend

EQ1: Efficacy

EQ1a: Optimal frequency, dose, and duration of HBOT

EQ 2: Subpopulations

SQ: Safety

CQ: Cost



HBOT with Steroids vs Steroids

Study and Population Characteristics

Idiopathic SSNHL: HBOT with Steroids vs Steroids

7 RCTs

- ♦ Years published: 2004 to 2022 ♦ N range: 50 to 111
- ♦ Follow-up: immediately post-treatment to 180 days

3 in Europe

2 in Turkey

2 in Asia

3 low RoB

3 some concerns RoB

1 high RoB

3 did not report funding

3 reported no external funding

1 government

Abbreviations: N = number of participants; RCT = randomized controlled trial | RoB = risk of bias

HBOT with Steroids vs Steroids (k = 7)

Time to Treatment

- HBOT treatment occurred within 14 days of hearing loss onset in 6 of 7 RCTs
- Mean symptom duration before treatment
 - NR in 4 RCTs
 - Range in 3 RCTs: 3.5 days to 4.8 days
 - 1 RCT: 96% (55 of 57) within 3 days



Abbreviations: k = number of studies

HBOT with Steroids vs Steroids (k = 7)

HBOT Regimens

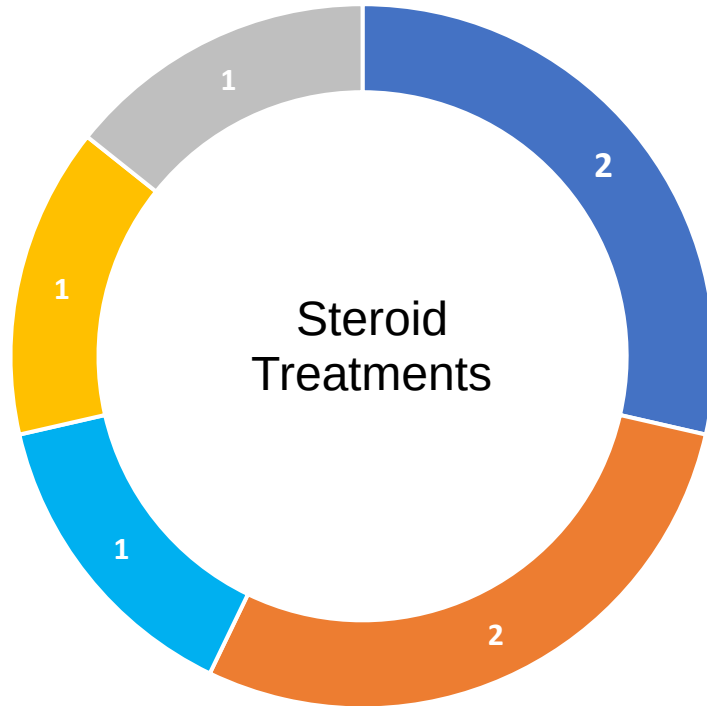
Number of Sessions	5 RCTs: 10 sessions		1 RCT: 15 sessions	1 RCT: 25 sessions
Length of Sessions	5 RCTs: 90-minutes		1 RCT: 2 40-minute sessions	1 RCT: 60-minutes
Duration of Treatment	3 RCTs: 10 days	2 RCT: 15 days	1 RCT: 20 days	1 RCT: 5 days*
Pressure	5 RCTs: 2.5 ATA		1 RCT: 2.2 ATA	1 RCT: 2.0 ATA

*2 sessions per day

Abbreviations: k = number of studies; N = number of participants; RCT = randomized controlled trial; RoB = risk of bias

HBOT with Steroids vs Steroids (k = 7)

Steroids and other medications



- Oral Steroid
- Oral Steroid + hemorheological agent + plasma expander
- IV steroid
- Oral Steroid + Intratympanic Steroid
- Oral and IV Steroid + hemorheological agent + plasma expander

Abbreviations: k = number of studies

HBOT with Steroids vs Steroids (k =5)

Recovery Definitions

Complete Recovery

1 RCT (N=57)	>50 dB PTA improvement
2 RCTs (total N=110)	>25 dB PTA improvement
1 RCT(N=60)	Final PTA within 10 dB and WDS 5 to 10% of unaffected ear

Partial Recovery

2 RCTs (total N=124)	≥10 dB PTA improvement
2 RCTs (total N=110)	>15 dB PTA improvement and final PTA <45 dB
1 RCT (N=60)	Final PTA ≤50 dB and WDS ≥50%

No Recovery

3 RCTs (total N=184)	<10 dB PTA improvement
2 RCTs (total N=110)	<15 dB PTA improvement and hearing poorer than 75 dB

Abbreviations: k = number of studies; N = number of participants; RCT = randomized controlled trial; PTA = pure-tone average; WDS = word discrimination scores.

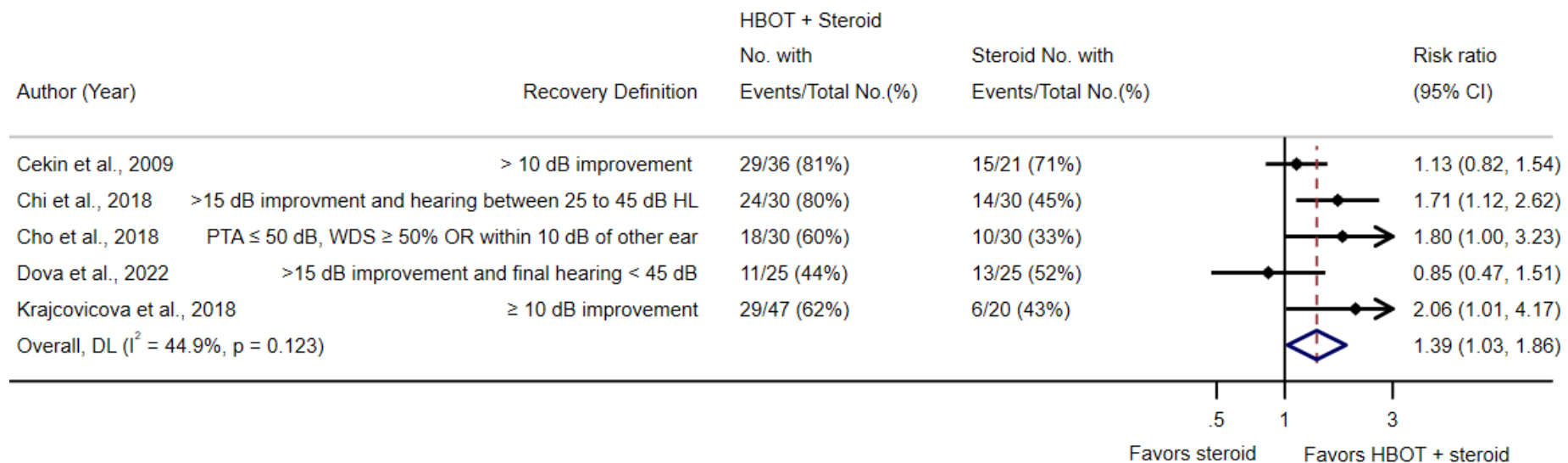


HBOT with Steroids vs Steroids

Efficacy Question 1 Findings

HBOT with Steroids vs Steroids: Complete or Partial Recovery (k = 5)

Participants treated with HBOT plus steroids within 14 days of symptom onset were 39% more likely to achieve complete/ partial hearing recovery vs. steroids treatment
Pooled RR: 1.39; 95% CI, 1.03 to 1.86; 5 RCTs; 294 participants; $I^2=44.9\%$.



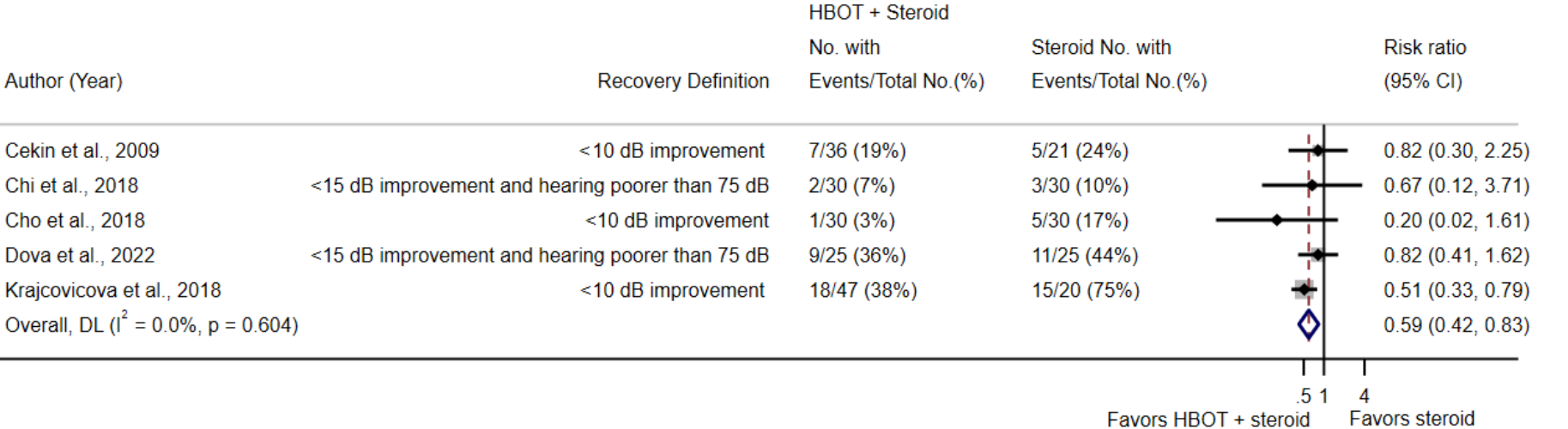
Abbreviation: ARD = absolute risk difference, HBOT = hyperbaric oxygen therapy; k = number of studies RR = risk ratio.

HBOT with Steroids vs Steroids: No Recovery (k = 5)

Participants treated with HBOT plus steroids within 14 days of symptom onset were 41% less likely to experience no recovery vs. steroids

Pooled RR: 0.59; 95% CI, 0.42 to 0.83; 5 RCTs; 294 participants; $I^2=0\%$

ARD: 127 fewer per 1,000 people (ranging from 180 fewer to 53 fewer)



Abbreviation: ARD = absolute risk difference, HBOT = hyperbaric oxygen therapy; k = number of studies; RR = risk ratio.

HBOT with Steroids vs Steroids (k = 4)

Mean or Median Hearing Improvement

- Mixed findings among 4 RCTs
 - All treatment groups improved from baseline
- 2 RCTs found no significant difference between groups
 - 1 RCT mean difference between groups: 8.8 dB favoring HBOT+ steroids
 - 1 RCT median improvement, HBOT with steroids: 17.5 vs. steroids: 22.5
- 2 RCTs found a statistical difference favoring HBOT with steroids
 - 1 RCT mean difference between groups: 15.9 dB favoring HBOT with steroids
 - 1 RCT favored HBOT with steroids ($p < 0.05$, data NR)

Abbreviation: HBOT = hyperbaric oxygen therapy; k = number of studies.

HBOT with Steroids vs Steroids ($k = 1$)

Word Discrimination Scores (WDS)

- WDS reflects the proportion of words a person repeats correctly from a recorded list of common, phonetically balanced words
- 1 RCT favored HBOT with steroids
 - Mean (SD) 3-months post treatment
 - HBOT with steroids: 65.9% correct (14.1)
 - Steroid only: 56.7% correct (19.1)
 - $P = 0.035$

Abbreviation: k = number of studies; WDS = word discrimination scores.



HBOT with Steroids vs Steroids

EQ2 (Sub-populations) Findings

HBOT with Steroids vs Steroids (k = 4)

Sub-populations

- Time to treatment
 - 1 RCT found participants treated with HBOT plus steroids in ≤ 7 had significant hearing recovery and those treated > 7 days did not
- Hearing Loss at baseline
 - 1 RCT found better outcomes for those with greater hearing loss at baseline
 - 1 RCT found no difference
- Age
 - 1 RCT no difference
- Sex
 - 1 RCT found women, compared to men, had better hearing improvement

Abbreviation: k = number of studies.

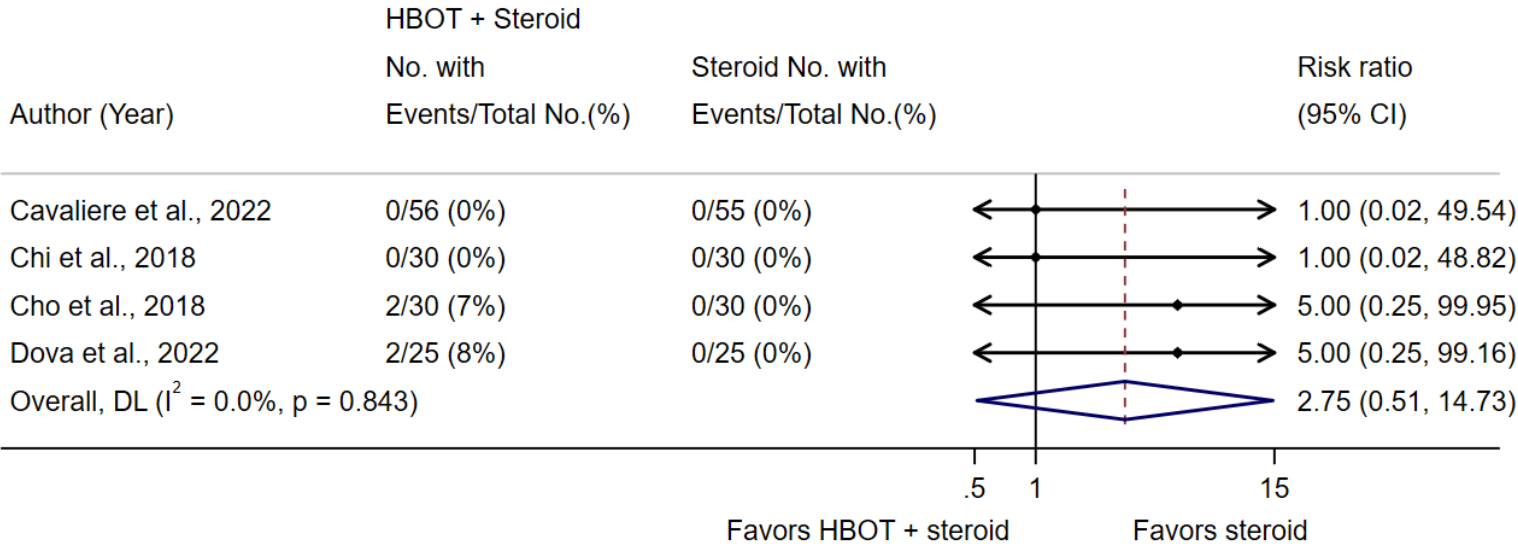


HBOT with Steroids vs Steroids

Safety Question Findings

HBOT with Steroids vs Steroids: Adverse Events (k = 4)

No major complications reported, and AEs were rare.
No significant difference between groups based on 4 AEs (all mild ear pain) in HBOT with steroid groups vs. 0 in steroid groups.
Pooled RR: 2.75, 95% CI, 0.51 to 14.73; 4 RCTs, N = 281; $I^2=0.0\%$.



Abbreviation: HBOT = hyperbaric oxygen therapy; k = number of studies.

HBOT with Steroids vs Steroids (k = 5)

Summary of Findings and Certainty of Evidence (COE)

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
Complete/partial hearing recovery	5 RCTs (294)	Pooled RR 1.39 (95% CI, 1.03 to 1.86)		Favors HBOT + Steroids
No hearing recovery	5 RCTs (294)	Pooled RR 0.59 (95% CI, 0.42 to 0.83)		Favors HBOT + Steroids
Hearing improvement (change in PTA)	4 RCTs (332)	Mixed findings		Favors HBOT + Steroids
Word discrimination (% correct)	1 RCT (60)	9.2% point larger improvement with HBOT (95% CI, 0.52% to 17.9%)		Favors HBOT + Steroids
Safety (AEs)	4 RCTs (281)	Pooled RR 0.36 (95% CI, 0.07 to 1.94)		No effect

COE ratings:  High,  Moderate,  Low,  Very Low

Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; k = number of studies; SSNHL = sudden sensorineural hearing loss.



HBOT Only vs Steroids

Study and Population Characteristics

HBOT Only vs Steroids Only

1 RCT

- ◆ Years published: 2022 ◆ N: 115 ◆ Follow-up: 20 days post-treatment
 - ◆ Included 3-arms, HBOT with steroids previously described

Italy

Some concerns RoB

Received no external funding

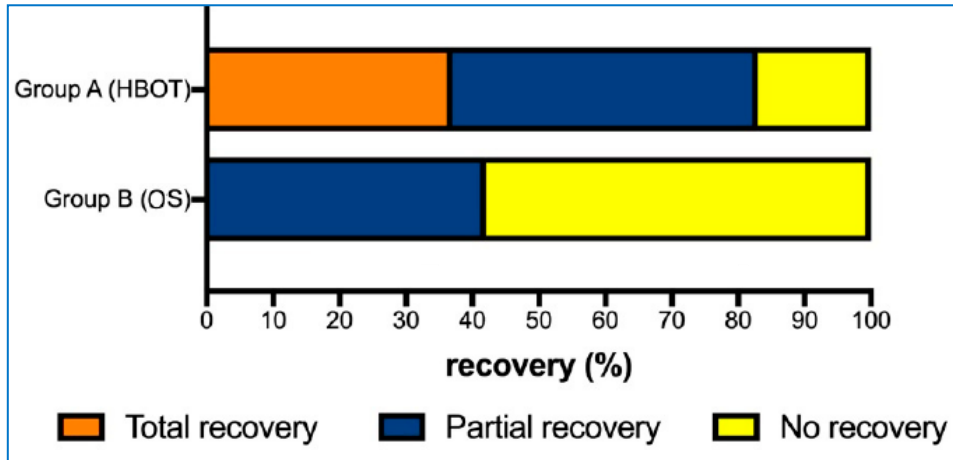
Abbreviations: N = number of participants; RCT = randomized controlled trial | RoB = risk of bias

HBOT Only vs Steroids Only ($k = 1$)

- Time to HBOT treatment: <30 days
- HBOT sessions: 10 sessions, 1 per day, 90 minutes per session
- Steroids: 1 mg/kg prednisone per day (for a maximum dose of 60 mg per day), oral, 12-14 consecutive days

Abbreviation: k = number of studies.

HBOT Only vs Steroids Only: Hearing Recovery & Improvement (k = 1)



Source: Cavaliere M, De Luca P, Scarpa A, et al. Combination of hyperbaric oxygen therapy and oral steroids for the treatment of sudden sensorineural hearing loss: early or late? *Medicina (Kaunas)*. 2022;58(10). PMID: [36295581](https://pubmed.ncbi.nlm.nih.gov/36295581/). doi: 10.3390/medicina58101421

- Significant improvement both groups ($p < 0.05$ for each within group difference).
- The HBOT only group had a significantly greater improvement vs steroid only group ($p < 0.05$ for between group difference).

Abbreviation: HBOT = Hyper baric oxygen therapy; k = number of studies; OS = Oral steroids.

HBOT Only vs Steroids Only: Sub-populations (k = 1)

- Time to treatment
 - ≤ 7 days or 8 to 14 days:
 - significant hearing improvement in the HBOT only group ($p < 0.05$ compared with baseline PTA)
 - No significant recovery in the oral steroid group
 - > 14 days of symptom onset:
 - No significant recovery in either group
- Sex
 - Improvements significantly were greater for women compared to men

Abbreviation: k = number of studies.

HBOT Only vs Steroids Only: Safety ($k = 1$)

- Authors observed no short- or long-term posttreatment complications.

Abbreviation: k = number of studies.

HBOT Alone vs Steroids Alone (k = 1)

Summary of Findings and Certainty of Evidence (COE)

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
Hearing improvement	1 RCT (115)	Favors HBOT (p<0.05)		Favors HBOT

COE ratings:  High,  Moderate,  Low,  Very Low

Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; k = number of studies; SSNHL = sudden sensorineural hearing loss.



Salvage Therapy

Study and Population Characteristics

Salvage Therapy

1 RCT

- ♦ Years published: 2013 ♦ N: 50 ♦ Follow-up: End of 20 days of treatment

Serbia

Some concerns RoB

Funding Not Reported

Abbreviations: N = number of participants; RCT = randomized controlled trial | RoB = risk of bias

Salvage Therapy (k = 1)

- All participants failed initial 6-days of IV steroid therapy
 - Failure was hearing improvement of < 10 dB
- All participants started treatment ≤ 4 weeks of symptom onset
 - Mean symptom duration NR
- Randomized to:
 - HBOT Treatment: 20, 60-minute sessions over 20 days
 - Steroids: Intratympanic injections over a 13-day period

Abbreviation: dB = decibels; k = number of studies; NR = Not reported.

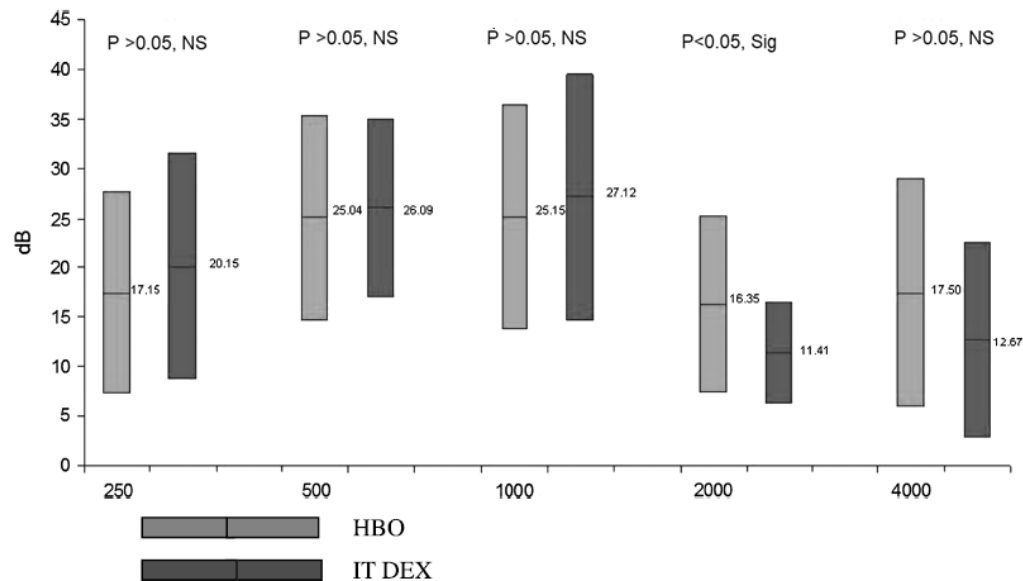
Salvage Therapy: Hearing Improvement (k = 1)

- Hearing improvement was significantly better in the HBOT salvage therapy group vs. steroid group at only 1 of 5 frequencies

- 2,000 Hz: HBOT: 16.4 dB, steroids: 11.4 dB; $p < 0.05$

- The difference between groups was not significant at 250 Hz, 500 Hz, 1,000 Hz, or 4,000 Hz

Abbreviation: k = number of studies.



Abbreviations: IT DEX = intratympanic dexamethasone; HBO = hyperbaric oxygen; NS = not significant.; Sig = significant.

Source: Cvorovic L, Jovanovic MB, Milutinovic Z, Arsovic N, Djerić D. Randomized prospective trial of hyperbaric oxygen therapy and intratympanic steroid injection as salvage treatment of sudden sensorineural hearing loss. *Otol Neurotol*. 2013;34(6):1021-1026. PMID: [23820795](https://pubmed.ncbi.nlm.nih.gov/23820795/). doi: 10.1097/MAO.0b013e318297638a

Salvage Therapy: Sub-populations (k = 1)

- Severity of hearing loss at baseline:
 - Improvements worse with HBOT for those with more severe hearing loss vs. steroid
 - No difference for those with less severe hearing loss

Hearing Improvement			
Baseline Hearing Loss	HBOT	Steroid	Significance
≥81 dB	13.5	40.7	P < 0.05
61 dB to 80 dB	25.2	28.7	NS
≤60 dB	23.3	25.5	P = NS

Abbreviations: dB = decibels; k = number of studies.

Salvage Therapy: Safety (k = 1)

- No significant difference in AEs between HBOT use and steroid use
 - RR: 1.67; 95% CI, 0.45 to 6.24
- In the HBOT group, 3 of 25 (12%) had serous otitis media or fluid in the ear without infection
- In the intratympanic steroid group, 5 of 25 (20%) had mild ear pain immediately after injections

Abbreviation: k = number of studies.

Salvage Therapy (k = 1)

Summary of Findings and Certainty of Evidence (COE)

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
Hearing improvement	1 RCT (50)	Difference of 5 dB at 2,000 Hz (P<0.05), difference of -3.0 to 4.8 at other frequencies (P=NS)		No Effect
Safety (AEs)	1 RCT (50)	12% vs. 20%; P=NS		No Effect

COE ratings: High, Moderate, Low, Very Low

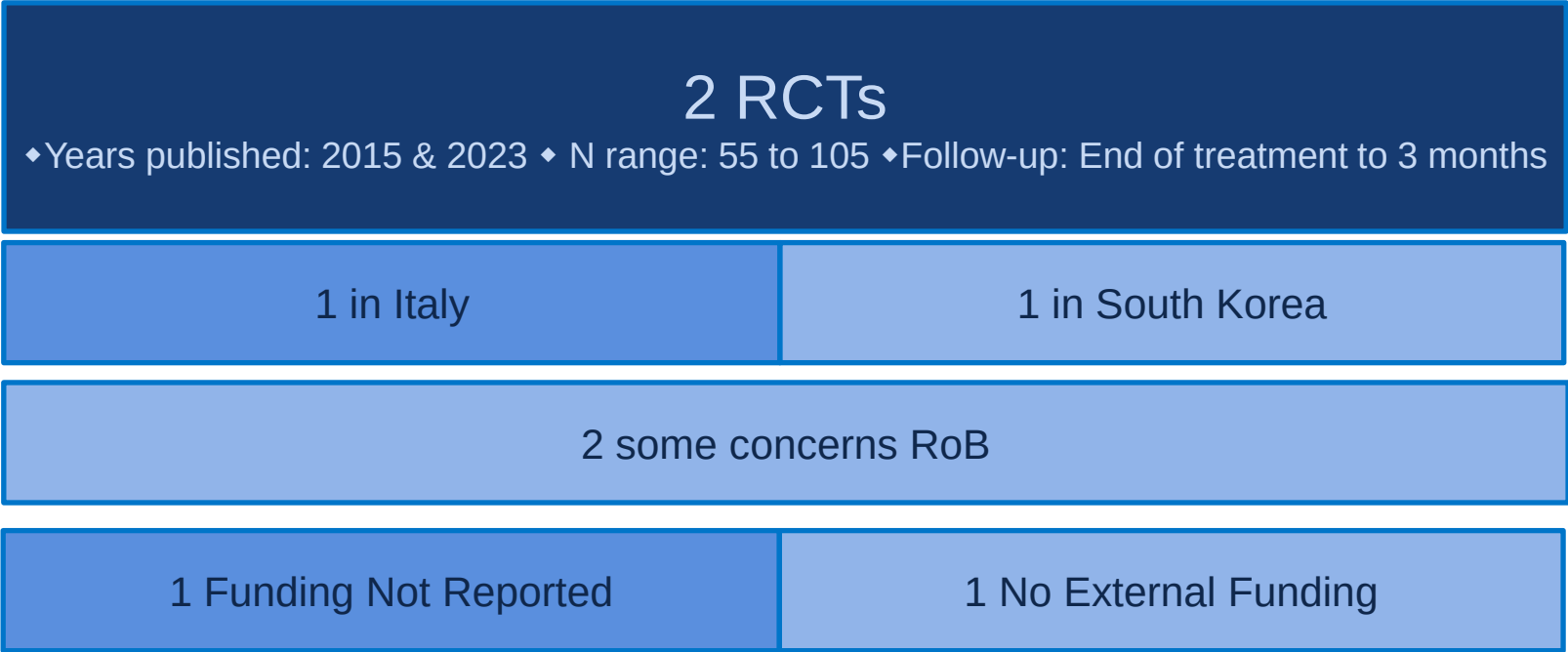
Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; k = number of studies; SSNHL = sudden sensorineural hearing loss.



Optimal Frequency, Dose, and Duration of HBOT (EQ1A)

Study and Population Characteristics

Optimal Frequency, Dose, and Duration of HBOT (EQ1a)



Abbreviations: N = number of participants; RCT = randomized controlled trial | RoB = risk of bias

Optimal Frequency, Dose, and Duration of HBOT (k = 1)

Study Characteristics

- Enrolled 55 participants with symptom onset in last 15 days
 - Actual time to treatment: NR
- Baseline hearing loss: 85.5 dB (severe hearing loss)
- All participants received HBOT at 2.4 ATA with intratympanic prednisolone over the first 3 days
- Comparison:
 - 2 90-minute HBOT sessions per day for 5 days vs.
 - 1 90-minute HBOT session per day for 10 days

Abbreviation: dB = decibels; k = number of studies.

Optimal Frequency, Dose, and Duration of HBOT (k = 1)

Findings

- No significant differences in hearing outcomes between groups
- Similar improvements in PTA:
 - Absolute difference pre-post treatment within each group ~ 29 dB
 - Calculated mean difference between groups, 0.1; 95% CI, -12.6 to 12.8; P=0.98
- Subpopulations
 - *Hearing loss at baseline*: No significant differences were found between those with severe versus profound hearing loss at baseline between the 2 treatment protocols (P=0.27)

Abbreviation: k = number of studies; PTA = pure-tone average.

Optimal Frequency, Dose, and Duration of HBOT (k = 1)

Study Characteristics

- 1 RCT compared 3 HBOT regimens, N = 105
 - Enrolled participants with symptom onset in the last 14 days
 - Mean time to treatment: 3.5 days to 5.4 days across groups
 - Baseline hearing loss: 98.8 dB (profound hearing loss)
 - All received oral steroids, intratympanic dexamethasone, and 10 HBOT sessions
- Comparison:
 - Group 1: 1-hour sessions at 2.5 ATA
 - Group 2: 2-hour sessions at 2.5 ATA
 - Group 3: 1-hour sessions at 1.5 ATA

Optimal Frequency, Dose, and Duration of HBOT (k = 1)

- Mean hearing improvement
 - Group 1 (1-hour sessions at 2.5 ATA): 53.8 dB (SD, 16.0)
 - Group 2 (2-hour sessions at 2.5 ATA): 52.5 dB (SD, 18.0)
 - Group 3 (1-hour sessions at 1.5 ATA): 36.5 dB (SD, 24.8)

- Between group comparisons
 - Group 1 vs. Group 3, calculated AMD, 17.6; 95% CI, 6.6 to 28.6
 - Group 2 vs. Group 3, calculated AMD, 16.3; 95% CI, 5.2 to 27.4

- No significant differences between Group 1 and Group 2
 - No benefit to 2-hour HBOT sessions vs. 1-hour HBOT sessions at 2.5 ATA

Optimal Frequency, Dose, and Duration of HBOT (k = 1)

Word Discrimination Score

- Word Discrimination Score
 - Pre-treatment scores < 10.5% for all groups
 - Group 1 (1-hour sessions at 2.5 ATA): 73% correct
 - Group 2 (2-hour sessions at 2.5 ATA): 76% correct
 - Group 3 (1-hour sessions at 1.5 ATA): 54% correct
- Comparison
 - Group 1 vs. Group 3; $P=0.041$
 - Group 2 vs. Group 3, $P=0.017$

Optimal Frequency, Dose, and Duration of HBOT (k = 1)

Safety

- No significant differences in the number of AEs between groups
 - Group 1 (1-hour sessions at 2.5 ATA): 4 (12%)
 - Group 2 (2-hour sessions at 2.5 ATA): 2 (6%)
 - Group 3 (1-hour sessions at 1.5 ATA): 2 (6.3%)
- All AEs were mild, mostly middle ear effusion or ear pain, and improved with treatment.

The background of the slide is a solid dark blue. It is decorated with several white geometric elements: large, faint circles; thin white arcs; and small white circles, some of which contain a dot. Some of these elements have small curved arrows indicating a clockwise direction, suggesting a sense of motion or a process. The overall aesthetic is clean, modern, and technical.

Acute Acoustic Trauma (AAT)

AAT Study Characteristics

- 7 studies
 - 1 RCT and 6 Non-randomized Studies of Interventions (NRSIs)
- 5 studies recruited from military hospitals or medical centers
 - Studies mostly enrolled soldiers exposed to firearms
- 5 were conducted in Europe, 1 in Japan and 1 in Turkey

AAT Study Characteristics: Hearing Loss Risk of Bias

- Meaningful Risk of Bias concerns
 - 1 RCT was high risk of bias
 - lack of information about baseline differences and allocation concealment
 - concerns regarding outcome selection
 - lack of blinding for outcome assessors
 - 3 NRSIs were serious RoB
 - poor attempts to control for confounding
 - 3 NRSIs were critical RoB
 - due to no attempt to control for confounding

AAT Comparisons by Key Question

Comparison	EQ1	EQ1a	EQ2	SQ	CQ	Total
HBOT + steroids vs. steroids only	3	0	1	2	0	3
HBOT vs. control or usual care	2	0	0	1	0	2
HBOT + steroid early treatment vs. HBOT + steroid late treatment	1	0	0	1	0	1
Alternative HBOT Therapies	0	1	0	0	0	1

Legend

EQ1: Efficacy

EQ1a: Optimal frequency, dose, and duration of HBOT

EQ 2: Subpopulations

SQ: Safety

CQ: Cost



AAT: HBOT with Steroids vs Steroids

AAT HBOT with Steroids vs Steroids

3 NRSIs

◆ Years published: 1995 to 2020 ◆ N range: 41 to 78 ◆ Follow-up: 6.5 days to 1 year

1 in Netherlands

1 in Belgium

1 in Switzerland

2 Serious RoB

1 Critical RoB

2 did not report funding

1 reported no external funding

Abbreviations: N = number of participants; NRSI = non-randomized study of interventions; RoB = risk of bias

AAT: HBOT with Steroids vs Steroids (k = 3)

Study and Population Characteristics

- The cause of AAT was firearm shots in 2 of 3 studies
- Mean symptom duration prior to HBOT
 - < 36 hours, 15 to 72 hours; < 2 weeks (mean: 4.4 days).
- Baseline hearing loss ranged from 22.6 dB to 46.6 dB
 - Most severe at higher frequencies
- Number of HBOT sessions ranged from 5 to 13 sessions for 1 to 2 hours
- Steroid dose, route, and duration varied
 - Oral prednisone, IV methylprednisolone, IV and oral cortisone

AAT: HBOT with Steroids vs Steroids (k = 3)

Findings

- *Hearing Improvement*
 - All 3 NRSIs found statistically significant hearing improvement favoring HBOT with steroids compared with steroids
 - Mean hearing improvement range across studies
 - HBOT with steroids: 15.2 dB to 23.5 dB
 - Steroids alone: 5.6 dB to 12.5 dB

AAT: HBOT with Steroids vs Steroids (k = 3)

Findings

- *Residual Hearing Loss*

- 1 NRSI favored HBOT with steroids
 - Mean (SD) residual hearing loss at 10 days posttreatment
 - HBOT with steroids: mean 2.4 dB (10.7)
 - Steroids alone: mean 5.0 dB (8.3)
 - $p < 0.05$

- *Tinnitus*

- 1 NRSI reported no statistically significant difference between groups

AAT: HBOT with Steroids vs Steroids (k = 3)

Safety Findings

- 2 NSRIs reported harms
 - 1 reported no side effects from either HBOT with steroids or steroids only
 - 1 reported no serious side effects associated with HBOT with steroids

HBOT with Steroids vs Steroids (k = 3)

Summary of Findings and Certainty of Evidence (COE)

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
Mean Hearing Improvement	3 NRSIs (224)	Significant improvement favoring HBOT plus steroids in all 3 NRSIs		Favors HBOT + Steroids
Mean residual hearing loss	1 NRSI (68)	HBOT with steroids (early: 2.4 dB; SD 10.7 and late: 5.0 dB; SD 8.0) significantly better than steroids (14.7 dB, SD 8.3) (p<0.05 for any HBOT vs. steroids only).		Favors HBOT + Steroids
Tinnitus	1 NRSI (78)	No significant difference between groups		No Effect
Safety (AEs)	2 NRSIs (119)	1 NRSI reported no AEs and 1 NRSI reported no serious AEs from HBOT		No effect

COE ratings:  High,  Moderate,  Low,  Very Low

Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; SSNHL = sudden sensorineural hearing loss.



AAT: HBOT vs. Control or Usual Care (other than steroids)

AAT HBOT vs. Control or Usual Care

1 RCT and 1 NRSI	
♦ Years published: 1985 to 2008 ♦ N range: 118 and 120 ♦ Follow-up: 7 days or end of military service	
1 in Germany	1 in Finland
1 RCT High RoB	1 NRSI Serious Rob
2 did not report funding	

Abbreviations: N = number of participants; NRSI = non-randomized study of interventions; RCT = randomized controlled trial; RoB = risk of bias

AAT: HBOT vs. Control or Usual Care (k = 2)

Study and Population Characteristics

- AAT from exposure to firearms or explosives during military service
- Mean symptom duration prior to HBOT ranged from 17 to 72 hours
- Number of HBOT sessions
 - RCT: 10, 60-minute HBOT sessions
 - NRSI: Mean of 3.2 sessions for 90-minutes once per day at 2.4 ATA
- Comparator
 - RCT: Infusions of plasma expander with and without anti-vertigo medications
 - NRSI: Mean of 6.2 normobaric oxygen therapy (NBOT) sessions 90-minutes twice per day, normal pressure

AAT: HBOT vs. Control or Usual Care (k = 2)

EQ1 Findings

- *Hearing recovery*
 - RCT: a greater proportion of participants who received HBOT with infusions achieved hearing recovery compared with those who received infusion only
 - HBOT + infusions: 92% recovered
 - Infusions only: 72% recovered
 - NRSI: a greater proportion of participants who received HBOT experienced hearing recovery compared with NBOT
 - HBOT: 69.3%; SD 17.1
 - NBOT: 56.2%; SD 20.3

AAT: HBOT vs. Control or Usual Care (k = 1)

EQ1 Findings

- *Tinnitus*

- NRSI: fewer participants who received HBOT reported tinnitus compared with those who received NBOT
 - HBOT: 5%
 - NBOT: 18%
 - $p < 0.05$.

AAT: HBOT vs. Control or Usual Care (k = 1)

SQ Findings

- The RCT reported AEs N (%)
 - HBOT plus infusions of plasma expanders: 1 (3%) instance of sinus barotrauma
 - HBOT plus infusions of plasma expanders and anti-vertigo medication: 1 (3%) oxygen intoxication
 - Infusions of plasma expanders: 0 (0%)
 - Infusions of plasma expanders and anti-vertigo medication: 0 (0%)
- The NRSI did not report harms

AAT: HBOT vs. Control or Usual Care (k = 2)

Summary of Findings and Certainty of Evidence (COE)

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
Hearing recovery	1 RCT (120)	Greater % PTA recovery with HBOT plus infusions vs. infusions only		Favors HBOT
Hearing recovery at high frequencies	1 NRSI (118)	Greater % HPTA recovery at 4, 6, and 8 kHz among patients receiving HBOT vs. NBOT, 69.3% (17.1) vs. 56.2% (20.3); p<0.001		Favors HBOT
Tinnitus	1 NRSI (118)	Lower reported tinnitus among patients receiving HBOT vs. NBOT (5% vs. 18%; p<0.05)		Favors HBOT
Safety (AEs)	1 RCT (120)	2 AEs in HBOT + infusions groups 0 AEs in infusion only groups		No effect

COE ratings:  High,  Moderate,  Low,  Very Low

Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; SSNHL = sudden sensorineural hearing loss.



AAT: Early vs. Late Treatment with HBOT EQ1a

AAT: Early vs. Late Treatment with HBOT EQ2

1 NRSI

- ◆ Year published: 2015 ◆ N: 73 ◆ Follow-up: 6 weeks ◆

Turkey

Critical RoB

Funding Not Reported

Abbreviations: N = number of participants; NRSI = non-randomized study of intervention; RoB = risk of bias

AAT: Early vs. Late Treatment with HBOT (k = 1)

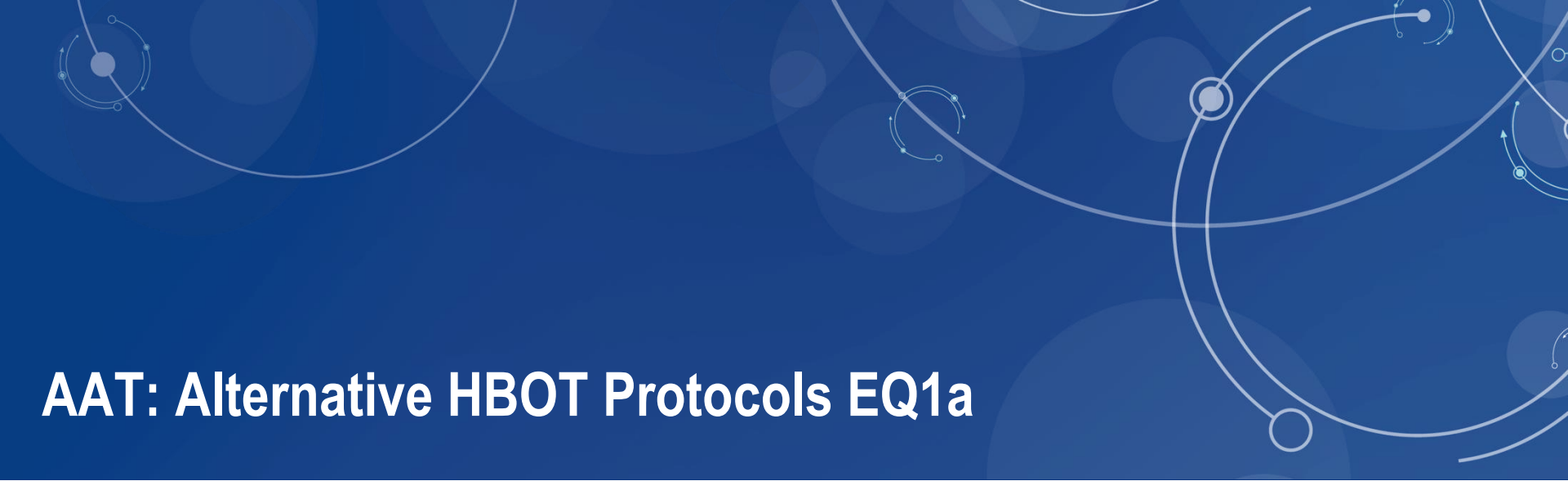
Study Characteristics

- Cause of AAT was firearm shots
- Patient's self-selected treatment group
- All participants received 10 to 20 90-minute HBOT sessions and oral steroids
- Early HBOT (within first 10 days)
 - Mean time to treatment: 7.4 days
 - Baseline hearing: 41.1 dB
- Late HBOT (11 to 30 days)
 - Mean time to treatment: 18.9 days
 - Baseline hearing: 45.9

AAT: Early vs. Late Treatment with HBOT (k = 1)

Findings

- No statistically significant difference in complete, partial, and no hearing recovery between early and late HBOT treatment groups.
- 2 participants had an adverse event
 - Eustachian tube dysfunction
 - Barotrauma



AAT: Alternative HBOT Protocols EQ1a

AAT: Alternative HBOT Protocols EQ2

1 NRSI

- ◆ Year published: 2019 ◆ N: 35 ◆ Follow-up: 3 weeks after treatment ◆

Japan

Critical RoB

Funding Not Reported

Abbreviations: N = number of participants; NRSI = non-randomized study of intervention; RoB = risk of bias

AAT: Alternative HBOT Protocols (k = 1)

Study Characteristics

- Cause of AAT was exposure to firearms
- Protocol one: U.S. Navy HBOT Treatment Table 5 (TT5), N = 7
 - HBOT: 2-hour and 15-minutes sessions at 180 kPa (1.8 ATA) decreasing to 90 kPa (0.9 ATA)
 - Mean (SD) time to treatment: 10.3 days (7.6)
- Protocol 2: U.S. Navy HBOT Treatment Table 9 (TT9), N = 28
 - HBOT: 1-hour and 45-minutes HBOT sessions at 135 kPa (1.35 ATA)
 - Mean (SD) time to treatment: 27.8 days (53.7)

AAT: Alternative HBOT Protocols (k = 1)

Findings

- No significant difference in mean PTA (measured at 0.5, 1, and 2 kHz) recovery between groups
 - TT5: 37.9%
 - TT9: 41.7%
 - $p = 0.738$
- Patients receiving the TT9 HBOT protocol had statistically greater High-PTA (measured at 4 and 8 kHz) recovery
 - TT5: 17.1%
 - TT9: 43.6%
 - $p = 0.028$



DISCUSSION

Summary of Findings and COE for HBOT for Idiopathic SSNHL

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
HBOT with steroids vs. steroids only				
Complete/partial hearing recovery	5 RCTs (294)	Pooled RR 1.39 (95% CI, 1.03 to 1.86)		Favors HBOT
No hearing recovery	5 RCTs (294)	Pooled RR 0.59 (95% CI, 0.42 to 0.83)		Favors HBOT
Hearing improvement	4 RCTs (332)	Mixed findings		Favors HBOT
Word discrimination (% correct)	1 RCT (60)	9.2% point larger improvement with HBOT (95% CI, 0.52% to 17.9%)		Favors HBOT
Safety (AEs)	4 RCTs (281)	Pooled RR 0.36 (95% CI, 0.07 to 1.94)		No effect
HBOT alone vs. steroids alone				
Hearing improvement	1 RCT (115)	Favors HBOT (p<0.05)		Favors HBOT
Salvage HBOT vs. intratympanic steroids, both after failed intravenous steroids				
Hearing improvement	1 RCT (50)	Difference not significant at 4 of 5 frequencies		No effect
Safety (AEs)	1 RCT (50)	12% vs. 20%; P=NS		No effect

COE ratings: High, Moderate, Low, Very Low

Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; SSNHL = sudden sensorineural hearing loss.

Summary of Findings and COE for HBOT for AAT

Outcome	Studies (N)	Effect	Certainty of Evidence	Direction of Effect
HBOT + steroids vs. steroids only				
Mean hearing improvement	3 NRSIs (224)	Significant improvement favoring HBOT plus steroids	●●●●●	Favors HBOT
Mean residual hearing loss	1 NRSI (68)	HBOT with steroids significantly better than steroids	●●●●●	Favors HBOT
Tinnitus	1 NRSI (78)	No significant difference between groups	●●●●●	No effect
Safety (AEs)	2 NRSIs (119)	1 NRSI reported no AEs and 1 reported no serious AEs	●●●●●	No effect
HBOT vs. control/usual care				
Hearing recovery vs. Usual care	1 RCT (120)	Greater % PTA recovery with HBOT plus infusions vs. infusions only	●●●●●	Favors HBOT
Hearing recovery vs. NBOT	1 NRSI (118)	Greater % HPTA recovery at 4, 6, and 8 kHz among patients receiving HBOT vs. NBOT, 69.3% (17.1) vs. 56.2% (20.3); $p < 0.001$	●●●●●	Favors HBOT
Tinnitus	1 NRSI (118)	Less self-reported tinnitus among patients receiving HBOT vs. NBOT (5% versus 18%; $p < 0.05$)	●●●●●	Favors HBOT
Safety (AEs)	1 RCT (120)	2 AEs in HBOT groups, no AEs in infusion groups	●●●●●	No effect

COE ratings: ●●●●● High, ●●●●● Moderate, ●●●●● Low, ●●●●● Very Low

Abbreviations: AE = adverse event; COE = certainty of evidence; HBOT = hyperbaric oxygen therapy; NS = not significant; RCT = randomized controlled trial; SSNHL = sudden sensorineural hearing loss.

Discussion

- Our findings for idiopathic SSNHL align with recent systematic reviews
 - Joshua et al. (2022) also found evidence that HBOT plus steroid treatment was more effective than steroid treatment alone for hearing improvement and recovery
 - Included 3 RCTs with 88 participants
 - Pooled mean improvement in PTA following HBOT was 10.3 dB (95% CI, 6.5 to 14.1; I²=0.0%)

Discussion

- We included 1 RCT of salvage therapy (after failed IV steroid treatment) that concluded both HBOT or intratympanic steroids could be successful treatment options.
- A systematic review of salvage therapy that included NRSIs found the largest improvements in PTA among those who received both HBOT and intratympanic steroids compared with those who received steroids alone
- Notably, AAO recommends offering hyperbaric oxygen therapy combined with intratympanic steroid therapy **within 1 month**
 - This timeframe reflected their understanding of logistical issues that may delay HBOT treatment

Limitations of Evidence Base

- Studies were generally small (range: 50 to 171 participants)
- No U.S. based studies
- Steroid and HBOT regimens varied
- Definitions of hearing recovery varied
 - Unclear what amount of hearing recovery is clinically significant
- Variation in the frequencies included to calculate PTA
- Methodological limitations leading to RoB concerns
- Short follow-up periods
- No cost-effectiveness data

Limitations of This HTA

- Limited to:
 - Peer-reviewed articles published in English
 - Studies conducted in countries listed as *very high* on the UN Human Development Index
 - RCTs, for idiopathic SSNHL

Ongoing and Future Research

- 2 potentially relevant trials identified in ClinicalTrials.gov
 - 1 prospective cohort study in South Korea that is currently recruiting participants with SSNHL who receive HBOT in conjunction with other treatments
 - 1 study of AAT in military personnel
 - This study had a target completion date of 2020 but we found no results related to this study

Idiopathic SSNHL Conclusion

- These findings suggest HBOT may provide meaningful additional benefit when combined with standard steroid therapy for idiopathic SSNHL, particularly for those who can begin treatment within 14 days.

AAT Conclusion

- Low to very low COE across outcomes seriously limits our ability to draw meaningful conclusions regarding the effectiveness of HBOT to treat SSNHL resulting from AAT.
- It is unclear whether the body of evidence for the effectiveness of HBOT to treat idiopathic SSNHL is relevant to the treatment of AAT.



Thank you

Contact: sarakennedy@rti.org

2013 HBOT Coverage Decision

Covered with limitations:

1. Crush injuries and suturing of severed limbs
2. Compromised skin grafts and flaps
3. Unresponsive chronic refractory osteomyelitis
4. Osteoradionecrosis
5. Prevention of osteoradionecrosis associated with tooth extraction
6. Soft tissue radionecrosis
7. Diabetic wounds

Non-Covered Indicators:

1. Brain injury including traumatic and chronic brain injury
2. Cerebral Palsy
3. Multiple Sclerosis
4. Migraine or cluster headaches
- 5. Acute and chronic sensorineural hearing loss**
6. Thermal burns
7. Non-healing venous, arterial and pressure ulcers

Source: [Washington State Health Care Authority \(2013\)](#)

Idiopathic SSNHL Study Characteristics

Characteristic	Number of Studies	Characteristic	Number of Studies
Country setting	European countries: 5 South Korea: 2 Turkey: 2 Taiwan: 1	Number analyzed	Median: 58.5; range: 50 to 171
		Sex	% Female: Range 10 to 55 NR: 2
		Race or ethnicity	Not reported by any study
Study funding	Government: 1 None: 4 Not reported: 5	Required duration of hearing loss at baseline for study inclusion	<7 days: 2 <10 to 15 days: 4 <28 or 30 days: 2 No inclusion criteria specified: 2
Unilateral or bilateral hearing loss	Unilateral hearing loss only: 6 Unilateral or bilateral hearing loss permitted: 3 NR: 1	Mean baseline hearing loss	Range: 40.7 dB (mild to moderate hearing loss) to 98.9 dB (profound hearing loss)
RoB	Low: 3 Some concerns: 6 High: 1	Required severity of hearing loss at baseline for study inclusion	At least 30 dB (at least mild hearing loss or more): 3 41 to 60 dB (moderate to moderately severe): 1 >70 dB (severe to profound): 2
Age of participants	Adults: 8 Children and adults: 2 (age range in these studies: 13 to 75 years)		Salvage therapy (<10 dB improvement after initial steroid treatment): 1 No related inclusion criteria: 3

Idiopathic SSNHL: HBOT + Steroids vs. Steroids

Steroid Details

	Oral Steroid Only		Oral Steroid + hemorheological agent + plasma expander		IV steroid	Oral + Intratympanic steroid	Oral and IV Steroid + hemorheological agent + plasma expander
	Cekin 2009	Cavaliere	Topuz 2004	Chi 2018	Dova 2022	Cho 2018	Krajcovicova 2018
Steroids	Prednisolone	Prednisone	Prednisone	Prednisolone	Dexamethasone	Methylprednisolone	Solu-Medrol
Steroid Mode of Administration	Oral	Oral	Oral	Oral	IV	Oral	IV
Steroid Dosage	5 mg (1 mg/kg starting dose, reducing thereafter)	1 mg/kg prednisone per day (for a maximum dose of 60 mg per day), oral, 12-14 consecutive days	1 mg/kg per day	1mg/kg per day for 1 week and then gradually tapered to 20mg every 3 days for the next week	8 mg x 3 for 3 days, 8 mg x 2 for 3 days, 8 mg x 1 for 3 days	0.8 mg/kg/day (maximum dose of 48 mg/day for 7 days), tapered over the subsequent 5 days (to 40, 32, 24, 16, and 8 mg)	250 mg for days 1 to 2, 125 mg for days 3 to 4, 80 mg on day 5
Duration of steroid treatment	3 weeks		2 weeks	2 weeks	9 days	12 days	5 days
Steroids 2			Rheomacrodex	Pentoxifylline		Dexamethasone	Prednisone
Steroid Mode of Administration 2			IV	Oral		Intratympanic	Oral
Steroid Dosage 2			500 ml/d (infusion in 6 h)	400mg twice a day		4 mg/mL per day	400 mg for days 6 to 10, 20 mg for days 11 to 15
Duration of steroid treatment 2			5 days	2 weeks		7 days	10 days
Steroids 3			Pentoxiphyllin	Dextran			Agapurin
Steroid Mode of Administration 3			IV	IV			Oral
Steroid Dosage 3			200 mg twice a day	500mL once a day			100 mg twice daily
Duration of steroid treatment 3			NR	1 week			NR
Steroids 4			Diazepam				Betahistin
Steroid Mode of Administration 4			Oral				Oral
Steroid Dosage 4			5 mg twice a day				16 mg three times daily
Duration of steroid treatment 4			NR				NR

Legend: Green indicates steroid; blue indicates hemorheological agent; purple indicates plasma expander.

HBOT with Steroids vs Steroids: Summary of Findings and Certainty of Evidence (COE)

No. Studies/No. Participants	RoB	Consistency	Precision	Directness	Overall COE/ Direction
Complete or partial hearing recovery; follow-up time 10 days to 180 days					
5 RCTs/ 294	Not serious	Not serious ^a	Serious ^b	Not serious	Moderate for greater effect with HBOT plus steroids ^{a, b} ●●●○
No hearing recovery; follow-up time 10 days to 180 days					
5 RCTs/ 294	Not serious	Not serious	Serious ^c	Not serious	Moderate for greater effect with HBOT plus steroids ^c ●●●○
Hearing Improvement (mean or median change in PTA); follow-up time 20 days to 3 months					
4 RCTs /332	Serious ^d	Serious ^e	Serious ^f	Not serious	Very low for greater effect with HBOT plus steroids ^{d, e, f} ●○○○
Word discrimination scores (% correct); follow-up time 3 months					
1 RCT/ 60	Not serious	Not applicable—single study	Serious ^g	Not serious	Moderate for greater effect with HBOT plus steroids ●●●○

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-effective¹ as expressed by the following standards²:

- 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 harms³:

- 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.

Based on Legislative mandate: RCW 70.14.100(2).

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

- 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.

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 evidence⁴ using characteristics such as:

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

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

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

⁴ Based on GRADE recommendation: <http://www.gradeworkinggroup.org/FAQ/index.htm>

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;
- 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.

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.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Pain in the ear		
Serious otitis media/middle ear effusion		
Hemotympanum		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Hearing improvement		
Tinnitus		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
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Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	Low Risk Safe	Moderate Risk	High Risk Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	Less Less effective	Equivocal	More More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	Less Less cost effective	Equivocal	More More cost effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

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 with conditions

Discussion item

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

Medicare Coverage

[see page ES-17 of final report]

No National Coverage Determination identified for HBOT that was specific to the SSNHL indication.

Clinical Practice Guidelines

[see pages 47 and 48 of final report]

Title	Year	AGREE II Rating ^a	Summary of Recommendation(s)
American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF): Clinical practice guideline: sudden hearing loss (update) ¹	2019	5	HBOT is treatment option but only when combined with steroid therapy for either initial treatment (within 2 weeks of onset) or delayed therapy (between 2 weeks and 1 month of onset).
European Committee for Hyperbaric Medicine (ECHM): The Tenth European Conference on Hyperbaric Medicine: recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment ⁴⁰	2017	4	Recommends HBOT combined with medical therapy in patients with acute idiopathic SSNHL who present within 2 weeks of disease onset (Type 1 recommendation, Level B evidence). Do not recommend the use of HBOT alone or combined with medical therapy in patients with idiopathic SSNHL who present after 6 months of disease onset (Type 1 recommendation, Level C evidence). It would be reasonable to use HBOT as an adjunct to corticosteroids in patients presenting after the first 2 weeks but not later than 1 month, particularly in patients with severe and profound hearing loss (Type 3 recommendation, Level C evidence).
National Institute of Health and Care Excellence (NICE): Hearing loss in adults: assessment and management ³⁹	2018 (updated 2023)	5	Consider a steroid to treat idiopathic SSNHL in adults; no mention of HBOT.
The Underseas and Hyperbaric Medical Society (UHMS): Idiopathic SSNHL ¹²	2011	3	Patients with moderate to profound idiopathic SSNHL (≥ 41 dB) who present within 14 days of symptom onset should be considered for HBOT. While patients presenting after this time may experience improvement when treated with HBOT, the medical literature suggests that early intervention is associated with improved outcomes. The best evidence supports the use of HBOT within 2 weeks of symptom onset.

Abbreviations: AAO-HNSF = American Academy of Otolaryngology - Head and Neck Surgery Foundation; AGREE = Appraisal of Guidelines for Research & Evaluation II instrument; ECHM = European Committee for Hyperbaric Medicine; HBOT = hyperbaric oxygen therapy; NICE = National Institute of Health and Care Excellence; SSNHL = sudden sensorineural hearing loss; UHMS = Underseas and Hyperbaric Medical Society.

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 unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

FINAL Key Questions and Background

Hyperbaric Oxygen Therapy (HBOT) for Sudden Sensorineural Hearing Loss (SSNHL)

Background

SSNHL or sudden deafness is rapid loss of hearing with onset over a period of less than 72 hours. It involves a decrease in hearing of ≥ 30 decibels (dB) affecting at least 3 consecutive frequencies.¹ More than 90% of cases are idiopathic. It is accompanied by tinnitus in nearly all cases and vertigo in 30% to 60% of cases. The rationale for the treatment of SSNHL with HBOT is that the hearing loss may be caused by a hypoxic event in the cochlear apparatus; therefore, HBOT may reverse the oxygen deficit, increase oxygen pressures in the cochlea, and improve microcirculation. Notably, 32% to 62% of cases of SSNHL recover spontaneously, which complicates the evaluation of treatments for this condition.¹

HBOT has also been studied as a treatment for acute acoustic trauma (AAT), which is a less common cause of SSNHL.^{2,3} In AAT, exposure to a short-impact, acoustic impulse with an intensity of 90 to 130 dB for a duration of 1 millisecond causes the inner ear to become mechanically damaged with resulting microcirculation vasospasm and hypoxia of cochlear sensory cells occur.⁴ Symptoms include high-frequency sensorineural hearing loss (4 kHz and higher) and tinnitus. Exposure to HBOT could provide increased oxygen to the cochlear apparatus, promoting healing. Thus, the rationale for HBOT for AAT is similar to the rationale for idiopathic SSNHL.⁴⁻⁶ AAT is primarily seen in military or law enforcement personnel, who are exposed to impulse noises from firearms.⁴⁻⁶

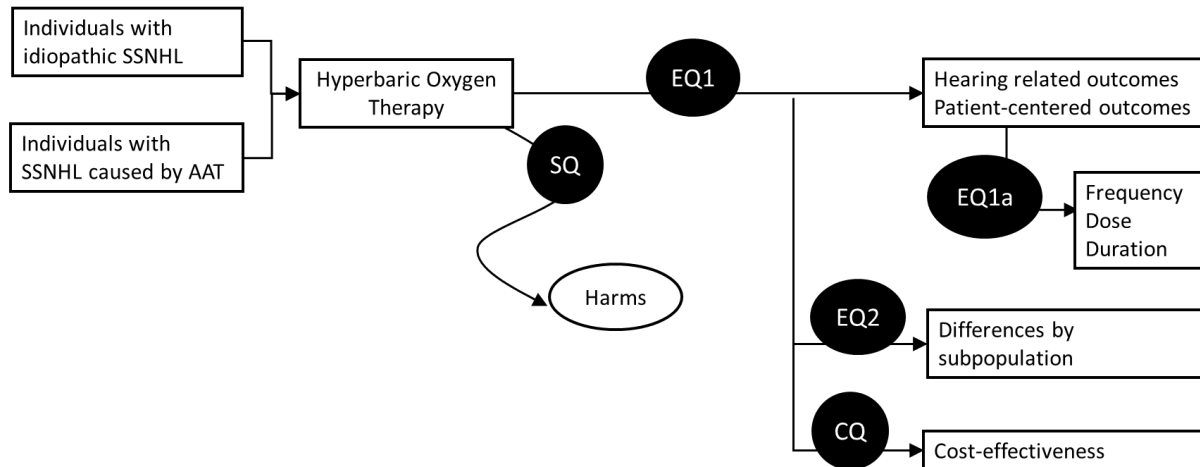
Policy Context

The State of Washington Health Care Authority selected HBOT for idiopathic SSNHL or AAT for a HTA because of medium concerns for safety and high concerns for efficacy and cost.

Scope of this HTA

The analytic framework (**Figure 1**), research questions, and key study selection criteria (**Table 1**) are listed in this section.

Figure 1. Analytic Framework Depicting Scope of this Health Technology Assessment



Abbreviations: AAT = acute acoustic trauma; CQ = cost question; EQ = efficacy question; SSNHL = sudden sensorineural hearing loss; SQ = safety question.

Research Questions

Efficacy Question 1. Is HBOT effective in improving patient-centered outcomes for individuals with idiopathic SSNHL or AAT?

Efficacy Question 1a. What is the optimal frequency, dose, and duration of HBOT treatment for idiopathic SSNHL or AAT?

Efficacy Question 2. What is the differential effectiveness and safety of HBOT according to factors such as age, sex, race or ethnicity, disability, comorbidities, treatment setting, hearing loss duration, severity, or type of hearing loss (e.g., idiopathic vs noise-induced or acute vs. chronic)?

Safety Question. What are the harms associated with HBOT for idiopathic SSNHL or AAT?

Cost Question. What is the cost effectiveness of HBOT for idiopathic SSNHL or AAT?

Studies investigating idiopathic SSNHL and AAT will be analyzed separately.

Study Selection Criteria

Table 1 provides the study selection criteria we will use to include studies in the HTA.

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for Health Technology Assessment on HBOT for idiopathic SSNHL or AAT

Domain	Included	Excluded
Population	Adults or children with sudden idiopathic or noise-induced acute or chronic SSNHL. Acute acoustic trauma with SSNHL.	Adults or children with other forms of hearing loss.
Intervention	Hyperbaric oxygen treatment, delivered via a hyperbaric oxygen chamber, with or without steroid therapy or other medical management.	
Comparator	No treatment, other treatments, or sham HBOT treatments EQ1a. Varying HBOT protocols	No comparator group.
Outcomes	EQ1 and EQ1a. Patient-centered outcomes: • Hearing improvement • Hearing recovery • Return of hearing (> 25%, >50%, complete) • Improvement in pure-tone average (PTA) • Speech discrimination score • Depression • Functional status • Quality of life • Return to school or work EQ2. Differential effectiveness or safety by factors such as: • Age • Sex • Race or ethnicity • Disability • Comorbidities • Severity of hearing loss • Etiology (idiopathic vs. acute trauma) • Treatment setting SQ. Harms: • Barotrauma • Temporary visual disturbances • Oxygen toxicity • Other adverse events CQ. • Cost-effectiveness; cost-utility	• Inflammatory markers, such as neutrophil-lymphocyte ratio (NLR) and platelet-lymphocyte ratio (PLR). • Oxidative stress markers • Cost-effectiveness or cost-utility measures based on non-U.S. based costs
Setting	Any clinical setting in countries categorized as <i>very high^a</i> on the 2022 UN Human Development Index	Countries categorized as other than <i>very high^a</i> on the 2022 UN Human Development Index

Domain	Included	Excluded
Study Design	EQ1, EQ1a, EQ2, SQ <u>Idiopathic SSNHL</u> - Randomized controlled trial; AAT - Randomized controlled trial; controlled clinical trial; comparative cohort studies CQ4 - Cost utility analysis or cost-effectiveness analysis performed from societal or payor perspective	- Editorials, commentaries, narrative reviews, letters, conference abstracts, case reports or case series. - Pre- post studies, case-control studies; non-comparative observational study designs; non-randomized studies of interventions - Qualitative studies - Relevant systematic reviews and meta-analyses will be excluded but may be manually searched to identify potentially eligible studies.
Language and Time Period	- English - No restrictions on publication date	Any language other than English

Abbreviations: AAT = acute acoustic trauma; CQ = cost question; EQ = efficacy question, HBOT = hyperbaric oxygen therapy; SQ = safety question; SSNHL = sudden sensorineural hearing loss; UN=United Nations; US = United States.

Notes: ^a Countries identified as *very high* on the 2022 UN Human Development Index: Andorra, Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Bahrain, Barbados, Belarus, Belgium, Brunei Darussalam, Canada, Chile, Costa Rica, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong, China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Montenegro, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saint Kitts and Nevis, San Marino, Saudi Arabia, Serbia, Seychelles, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Thailand, Trinidad and Tobago, Türkiye, United Arab Emirates, United Kingdom, United States, Uruguay.²

What is Excluded from this HTA

This HTA will not include studies conducted among healthy individuals or individuals with conductive hearing loss, or any kind of hearing loss other than idiopathic SSNHL or AAT. We will exclude studies that do not include a comparator or studies in which we cannot isolate the impact of HBOT (e.g., HBOT with steroid treatment compared with HBOT alone would not be included). We will not include intermediate outcomes such as inflammatory markers or oxidative stress markers. For idiopathic SSNHL, we will exclude comparative cohort studies for EQ1, EQ1a, EQ2, and SQ. We will exclude pre- post studies, case-control studies, non-comparative observational study designs, and qualitative studies since we believe a sufficient volume of trials and comparative cohorts are available, which will provide a more methodologically rigorous evidence based for informing coverage decisions. Relevant systematic reviews and meta-analyses will be excluded but may be manually searched to identify potentially eligible studies. For the CQ, we will exclude any non-U.S. based cost studies. Finally, we will exclude studies published in any language other than English for feasibility reasons.

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