Washington State Health Care Authority
Health Technology Assessment

Cochlear Implants: Bilateral versus Unilateral

Clinical Expert

Jay T. Rubinstein, MD, PhD

Disclosure

Any unmarked topic will be considered a "Yes"

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

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

Advanced Bionics
Cochlear, Ltd
#6 I have travelled to lecture on behalf of those entities.

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

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

University of Washington

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

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

X _____ _____ Jay Rubinstein MD, PhD

Signature *Date* *Print Name*

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COLLEGE OF MEDICINE CURRICULUM VITAE

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

December 10, 2012

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

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- 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

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 Amicitae Sacrum
2007-08 President-elect, American Auditory Society
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

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.
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
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 Imenov, 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

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, FA 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 Otology, 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

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**, Srireddy 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.

62. Yoo SK, Wang G, Collison F, **Rubinstein JT,** Vannier MW, Kim HJ, Kim NH. Three-dimensional localization of cochlear implant electrodes using epipolar stereophotogrammetry. IEEE Transactions on Biomedical Engineering 51(5): 838-846, 2004.

63. **Rubinstein JT.** How cochlear implants encode speech. Currrent Opinion in Otolaryngology **12**(5): 444-448, 2004.

64. Runge-Samuelson CL, Abbas PJ, **Rubinstein JT**, Miller CA, Robinson BK. Response of the auditory nerve to sinusoidal electrical stimulation: effects of high-rate pulse trains. Hearing Research **194**(1-2):1-13, 2004.

65. **Rubinstein, JT.** An introduction to the biophysics of the eCAP. International Journal of Audiology, 43: suppl 1: S3-9, 2004.

66. Wang G, Zhao S, Yu H, Miller CA, Abbas PJ, Gantz BJ, Lee SW, **Rubinstein JT**. Design, analysis and simulation for development of the first clinical micro-CT scanner. Acad Radiol. Apr;12(4):511-25, 2005.

67. Hong RS and **Rubinstein JT.** Conditioning pulse trains in cochlear implants: Effects on loudness growth. Otology & Neurotology 27(1):50-6, 2006.

68. Meyer, TA, Canty, PA, Wilkinson, EP, Hansen, MR, **Rubinstein, JT,** Gantz, BJ**.** Small Acoustic Neuromas: Watch and Wait versus Surgical Excision. Otology & Neurotology 27(3):380-392, 2006.

69. Mino H, **Rubinstein JT.** Effects of neural refractoriness on spatio-temporal variability in neural spike initiations with electrical stimulation. IEEE Transactions on Neural Systems and Rehabilitation Engineering 14(3): 273-80, 2006.

70. White JA, **Rubinstein JT** and Mino H. Implementation Issues in Approximate Methods for Stochastic Hodgkin-Huxley models. Ann Biomed Eng. 35(2):319, 2007.

71. Drennan WR, Won JH, Dasika VK and **Rubinstein JT.** Effects of temporal fine-structure on lateralization and the BILD of spondees in babble and steady-state noise. JARO 8(3): 373-83, 2007.

72. Ruffin CV, Tyler RS., Witt SA, Dunn CC, Gantz BJ, **Rubinstein JT.** Long-term Performance of Clarion 1.0 Cochlear Implant Users. Laryngoscope 117(7): 1183-90, 2007.

73. Wilkinson, EP, Meyer, TA and **Rubinstein, JT.** Spontaneous otogenic pneumocephalus managed with the Middle Fossa Approach. Acta Otolaryngologica 127(8): 892-6, 2007.

74. Won JH, Drennan WR and **Rubinstein JT.** Spectral ripple resolution and speech perception in noise by cochlear implant listeners. JARO 8(3): 384-92, 2007.

75. Nimmons GL, Kang RS, Drennan WR, Longnion J, Ruffin C, Worman T, Yueh B, and **Rubinstein JT.** Clinical Assessment of Music Perception in Cochlear Implant Listeners, Otology & Neurotology 29: 149-155, 2008.

76. Drennan W, Longnion JK, Ruffin C, **Rubinstein JT.** Discrimination of Schroeder-Phase Harmonic Complexes by Cochlear Implant Users. JARO 9: 138-149, 2008.

77. Won JH, Schimmel S, Drennan WR , Souza PE, Atlas L and **Rubinstein JT.** Improving performance in noise for hearing aids and cochlear implants using coherent modulation filtering. Hearing Research 239: 1-11, 2008.

78. Drennan WR and **Rubinstein JT**. Music perception in cochlear implant users and its relationship with psychophysical capabilities, J Rehabil Res Dev. 45(5): 779-790, 2008.

79. Tyler RS**, Rubinstein J**, Pan T, Chang SA, Gogel S, Gehringer A, Coelho C. Electrical Stimulation of the Cochlea to Reduce Tinnitus. Seminars in Hearing 29(4): 327-333, 2008.

80. Dasika VK, Werner LA, Norton SJ, Nie K, **Rubinstein JT**. Measuring detection and reaction time in electric hearing infants and toddlers using an observer-based procedure, Ear & Hearing, 30:250-261, 2009.

81. Kang R, Nimmons GL, Drennan W, Longnion J, Ruffin C, Nie K, Won JH, Worman T, Yueh B, **Rubinstein JT.** Development and Validation of the University of Washington Clinical Assessment of Music Perception (CAMP) Test. Ear & Hearing, 30:411-418, 2009.

82. Friesen, LM, Tremblay, KL, Rohila, N, Wright, RA, Shannon, RV, Başkent, D, **Rubinstein, JT.** Evoked cortical activity and speech recognition as a function of the number of simulated cochlear implant channels. Clinical Neurophys 120:776-

782, 2009.

83. Imennov N, **Rubinstein JT.** Stochastic Population Model for Electrical Stimulation of the Auditory Nerve, IEEE Trans Biomed Engin 56(10):2493-2501, 2009.

84. Jung KH, Cho YS, Cho JK, Park GY, Kim EU, Hong SH, Chung WH, Won JH, **Rubinstein JT.** Clinical assessment of music perception in Korean cochlear implant listeners. Acta Otolaryngologica 130(6):716-23, 2010.

85. Drennan WR, Won JH, Jameyson E, Nie K, **Rubinstein JT.** Sensitivity of psychophysical measures to signal processor modifications in cochlear implant users. Hearing Research 262(1-2):1-8, 2010.

86. Goldwyn JH, Shea-Brown E, **Rubinstein JT.** Encoding and decoding amplitude modulation via cochlear implants - a computational study. J Computational Neuroscience 28(3):405-424, 2010.

87. Cushing SL, Ishak G, Perkins JA, **Rubinstein JT**. Gorham Stout Syndrome of the Petrous Apex Causing Chronic Cerebrospinal Fluid Leak. Otology & Neurotology 31(5):789-92, 2010.

88. Won JH, Drennan W, Kang RS, **Rubinstein JT.** Psychoacoustic elements contributing to good music perception in cochlear implant users. Ear & Hearing, 31(6):796-805, 2010.

89. **Rubinstein JT**, Nie K, Bierer S, Ling L, Phillips JO. Signal Processing for a vestibular neurostimulator. Conf Proc IEEE Eng Med Biol Soc. 2010;1:6247.

90. Nie K, Bierer SM, Ling L, Oxford T, **Rubinstein JT,** Phillips JO. Characterization of the electrically-evoked compound action potential of the vestibular nerve. Otology & Neurotology, 2011.

91. Won JH, Clinard CG, Kwon SY, Dasika VK, Nie K, Drennan W, Tremblay KL, **Rubinstein JT.** Relationship between behavioral and physiological spectral-ripple discrimination. JARO Jun;12(3):375-93, 2011.

92. Won JH, Drennan WR, Nie K, Jameyson E, and **Rubinstein JT.** Acoustic temporal modulation detection and speech perception in cochlear implant listeners. JASA 130:376-88, 2011.

93. Won JH, Jones G, Drennan WR, Jameyson E, and **Rubinstein JT.** Evidence of

across-channel processing for spectral-ripple discrimination in cochlear implant listeners. JASA 130(4):2088-2097, 2011.

94. Phillips JO, Bierer SM, Ling L, Nie K, **Rubinstein** JT. Real-time communication of head velocity and acceleration for an externally mounted vestibular prosthesis. Conf Proc IEEE Eng Med Biol Soc. 3537-41, 2011.

95. Limb CJ and **Rubinstein JT.** Current Research on Music Perception in Cochlear Implant Users. Otolaryngol Clin N Am 45:129-140, 2012.

96. Golub JS, Won JH, Drennan WR, Worman TD, **Rubinstein JT**. Spectral and Temporal Measures in Hybrid Cochlear Implant Users: On the Mechanism of Electroacoustic Hearing Benefits, Otology & Neurotology 33(2):147-153, 2012.

97. Jung KH, Won JH, Drennan WR, Jameyson E, Miyasaki G, Norton SJ, **Rubinstein JT**. Psychoacoustic performance and music and speech perception in prelingually deafened children with cochlear implants. Audiology & Neurotology 17(3):189-97, 2012.

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99. **Rubinstein JT**, Bierer S, Fuchs AF, Kaneko C, Ling L, Nie K, Oxford T, Newlands S, Santos F, Risi F, Abbas PJ, Phillips JO. Implantation of the Semicircular Canals with Preservation of Hearing and Rotational Sensitivity: a vestibular neurostimulator suitable for clinical research. Otology & Neurotology 33(5):789-96, 2012.

100. Won JH, Lorenzi C, Nie K, Li X, Jameyson E, Drennan W, and **Rubinstein JT**. The ability of cochlear implant users to use temporal envelope cues recovered from speech frequency modulation. JASA 132(2):1113-19, 2012.

101. **Rubinstein, JT.** Cochlear implants: the hazards of unexpected success. By invitation to the Canadian Medical Association Journal 184(12):1343-1344, 2012.

102. Goldwyn J, **Rubinstein JT**, and Shea-Brown E. A point process framework for modeling electrical stimulation of the auditory nerve. J Neurophysiol. 108:1430-52, 2012.

103. Won JH, **Rubinstein JT.** Cl Performance in Prelingually Deaf Children and

Postlingually Deaf Adults. The Hearing Journal 65(9):32-33, 2012.

104. Li X, Nie K, Imennov NS, Won JH Drennan WR, **Rubinstein JT,** Atlas LE. Improved perception of speech in noise and Mandarin tones with acoustic simulations of harmonic coding for cochlear implants. JASA 132(5):3387-98, 2012.

Papers in press

Won JH, Nie K, Drennan W, Jameyson E, and **Rubinstein JT**. Maximizing the spectral and temporal benefits of two clinically used sound processing strategies for cochlear implants. Trends in Amplification, 2012.

Jones G, Won JH, Drennan W, **Rubinstein JT.** Relationship between channel interaction and spectral-ripple discrimination in cochlear implant users. JASA, 2012.

Imennov NS, Won JH, Drennan WR, Jameyson E, **Rubinstein JT.** Perception of Within-Channel Temporal Cues in Cochlear Implant Listeners: Behavioral Results and Biophysical Modeling. Hearing Research, 2012.

Kang R, **Rubinstein JT.** Middle cranial fossa surgery for craniometaphyseal dysplasia before the age of two. International J Pediatric ORL, 2012.

Nie K, Ling L, Bierer SM, Kaneko CRD, Fuchs AF, Oxford T, **Rubinstein JT**, Phillips JO. An Experimental Vestibular Neural Prosthesis: Design and Preliminary Results with Rhesus Monkeys Stimulated with Modulated Pulses. IEEE Trans Biomed Engineering, 2012.

Papers submitted

Won JH, Park M, Nie K, and **Rubinstein JT,** Unequal effects of phase on speech perception in steady and modulated noise. Submitted to Hearing Research, 2012.

Jameyson EM, Bierer JA, **Rubinstein JT**. Cochlear implantation in Charcot-Marie-Tooth (CMT): A case report and pathophysiologic analysis. Submitted to Otology & Neurotology, 2012.

Shepherd SJ, Nowack A, Ling L, Nie K, Phillips C, Bierer S, Kaneko C, **Rubinstein JT**, Phillips JO. Long term effects of a chemical lesion on a vestibular prosthesis.

Submitted to JARO, 2012.

Won JH, Shim HJ, Lorenzi C, **Rubinstein JT**. Use of amplitude modulation cues recovered from frequency modulation for cochlear implant users when original speech amplitude modulation cues are severely degraded. Submitted to JARO, 2012.

Drennan WR, Oleson JJ, Gfeller K, Crosson J, Won JH, Anderson ES, **Rubinstein JT.** On the relationships among musical perception, appraisal and experience in cochlear implant users. Submitted to Ear and Hearing, 2012.

Anderson ES, Won JH, **Rubinstein JT**, Drennan WR. Validation of a clinical assessment of spectral ripple resolution for cochlear implant users. Submitted to Ear and Hearing, 2013.

Books/Chapters Published

Rubinstein JT and Gantz BJ. *Facial Nerve Disorders*. Clinical Otology, 2nd Edition, Chapter 25:367-380, 1997. Hughes & Pensak, editors. Thieme Medical Publishers.

Gantz BJ and **Rubinstein JT**. *Intratemporal facial nerve surgery.* Otolaryngology-Head and Neck Surgery, 3rd Edition, C. Cummings, ed-1, Mosby Year Book, 1998.

Gantz BJ, Perry BP, and **Rubinstein JT.** *Cochlear Implants.* The Ear: Comprehensive Otology, Chapter 39, 633-645, RF Canalis and PR Lambert , Editors. Lippincott Publishers, 2000.

Gantz BJ, Tyler RS, and **Rubinstein JT** eds**.** Seventh symposium on cochlear implants in children. Supplement 185, Ann. Otol, Rhinol. Laryngol. 109, 2000.

Rubinstein JT and Tyler RS. *Electrical suppression of tinnitus*. Tinnitus: theory and management. J Snow ed., Decker, 2004.

Drennan WR and **Rubinstein JT**. *Sound processors in cochlear implants,* in Cochlear Implants, 2nd Edition, SB Waltzman and JT Roland eds., Thieme Publications, NY, NY, pp 40-47, 2006.

Nie K, Drennan WR and **Rubinstein JT.** *Cochlear Implant Coding Strategies and Device Programming* in Ballenger's Otorhinolaryngology Head and Neck Surgery, J Snow and PA Wackym eds, BC Decker, 2007.

Golub JS, Phillips JO, **Rubinstein JT.** *Vestibular Implants,* in Auditory Prostheses: New Horizons, Zeng, Popper & Fay eds., Springer, NY, pp 109-33, 2011.

Selected Abstracts

1. Daniels, J.D., Schwartz, M., Ellis, M.K., Bianco, S.A., **Rubinstein, J.T**. and Garrett, M. "Effect of Strabismus Onset Age and Duration on Loss of Binocularity in Kitten Visual Cortex," Abstracts of the Association for Research in Vision and Ophthalmology, pp 71, 1981.

2. Spelman, F.A., Soma, M. and **Rubinstein, J.T**. "Field Models of the Implanted Ear", West Coast Cochlear Prosthesis Workshop, 1984.

3. Spelman, F.A., Soma, M. and **Rubinstein, J.T**. "Electric Field Models of the Implanted Ear", Abstracts of the Sixth Midwinter Research Meeting, Association for Research in Otolaryngology, pp 81, 1984.

4. Soma, M., Spelman, F.A. and **Rubinstein, J.T.** "Fields Produced by the Cochlear Prosthesis: The Ear as a Multilayered Medium", IEEE Frontiers of Engineering and Computing in Health Care, pp 401-405, 1985.

5. **Rubinstein, J.T.**, Spelman, F.A. and Soma, M. "Analytical Electric Field Models of Bipolar Middle Ear Stimulation", Abstracts of the Seventh Midwinter Research Meeting, Association for Research in Otolaryngology, pp 104-105, 1985.

6. **Rubinstein, J.T.**, Spelman, F.A. and Soma, M. "Analytical Models of Finite Prosthetic Electrodes", West Coast Cochlear Prosthesis Workshop, 1986.

7. **Rubinstein, J.T.**, Soma, M. and Spelman, F.A. "An Analytical Model of a Rectangular Stimulating Electrode on a Conducting Half-Space", Abstracts of the Eighth Midwinter Research Meeting, Association for Research in Otolaryngology, pp 173, 1986.

8. **Rubinstein, J.T.**, Spelman, F.A. and Soma, M. "Recessed Electrodes for Auditory Prostheses: Effects on Histopathology", Abstracts of the Ninth Midwinter Research Meeting, Association for Research in Otolaryngology, 1987.

9. **Rubinstein, J.T.**, Suesserman, M.F. and Spelman, F.A. "Measurements and Models of Recessed Electrodes", Proceedings of the Tenth Annual Conference of the IEEE Engineering in Medicine and Biology Society, pp 913-914, 1987.

10. **Rubinstein, J.T.** and Spelman, F.A. "A Model for Electrical Stimulation of Auditory Nerve", Abstracts of the Eleventh Midwinter Research Meeting, Association for Research in Otolaryngology, 1988.

11. **Rubinstein, J.T.** "Analytical Model for Passive Electrotonus and Electrical Stimulation of Mammalian Myelinated Fibers", Abstracts of the Thirteenth Midwinter Research Meeting, Association for Research in Otolaryngology, 1990.

12. **Rubinstein, J.T.** "Analysis of Latency Shifts with Suprathreshold Biphasic Electrical Stimulation", Abstracts of the Fourteenth Midwinter Research Meeting, Association for Research in Otolaryngology, 1991.

13. **Rubinstein, J.T.** "McNeal-type Models for Auditory Nerve Stimulation Require Correction for Azimuthal Stimulus Asymmetry", Abstracts of the Fifteenth Midwinter Research Meeting, Association for Research in Otolaryngology, 1992.

14. **Rubinstein, J.T.** and Dynes, S.B.C. "Latency, Polarity and Refractory Characteristics of Electrical Stimulation: Models and Single-Unit Data," Abstracts of the Sixteenth Midwinter Research Meeting, Association for Research in Otolaryngology, 1993.

15. **Rubinstein, J.T.** "Stochastic Properties of Electrical Stimulation", Abstracts of the Seventeenth Midwinter Research Meeting, Association for Research in Otolaryngology, 1994.

16. Eddington, D.K., **Rubinstein, J.T**., Dynes, S.B.C. 1994. Forward masking during intracochlear electrical stimulation: models, physiology and psychophysics. J Acoust Soc Am 95 (5 Pt.2), 2904.

17. **Rubinstein, J.T.** "A Distributed N Sodium Channel Multinode Axon Model for Electrical Stimulation", Abstracts of the Eighteenth Midwinter Research Meeting, Association for Research in Otolaryngology, 1995.

18. **Rubinstein, J.T.** "Stochastic Modeling of Spiral Ganglia Cells", Annals of Biomedical Engineering, Vol. 23 Supplement 1, pp 5-80, 1995.

19. Brown, C.J., **Rubinstein, J.T.**, Abbas, P.J. Comparison of techniques for assessing the integrity of the internal components of the Nucleus 22-channel cochlear implant. Sixth Symposium on Cochlear Implants in Children. Miami, Florida, 1996.

20. **Rubinstein, J.T.** Characterization of the electrically evoked compound action potential in a stochastic, ionic channel-based auditory nerve model. Nineteenth Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg, FL, 1996.

21. Matsuoka AJ, Miller CA, Abbas PJ, **Rubinstein JT**. Temporal properties of the electrically evoked compound action potential with repetitive stimulation. Twentieth Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg, FL, 1997.

22. Miller CA, Abbas PJ, Matsuoka AJ, **Rubinstein JT**. A comparison of the electrically evoked compound action potential from guinea pig and cat using monophasic anodic and cathodic pulsatile stimuli.Twentieth Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg, FL, 1997.

23. **Rubinstein JT**, Matsuoka AJ, Miller CA, Abbas PJ. Computational model of the auditory nerve: Interesting aspects of the recovery process. Twentieth Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg, FL, 1997.

24. **Rubinstein JT.** Information transfer in cochlear implants. Fifth International Cochlear Implant Conference, New York, 1997.

25. **Rubinstein JT**, Miller CA, Matsuoka AJ, Abbas PJ. Stochastic resonance - can it be exploited by speech processor? Conference on Implantable Auditory Prostheses, Asilomar, CA, 1997.

26. Brown CJ, Abbas PJ, **Rubinstein JT**, Hughes M, Moore S, Hong SH. Comparison of techniques for assessing the integrity of the Nucleus 22-channel cochlear implant. 5th International Cochlear Implant Conference, New York City, 1997.

27. Matsuoka AJ, Abbas PJ, **Rubinstein JT**, Miller CA. Temporal properties of the electrical evoked potentials with pulse train stimulation. Conference on Implantable Auditory Prostheses, Asilomar, CA, 1997.

28. Abbas PJ, Brown CJ, Hong SH, Hughes ML, Miller CA, **Rubinstein JT**, Dillier N. Characterization of the electrically evoked whole nerve potential action potential using different recording methods. Conference on Implantable Auditory Prostheses, Asilomar, CA, 1997.

29. Miller CA, Abbas PJ, **Rubinstein JT**, Robinson BK, Matsuoka AJ. Single-fiber and compound action potential recordings from cat auditory nerves using monophasic current pulses delivered through monopolar intracochlear electrodes. Association for Research in Otolaryngology Midwinter Meeting, St Petersburg Beach, FL, 1998 .

30. Matsuoka AJ, Abbas PJ, **Rubinstein JT**, Miller CM. Compound action potential responses to constant electrical pulse trains: effects of stimulus parameters on response pattern. Association for Research in Otolaryngology Midwinter Meeting, St Petersburg Beach FL, 1998.

31. Abbas PJ, Matsuoka AJ, McDougall VM, Miller CA, **Rubinstein JT.** Compound action potential patterns in response to electrical amplitude-modulated pulse trains in the guinea pig auditory nerve. Association for Research in Otolaryngology Midwinter Meeting, St Petersburg Beach, FL, 1998.

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 N01-DC-6-2111, The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 1997.

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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.

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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.

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

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
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 CochlearImplant 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.
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
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

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.

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**, James Phillips, Felipe Santos, Colin Irwin, and Frank Risi. Vestibular Stimulation Device, 2009

4. Kaibao Nie, **Jay Rubinstein**, Les Atlas, Xing Li, and Pascal Clark. Enhanced Signal Processing for Cochlear Implants, 2009

5. **Jay Rubinstein,** William Harrison. Electrodes for the Treatment of Tinnitus, 2008

6. **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.	
	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
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
Neurophysiological Studies of Electrical Stimulation for the Vestibular Nerve
Investigator (Phillips, PI) $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
The development of sensitivity to electrical stimulation with cochlear implants.
Role: Mentor (Dasika, PI) $58,898

2009-11 National Institutes of Health F31 DC009755
Psychophysics of speech processor modifications in cochlear implants.
Role: Mentor (Won, PI) $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
Auditory Training to Improve Spectral Resolution in Cochlear Implant Listeners

Role: Co-mentor (Faulkner, PI) $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
Vestibular Prosthesis for Bilateral and Uncompensated Unilateral Loss
Role: Co-investigator (Phillips, PI) $75,000

2011-14 Kranwinkle Family
Clinical Feasibility of a Vestibular Implant for Meniere's disease
Role: PI $1,004,000

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- Vice-President, CORLAS-US group
2012-13 President-elect, Association for Research in Otolaryngology

Collegiate, University and National Committees

1992-94 Graduate Medical Education Committee, Massachusetts Eye and Ear Infirmary
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
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

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- Board of Directors, SightLife, LLC, Seattle, WA
2010-13 Board of Directors, Otology & Neurotology
2010- Research 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
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

Washington State Health Care Authority
Health Technology Assessment

Cochlear Implants: Bilateral versus Unilateral

Order of Scheduled Presentations

	Name	Representing
1	Kathy Sie, MD She will present comments via conference phone	Seattle Children's Hospital
2	John K Niparko, MD He will present comments via conference phone.	Chair, American Cochlear Implant Alliance, Tiber Albert Professor, Chair, Otolaryngology-Head & Neck Surgery, University of Southern California
3	Douglas Backous, MD	Swedish Medical Center
4	Stacy Watson, MS, CCC-A	Swedish Medical Group

Disclosure

Any unmarked topic will be considered a "Yes"

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

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

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

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

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

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

X _____ 4-18-13 Kathleen C. Y. Sie

Signature *Date* *Print Name*

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

Disclosure

Any unmarked topic will be considered a "Yes"

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

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

Medical Advisory Board on voluntary basis without remuneration

Customary travel support to 3 meetings over past 5 years

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

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

American Cochlear Implant Alliance is supported by member's dues

Proceeds from national meetings, participating clinics, and private and corporation donations

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

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

X _____ 4/22/13 _____

Signature *Date* *Print Name*

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

ACI ALLIANCE
AMERICAN COCHLEAR IMPLANT ALLIANCE
RESEARCH. ADVOCACY. AWARENESS.

Benefits & Cost-Effectiveness of Bilateral Cochlear Implants

John K. Niparko MD
Chair, American Cochlear Implant Alliance

Tiber Albert Professor and Chair
Dept of Otolaryngology-Head & Neck Surgery
University of Southern California

The American Cochlear Implant Alliance
Unique Organization in Field

- Membership organization concerned with cochlear implantation and access to care
- Membership comprised of physicians, audiologists, speech pathologists, educators and others working with CI recipients in the US

ACI ALLIANCE
AMERICAN COCHLEAR IMPLANT ALLIANCE
Research. Advocacy. Awareness.

www.acialliance.org

ACI ALLIANCE

Binaural Hearing
Fundamental to Human Perception

- Two sets of ACI Alliance written comments to Washington State summarize the peer-reviewed literature on benefits of bilateral cochlear implants
  - Improved detection and localization of sound
  - Enhanced accuracy in production/perception of speech
  - Functional benefits reduced social isolation
  - Health-related quality of life enhancement

ACI ALLIANCE

Effect of Unilateral Hearing Loss in Real World Environments

- Considerable effects of even mild unilateral "untreated" hearing loss on educational outcomes
- 22-35% of children with mild (untreated) hearing loss failed at least one grade (*Studies of 1966-2008*)
- Permanent unilateral *mild* hearing loss impact children's educational outcomes as well as psychosocial well-being
- Impacts when the loss is severe to profound are clearly much more significant

ACI ALLIANCE

Minimal Unilateral Hearing Loss References

- Tharpe AM. Unilateral and Mild Bilateral Hearing Loss in Children: Past and Current Perspectives. *Trends in Amplification*, 2008:12;1, 7-15.
- School failure rates with mild, unilateral hearing loss:
  - Bess & Tharpe 1986 (35%)
  - Oyler 1987 (27%)
  - Jensen 1988 (18%)
  - Martini 1988 (25%)

ACI ALLIANCE

Unilateral Hearing Loss in Adults

- Adults with normal hearing in one ear and "unaidable" hearing in the other experience significant difficulty in the workplace, in social settings, and in other aspects of daily life
  - Problems of hearing speech, localization, hearing in noise are extensively documented
- Impacts are far more significant for individuals with bilateral deafness (and one CI)

ACI ALLIANCE

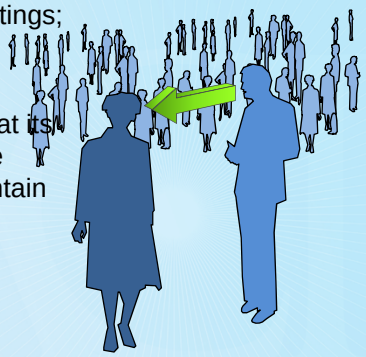
Summary

Hearing with Both Ears

• Binaural hearing: Essential for spatial separation of salient speech from corrupting, background noise.

• Binaural listening: Difficult to test in clinical settings; but essential in challenging listening conditions.

• Such conditions exist when hearing should be at its best: In classrooms, workplaces, settings where people gather to learn new information and maintain the social connectivity essential to cognition and general health status.



ACI ALLIANCE

Disclosure

Any unmarked topic will be considered a "Yes"

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

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

Surgical Advisory Board, Cochlear Corporation.
one meeting per year with $2300.00 honorarium.

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

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

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

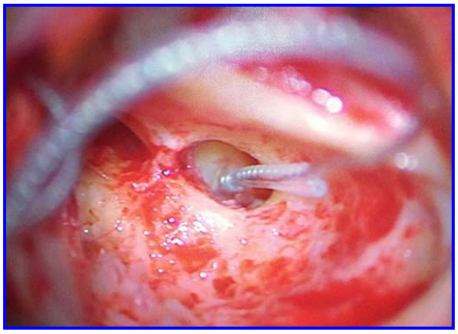
I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ _____ Douglas D. Backous MD
Signature *Date* *Print Name*

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

Cochlear Implants: Bilateral vs Unilateral

Douglas D. Backous, MD, FACS
Medical Director
Center for Hearing and Skull Base Surgery
Swedish Neuroscience Institute



Health Technology Assessment Program
May 17, 2013

SWEDISH

Swedish Program

- Started implanting CI in January, 2011
- 11 bilateral implants placed
- 4 adults
  - 3 simultaneous
  - 1 sequential
- 7 children
  - 23 months- 9 years
  - 3 simultaneous/4 sequential

SWEDISH

Swedish Program

- No surgical complications
- All activated within 7-10 days of implant
- One device failure (Nucleus 5) was removed and re-implanted with return to pre-failure performance
- All patients using both implants

SWEDISH

National Institute for Health and Care Excellence (NICE)

- United Kingdom agency looked into CI in 2009
- Unilateral implants for all severe to profound hearing loss patients if no hearing aid benefit
- Bilateral CI for:
  - Children
  - Adults who are blind or have disabilities where they depend on haring sounds for spatial awareness

SWEDISH


Thank you
SWEDISH

Disclosure

Any unmarked topic will be considered a "Yes"

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

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

- Cochlear America Advisory Board- Audiology
- Med-El EAS Study- manufacture sponsored

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

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

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

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

X _____ _____ Stacey D. Watson

Signature *Date* *Print Name*

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

Stacey D. Watson, MS
Cochlear Implant Audiologist
Center for Hearing and Skull Base Surgery
Swedish Neuroscience Institute

Audiological Numbers

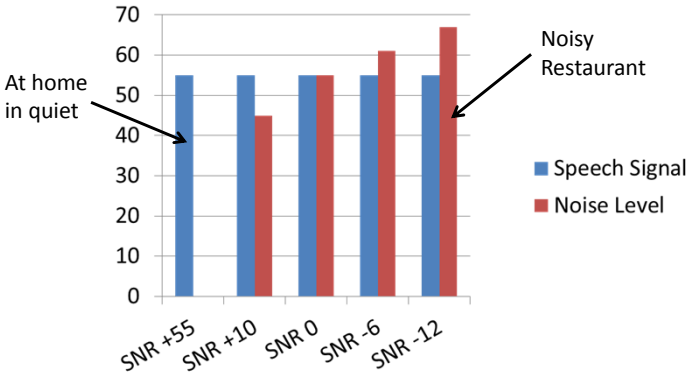
Is a larger number better?

- Hearing Level – dB HL or dB A
  - Measurement of sound intensity most often referred to when talking about threshold
  - Smaller is better
- Speech Perception – percent correct
  - How much is the listener able to hear and understand
  - Larger is better
- Speech Reception Threshold – SRT
  - Minimum intensity at which someone can understand 50% of the spoken word
  - Smaller is better

Audiological Numbers

Is a larger number better?

- Signal to Noise Ratio (SNR) – dB SNR
  - How loud is background noise in relation to the speech
  - Smaller, more negative score is better



SNR Unilateral vs. SNR Bilateral

- Bilateral input allows the listener to pull speech out of the noise more efficiently
  - Brain is more effective with two ears
    - Bilateral squelch
    - Binaural summation
    - Head shadow

Bilateral Implantation = Better SNR

- Schoen et al 2002
  - Effects of summation and squelch
  - 4dB SNR improvement for bilateral compared to unilateral implant use
- Schleich et al 2004
  - Effects of summation and squelch
  - 3dB SNR improvement for bilateral compared to unilateral implant use

Schoen, F, Muller, J, Helms, J. (2002). Speech reception thresholds obtained in a symmetrical four-loudspeaker arrangement from bilateral users of Med-El cochlear implants. Otol. Neurotol., 23(5): 710-714

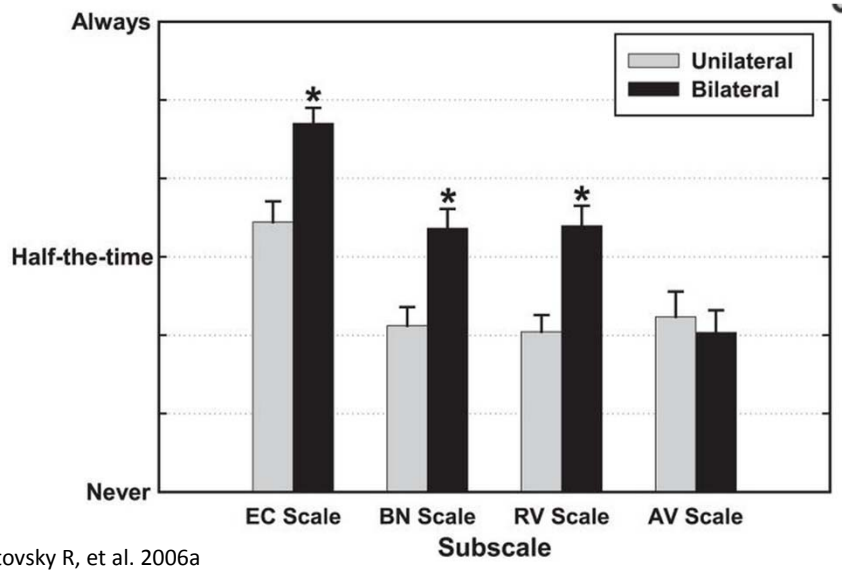
Schleich P, Nopp P, D'Haese P. Head shadow, squelch, and summation effects in bilateral users of the MED-EL COMBI 40/40+ cochlear implant. *Ear Hear.* 2004;25(3):197-204

- Litovsky R, et al. 2006a:
  - 37 post lingual, bilaterally implanted adults
  - Results:
    - Testing in quiet – CNC and HINT tests: speech perception improvement in the bilateral condition compared to unilateral condition
    - Testing in noise – BKB-SIN test: Significant improvement in SNR in the bilateral condition compared to unilateral

3-month post activation:	6-month post activation:
Unilateral -1.75 to 5.75dB	Unilateral -4.0 to 6.0dB
Bilateral -4.75 to 2.75dB	Bilateral -5.5 to 3.75dB

Litovsky R, Parkinson A, Arcaroli J, Sammeth C. Simultaneous bilateral cochlear implantation in adults: a multicenter clinical study. Ear Hear. 2006a;27(6):714-731

Abbreviated Profile of Hearing Aid Benefit (APHAB)



Litovsky R, et al. 2006a

Translate SNR to Speech Perception

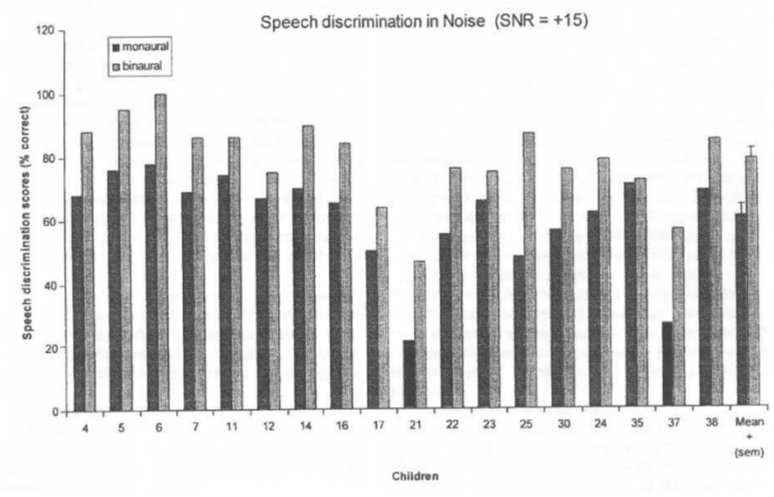
Adult Performance

- Mueller-Diele, J. Sprachverständlichkeitsuntersuchungen bei Kochleaimplantatpatienten. HNO (57)6:580-92. June 2009. German
  - 1dB SNR improvement 8-11% speech perception improvement
- Litovsky: 1.5 to 3dB SNR improvement
  - 12%-33% improvement in speech perception by being able to utilize bilateral implants
- Schoen 2002: expected 28% improvement

Translate SNR to Speech Perception
Pediatric Performance

- Appropriate acoustical conditions in the classroom for listeners with a hearing loss should equal or exceed 15dB SNR
- Kuhn-Inacker et al (2004)
  - 39 German children bilateral implanted
  - +15dB SNR with speakers set up to minimize head shadow
  - All children did better bilaterally compared to unilateral [$p < .0001$ on paired t-test]
  - Open set speech discrimination scores: (N = 35)
    - Unilateral 21% to 78% correct
    - Bilateral 46% to 100% correct
    - Mean difference of 18.4% (+/- 8.2%)

Crandall, C, Smaldino, J, Classroom Acoustics for Children with Normal Hearing and Hearing Impairment. Language, Speech and Hearing Services in Schools. 2000, Vol 31 (362-370)



Kuhn-Inacker et al (2004)

Conclusion

- Listening in noise is challenging
- The brain has the ability to make listening in noise easier – if you have two ears
- Bilateral implant use allows adults and children to take advantage of the brains natural processes for communication

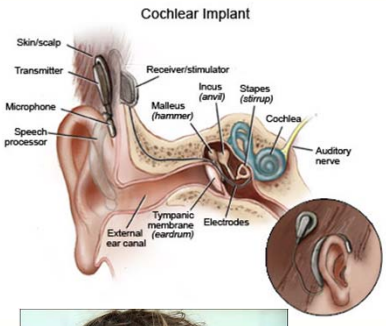
Washington State Health Care Authority

Cochlear Implants: Bilateral versus Unilateral

State Agency Utilization & Outcomes

Kerilyn K. Nobuhara MD MHA
Senior Medical Consultant
Health Care Authority
May 17, 2013

Cochlear Implants: Background



- Replace function of absent or nonfunctioning cochlea
- Technology differs from hearing aid, implanted bone conduction device, auditory brainstem implant
- Use requires both surgical implantation and post-implantation therapy to learn or re-learn sense of hearing
- 2000 - FDA lowered age of eligibility to 12 months of age
- FDA 510k device or PMA

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Cochlear Implants: FDA label

Manufacturer	Adults	Children
Advanced Bionics® HiRes 90K Clarion Multi-Strategy HiResolution Bionic Ear System	• 18 years of age • Post-lingual onset of severe to profound bilateral sensorineural hearing loss (>70 dBs) • Limited benefit from appropriate fitted hearing aids, defined as scoring <50% on a test of open-set Hearing in Noise Test sentence recognition	• 12 months to 17 years of age • Profound bilateral sensorineural deafness (>90dB) • Use of appropriately fitted hearing aids for at least 6 months in children 2 to 17 years of age or at least 3 months in children 12 to 23 months of age. • Lack of benefit in children <4 years of age is defined as a failure to reach developmentally-appropriate auditory milestones (e.g., spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or < 20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice [70 dB SPL (sound pressure level)] • Lack of hearing aid benefit in children >4 years of age is defined as scoring < 12% on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or < 30% on an open-set sentence test (HINT for Children) administered using recorded materials in the sound field (70 dB SPL)

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Cochlear Implants: FDA label

Manufacturer	Adults	Children
Cochlear® Nucleus® 5* Nucleus® 22, Freedom	• ≥ 18 years old • Pre- or post-lingual onset of moderate to profound bilateral sensorineural hearing loss • Limited benefit from amplification defined by preoperative test scores of ≤50% sentence recognition in the ear to be implanted and ≤ 60% in the opposite ear or binaurally • ≤60% sentence recognition in the opposite ear or binaurally	**Children 12 months to 24 months:** • Profound sensorineural hearing loss bilaterally • Limited benefit from appropriate binaural amplification trial • Lack of progress in the development of auditory skills **Children 25 months to 17 years 11 months:** • Severe to profound bilateral sensorineural hearing loss • Limited benefit from binaural amplification with Multi-syllabic Lexical Neighborhood Test (MLNT) scores of ≤30% • Limited benefit from binaural amplification with Lexical Neighborhood Test (LNT) scores of ≤30%

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Cochlear Implants: FDA label

Manufacturer	Adults	Children
Med El® Maestro (Sonata or Pulsar) Combi 40+	• ≥ 18 years old • Severe to profound bilateral sensorineural hearing loss (≥70dB or greater at 500 Hz, 1000 Hz, 2000 Hz) • ≤40% correct Open set Hearing in Noise test sentences with best-aided listening condition	• 18 months to 17 years 11 months with profound bilateral sensorineural hearing loss (≥90dB at 1000 Hz) • In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3-6 month period • In older children, lack of aided benefit is defined as <20% correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT) depending upon the child's cognitive ability and linguistic skills • A 3-6 month trial with hearing aids is required if not previously experienced with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.

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Cochlear Implants: Background

For HTCC consideration:

Bilateral versus Unilateral Cochlear Implants

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Washington State Health Care Authority

Current State Policy

Labor and Industries

- Prior authorization

Department of Corrections

- Prior authorization

Medicaid

- Prior authorization for unilateral cochlear implant for clients 20 years of age or younger
- No hearing services or hearing hardware benefit for clients 21 years of age or older
- Bilateral cochlear implants not covered

Washington State Health Care Authority

Current State Policy

Medicaid

Unilateral cochlear implantation for clients age 18 through 20 with post-lingual hearing loss and clients (age 12 months-17 years) with prelingual hearing loss when all of the following are true:

- The client has a diagnosis of profound to severe bilateral, sensorineural hearing loss;
- The client has stimulable auditory nerves but has limited benefit from appropriately fitted hearing aids (e.g., fail to meet age-appropriate auditory milestones in the best-aided condition for young children, or score of less than ten or equal to 40% correct in the best-aided condition on recorded open-set sentence recognition tests;
- The client has the cognitive ability to use auditory cues;
- The client is willing to undergo an extensive rehabilitation program;
- There is an accessible cochlear lumen that is structurally suitable for cochlear implantation;
- The client does not have lesions in the auditory nerve and/or acoustic areas of the central nervous system; and
- There are no other contraindications to surgery

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Washington State Health Care Authority

Current State Policy

Regence

Lateral implantation of fully FDA approved cochlear implants (i.e., PMA or 510k only) and associated aural rehabilitation may be considered ***medically necessary*** when ***all*** of the following criteria are met:

- Age 12 months or older
- Bilateral severe to profound pre- or postlingual (sensorineural) hearing loss, defined as a hearing threshold of pure-tone average of 70 decibels (dB) or greater hearing loss at 500 Hz (hertz), 1000 Hz and 2000 Hz
- Limited or no benefit from hearing aids unless hearing aids are unreasonable

- ***Adults:*** Scores < 50 percent correct on tape recorded sets of open-set sentence recognition in the ear to be implanted
- ***Children:*** Failure to develop basic auditory skills, and in older children, < 30 percent correct on open-set tests

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Medicare National Coverage Determination

Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with FDA approved labeling.

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AMDG Workgroup Perspective

Primary Criteria Ranking

Safety = High
Effectiveness = Medium
Cost = High

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Agency Key Questions

Safety = High

- Is bilateral cochlear implantation safe?
- What is the best available evidence supporting a sequential vs. simultaneous approach to bilateral implantation?
- What are the associated harms and which of these result in permanent explanation?

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Agency Key Questions

Effectiveness = Medium

- What is the evidence for differential effectiveness for unilateral vs. bilateral cochlear implantation?
- What is the preferred study design in the absence of randomized controlled trials?
- Do measured outcomes such as sound localization, open and closed set speech perception tests, speech comprehension and speech production tests serve as accurate surrogate markers of hearing-related function and overall health outcomes?
- What is the evidence for the contribution of unilateral vs. bilateral cochlear implantation to neurodevelopment in children, return to work for adults and prevention of dementia in older adults?

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Agency Key Questions

Cost = High

- Do utility estimates derived from an adult experience apply to prelingual children with severe to profound bilateral hearing loss?
- Is the economic burden of hearing loss known and can an ICER for unilateral vs. bilateral cochlear implantation be calculated in this context?

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Washington State Health Care Authority

State Agency Utilization

Agency/Year PEBB	2008	2009	2010	2011	4 -Yr Overall[2]	Average % Change
Agency Pop. (Fee for Service)	204,804	210,501	213,487	212,596		1.3%
All Cochlear Implant Procedures:						
Patient Count [2]	9	11	11	4	32	-15.3%
Procedure Count	10	11	11	4	36	-19.3%
Amount Paid	$320,669	$543,480	$437,530	$166,780	$1,468,459	-3.7%
Per Procedure Average [3]	$32,067	$49,407	$39,775	$41,695	$52,778	
Per Procedure Maximum	$71,913	$159,289	$78,637	$88,777	$159,289	
Unilateral Cochlear Implants (Non-Medicare)						
Procedure Count	6	5	6	2	16	
Per Procedure Average	$52,611	$75,282	$71,496	$81,898	$70,874	
Bilateral Cochlear Implant Average (1 only)						
Per Procedure Average		$159,289				
Procedures including Device Malfunction						
Procedure Count			1		1	

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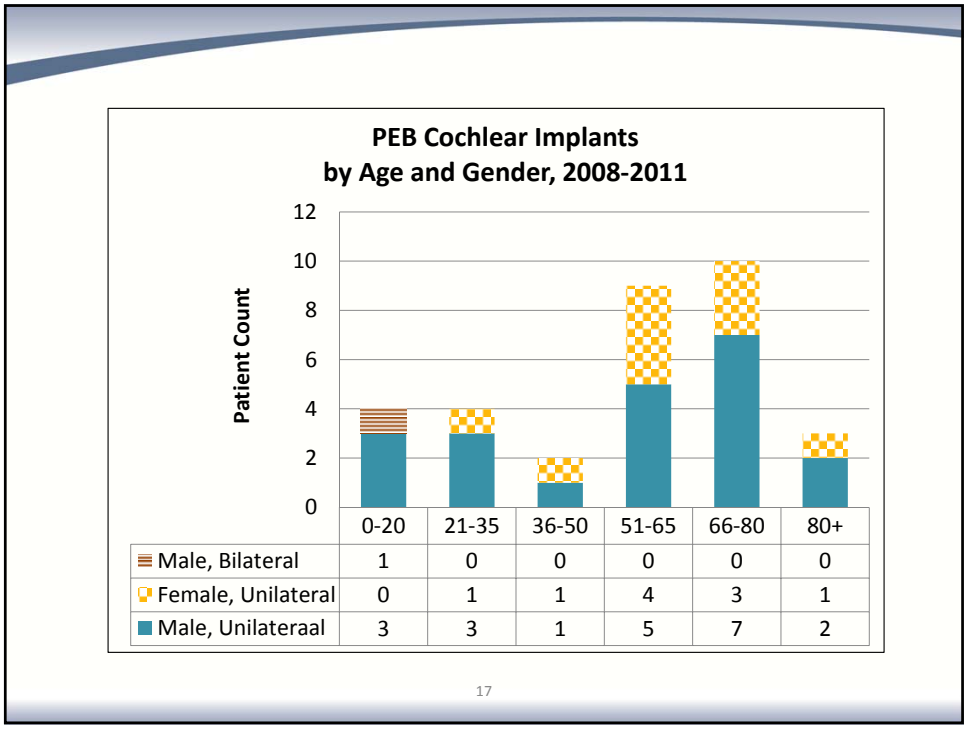
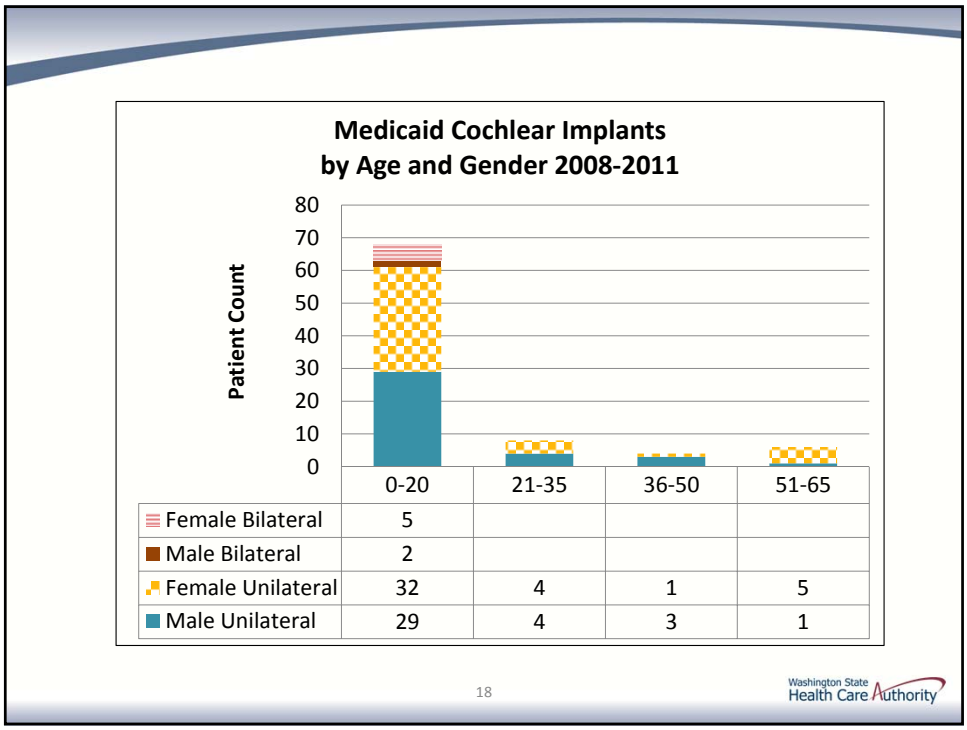
Washington State Health Care Authority

State Agency Utilization

Agency/Year Medicaid	2008	2009	2010	Medicaid	4-Yr Overall[2]	Average % Change
Agency Pop. (Fee for Service)	392,808	416,871	424,230	435,187		3.5%
All Cochlear Implant Procedures:						
Patient Count[2]	20	17	25	18	79	-1.7%
Procedure Count	20	17	27	19	83	1.6%
Amount Paid	$397,337	$391,359	$540,395	$606,041	$1,935,132	12.6%
Per Procedure Average[3]	$19,867	$23,021	$20,015	$30,302	$23,037	
Per Procedure Maximum	$26,822	$48,071	$27,267	$74,306	$74,306	
Unilateral Cochlear Implants (Excluding 6 Medicare procedures - $400 total)						
Procedure Count	20	15	23	19	77	
Per Procedure Average	$19,867	$21,380	$21,572	$30,001	$23,172	
Bilateral Cochlear Implant Average (None performed under Medicare)						
Procedure Count	0	2	4	1	7	
Per Procedure Average	0	$35,326	$11,059	$36,029	$21,559	
Procedures Including Device Malfunction						
Procedure Count	3	1	1**	1	5	
Percent Total Procedures	15.0%	5.9%	3.7%	5.3%	6.0%	


PEB Cochlear Implants
by Age and Gender, 2008-2011
Patient Count
12
10
8
6
4
2
0
0-20 21-35 36-50 51-65 66-80 80+
Male, Bilateral 1 0 0 0 0 0
Female, Unilateral 0 1 1 4 3 1
Male, Unilateraal 3 3 1 5 7 2
17


Medicaid Cochlear Implants
by Age and Gender 2008-2011
Patient Count
80
70
60
50
40
30
20
10
0
0-20 21-35 36-50 51-65
Female Bilateral 5
Male Bilateral 2
Female Unilateral 32 4 1 5
Male Unilateral 29 4 3 1
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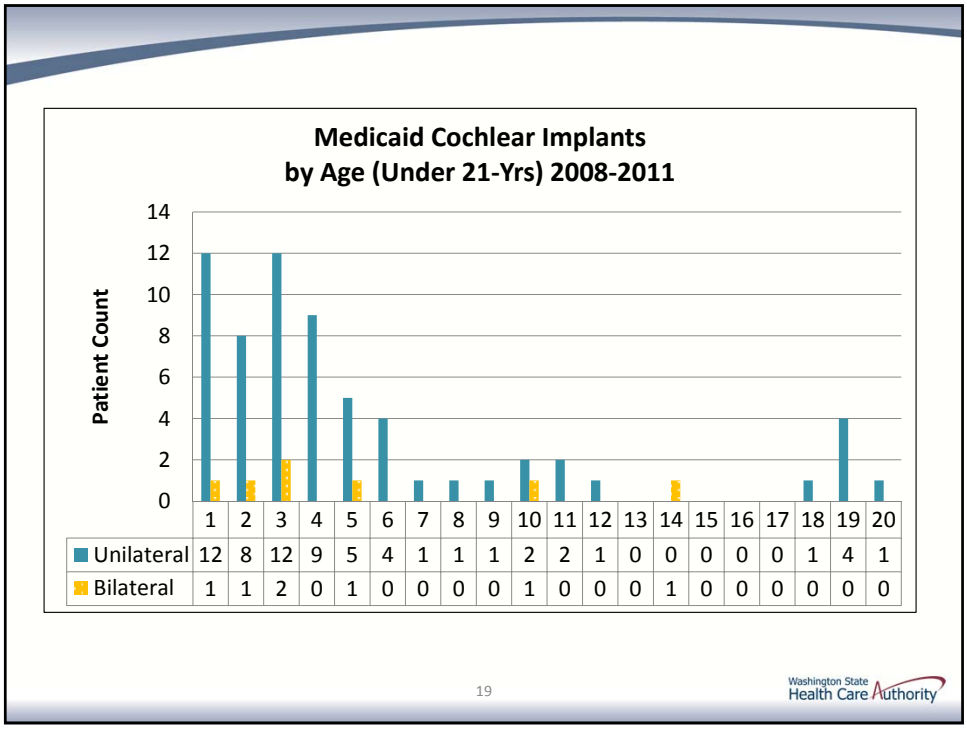
Washington State Health Care Authority



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State Agency Utilization

Agency and Implant Type (Procedure Count)	Medicaid Unilateral (64)*	Medicaid Bilateral (7)	Medicaid Medicare, Unilateral (6)	PEB Primary, Unilateral (19)	PEB Primary, Bilateral (1)	PEB Medicare (16)
Cost Breakdown 1						
Facility	$27,418	$29,923	$33,331	$66,280	$154,089	$96792
Professional	$1402	$2152	$1229	$2535	$5300	$423
Cost Breakdown 2						
Implant (Facility & Professional)	$23,818	$22,021	$33,080	$41,389	$35,144	$24,607
Post Procedure Hearing & Implant Testing, Analysis & Reprogramming	$632	$515	$178	$992	$1583	$650
Other Day of Treatment Costs**	$3919	$9539	$1302	$25,243	$122,662	$71,958
Per Procedure Average	**$28,370**	**$32,075**	**$34,560**	**$67,624**	**$159,389**	**$97,215**

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State Agency Utilization

Medicaid CI Repairs & Service	Rpts	Pts	Bilateral Pts	Unilateral Pts	Total ($37,037)	Avg per Pt
Batteries	55	37	5	32	$11,759	$318
Service and Repair	21	14	3	11	$23,666	$1,690
Replace Major Components	25	19	2	17	$1,612	$85

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State Agency Utilization

Medicaid CI Patient Hearing Services	Before Implant (73 patients)			After Implant (66 patients)			Bilateral After Implant (5 patients)		
	Total	Pts	Svcs	Total	Pts	Svcs	Total	Pts	Svcs
Auditory Rehab	$3,946	6	81	$43,181	15	549	$3,690	1	36
Auditory Rehab, Evaluation	$4,333	34	55	$7,774	36	89	$445	2	4
Hearing Aid	$29,528	30	34	$1,755	3	3			
Hearing Aid Repair/Supplies	$6,691	33	90	$1,805	18	35			
Other Hearing Services	$6,397	3	3	$4,554	2	2			
Speech/Hearing, Evaluation	$3,683	32	49	$4,337	29	68	$81	1	3
Speech/Hearing, Therapy	$53,299	42	1384	$101,959	53	2729	$4,297	4	150
Grand Total	**$107,878**			**$165,364**			**$8,513**		
Per Patient Average	$1,478			$2,506			$1,703		

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Agency Considerations

- **For the pediatric population:**
  - Moderate evidence demonstrating benefit for speech perception and sound localization in favor of bilateral cochlear implantation
  - Very low quality evidence for speech comprehension and speech production tests
- **For the adult population:**
  - Moderate evidence demonstrating benefit for speech perception in noise and sound localization in favor of bilateral cochlear implantation
  - Moderate quality evidence demonstrating benefit for disease specific measures of hearing function in favor of bilateral cochlear implantation
- **Variation in study design and selection of comparator groups**
  - Impact on quality rating
  - Testing of prelingual pediatric population poses unique challenge
- **Inadequate evidence regarding simultaneous vs. sequential bilateral cochlear implant.**

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Bilateral Cochlear Implants: AMDG Recommendations

Cover with conditions:

- Age 12 months or older
- Bilateral severe to profound hearing loss
- Limited, or no benefit from hearing aids
- Cognitive ability to participate in an extensive auditory rehabilitation program
- Accessible cochlear lumen and stimulable auditory nerve
- Does not have lesions in the auditory nerve and/or acoustic areas of the central nervous system
- No other contraindications for surgery
- Device used in accordance with the FDA label

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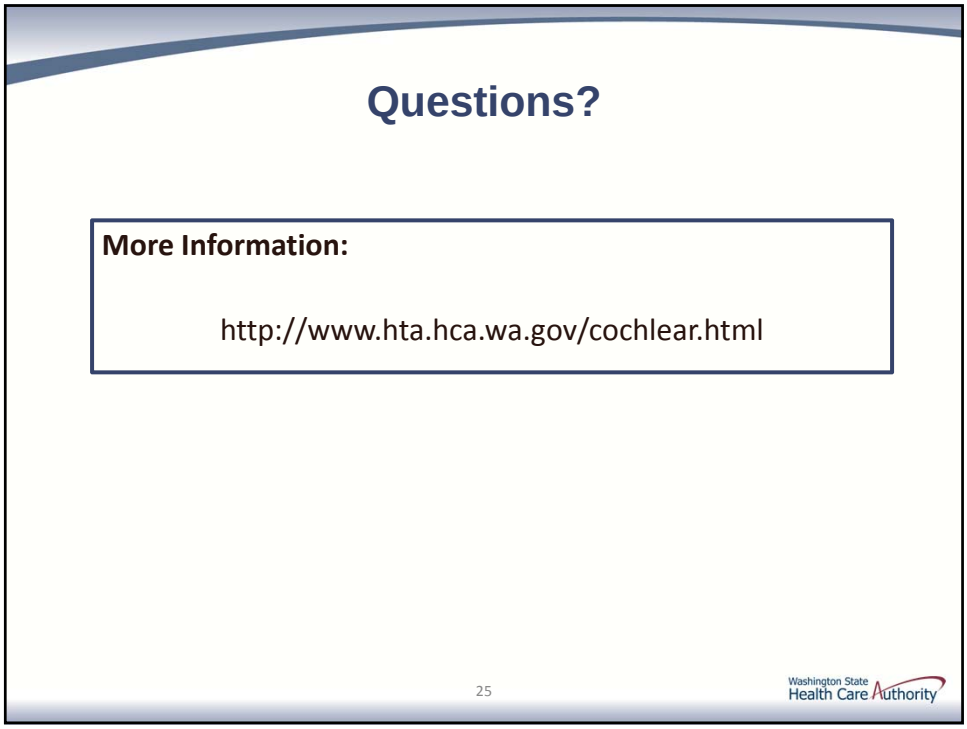
Questions?
More Information:
http://www.hta.hca.wa.gov/cochlear.html
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Cochlear Implants: Bilateral Versus Unilateral

Teresa Rogstad, MPH
Research Project Leader

Hayes

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Hayes

Presentation Overview

- Background and Policy Context
- Review Objectives
- Methods
- Findings
- Practice Guidelines and Payer Policies
- Summary

Abbreviations

- CI, cochlear implant(ation)
- dB, decibel
- HA, hearing aid
- HL, hearing level
- KQ, Key Question
- PTA, pure tone average
- NS, nonsignificant
- QALY, quality-adjusted life-year
- QOL, quality of life
- Sig, (statistical) significance
- SNR, signal-to-noise ratio
- SRT, speech reception threshold

Background and Policy Context

Hearing Loss

- 5 per 1000 children
- 16% adults (30% adults > 64 years)
- Sensorineural hearing loss (SNHL)
  - Indication for CI
  - Loss of cochlear hair cells (cilia)
  - Prelingual or postlingual

Cochlear Implantation

- Developed for severe to profound hearing loss
  - No or nearly no residual hearing
  - Minimal or no benefit from HA
- Audiological measurements
  - Severe hearing loss: PTA 70-90 dB HL
  - Profound: PTA ≥ 95 dB HL
  - (normal: PTA < 20 dB HL)
- Electrodes inserted into the cochlea perform the function of cilia

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Theoretical Benefits Bilateral CI

- Normal hearing individuals benefit from 2 ears
  - Head shadow effect
  - Binaural squelch
  - Binaural summation
- Binaural cues required for localization
- Sequential vs simultaneous implantation

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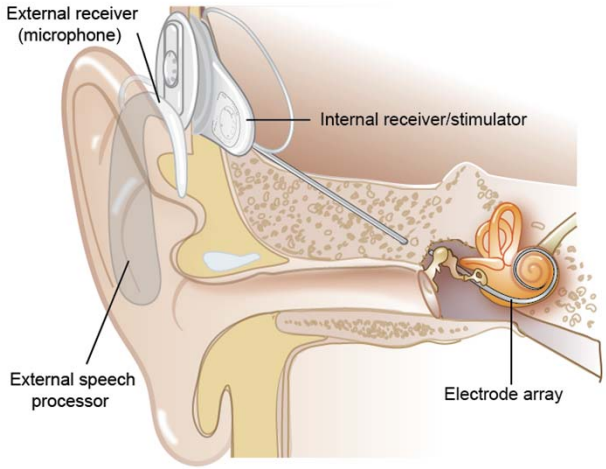
Technical Description:
Cochlear Implant and Related Parts



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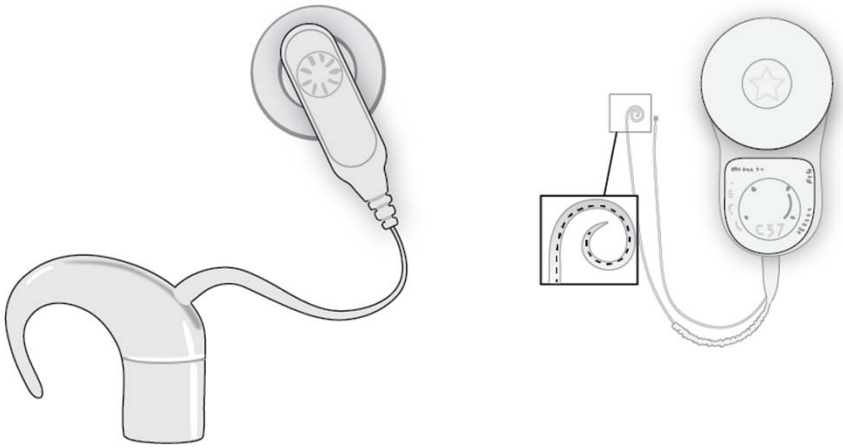
Technical Description:
External Parts; Implant



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Policy Context

- Bilateral CI
  - Increases cost
  - Increases risk
  - Uncertain benefit
- In recent years, substantial bilateral CI evidence has accumulated

Review Objectives: PICO

Populations: Children, adolescents (20 years of age and younger), and adults with hearing loss.

Intervention: Bilateral implantation of multichannel cochlear devices that use whole-speech processing coding strategies.

Comparator: Unilateral CI only, unilateral CI plus acoustic hearing aid.

PICO (cont.)

Outcomes:

- *Primary:* Detection of sound (measured directly or measured indirectly by hearing aid use), neurocognitive development, perception and production of speech, functional status, quality of life (QOL), procedure- and device-related complications.
- *Secondary:* Tinnitus, telephone usage, patient acceptance, employment or job performance, educational outcomes.

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Key Questions

1. Compared with unilateral cochlear implantation or with unilateral cochlear implantation plus acoustic hearing aid, does bilateral cochlear implantation for hearing loss **improve detection of sound, neurocognitive development, perception or production of speech, functional status, QOL, or other patient-important outcomes?**
2. Is bilateral cochlear implantation **safe?**
3. Does the effectiveness or safety of bilateral cochlear implantation **vary** according to **age** at implantation, **prelingual versus postlingual** onset of hearing loss, **duration or degree of deafness, choice of implanted ear, time interval between implantations, specific device, or provider characteristics?**
4. What are the **cost implications,** including cost-effectiveness, of bilateral cochlear implantation?

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Methods

Evidence Sources

- Systematic reviews (SRs)/guidelines (GLs)/cost studies (5 years)
  - Core databases
  - MEDLINE (filters)
  - Several SRs: missing studies and/or insufficient study detail
- De novo approach (primary studies)
  - SR bibliographies (< July 2009)
  - MEDLINE/Embase (≥ July 2009)
- 1st search, Nov. 28, 2012; 2nd, Feb. 17, 2013

Evidence Sources (cont.)

- Additional GLs
  - American Academy of Neurology (AAN)
  - American Academy of Pediatrics (AAP)
  - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
  - American Auditory Society
  - American Speech-Language-Hearing Association
  - International Hearing Society

Evidence Selection

- Studies designed to compare bilateral vs unilateral CI (all KQs)
  - ≥ 20 evaluable patients assessed with objective measurement or formal instrument
- Treatment success predictors in patients undergoing bilateral CI (KQ #3)
- Case series or systematic review of case series of unilateral or bilateral CI: safety data (KQ #2)

Quality Assessment

- Hayes methodology aligns with GRADE system
- Appendix III
- Two main steps
  1. Individual study appraisal
  2. Evaluation of body of evidence for each outcome

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Quality Assessment: Individual studies

- *Good-Fair-Poor-Very Poor*
- Study design, execution and analysis (checklist)
- Internal validity (minimization of bias)

- *Is this evidence valid and reliable?*

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Quality Assessment:
Body of evidence, each outcome

- *High-Moderate-Low-Very Low*
- Considerations
  - Study design and weaknesses
  - Applicability to PICO
  - Quantity/precision of data
  - Consistency of study findings
  - Publication bias
- *How well does this evidence answer key questions?*

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Quality Assessment:
Study designs in CI research

Timing of Outcome Assessment	Intergroup Comparison	Intrasubject Comparison
Simultaneous Data Collection	**Design A:** Cross-sectional, case-control **Very poor**	**Design B:** Binaural listening (both CIs activated) vs monaural listening (1 CI activated) **Good**
Longitudinal Assessment	**Design C:** Cohort, nested case-control, historical controls **Poor**	**Design D:** Before-and-after (pre-/posttest) **Poor (children), Fair (adults)**
See Table 1, page 42 in report.		

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"Design B": Good

		2 CIs vs 1 CI?	2 CIs vs 1 CI?	2 CIs vs 1 CI?
Bi Grp:	2nd CI----------X	----------X	----------X	
		3 mos	6 mos	1 yr

- Intrasubject binaural-monaural comparison
  - 2 CIs activated vs 1st CI (children) or better CI (adults) activated
  - Experimental
  - Minimal risk of bias (confounders controlled)
- Does the monaural condition after 2nd CI represent the unilateral CI comparator of interest?

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Outcome Measures (Appendix I)

- Speech perception tests
  - % correct
  - Speech reception threshold (SRT)
  - Signal to noise ratio (SNR)
- Localization (left-right discrimination)
  - % correct
  - Minimum audible angle, angle error
- Functional/health/QOL questionnaires
  - Disease-specific
  - Generic
- No standard tests/protocols for auditory tests

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Findings

Search Results

- Key Question #1
  - Children and adolescents: 18 studies, 21 reports
  - Adults: 17 studies, 19 reports
- Key Question #2
  - 1 technology assessment (15 case series)
  - 4 case series
- Key Question #3
  - KQ #1 studies, where applicable
  - 2 comparator trials (sequential vs simultaneous; children)
  - 2 case series with success predictor analyses; children
- Key Question #4
  - A systematic review of 5 economic evaluations

(Children) Summary of Findings, KQ #1: Preview

Outcome	**Findings** (direction, quality)
• Sound detection*	• Insufficient evidence
• Neurocognitive development*	• Insufficient evidence
• **Speech perception in quiet**	• **Positive*, moderate**
• **Speech perception in noise**	• **Positive*, moderate**
• **Localization**	• **Positive*, moderate**
• Speech comprehension and production	• Mixed, very low
• Functional/QOL outcomes	• Positive†, low

*No slide

* Functional relevance?

†Only according to disease-specific functional scales

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Interpreting Auditory Outcomes

- dBs
  - Logarithmic scale; difference of 1 dB=10-fold difference

  Expert comments
  - 5 dB improvement is a large benefit in noise; not relevant in quiet
  - 2 dB improvement is small but noticeable benefit in noise
- Lateralization (chance, e.g., 50%, performance?)
- Other forms of measurement (% correct responses)
  - Unknown clinical/functional relevance

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(Children) Summary of Findings, KQ #1: Speech Perception in Quiet

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
8 (340) 3 good, 2 fair, 2 poor, 1 v poor	Moderate, small sample sizes	% correct responses: 60%-89% (6 studies) Binaural-monaural reduction in SRT-79.4%: –3 dB (1 study) *SRT-71%: 42-45 dB (1 study)*	% correct responses: 79%-94% (6 studies) Binaural-monaural reduction in SRT-79.4%: 4 dB (1 study) *SRT-71%: 42-48 dB* (1 study)
		+ sig results, all 8 studies; also, some + but NS analyses, 2 studies. ***Statistically sig* absolute differences (8 studies): 4%-25% for % correct responses, 5-7 dB for SRTs** Clinical and functional significance are uncertain.	
Age last CI: Mean 21 mos to mean 8 yrs. 1st CI to 2nd CI: 6 mos to mean 9 yrs. F/u: Mean ≥1 yr in 6 studies			

(Children) Summary of Findings, KQ #1: Speech Perception in Noise

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
10 (278) 3 good, 2 fair, 3 poor, 2 very poor	Moderate, small sample sizes	% correct responses: 36%-62% (6 studies) Binaural-monaural reduction in SRT-79.4% by noise condition and comparison*: –2 to 0 dB (1 study) *SNR: 2 dB (1 study)*	% correct responses: 56%-79% (6 studies) Binaural-monaural reduction in SRT-79.4% by noise condition and comparison*: 2-4 dB (1 study) *SNR: –4 dB (1 study)*
		+ sig results, 8 studies; no difference, 2 poor-quality studies. ***Statistically sig* absolute differences (8 studies): 6%-37% for % correct responses, 4 dB for SRTs, 4-6 dB for SNR** Clinical and functional significance are uncertain.	
Age at last CI: Mean 21 mos to mean 8 yrs; age 10-20 yrs in 1 study. 1st I to 2nd CI: 6 mos to mean 9 yrs; 6-17 yrs in 1 study. F/u: Mean ≥1 yr in 7 studies *Comparator was bimodal stimulation (CI+HA).			

(Children) Speech Perception in Noise: 3 good studies. App. IV-B

- **Peters 2007: n=23, age 3-13 yrs, f/u 9 mos; CRISP, speech from the front (% correct responses)**
  - *Noise from the front:* 69% vs 62% (*P*=0.018); difference **7%***
  - *Noise to 1st CI:* 69% vs 55% (*P*<0.001); difference **14%***
  - *Noise to 2nd CI:* 79% vs 72% (*P*=0.018); difference **5%***
- **Steffens 2008: n=20, mean age 5.6 yrs, mean f/u 1.4 yrs; OLKI, speech near 1st CI; speech front, noise near 2nd CI (% correct responses)**
  - 73% vs 36%; mean difference **37%** (*P*<0.001)*
- **Sparreboom 2011: n=29 Bilateral and 9 Unilateral, mean age 5.3 yrs, f/u 2 yrs; ATT Test, speech front (SNR for 50% correct responses)**
  - *Intrasubject ("B"):* Coincident signal-noise, −4 dB vs 2 dB (NS), binaural advantage 6 dB. Separated, −2 dB vs 2 dB (NS), binaural advantage 4 dB.*
  - *Vs Unilateral Grp ("C"):* Coincident, −4 dB vs 2 dB. Separated, −2 dB vs 2 dB; group differences **4-6 dB** (global *P*=0.01)†

*Intrasubject ("B"), binaural (2 CI's) vs monaural (1st CI alone) listening condition. †Bilateral Grp vs Unilateral Grp. CRISP, Children's Realistic Index of Speech Perception; OLKI, Oldenburger Kinder Reimtest; ATT, Auditory Toy Discrimination

(Children) Summary of Findings, KQ #1: Localization (left-right)

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
5 (170) 2 good, 2 fair, 1 poor	Moderate, small sample sizes	% correct: 25%-58% (chance levels) Minumum audible angle: ±78°	% correct: 50% (where chance level was 25%) to 100% Minimum audible angle: ±42°
		+ sig results in all studies. ***Statistically sig* absolute differences (5 studies): 18%-36% for % correct responses and 36° for angles** Clinical and functional significance are uncertain.	
Age at last CI: <3 to mean 6 yrs. 1st CI to 2nd CI: <2-4 yrs. F/u: Mean 1-4 yrs			

(Children) Localization (left-right): 2 good studies. App. IV-C

- **Steffens 2008: n=20, age mean 5.6 yrs, f/u 1.4 yrs; loudspeaker choice (% correct responses)**
  - 75% vs 58%, mean difference **18%** (*P*=0.009)*
  (50% represents chance performance)
- **Sparreboom 2011: n=29, age mean 5.3 yrs, f/u 2 yrs**
  - Minimum audible angle at which discrimination was possible: ±42° vs ±78° (*P*<0.01), difference **36**°*
  - % children performing significantly above chance: 83% vs 41%*

*Both studies were intrasubject design ("B"): binaural (2 CI's) vs monaural (1st CI alone) listening condition

(Children) Summary of Findings, KQ #1: Speech Comprehension & Production

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
4 (188) 4 very poor	Very low for small samples sizes, poor study quality, and inconsistency	Mixed findings	
Age at last CI: 1-1.5 yrs. 1st CI to 2nd CI: 0-3 yrs. F/u: 3 mos to 2 yrs			

(Children) Summary of Findings, KQ #1: Functional/QOL Outcomes

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)		Bilateral CI Results
5 (175) 5 poor	Low; small sample sizes, poor study quality, and short f/u	Mainstream (% children): 47%-59% (1 study, 2 age groups)		69%-79%
		Exclusive oral communication (% children): 3%-71% (1 study, 2 age groups)		35%-100%
		Disease	0-51 scale: 33	34-40
			0-1.0 scale: 0.48-0.74	0.62-0.78
			0-10 scale: 4.85-5.88	7.47-7.55
			–100 to 100 scale: Similar	Similar
			0-200 scale: 118	160
		Gen	0-1.0: 0.78	0.83
			0-100: Similar	Similar
		***Statistically sig* absolute differences only in disease-specific function: 6%-69% children (1 study); 0.12-0.13 (0-1.0 scale), 1.67-2.62 (0-10), 42 (0-200) (3 studies)**		
Age at last CI: Mean 3.5 to 20 yrs. 1st CI to 2nd CI: 2-17 yrs. F/u: 1-4 yrs				

(Children) Functional/QOL Outcomes:

3 studies (all poor), sig findings on comprehensive disease-specific function. App. IV-E.

- **Lovett 2010 (cross-sectional), n=50, age not reported, f/u mean 47-50 mos, SSQ (0-10 scale)**
  - *By subscale:* Speech, median 7.53 vs 5.88 (*P*=0.04), difference **1.72**. Spatial, 7.47 vs 4.85 (*P*=0.00), difference **2.62**. Qualities, 7.60 vs 7.16 (NS).
- **Sparreboom 2012, n=39, mean age 5 yrs, f/u 2 yrs; SSQ (0-1.0 scale) by comparator**
  - *Vs preop (1 CI):* 0.62 vs 0.49 (*P*<0.001); difference **0.13**
  - *Vs Unilateral Grp:* 0.62 (CI, 0.56-0.72) vs 0.50 (CI, 0.43-0.65; *P*=0.04), difference **0.12**
- **Kim 2013 (vs preop CI+HA), n=42, mean age 9.7 yrs, f/u 6 mos; SSQ (0-200 scale)**
  - 160 vs 118 (*P*=0.018), difference **42**†

SSQ, Speech, Spatial, and Quality of Hearing Scale; GCBI, Glasgow Children's Benefit Inventory; NCIQ, Nijmegen Cochlear Implant Questionnaire

(Children) Summary of Findings, KQ #1: Recap

Outcome	**Findings** (direction, quality)
• Sound detection*	• Insufficient evidence
• Neurocognitive development*	• Insufficient evidence
• **Speech perception in quiet**	• **Positive*, moderate**
• **Speech perception in noise**	• **Positive*, moderate**
• **Localization**	• **Positive*, moderate**
• Speech comprehensive and production	• Mixed, very low
• Functional/QOL outcomes	• Positive†, low

*No slide

* Functional relevance?
†Only according to disease-specific function

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(Adults) Summary of Findings, KQ #1: Preview

Outcome	Findings (direction, quality)
• Sound detection*	• Insufficient evidence
• Neurocognitive development*	• Insufficient evidence
• Speech perception in quiet	• Positive*, low
• **Speech perception in noise**	• **Positive*, moderate**
• **Localization**	• **Positive*, moderate**
• Speech comprehension and production	• Insufficient evidence
• **Functional/QOL outcomes**	• **Positive†, moderate**
• Tinnitus, music perception*	• Insufficient evidence

*No slide

*Functional relevance?
†Only according to disease-specific scales; variable magnitude of benefit

Hayes

(Adults) Summary of Findings, KQ #1: Speech Perception in Quiet

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
11 (342) 5 good, 6 fair	Low, small sample sizes and unexplained inconsistency	% correct: 2%-95%	% correct: 59%-100%
		+ significant findings in 8 studies; negative or inconclusive results in 3 studies. ***Statistically sig* absolute differences, 5% to 77% (8 studies).** Clinical and functional significance are uncertain.	
Duration deafness: Mean 3-32 yrs. F/u: 6 mos-1 yr			

(Adults) Summary of Findings, KQ #1: Speech Perception in Noise

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
11 (350) 4 good, 5 fair, 2 very poor	Mod-erate, small sample sizes	% correct: 12%-55% (generally, better ear) (6 studies) *SNR: 5.42 to –7 dB (generally, better ear) (1 study)*	% correct: 42%-82% (6 studies) *SNR: –0.26 to –18 (1 study)*
		+ sig findings in 7 studies; + findings without significance in 2 (fair); no difference in 2 (fair, very poor). ***Statistically sig* absolute differences (7 studies): 8% to 37% for correct responses and 0.53 to 11 dB for SNRs .** Clinical and functional significance are uncertain.	
Duration deafness: Mean 3-32 yrs. F/u: 6 mos-1 yr			

(Adults) Speech Perception in Noise, 4 good studies. App. V-A

- **Litovsky 2006a (simultaneous), n=37, mean duration deafness 6 yrs, f/u 6 mos; BKB-SIN test (SNR-50%, binaural-monaural differences in means)**
  - *Noise and signal coincident:* vs right ear, 2 dB (NS), vs left ear: **2 dB** (*P*<0.017)*
  - *Noise at 90° to signal:* **2 dB** in each condition vs better ear; differences sig (*P*≤0.002)*
  - 1st CI ear not identified
- **Mosnier 2009 (simultaneous), n=27, mean duration deafness 3 yrs, f/u 1 yr; Fournier word test (% correct responses by intensity of signal)**
  - 63% vs 55% (mean difference **8%,** *P*<0.05); 53% vs 48% (NS); 42% vs 33% (mean difference **9%,** *P*<0.05)*

(continued next slide)

Both studies were intrasubject design ("B"): binaural (2 CI's) vs monaural (better ear CI) listening condition
BKB-SIN, Bamford-Kowal-Bench Signals in Noise

(Adults) Speech Perception in Noise, 4 good studies. App. V-A

- **Ramsden 2005, n=28, mean duration deafness 6-8 yrs, f/u 9 mos; CUNY sentence test (% correct responses) by comparator**
  - *Intrasubject ("B"):* Coincident signal-noise, 58% vs 46% (mean difference **12.6%,** *P*<0.001). Separated, group means not reported (mean difference, **7.7%** *P*=0.002) and 69% vs 48% (mean difference **21%;** *P*<0.0001).*
  - *Intrasubject longitudinal ("D"):* Coincident, no difference. Separated, 58% vs 47% (sig not reported, difference 31%).†
- **Olze 2012: n=40, mean duration deafness 9 yrs, f/u ≥ 6 mos, by test**
  - *HSM test (% correct responses):* Coincident, 81% vs 72% (*P*<0.001) (difference **9%**); 87% vs 85% (NS). Separated, 82% vs 45% (*P*<0.0001) (difference **37%**).*
  - *OLSA sentence (SNR-50%, smaller score, better performance):* Coincident, −0.26 vs 0.74 (*P*<0.0001). Separated, −5.29 vs −4.76 (*P*<0.05), −3.78 vs 5.42 (*P*<0.0001) (difference between means **0.48-9.2**).*

*Intrasubject design ("B"): binaural (2 CI's) vs monaural (better ear CI or 1st CI alone) listening condition. †Vs preoperative CI+HA.
CUNY, City University of New York; HSM, Hochmair-Schulz-Moser; OLSA, Oldenburger test

(Adults) Summary of Findings, KQ #1: Localization (left-right)

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)	Bilateral CI Results
5 (172) 3 good, 2 fair	Moderate for small sample sizes	Angle errors: 44°-87°	Angle errors: 5°-50°
		+ sig findings in all 5 studies. ***Statistically sig* absolute differences, 8° to 43° (5 studies).** Clinical and functional significance are uncertain.	
Duration deafness: Mean 6-14 yrs. F/u: Mean 3 mos-5 yrs			

(Adults) Localization (left-right): 3 good studies. App. V-B.

- **Grantham 2007: n=22, duration deafness 4.8 yrs, f/u 3.7-16.5 mos; mean adjusted constant error between actual source and patient localization**
  - *Noise signal:* 24.1° vs 50.5° (*P*<0.001); difference **26.4°**
  - *Speech signal*: 21.1° vs 47.9° (*P*<0.001); difference **26.8°**
- **Verschuur 2005: n=20, duration deafness not reported, f/u 3-9 mos; mean adjusted error between actual and patient localization**
  - *Overall:* 24° vs 67° (*P*<0.005); difference **43°**
  - *Advantage of spatially separate (vs coincident) signal and noise:* 5° (NS advantage) vs 13° (sig advantage, *P*<0.001)
- **Nopp 2004; n=20, mean duration deafness 14 yrs, mean f/u 1.85 yrs; root mean square of difference between actual and patient localization**
  - 28.9° vs 45.0° (*P*<0.05); difference **15.1°**

*All analyses were intrasubject design ("B"): binaural (2 CI's) vs monaural (better ear CI) listening condition

(Adults) Summary of Findings, KQ #1: Functional/QOL Outcomes

Quantity and Quality, Studies	Overall Quality	Comparator Results (all forms of comparison)		Bilateral CI Results
7 (432) 1 good, 2 fair, 2 poor, 2 very poor	Moderate, small sample sizes and short f/u	Disease	1-7 scale: 3-4.4 0-10 scale :4.0-5.8 0-100 scale: 64	4.4-5.7 5.7-6.9 71
		Gen	Similar to bilateral CI	Similar to comparator
		+ results on disease-specific functional scales in 5 studies (sig in all but 1 study). + sig findings on disease-specific QOL scales in 2 studies. ***Statistically sig* absolute differences, 1.3 to 1.4 (1-7 scale), 1.0-1.8 (0-10); 6 (0-90), and 7 (0-100) (4 studies).**		
Duration deafness: Mean 3.5-9 yrs. F/u: Mean 6 mos to mean 2.6 yrs				

(Adults) Functional/QOL Outcomes: 3 best studies. App. V-D.

- **Litovsky 2006a; n=37, duration of deafness 6 yrs, f/u 6 mos; APHAB (1-7 scale), binaural (2 CIs) vs monaural (better ear CI) listening condition following simultaneous bilateral CI**
  - *Ease of communication:* 5.7 vs 4.4 (*P*<0.0001); difference in means **1.3**
  - *Background noise:* 4.4 vs 3.1 (*P*<0.0001); difference **1.3**
  - *Reverberant listening:* 4.4 vs 3.0 (*P*<0.0001); difference **1.4**
  - *Aversion to sounds:* 3.0 vs 3.3 (NS)
- **Summerfield 2006; n=24, duration of deafness not reported, f/u 9 mos; SSQ (0-10 scale), difference in means by subscale; RCT†**
  - *Speech:* 2.0 (NS)
  - *Spatial:* **1.68** (CI, 0.62-2.75)
  - *Qualities of hearing:* **1.8** (*P*<0.01)
- **Olze 2012; n=40; duration deafness 9 yrs, f/u ≥ 6 mos; bilateral vs preop 1st CI alone**
  - *OI:* 3.7 vs 3.13 (*P*<0.0001); **difference 0.57**, total possible score unclear
  - *NCIQ (0-100 scale):* 71.3 vs 64.5 (*P*<0.01); **difference 5**

APHAB, Abbreviated Profile of Hearing Aid Benefit; NCIQ, Nijmegen Cochlear Implant Questionnaire; OI, Oldenburg Inventory; SSQ, Speech, Spatial, and Quality of Hearing Scale

(Adults) Summary of Findings, KQ #1: Recap

Outcome	Findings (direction, quality)
• Sound detection*	• Insufficient evidence
• Neurocognitive development*	• Insufficient evidence
• Speech perception in quiet	• Positive*, low
• **Speech perception in noise**	• **Positive*, moderate**
• **Localization**	• **Positive*, moderate**
• Speech comprehension and production	• Insufficient evidence
• **Functional/QOL outcomes**	• **Positive†, moderate**
• Tinnitus, music perception*	• Insufficient evidence

*No slide

*Functional relevance?

†Only according to disease-specific scales; variable magnitude of benefit

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(Children/Adults) Findings, KQ #2 (safety): Major complications

- Examples: flap breakdown, facial nerve damage, meningitis, device failure
- Major complications requiring surgical intervention (including explantation) (smallest and largest estimates in 5 studies)
  - 1.7 per 100 person-years (=1.7% if all patients were followed for 1 year) (n=100 adults; unpublished FDA data)
  - 8.9%, mean follow-up 4 years (n=550 children and adults)
- Explantation (usually device failure) (smallest and largest estimates in 7 studies)
  - 0.9%, follow-up 2 years (n=118)
  - 5.1%-10%, follow-up ≥ 11 years (n=192 to 16,427)

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(Children/Adults) Findings, KQ #2 (safety): Minor complications

- Examples: Wound infection, tinnitus
- 3 studies
  - 1%, ≥ 6 months follow-up (n=212 adults)
  - 7.8%, mean 4 years follow-up (n=550 adults and children)
  - 35 per 100 patient-years (=35% if all patients were followed for 1 year) (n=288 adults and children, unpublished FDA submission data)

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(Children) Summary of Findings, KQ #3 (differential effectiveness and safety)

Quantity and Quality, Studies	Overall Quality	Main Findings
Age at Deafness Onset: 2 (70); 1 good, 1 poor	Very low, very small quantity of data	No relationship w/ speech perception or lateralization.
Age at 1st CI: 6 (247); 2 good, 1 good/poor, 1 fair, 2 very poor	Low, small sample sizes	No relationship w/ speech perception, lateralization, or functional status in comparative studies. Mixed findings in noncomparative studies
Age at 2nd CI: 5 (197); 2 good, 1 poor, 2 very poor)	Very low, small sample sizes and inconsistency	Insufficient evidence
Time Between 1st and 2nd CIs – Effectiveness: 6 (269); 3 good, 1 poor, 2 v poor	Moderate , small sample sizes	Generally suggests no relationship w/ speech perception, or lateralization. Studies suggesting an advantage from shorter inter-implant interval: fewer patients and weaker analyses.
Time Between 1st and 2nd CIs: Safety: 2 (155); 2 very poor	Very low, very small quantity of data and inconsistency	Conflicting evidence regarding differences in analgesic and anti-emetic medication use and minor complications, simultaneous vs sequential.

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(Children) Summary of Findings, KQ #3: Recap

Factor of Interest	Findings (direction, quality)
• Age at deafness onset	• No relationship, very low
• Age at 1st CI	• No relationship, low
• Age at 2nd CI	• Insufficient evidence
• **Time between implants, effectiveness**	• **No relationship, moderate**
• Time between implants, safety	• Conflicting, very low
• Pre- vs postlingual deafness, duration/degree of deafness, choice of 1st implanted ear, specific device, provider characteristics; safety other than interimplant interval	• No evidence

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(Adults) Summary of Findings, KQ #3 (differential effectiveness and safety)

- Evidence is insufficient
  - Comparable data from > 1 study not available for any particular factor
  - No data on many factors of interest

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Findings, KQ #4: Cost implications

- Shorter hospital stay w/ simultaneous bilateral CI than cumulatively w/ sequential bilateral CI (2 studies, very poor quality)
- 1 systematic review (Lammers et al., 2010): 5 cost-utility studies
  - 1 U.S. study
  - 4 U.K. studies

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Findings, KQ #4: Cost implications (cont.)

- Children
  - $39,115/QALY-$94,340/QALY, sequential
  - $30,100/QALY-$70,470/QALY, simultaneous
- Adults
  - $38,189/QALY-$127,767/QALY, sequential
  - $86,425/QALY-$118,387/QALY, simultaneous

All figures are in 2009 dollars.

2013 dollars: $32,071/QALY-$136,179/QALY.

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Findings, KQ #4: Cost implications (cont.)

- Cost-utility estimates are unreliable and of limited use
  - Variable assumptions about utility values (0.03-0.09; 0.03-0.076)
  - Very-low-quality sources of utility estimates
  - ICERs sensitive to utility estimates
  - Cost and utility data from different sources
  - No studies using current U.S.-specific cost data

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Findings, KQ #4: Conclusion of (Lammers et al., 2010)

The incremental cost-effectiveness ratios for bilateral cochlear implantation vary widely and appear to depend on the gain in QALY due to the second implant. The results of this review confirm that more empirical data are required to estimate the cost-effectiveness of bilateral implantation.

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Practice Guidelines and Payer Policies

Practice Guidelines

- 2 guidelines, 1 position statement
- **Cincinnati Children's Hospital and Medical Center (poor)**
  - Recommends *sequential* bilateral CI for improving QOL in children
- **NICE (good, but pre-2009 evidence base)**
  - Recommends *simultaneous* bilateral CI as an *option* for
    - Children w/ inadequate HA benefit
    - Adults w/ inadequate HA benefit plus blindness or other relevant disabilities
  - Recommends *against sequential* bilateral CI
    - With exceptions for unilateral implant before 2009
- **AAO-HNS (no accompanying report or literature review)**
  - Considers CI appropriate for adults and children with severe-profound hearing loss.

AAO-HNS = American Academy of Otolaryngology-Head and Neck Surgery

Payer Policies

- CMS, Aetna, Regence, and GroupHealth
  - CI for bilateral hearing loss is covered
- Aetna, Regence, and GroupHealth
  - Children and adults
  - Pre- and postlingual hearing loss
  - Unilateral CI and bilateral CI
- CMS
  - No distinctions between pre- and postlingual hearing loss or unilateral/bilateral CI
  - Adults only

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Summary

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(Children) Evidence-Based Conclusions

- Moderate-quality positive evidence:
  - Speech perception (especially noise); sound localization (improvement from typically chance results in unilateral CI)
- Low-quality positive evidence
  - Functional hearing
  - (sparse data, disease-specific QOL; negative, generic QOL)
- Unknown connection, degree of auditory gains and function/QOL
- Serious adverse effects (possibly ≥ 10% over long term)
- Insufficient evidence
  - Effect on sound detection and neurocognitive development
  - Differential effectiveness/safety (*except* moderate-quality evidence that interimplant interval has no effect)
  - Cost-effectiveness

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(Children) Evidence-Based Conclusions (cont.)

- Evidence applies most directly* to
  - Prelingual deafness
  - Good success with initial implant
  - Implant accompanied by auditory and language learning
  - No significant concomitant disabilities
  - No structural abnormalities
  - 2nd CI before adolescence

**According to inclusion criteria and reported baseline data*

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(Adults) Evidence-Based Conclusions

- Moderate-quality positive evidence:
  - Speech perception (especially in noise) and sound localization
- Moderate-quality positive evidence
  - Functional hearing and disease-specific QOL
  - (No improvement on generic scales)
- Unknown connection between magnitude of auditory gains and impact on function/QOL
- Serious adverse effects (possibly ≥ 10% over long term)
- Insufficient evidence
  - Differential effectiveness/safety
  - Cost-effectiveness

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(Adults) Evidence-Based Conclusions (cont.)

- Evidence applies most directly* to
  - Postlingual deafness
  - No significant concomitant disabilities?

**According to inclusion criteria and reported baseline data*

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Gaps in the Evidence

- Optimal age
- Subpopulations (adolescents, children w/ postlingual or adults w/ prelingual hearing loss, moderate hearing loss, concomitant disabilities)
- Impact on function, QOL, educational achievement, and employment gains, especially long term
- Correspondence of auditory performance to function/QOL
- Comparative effectiveness of different devices
- Safety specific to 2nd CI
- Cost-effectiveness
- 1 RCT

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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 these questions:

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

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

Principle One: Determinations are Evidence-Based

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

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

Principle Two: Determinations Result in Health Benefits

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

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

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

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

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

Using Evidence as the Basis for a Coverage Decision

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

1. *Availability of Evidence:*

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

2. *Sufficiency of the Evidence:*

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

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

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

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

3. *Factors for Consideration - Importance*

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

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

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

Medicare Coverage and Guidelines (Page 67, Final Report)

Centers for Medicare & Medicaid Services (CMS)

A technology assessment of cochlear implants (CIs) in adults that was recently published by the Agency for Healthcare Research and Quality (AHRQ) (Raman et al., 2011) reported having been commissioned by CMS since additional studies had been published following the 2009 National Institute for Health and Clinical Excellence (NICE) guidelines (NICE, 2009). The AHRQ report concludes with the following finding:

Bilateral cochlear implantation provides added improvements in speech perception outcomes in noisy environments over unilateral cochlear implantation. Bilateral cochlear implants show significant binaural head-shadow benefit, small benefits in binaural summation, binaural squelch effects, and better sound localization (Raman et al., 2011, p. 45).

The authors of the AHRQ report recommended additional research to determine whether demonstrated improvements in perceptual abilities following bilateral CI translate into quality of life (QOL) outcomes. They recommended the development of more disease-specific QOL instruments for individuals with severe to profound hearing loss. However, no new decision memo has been published since the AHRQ report was issued.

The currently effective National Coverage Determination (NCD) allows coverage of CI for the treatment of bilateral pre- or postlinguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores ≤ 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Coverage is additionally approved for individuals who have test scores ≤ 60% on such tests when the provider is participating in, and patients are enrolled in, either a Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective controlled comparative trial approved by CMS (CMS, 2005).

In addition to these hearing loss parameters, CMS stipulates that recipients of CIs have the cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation. Implanted devices must also be used in accordance with FDA-approved labeling.

CMS policy does not currently differentiate between unilateral and bilateral CI.

Link to full policy statement:
https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=14792&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3D%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3DDirectoryReport%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3Ddtransformdatesort&sectionSelector=SourcesOfInformation.

Guidelines (Page 64, Final Report)

Guidelines with Relevant Recommendations

Cincinnati Children's Hospital Medical Center: A 2011 Best Evidence Statement from Cincinnati Children's Hospital states that there is insufficient evidence and a lack of consensus to allow a recommendation regarding sequential bilateral cochlear implantation (CI) rather than unilateral CI for purposes of improving quality of life (QOL) in children with hearing loss (CCHMC, 2011). This guideline was considered to be of poor quality because of a lack of detail about how evidence was identified and selected and a lack of detail on study findings and quality. Although conclusions are consistent with the conclusions of the present report, this statement is based on a somewhat different evidence base. Four studies are cited: 2 cost-utility studies (Bichey and Miyamoto, 2008; Summerfield et al., 2010), a study included in the present report for evidence pertaining to Key Question #1 (Lovett et al., 2010), and a study excluded from the present report because of small sample size (Beijen et al., 2007).

National Institute for Health and Clinical Excellence (NICE): Guidance on Cochlear implants for children and adults with severe to profound deafness was issued in 2009 (NICE, 2009) following a systematic review and technology assessment conducted by the National Institute for Health and Research (NIHR) (Bond et al., 2009). This guideline was considered to be of good quality, when considered in combination with the supporting technology assessment, the only deficiency being the lack of a clear characterization of the strength of recommendations. However, this guidance does not reflect evidence published after 2009, which is substantial.

The document includes this guidance regarding bilateral implantation:
Simultaneous bilateral implantation is recommended as an option for (a) children with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids (based on expert testimony, no distinction is made between prelingual and postlingual hearing loss) and (b) adults with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids and who are also blind or have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

- Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.
- For individuals who received a unilateral implant before publication of the 2009 guidance, a contralateral implant should be offered only if this is considered to provide sufficient benefit by the responsible clinician after an informed discussion with the individual and his or her caregivers.

The document also provides these definitions:

- Severe to profound deafness: Hearing only sounds that are louder than 90 decibels hearing level (dB HL) at frequencies of 2000 and 4000 hertz (Hz) without hearing aids.
- Adequate benefit from acoustic hearing aids: For children, speech, language, and listening skills appropriate to age, developmental stage, and cognitive ability. For adults, ≥ 50% score on Health Technology Assessment April 17, 2013

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Bamford-Kowal-Bench (BKC) sentence testing at a sound intensity of 70 dB sound pressure level (SPL).

Guidelines Without Relevant Recommendations (No Quality Assessment)

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): A 2012 practice guideline on Sudden Hearing Loss, which focused on managing sudden sensorineural hearing loss (sudden SNHL) advises clinicians to counsel patients about amplification and hearing-assistive technology when there is residual hearing loss after treatment, but the only comment on CIs is that research is ongoing on the utility of CI for single-sided deafness (Stachler et al., 2012). The authors note that bilateral sudden SNHL is relatively rare. (The guideline defines sudden SNHL as occuring over a 72-hour period and indicating an abnormality of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing.) This guideline was not assessed for quality since it entails no recommendations regarding bilateral CI.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

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

Safety Outcomes	Safety Evidence
Surgical complications	
Device failure	
Reoperation/revision	
Wound infection	
Tinnitus	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Sound detection	
Neurocognitive development	
Speech perception in quiet	
Speech perception in noise	
Sound localization	
Speech comprehension and speech production	
Functional outcomes	
Quality of life (QOL)	

	Special Population Evidence
Age	
Gender	
Race	
Ethnicity	
Disability	
Time Between Implants	
Cost	**Cost Evidence**
Cost-effectiveness	

Clinical Committee Evidence Votes

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

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

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

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

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

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

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

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

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

Clinical Committee Findings and Decisions

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.

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?