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American Cochlear Implant Alliance Task Force for Determining Cochlear Implant Candidacy in Adults

Sandra Prentiss, PhD, CCC-A

Daniel Zeitler, MD, FACS

Donna Sorkin, MA



Sandra Prentiss, PhD, CCC-A

Sandra Prentiss, PhD, CCC-A, is an Associate Professor at the University of Miami Ear Institute. She graduated from the University of Miami Miller School of Medicine and completed her postdoctoral studies at the Medical College of Wisconsin. Dr. Prentiss is an experienced clinician and researcher with a specific focus in cochlear implantation (CI). Her research centers around patient-oriented outcomes in cochlear implant recipients. She investigates peripheral and central factors affecting variations in speech understanding with efforts to individualize preoperative testing methods and counseling for potential candidates. She has published and presented at multiple national and international conferences regarding these topics.





Daniel Zeitler, MD, FACS

Daniel Zeitler, MD FACS is a fellowship-trained Otologist/Neurotologist at Virginia Mason Medical Center in Seattle, WA where he serves as Co-Director of the Listen for Life Cochlear Implant Center and Assistant Professor in the University of Washington Department of Otolaryngology. He earned his medical degree from New York University School of and completed his general surgery internship and residence.



and completed his general surgery internship and residency in Otolaryngology-Head and Neck Surgery at New York University Medical Center/Bellevue Hospital. He then completed his fellowship in Otology/Neurotology at the University of Miami Ear Institute. Dr. Zeitler has held numerous research chairs at Virginia Mason for his work investigating cochlear implant outcomes, cochlear implantation for single-sided deafness, and using artificial intelligence to predict outcomes following vestibular schwannoma surgery. He has published over 50 articles, numerous book chapters, and remains active in the American Academy of Otolaryngology-Head and Neck Surgery and the American Neurotology Society.



Donna Sorkin, MA

Donna Sorkin. MA is the executive director of the American Cochlear Implant Alliance, a non-profit organization working to expand access to cochlear implants through research, advocacy and awareness. Prior to joining ACI Alliance in late 2012, Donna was Vice President of Consumer Affairs for Cochlear Americas where she led public policy initiatives and activities aimed at the broad life needs of cochlear implant users including insurance practices, habilitation, and educational needs of children with cochlear implants. Ms. Sorkin was previously the executive director of Hearing Loss Association of America and the AG Bell Association for the Deaf and Hard of Hearing. She has served on federal, corporate and university boards including the U.S. Access Board, the National Institute on Deafness, NIH and Gallaudet University. She holds a Masters from Harvard's Kennedy School.







American Cochlear Implant Alliance Task Force Guidelines for Determining Cochlear Implant Candidacy

American Cochlear Implant Alliance

www.acialliance.org









Why another organization in hearing health?

- Membership organization focused on cochlear implantation and access to care
- Members are audiologists, physicians, speech pathologists, educators and others on CI teams + scientists, adults with CI/parents, advocates
- Website designed for those in and out of CI
- Highly collaborative with other organizations
- Welcome your involvement!

www.acialliance.org

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American Cochlear Implant Alliance

- Mission: Advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness
- Address factors contributing to underutilization of cochlear implants
- Improve awareness regarding candidacy and outcomes
- Objective today: Share information on how Cl candidacy is determined for specific population







Four Part Series on Determining Candidacy in Adults and Children

- In 2019, CI utilization by US adult candidates was 5-8%
- ACI Alliance Task Force on how we determine CI candidacy for different populations
- Adults: (1) Bilateral deafness and
 (2) SSD+Asymmetric hearing loss
- Children: (1) Bilateral deafness and (2) SSD





American Cochlear Implant Alliance Task Force for Determining Cochlear Implant Candidacy in Adults

Sandra Prentiss, PhD, CCC-A





Disclosures

Presenter Disclosure:

- Financial: Sandra Prentiss is a grant recipient of Med-El Corporation and Consultant for Sirroco Therapeutics. She received an honorarium for this presentation. Non-financial: Sandra Prentiss has no relevant non-financial relationships to disclose.
- Financial: Daniel Zeitler is an Otologist/Neurotologist at Virginia Mason Medical Center in Seattle, WA. He received an honorarium for this presentation. He is on the Medical Advisory Board Advanced Bionics and a consultant for Cochlear Americas.Non-financial: Daniel Zeitler has no relevant non-financial relationships to disclose.
- Financial: Donna Sorkin is employed by the American Cochlear Implant Alliance. Non-financial: Donna Sorkin wears a cochlear implant. She has served on federal, corporate and university boards including the U.S. Access Board, the National Institute on Deafness, NIH and Gallaudet University.
- Content Disclosure: This learning event does not focus exclusively on any specific product or service.
- Sponsor Disclosure: This course is presented by the American Cochlear Implant Alliance in partnership with AudiologyOnline.





Learning Outcomes

After this course, participants will be able to

- 1. List key components included in a cochlear implant evaluation.
- 2. Identify additional tests the surgeon may order as part of a CI evaluation.
- 3. Describe current cochlear implant criteria and when to refer for an evaluation.





Purpose

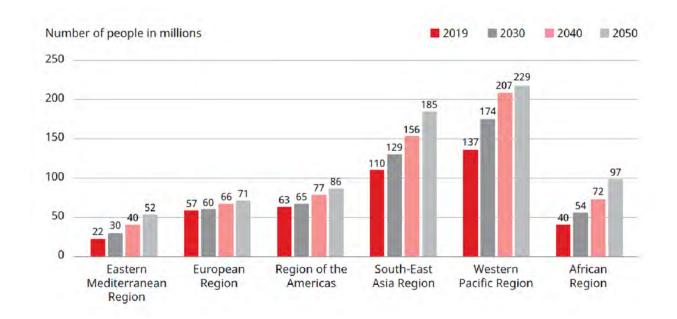
- Provide evidence-based guidelines for testing adults (Coverstone, 2019)
- Improve access to cochlear implants for potential candidates
- Provide consistent and high-quality testing (Coverstone, 2019)
- Promote confidence in the patients (Coverstone, 2019)





Impact of Hearing Loss

- Over 40 million
 Americans suffer from debilitating hearing loss and is projected to rise (WHO 2021)
- Untreated or ineffective treatments impacts physical, social and mental well-being (Collaborators, 2021)
- Highly associated with cognitive decline and dementia in older adults (Lin et al, 2011; Lin et al, 2012)







The Audiogram

- No predictive value for post treatment benefit (Walden and Walden, 2004)
- No predictive value for post treatment speech in noise performance (Taylor, 2004, Nilsson, 2007)
- No predictive value to speech outcomes in cochlear implant recipients (McRackan et al., 2018)

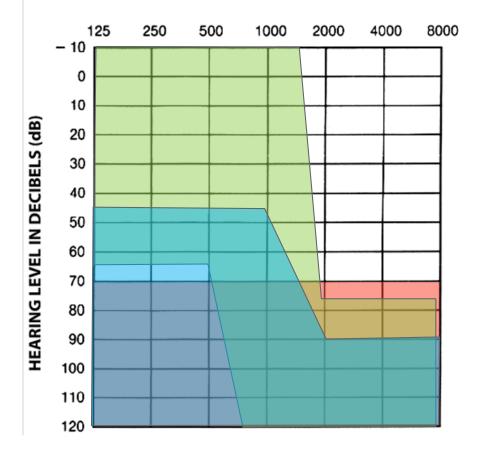




Treatment Options

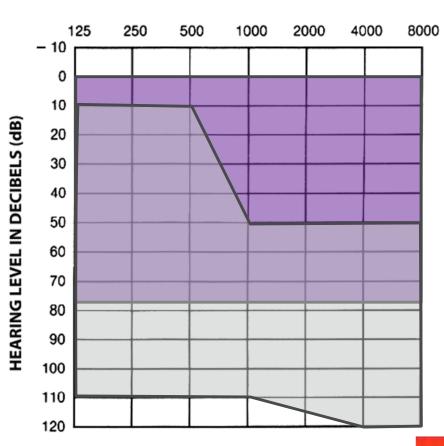
Cochlear Implants

FREQUENCY IN HERTZ



Hearing Aids

FREQUENCY IN HERTZ



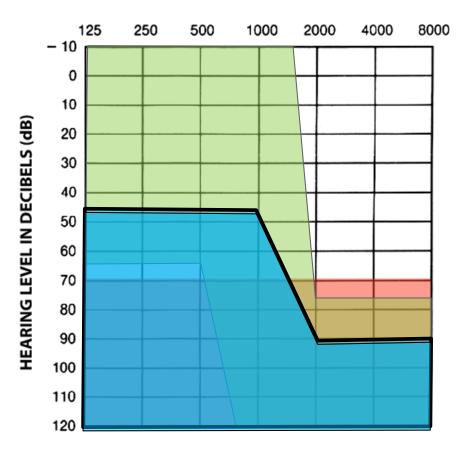




Treatment Options

- Research supports the benefit of CIs for many that may fall outside this criteria – specifically Medicare
- If thresholds fall outside these criteria, the patient would be considered "off-label".

FREQUENCY IN HERTZ

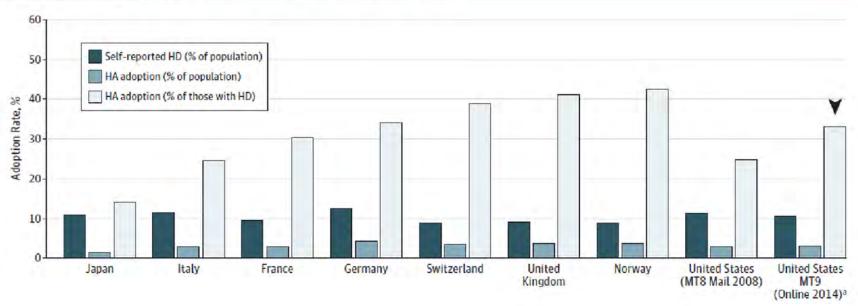






Transitioning from Hearing Aid to CI





(Valente and Amiani et al, 2017)



For broad (current) indications

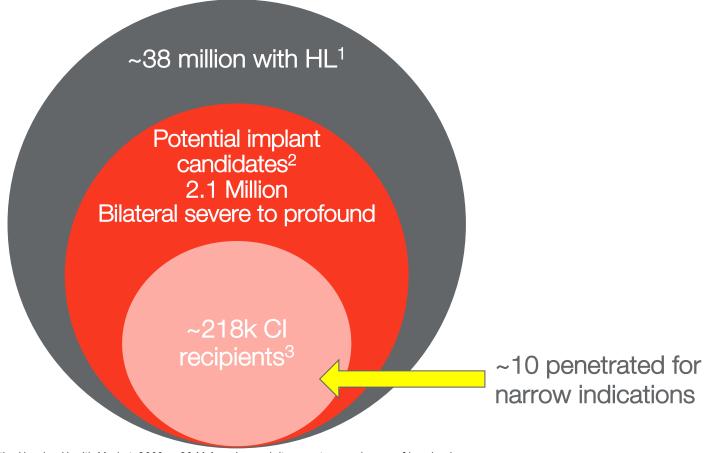
with SSD included: ~ 3%



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US Hearing Loss & CI Utilization 2019 Narrow Indications (Bilateral Severe-Profound) Estimate from American Cochlear Implant Alliance



Data Sources:

1 34.5M MarkeTrak VIII:25 Year Trends in the Hearing Health Market, 2009, ~ 36 M American adults report some degree of hearing loss, NIDCD website June 16, 2010. Other sources use 40 million. Epidemiology of hearing loss is poor 2 Goman & Lin. Prevalence of Hearing Loss by Severity in the United States. Am J Public Health. 2016 October. Based upon bilateral hearing loss.





Reasons for Low Utilization

- Low awareness in general population
- Low referrals from primary care physicians and hearing aid audiologists
 - Unfamiliar with candidacy criteria
 - Physician in the #1 influencer on hearing healthcare decisions (Kochkin, 2012)
- Inconsistencies in testing protocols





Criteria	1985	1990	1998	2000	2014	2019	2020
AGE of implantation	18 yrs +	2 yrs +	18 mos +	12 mos +	12 mos +	Adults & Children 5yrs+ (SSD, AHL) – Med EL	9mos+ - Cochlear
ONSET of hearing loss	Post- linguistic	Post- linguistic adults Pre- & post- linguistic children	Pre- & Post- linguistic	Pre- & Post- linguistic	Pre- & Post- linguistic	Pre- & Post- linguistic	Pre- & Post- linguistic
DEGREE of hearing loss	Profound	Profound	Adults: Severe to profound SNHL (all companie s) Peds: Profound	Adults: Moderate to profound SNHL in both ears Peds: Sev to prof 2 yrs + Prof < 2 yrs	Adults - EAS & Hybrid: Normal to moderate SNHL in low to mid frequencies; severe to profound HL in high frequencies (Med-El and Cochlear)	SSD: Profound SNHL, one ear Normal or mild SNHL, other ear Asymmetrical HL: Profound SNHL, one ear Mild to mod severe SNHL, other ear	Adults: Moderate to profound SNHL in both ears Peds: Sev to prof 2 yrs + Prof < 2 yrs
Speech SCORES	0%	0%	Adults: <40%	Adults: Sentences score < 50% in ear to be implanted < 60% in best aided condition Peds: <30% LNT/MLNT	EAS/Hybrid: CNC word score > 10% but < 60% in ear to be implanted (Med- EI); < 80% CNC words in contralateral ear (Cochiear)	≤5% correct on CNC word score	





Off-Label

- Implanting the device for a purpose that is not included as an indication of the FDA approved device labeling
 - Vestibular schwanomma in the ear to be implanted
 - Severe mixed hearing losses
- Over 75% of surgeons report that they perform "off-label" cochlear implant surgery (Carlson et al, 2018)





When to Refer for a CI Evaluation

60/60 Rule (Zwolan et al, 2020)

Pure-tone average ≥60 dB HL

and

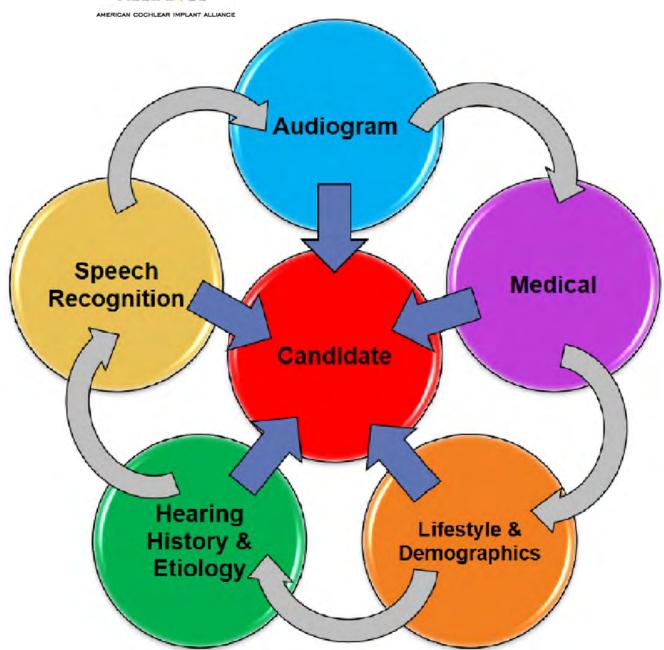
Unaided monosyllabic word score ≤60% correct and/ or Limited benefit with appropriately fit and verified hearing aids Poor quality of life

Refer for cochlear implant candidacy

(Prentiss et al, in review)











The CI Team

- Audiologist
- Rehabilitation Specialist
- Speech Language Pathologists
- Otologist
- Neuroradiologist
- Psychologist/Neuropsychologist
- Previously implanted peers
- Family members/Caregivers
- Social Workers





Demographics/Lifestyle

- Feasibility of care
- Understanding the patient's lifestyle and communication goals
- Commitment to the CI process
 - Adherence to aural rehabilitation
- Family Support





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Comprehensive Hearing History

- Hearing aid experience
- Etiology
- Duration of deafness
- Impact of hearing loss on daily life





Audiologic Evaluation

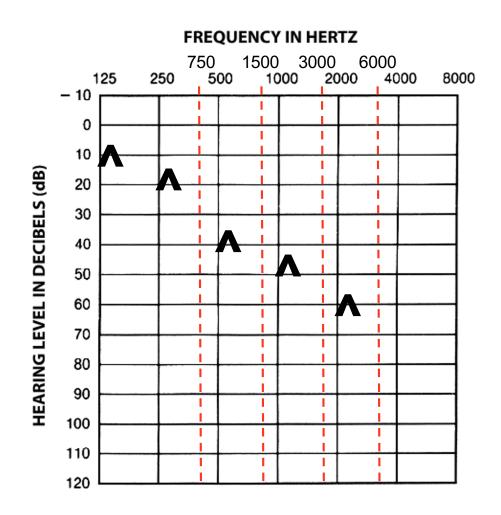
Minimum Reporting Standards for Adult Cochlear Implantation (Adunka et al, 2018)

Pure Tones

- Air: 125-8000 Hz including interoctaves
- Bone: 250, 500, 1000, 1500, 2000 and 4000 Hz

Speech Recognition

 Should use recorded speech measures in an appropriately calibrated soundbooth







Hearing Aid Verification

- Use patient hearing aids or clinic stock hearing aids if necessary
- Verify on ear or in the test box
- DSL adult, NAL-NL1, or NAL-NL2



Verifit® User's Guide Version 4.22 ©December 2020





Aided Testing

- Test each ear individually
- Minimum Speech Test Battery (MSTB) (MSTB, 2011)
 - Monosyllabic word score using consonant-nucleusconsonant (CNC)
 - Sentence recognition AzBio
 - Quiet
 - Noise (+10, +8, or +5)
 - Stimuli should be presented at 60 dB SPL





CNC Criteria

- Score of ≤40% in the best-aided condition demonstrate the patient can achieve equivalent or better outcomes with a CI (Perkins et al, 2021; Beiver et al, 2021)
- In cases of residual hearing, significant benefit with a CI was achieved with individual ear scores up to 60% (Dunn et al. 2020; Gantz et al. 2016; Pillsbury et al. 2018; Roland et al. 2015; Perkins et al, 2021).





Sentence Testing

- Important for counseling purposes
- Often required for insurances
- Fixed noise conditions should be measured with multitalker speech babble
 - Most clinics use SNR +10 or +5 (Prentiss et al. 2020)
 - Should test in the same condition post-operatively (Dunn, et al, 2020)
- Adaptive speech in noise test
 - Bamford-Kowal-Bench Speech-in-Noise (BKB-SIN)





Expectations and Quality of Life

- Subjective questionnaires should be included
 - Speech, Spatial and Qualities Questionnaire (SSQ)
 (Gatehouse et al, 2004)
 - Cochlear Implant Quality of Life Profile (CIQOL-35 Profile) (McRackan et al, 2019)
- Consider non-auditory factors (i.e. cognition, selfesteem, depression/anxiety, full-time employment)





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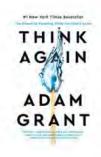
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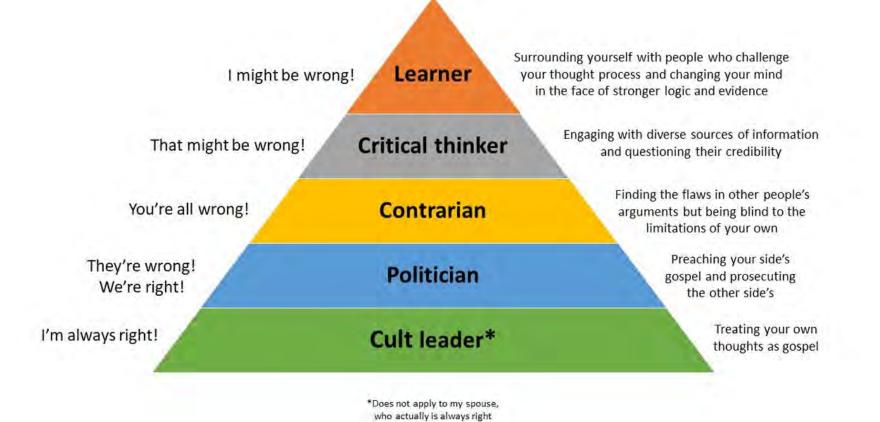
Medical and Surgical Considerations Daniel Zeitler, MD





A Hierarchy of Thinking Styles









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Medical evaluation

- Often complex, occasionally straightforward
- Multi-disciplinary team (surgeon, Cl audiologist) and others
- Candidate must possess motivation to rehabilitate & improve QOL¹
- Age is not a contraindication
 - Cognitive status, psychosocial status, fine motor skills, diminished central receptive and expressive language function
 - Successful octogenarians and nonagenarians^{2,3}

³Eshraghi AA, et al. (2009). Laryngoscope, 1180-1183.





Medical evaluation II



- General health status
- Thorough otologic/neurotologic history and physical exam
- Up to 35% adults > 40 years have vestibular dysfunction^{1,2}
- Vestibular testing advocated by some³
 - No uniformity⁴
 - Not required

¹Agrawal Y, Ward BK, Minor LB. (2013). J Vestib Res, 113-117.

²Barbara M, et al. (2020). Audiol Neurootol, 50-59.

³West N, Klokker M, Cayé-Thomasen, P (2021). Otol Neurotol, 42, e137-e144.

⁴Parmar A, et al. (2012). Otolaryngol Head Neck Surg, 127-131.





Vestibular dysfunction following CI

- Up to 50% report transient vertigo, most delayed
- No factors studied (i.e., age, technique, electrode, vestibular tests) correlated with short-, long-term vertigo¹
- 1/3 reduced function (caloric, VEMP) but without changes in DHI or clinical tests (posturography, HIT)²
- No correlation to symptomatic complaints^{3,4}





Medical evaluation III

- Chronic disease is not a contraindication to surgery
- Team approach (PCP, cardiologist, geriatrician, etc.)¹
- Outpatient surgery is safe²
- Local anesthesia in elderly patients is safe³

²Aldhafeeri AM, et al. (2020). J Int Adv Otol, 303-308.





Preoperative imaging

- Clinical equipoise
- High resolution CT vs. MRI
 - Additional history (i.e. neurologic)
 - Asymmetric hearing loss?
 - MRI compatibility no longer an issue
- Post-lingual adults, negative hx, normal exam, symmetric HL
 - Imaging alters management in < 2% of patients¹
- Cost/benefit considerations





Absolute contraindications

- Cochlea/VIII nerve aplasia
- Medical, psychiatric, developmental
- HA benefit > expected CI benefit
- Patient does not want surgery

Relative contraindications

- Pre-linguistic HL > 5 yo
- ASL/Deaf culture
- Chronic OM, canal wall down surgery
- Scalar obstruction
- Severe dysplasia
- Extremes of age
- Medical comorbidities





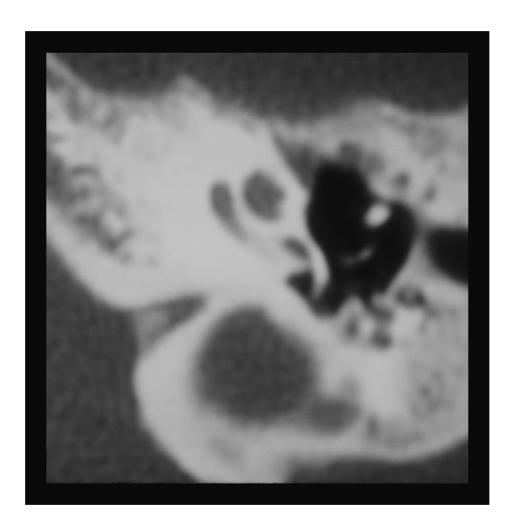
Ossified cochlea

- Number of etiologies
 - Infection (meningitis)
 - Otosclerosis
 - Chronic otitis media
 - Temporal bone trauma
 - Hematologic diseases (leukemia)
 - Autoimmune disease





Ossified Cochlea









Ear Selection

Patient preference, medical evaluation, imaging,

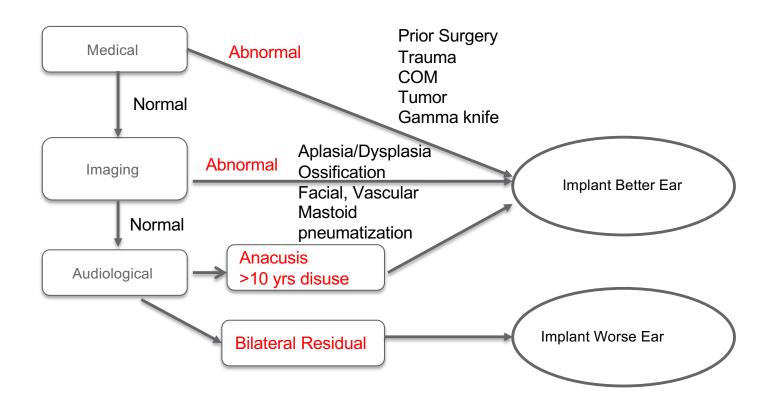
audiometric history and objective testing

- Historically, worst ear implanted
- Dogma outdated better ear often preferred¹⁻³

³Pelosi S, et al. (2013). Otol Neurotol, 1642-1647.











Duration of deafness Age at implantation Position of electrode in cochlea 25%
performance
variation in
quiet¹

Better vs. worse ear not predictive²

ECochG-TR accounts for 47% variance³





Cognitive testing in adult CI candidates

- No standard protocol
- No single test is predictive of postoperative outcomes
- Growing evidence that communication and speech recognition outcomes influenced by cognitive ability of Cl user¹
- Used as screening and/or counseling tool
- MOCA + ECochG-TR = 60% variability in SIN testing following CI²





Vaccination







Meningitis

- CDC children at higher risk
- 283 cases between 2002-2012
- Up to 20 new cases/yr worldwide following CI
- Incidence dramatically decreased
 - Cochleostomy seal
 - Age-appropriate vaccination standards
 - Electrode design





Vaccination

- Likely historical
- CI team must review records of all prospective candidates
- Recommendations per CDC guidelines (see table)
- May differ between patients (age, medical history, vaccination history)





Pneumococcal meningitis vaccine

No previous vaccinations

- Single dose of PCV13 followed by PPSV23 at least 8 weeks later
- Second dose of PPSV23 in adults 65 years and older at least 5 years after first dose

≥ 1 dose of PPSV23 but no PCV13

- Single dose of PCV13 at least 1 year after the last PPSV23 dose was received
- For those who require additional doses of PPSV23 (i.e. 65 years or older), the dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23

Previous dose of PCV13 but no PPSV23

- Single dose of PPSV23 at least 8 weeks after dose of PCV13
- Second dose of PPSV234 in adults 65 years and older at least 5 years after first dose

^{*}PCV20 recommendations currently unknown – may replace PPSV23 and PCV13





Managing Expectations

- CI team must attempt to understand the patient's goals and expectations
- Consistent and full-time use of the device (Holder et al., 2020)
- Post-operative improvements in speech understanding are not associated with subjective benefit (McRackan et al, 2021)
- Those with lower expectations pre-operatively demonstrate higher post-operative QOL (McRackan et al, 2021)





Therapy



- Aural rehabilitation
 - Shown to improve outcomes, yet few are incorporated as part of the standard follow-up care (Harris et al, 2016).
 - Often requires self-driven exercises
 - Many are computer-based or via app on a phone or tablet
- Psychology
 - Manage stress, anxiety and/or depression





Summary

- Unsuccessful hearing aid users should be considered for a CI referral even if outside FDA indications
- Understand patient-specific factors for each candidate
- 60/60 Guideline is a good clinical benchmark for traditional CI candidates
- There is no "bad" referral





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Thank you!

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