

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

Daniel M. Zeitler, MD, FACS ; Sandra M. Prentiss, PhD ; Sarah A. Sydlowski, AuD, PhD, MBA;
Camille C. Dunn, PhD, CCC-A 

The indications for cochlear implantation have expanded over time due to evidence demonstrating identification and implantation of appropriate cochlear implant (CI) candidates lead to significant improvements in speech recognition and quality of life (QoL). However, clinical practice is variable, with some providers using outdated criteria and others exceeding current labeled indications. As a result, only a fraction of those persons who could benefit from CI technology receive it. This document summarizes the current evidence for determining appropriate referrals for adults with bilateral hearing loss into CI centers for formal evaluation by stressing the importance of treating each ear individually and a “revised 60/60 rule”. By mirroring contemporary clinical practice and available evidence, these recommendations will also provide a standardized testing protocol for CI candidates using a team-based approach that prioritizes individualized patient care. This manuscript was developed by the Adult Cochlear Implantation Candidacy Task Force of the American Cochlear Implant Alliance using review of the existing literature and clinical consensus.

Key Words: adult, candidacy, cochlear implant, evidence, protocol, recommendation.

Level of Evidence: N/A

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BACKGROUND

Over the last several decades, improvements in cochlear implant (CI) technology, increased awareness of the technology, and changes in candidacy criteria have led to a rapid growth of evidence in the literature regarding the benefit of CI in adults. As such, recommendations for CI candidacy and referral continue to evolve. For instance, unlike historical CI recipients with bilateral profound sensorineural hearing loss (SNHL), CI candidates may now have an audiogram that mirrors or overlaps that seen in a hearing aid (HA) candidate and may have hearing in the contralateral ear up to and including normal hearing. Yet, the low utilization of CIs suggests hearing health care providers unfamiliar with current candidacy criteria may be relying on older, stricter criteria for referring potential CI candidates.

To assist in the standardization of practice, CI manufacturers have relied upon device labeling from national healthcare governing bodies (i.e., Food and Drug

Administration (FDA)). However, labeling has not kept pace with clinical practice. Many commercial payers use FDA labeling to inform their coverage policies, while the Center for Medicare and Medicaid Services (CMS) has a coverage determination policy that dictates payment for CI services. As a result, some patients who may benefit from CI technology yet fall outside of FDA labeling and/or CMS candidacy criteria are prevented from pursuing the technology. The inconsistency among clinical best practice, labeling, and coverage determination policies can create wide variability in practice methods and may lead to the inconsistent provision of CI services on a national, regional, and even a local level. Using established evidence, the recommendations summarized in this manuscript will serve to standardize the approach and testing protocol for determining adult candidacy for a CI and highlight the importance of a multi-disciplinary team-based approach for individualized patient care.

UNDERUTILIZATION OF COCHLEAR IMPLANTATION

An estimated 466 million persons worldwide live with disabling hearing loss (>6.1% of the world's population). Over 40 million people in the United States (US) alone suffer from disabling hearing loss (4.6%).^{1,2} In persons 12-years-and-older, the prevalence of bilateral severe-to-profound hearing loss is estimated to be approximately two million¹ making hearing loss the third most prevalent chronic health condition in the US.^{1–3} With the advent of the first multi-channel CI system in 1985, guidelines requiring bilateral severe-to-profound SNHL to qualify for CI became the standard of care. It would be

From the Listen for Life Center, Department of Otolaryngology-Head and Neck Surgery (D.M.Z.), Virginia Mason Medical Center, Seattle, Washington, U.S.A.; Department of Otolaryngology-Head and Neck Surgery (S.M.P.), University of Miami, Miami, Florida, U.S.A.; Cleveland Clinic Head and Neck Institute (S.A.S.), Cleveland, Ohio, U.S.A.; and the Department of Otolaryngology-Head and Neck Surgery, The University of Iowa Cochlear Implant Clinical Research Center (C.C.D.), University of Iowa, Iowa City, Iowa, U.S.A.

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Send correspondence to Daniel M. Zeitler, Department of Otolaryngology-Head and Neck Surgery, Virginia Mason Medical Center, 1100 Ninth Avenue, Mailstop X10-ON, Seattle, WA 98101. Email: daniel.zeitler@virginiamason.org

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TABLE I.
Evolution of Cochlear Implant Candidacy (Compiled from FDA PMA Database) <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm>.

Criteria	1985	1990	1998	2000	2014	2019	2020	2022
Age at implant	18 yr +	2 yr +	18 mo +	12 mo +	12 mo +	Adults & Children 5 yr + (SSD, AHL) (Med-EI)	9 mo + (Cochlear)	Adults & Children 5 yr + (UHL/SSD) (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	Pre- & Post-linguistic
Degree of hearing loss	Profound	Profound	Adults: Severe to profound SNHL (All companies) Peds: Profound	Adults: Moderate to profound SNHL in both ears Peds: Severe to profound: 2 yr + Profound: <2 yr	Adults: EAS & Hybrid: Normal to moderate SNHL in low to mid frequencies; severe to profound HL in high frequencies (Med-EI & Cochlear)	SSD: Profound SNHL, one ear Normal or mild SNHL, contralateral ear Asymmetrical HL: Profound SNHL, one ear Mild to mod severe SNHL, contralateral ear 1 mo HA trial (Med-EI) ≤5% correct on CNC word score (Med-EI)	Adults: Moderate to profound SNHL in both ears (all companies for traditional implants) Peds: Severe to profound: 2 yr + Profound: <2 yr	SSD: Severe to profound SNHL in one ear, normal or near normal hearing in contralateral ear; At least 2 weeks to 1 month wearing CROS device or suitable hearing device.
Speech Scores	0%	0%	Adults: ≤40%	Adults: Sentences score ≤ 50% in ear to be implanted, ≤60% in best aided condition (Cochlear) Peds: ≤30% LNT/MLNT	EAS/Hybrid: CNC word score > 10% but <60% in ear to be implanted (Med-EL); <80% CNC words in contralateral ear (Cochlear)			≤5% correct on CNC word score (Cochlear)

CROS = contralateral routing of signal; mo = months; SNHL = sensorineural hearing loss; SSD = single sided deafness; UHL = unilateral hearing loss; yr = years.

expected that hundreds of thousands if not millions of persons would have been implanted over the last four decades. However, as of 2015, 170,252 US adults have been implanted out of an estimated 1,337,144 traditional audiometric CI candidates for a utilization rate of 12.7%.⁴ Moreover, fewer than 1 million devices have been implanted worldwide.⁵

The under-penetration of CIs among adult candidates is multifactorial and may in part be explained by poor awareness among clinicians and consumers alike. Unfamiliarity with current candidacy criteria, lack of awareness of referral processes and clear referral pathways to a CI center, and financial incentives to sell hearing instruments may all contribute.^{6,7} In addition, hearing healthcare providers currently performing adult CI evaluations demonstrate considerable variability in their testing methodologies and in the definition of a “good candidate”, leading to inconsistent referrals.⁸ Last, patients unaware of CI technology, or those unfamiliar with candidacy criteria, may lack the impetus to discuss their options for hearing rehabilitation with their primary care physician, and vice versa. Collectively, these factors likely result in missed opportunities for persons with hearing impairment to be considered for CI.⁹

As technology has improved and outcomes data have been analyzed, candidacy has gradually expanded to include patients with increasing amounts of residual acoustic hearing and higher aided speech recognition scores (Table I). Evidence now demonstrates FDA device labeling is not always consistent with current clinical practice. An increasing number of patients with hearing loss who fall outside of labeling guidelines are receiving CIs¹⁰ and often demonstrate significant benefit.¹¹ For example, increasing numbers of patients with asymmetric SNHL (ASNHL) are undergoing CI in their poorer hearing ear and demonstrate significant benefit in both the implanted ear only condition and when using the CI and the contralateral HA together (bimodal, binaural condition).^{11–14} In addition, adults with unilateral severe-to-profound SNHL (USNHL) in the poorer ear and thresholds better than or equal to 20 dB HL in the unaffected ear (single-sided deafness; SSD) are now undergoing CI, and the results have been positive.^{15–18} Recipients demonstrate improved speech understanding in noise, improved sound source localization, reduction in tinnitus, improved QoL, and increased quality of hearing compared with other available technologies for SSD such as bone conduction implants and contralateral routing of signal HAs.^{19–24} Furthermore, using a CI in one ear does not alter or decrease performance on the contralateral side, even in cases of normal acoustic hearing.^{25,26}

There have been two versions of a recommended Minimum Speech Test Battery (MSTB)²⁷ and a third is currently in development. Although both versions recommend inclusion of a variety of test conditions (ear-specific and bilaterally aided; sentences in quiet and both fixed and pseudo-adaptive noise, and monosyllabic words), the suggested materials have evolved over time. Specifically, HINT sentences were replaced by AzBio Sentences²⁸ which were shown to be more ecologically valid.²⁹ However, the MSTB never specifically suggested how to use

the recommended materials to determine CI candidacy. As the criteria for CI continue to broaden, the materials and methods used to test potential CI candidates remain highly variable and open to interpretation, even for traditional, bilaterally deafened candidates.⁸ This variability has led to inconsistencies between testing centers making comparison of objective outcomes between patients more difficult and may impair the successful prognostication of postoperative outcomes.³⁰

In addition to objective measures, such as speech recognition scores and severity of hearing loss, determining whether a patient is a CI candidate relies on a center’s familiarity with outcomes, expanding criteria, and comfort recommending implantation for those outside of FDA indications. Although a few authors have published evidence-based criteria for recommending a CI,³¹ there is limited guidance regarding how other factors such as cognitive ability, willingness to participate in an aural rehabilitation program, duration of hearing loss, history of amplification use among others should be used in the candidacy process.

By developing and implementing standardized recommendations for assessing and confirming CI candidacy, uniformity in testing protocols will be improved, the number of potential CI recipients referred for testing will be increased, and consistency between those considered CI candidates amongst centers will be enhanced. Ultimately this standardization will lead to increased penetration of CI technology to those who could most benefit.

METHODS

The purpose of this article is to provide evidence-based recommendations for CI candidacy identification and referrals based on a comprehensive review of the literature. The recommendations encompassed in this article were developed following a predetermined methodological approach which included: (1) determining the need for a set of formal recommendations regarding adult cochlear implant candidacy and navigation of the CI referral pathway by the American Cochlear Implant Alliance (ACI Alliance) Board of Directors (BOD); (2) the formation of a team of subject matter experts in the field to serve as co-authors and the designation of a lead author; (3) numerous teleconferences to establish the rationale and methodology for development of the recommendations; (4) performing a comprehensive literature review assisted by medical librarians identifying the most up-to-date and state-of-the-art manuscripts on the topics of CI candidacy and referral guidelines; (5) the formation of the recommendations and the creation of an evidence-based pathway as guided by assimilation of the data based on the literature review; (6) a period of review and public comment by the ACI Alliance BOD followed by a unanimous vote of endorsement.

The comprehensive literature review was conducted with the help of medical librarians using a combination of keywords related to cochlear implants from multiple databases including PubMed, Cochrane Library, Dyna Med, Scopus, EMBASE, and Google Scholar. The articles were reviewed by the authors based on relevance and strength of evidence. The relevant articles were grouped into subtopics (i.e., aided speech recognition testing, candidacy referral recommendations), and the recommendations were formulated based upon discussion, analysis, and data synthesis by all authors.

The authors chosen to write these recommendations all have substantial experience in the CI field and as a result have conflicts of interest with the various cochlear implant manufacturers and other relevant enterprises. These relationships have been explicitly reported herein per journal guidelines. Furthermore, none of the authors received financial compensation for the writing of this manuscript, nor will any of the authors receive remuneration incentives for any outcomes following implementation of these recommendations.

COCHLEAR IMPLANT EVALUATION REFERRAL CONSIDERATIONS

Currently, there are no established criteria for routine office-based audiometry to determine who is an appropriate CI candidate. Several authors have published parameters to help determine the appropriateness of an adult CI referral and predict the likelihood the candidate will qualify. Gubbels et al. used audiometric findings to identify patients who are likely to meet CI candidacy following formal testing.³² Specifically, patients with low frequency (250, 500, 1000 Hz) thresholds greater than 75 dB HL and/or a monosyllabic word recognition test score of <40% have a greater than 80% probability of meeting CMS criteria at the time of publication (i.e., <40% sentence recognition score bilaterally in the best-aided condition). When using only a monosyllabic word score <32%, 86% of the patients met CMS criteria. In patients with private insurance, the accuracy of the model remained strong (>80%) if the monosyllabic word recognition test score was <45%.

Zwolan et al. performed a similar analysis in which audiometric data were used to predict patients who would qualify for CI under the same CMS criteria.³³ When only those patients who met traditional CI indications (i.e., consistent with Medicare coverage guidelines of <40% bilateral sentence recognition score at the time of study publication) were considered, 95% had a preoperative pure-tone-average (PTA) in their better hearing ear of 60 dB HL or greater and 92% had an unaided monosyllabic word score of 60% or lower. When applied retrospectively to a large sample of adult CI candidates, this “60/60 guideline” yielded a 96% sensitivity rate (i.e., candidates met both criteria) and a 65% specificity rate (i.e., non-candidates did not meet the 60/60 criteria).

Although the Zwolan paper uses a 60/60 guideline in the better hearing ear as a guideline for referral, due to FDA approval for cochlear implantation in cases of asymmetrical hearing loss and single-sided deafness, a “revised 60/60 guideline” is recommended where post-lingually deafened adults are referred for CI evaluations when one or both ears demonstrate a monosyllabic word score that is less than or equal to 60% correct and the unaided PTA (500, 1000, and 2000 Hz) is greater than or equal to 60 dB HL. It is important clinicians recognize use of this guideline will only capture the most clear-cut CI candidates and may overlook candidates who still meet FDA criteria with steeply sloping hearing loss.

Using objective audiological data will help hearing health professionals make high-yield and appropriate CI evaluation referrals. However, it is important to recognize

that other studies demonstrate a poor correlation between unaided speech recognition scores and eventual CI candidacy.³⁴ Therefore, if a patient demonstrates limited benefit from appropriately fit hearing aids, it is important to consider referral for a formal CI evaluation regardless of the performance on any single test or group of testing measures.

In summary, hearing health professionals should use the revised 60/60 guideline and refer any patient with an unaided PTA of 60 dB HL or greater and an unaided word score of 60% or less in one or both ears for formal CI evaluation. Importantly, those patients falling outside of the revised 60/60 guideline or those falling outside of traditional CI labeling who do not receive adequate benefit from their current technology (i.e., unilateral SNHL, asymmetric SNHL, low frequency thresholds in the normal to mild range) should also be referred for a formal CI evaluation. Although other information will be reviewed by the CI team prior to candidacy determination, using audiometric parameters such as these ensures a greater number of potential CI candidates will undergo consideration. If the patient is deemed a non-candidate following formal CI candidacy evaluation, the referring hearing health professional should monitor the patient's performance and re-refer with worsening performance or ongoing hearing difficulties.

COCHLEAR IMPLANT CANDIDACY CONSIDERATIONS

The adult CI candidacy evaluation should involve a multi-disciplinary team with experience treating CI patients. Typically, a CI team includes a CI surgeon(s) and audiologist(s) specializing in CI. Based on the complexity of the candidate's case, the pre-, peri-, and/or post-operative needs of the candidate, and/or the customs of a particular CI center, additional team members may include a rehabilitation specialist (auditory-based therapist), a neuro-radiologist, psychologists/neuropsychologists, social worker(s), previously implanted peers, and family members/caregivers.

In addition to audiometric thresholds and aided sentence recognition in quiet,^{8,34} other information must be obtained during the hearing health history including ear-specific aided speech recognition using monosyllabic words and sentences in noise, etiology and duration of hearing loss, history of amplification, patient's occupation and/or social hearing needs, demographics (i.e., social support, age, hearing needs such as occupation), decrement in hearing specific and/or overall quality of life (QoL), motivation, and underlying medical factors. Although specific recommendations based on these variables may differ between individual clinics, this holistic approach towards the CI candidate has been shown to be beneficial as part of healthy aging in CI recipients³⁵ (Fig. 1).

Multiple hearing health variables have been shown to correlate with CI outcomes including duration of deafness,^{36–41} HA usage,⁴² age at implantation,⁴³ and etiology of hearing loss.^{36,39,42} There is evidence that additional demographic variables may also be determinants of

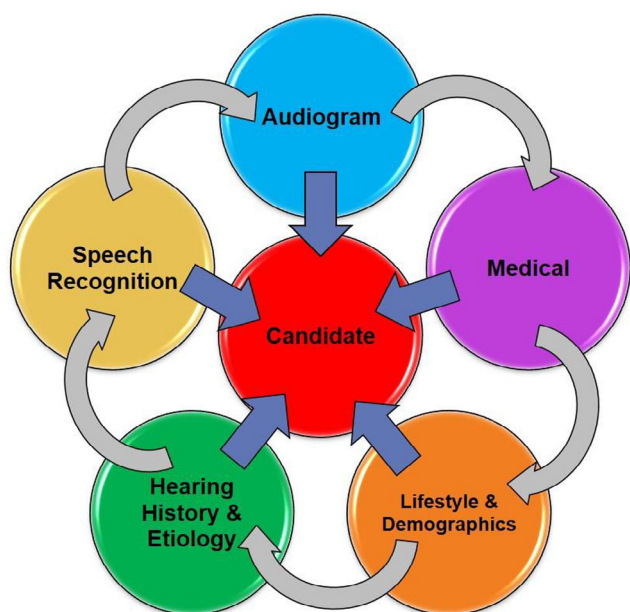


Fig. 1. Factors to consider in an evaluation for a CI candidate. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

future performance following CI. Tang and colleagues⁴⁴ showed factors including cohabitation with a spouse or family member(s), familiarity with technology, emotional intelligence, and adherence to postoperative aural rehabilitation programs can influence speech outcomes following CI. Therefore, during the CI evaluation process it is critical to discuss factors such as resources available to the CI candidate and family, a family's willingness to provide a strong support system, a commitment to post-implantation (re)habilitation, the proximity of the patient to the CI audiologist and/or qualified (re)habilitation provider, and the willingness and ability of the patient to wear the device.

DEMOGRAPHICS AND HEARING NEEDS

Although a diagnostic audiogram provides objective information, it does not accurately represent the patient's functional status as a result of their hearing loss. Specifically, it does not reflect the impact the hearing loss has on the patient in their everyday life (i.e., auditory fatigue, cognitive load, etc.) resulting from routine communication disabilities. It is well known that severe-to-profound hearing loss can have significant consequences on one's mental health, social inclusivity, and overall QoL.⁴⁵ Research demonstrates the advantages CIs have over HAs on the recipient's QoL in multiple domains including psychosocial health, functional health, and social inclusion.^{46,47} Despite the superiority of CI over HAs in these domains and others, CI penetration in the US has remained stagnant.⁹ Some evidence even suggests that the duration of severe-to-profound hearing loss prior to CI surgery is increasing, further exacerbating the deleterious effects on the patient's QoL.⁴⁸ Although a CI may

not be the optimal approach for every patient who qualifies audiometrically, understanding each person's hearing needs, communication goals, and QoL detriment are essential in providing additional insight for counseling on realistic expectations. Furthermore, each candidate must demonstrate a motivation for and commitment to the entire CI process.

AUDIOLOGIC EVALUATION

Hearing History

Obtaining an accurate and comprehensive hearing health history is critical to identifying appropriate CI candidates and understanding factors that may influence outcomes post-operatively. Information regarding the etiology of hearing loss (if known), rate of hearing loss progression (supplemented by prior audiometric testing where available), history of amplification, otologic history (i.e., prior operations and/or pathology), and post-implant expectations must be obtained during the clinic evaluation. In addition, age at onset of hearing loss and its relationship to language acquisition must be queried as these factors may help predict postoperative outcomes and/or device use compliance.^{49,50} Specifically, adult candidates with pre-lingual onset of deafness demonstrate large inter-individual performance variability and levels of satisfaction and may be at increased risk for device non-use.^{51,52}

Careful attention to duration of deafness is essential when discussing realistic expectations with the candidate. Duration of deafness can be difficult to accurately assess in some patients. An understanding of the estimated amount of time that the inner ear and auditory cortex has been without meaningful stimulation is critical as it is an important predictor of post-operative objective success. Lack of stimulation may be due to severe-to-profound hearing loss, lack of adequate amplification, and/or failure to engage in auditory-rich environments. As discussed above, longer durations of post-lingual deafness are associated with poorer outcomes after CI.^{36–41} However, successful outcomes following CI in cases of prolonged durations of deafness (>30 years) have been reported.⁵³ Therefore, duration of deafness in bilaterally deafened adults with a post-lingual onset should not be an absolute contraindication for CI, but rather an important consideration in setting appropriate post-implantation expectations.

In addition to age of onset and duration of deafness, the duration and consistency of amplification use in impaired ears must be determined. Even with consistent amplification, long-term severe-to-profound hearing loss can lead to auditory deprivation and may impact outcomes following CI.^{40,41,54} Critically, the fit and settings of current amplification must be verified by the CI audiologist as many potential CI candidates arrive with inappropriately fit HAs at the time of the evaluation.⁸

The etiology of the candidate's hearing loss should be obtained and documented. CI outcomes can vary widely among recipients based on the etiology of hearing loss and must be reviewed with the patient.^{55–59}

Although very few etiologies of deafness are contraindications to CI surgery, they may impact expected outcomes and must be considered when discussing realistic expectations with the patient.

During the hearing health history, the CI candidate should be asked to share the impact the hearing loss has on their daily life. It is important to understand how the hearing loss impairs or affects the candidate's ability to work, communicate with friends and family, or interact socially. It is helpful to ask patient-specific, closed-ended questions that clarify the impact of their hearing loss (i.e., "Can you use a telephone with one or both ears?", "Can you watch television without subtitles?", "Can you go out to dinner with friends and keep up with the conversation?", "Do you feel your HAs provide sufficient benefit?"). Many clinics are using validated screening questionnaires such as the Hearing Handicap Inventory for the Elderly Screening Test (HHIE-S)⁶⁰ to better understand the impact of the candidate's hearing loss. This should be repeated post-operatively and shared with the patient by discussing areas of benefit and areas that the patient could benefit from additional rehabilitation.

Diagnostic Unaided Audiologic Evaluation

A diagnostic audiogram is required as part of CI candidacy assessment. Objective assessment of the ear under consideration for CI as well as the contralateral ear is important for managing post-operative expectations for residual hearing,⁶¹ determining electrode array selection,^{62–64} determining the optimal surgical approach,⁶⁵ consideration for the use of intraoperative tools such as electrocochleography (ECoChG),⁶⁶ and future amplification of the implanted or non-implanted ear. Results of the diagnostic audiogram must be used together with the other components of the CI evaluation discussed below as part of a holistic candidacy approach (see above) (Fig. 1).

Consistent with the Minimum Reporting Standards for Adult Cochlear Implantation, a standard set of measures must be performed and documented for each patient.⁶⁷ Pre-operative air conduction (AC) pure tone thresholds including 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz are performed via insert earphones for each ear. Bone conduction (BC) pure tone thresholds including 250, 500, 1000, 1500, 2000, 3000 and 4000 Hz are performed for each ear. High frequency AC thresholds (2000, 3000, 4000, 6000, and 8000 Hz) are often in the severe-to-profound range and may not be measurable using standard audiometry. These are assigned the value of 120 dB for documentation purposes.

Significant residual low-frequency hearing in either ear (but especially in the ear-to-be-implanted) should not serve as an exclusion for CI candidacy. When low frequency thresholds (125, 250, and 500 Hz) are in the normal-to-moderately-severe range, hearing preservation is possible following CI. Electric and acoustic stimulation (EAS) using an acoustic component with a CI ear-level sound processor should be considered and discussed if functional hearing preservation is achieved. Functional hearing is defined as hearing in the low frequency

thresholds that can be adequately amplified (i.e., meeting targets on real-ear measurements). Patients using acoustic plus electric hearing demonstrate improved speech perception outcomes,⁶⁸ speech understanding in noise,^{69–72} binaural cues such as summation and squelch,⁷³ sound source localization,^{70,74} melody recognition and music appreciation,^{69,75,76} and perceived quality of speech.⁷⁷

Other objective measures such as tympanometry and acoustic reflex thresholds are performed when clinically indicated to screen for the presence of middle ear dysfunction (i.e., middle ear atelectasis, chronic serous otitis, acute otitis media, etc.).⁷⁸ Although not a contraindication to CI surgery, middle ear dysfunction may delay the implantation process and/or affect the decision regarding which ear to implant.

Unaided Speech Recognition Testing

As previously discussed, unaided speech recognition testing has historically served as a guide for CI referral. Significant variability exists in the testing methodologies (i.e., presentation level, recorded vs. monitored live voice, number of stimuli). Without standardization, the reliability of using unaided testing to identify CI candidates is diminished and the ability to compare results between practices is mitigated. The recommendation for best practice is to use recorded speech measures. When a patient is non-English-speaking, recommendation for CI evaluation may be made based on pure tone audiometry and reported amplification benefit.

Hearing Aid Fitting and Evaluation

CI candidacy evaluations must be performed using appropriately fitted and verified HAs. The term 'appropriately fitted and verified' refers to the use of real-ear or simulated real-ear measures conducted in a test box or on-ear to confirm the devices meet prescriptive targets for sufficient audibility (i.e., DSL adult, NAL-NL1).^{79,80} Verification can be performed on the patient's personal hearing instruments or clinic-owned instruments programmed to the patient's most recent hearing test.⁸¹ For CI candidates with underfit or poorly fit HAs (e.g., $\pm >5$ dB from the prescriptive targets), the audiologist will make recommendations regarding appropriate adjustments. Functional aided thresholds to determine audibility with the HA(s) can be included but are not essential and should not be the only verification method used.

Aided Speech Recognition Testing

Historically, sentence recognition testing has been the standard for aided speech measures in CI candidacy testing (Table I). However, Sladen and colleagues⁸² suggest sentence recognition scores less reflect how well a person can detect and process spectral and temporal components of speech, and more about how well one can use "top-down processing" to "fill in missing pieces". Top-down processing can also be altered by cognitive

resources.^{83,84} Previous studies show that post-lingually deafened adults score much higher on sentence testing than on word testing during CI evaluation.^{85,86}

Previous work demonstrates when monosyllabic word recognition scores are used for CI candidacy qualification, performance outcomes show significant improvement from pre- to post-CI. Furthermore, Sladen et al.⁸² showed a trend for improved performance on CNC word testing when less restrictive criteria (<40% CNC) are used for candidacy qualification rather than more restrictive criteria (<30% CNC).⁸⁷ Data from Dunn et al.⁸⁸ demonstrate in patients with bilateral deafness who undergo implantation in their worse ear, using a CNC score of ≤50% in the ear to be implanted had a 99.7% sensitivity for identifying candidates who ultimately qualified based on previous CMS criteria (≤40% sentence recognition testing). Pre to Postoperative CNC word score comparisons in the implanted ear demonstrated a significant improvement for those who scored up to 50% preoperatively. Previous CI clinical trials investigating EAS have used a best-aided CNC score of ≤60% in the ear to be implanted for candidacy inclusion, and a CNC word score of ≤80% in the contralateral ear.^{72,89–91}

These data and those from Sladen et al.⁸² suggest monosyllabic word recognition testing is more ecological than sentence testing and is as sensitive in predicting CI candidates. Moreover, sentence recognitions tasks are not useful for tracking CI performance outcomes over time due to the large numbers of CI users who achieve ceiling performance early during their post-operative course (60% of users scored >80% by 3 months post-CI). Conversely, CNC scores improved significantly at each of the time periods between surgery and 12-months post-CI with no patients scoring over 80% by the 12-month interval.

Aided Speech Recognition Testing Recommendations

Aided speech recognition testing should be conducted following recommended clinical guidelines outlined in the Minimum Speech Test Battery²⁷ and Minimum Reporting Standards for Adult Cochlear Implantation⁶⁷ to ensure standardization across centers. To test, a speaker is situated approximately 39 inches (1 meter) from the floor and the center of the listener's head. *Best aided speech recognition testing* is defined as the speech perception score in individual ear(s) using optimized hearing aid(s) on a monosyllabic word test (Consonant-nucleus-consonant,

CNC).⁹² The target presentation level for stimuli is 60 dB A.⁹³ When unaided hearing thresholds are 60 dB HL or better in the non-test ear, either plugging and muffing or masking using speech-shaped noise is performed. Any patient who scores ≤50% on CNC in the poorer hearing ear should be considered for CI⁸⁸ unless contraindicated by hearing history, etiology, or other pertinent factors gathered during the CI evaluation. The CNC word score in the contralateral ear should not be considered when determining candidacy using this test. Importantly, the clinical trials investigating CI for USNHL did not stipulate the CNC score in the contralateral ear.

It is important to note our recommendation is to use CNC word testing *to determine CI candidacy*. Because CNC word scores are not used for device labeling or insurance criteria, best aided connected speech testing (best aided defined as speech recognition testing in the individual ear[s] using optimized hearing aid[s]) should be performed using AzBio sentences⁸⁶ *to determine if a patient qualifies for coverage for their CI*. To date, no consensus exists on the SNR recommended for testing, and varies between clinics.⁸ Our recommendation is to test the ear to be implanted in the best aided condition using AzBio sentences in noise starting with a +10 dB SNR using a 10-talker babble (AzBio Sentences presented at 65 dB A and noise presented at 55 dB A). To further evaluate hearing status and to meet insurance qualification requirements, the clinician should consider decreasing the adversity (sentences presented in quiet at 60 dB A) or increasing the adversity (sentences in +5 dB SNR with sentences presented at 65 dB A and noise presented at 60 dB A) of the listening condition as needed (Table II).

Although clinically significant improvements in speech perception in noise can be achieved after implantation for patients qualifying for CI in noise conditions listed above, improvements tend to be smaller as SNR becomes more adverse.^{94,95} Specifically, persons qualifying for CI in only the +5 dB SNR condition can derive significant benefit from their device, but objective outcomes are more variable.^{96–98} These data provide useful counseling tools for patients considering CI, but consideration of listening needs and goals should be discussed with each candidate on an individualized basis. Varying the SNR represents real-life listening situations^{29,96,99} and can be beneficial for determining the SNR at which substantial difficulty is noted. Finally, testing AzBio Sentences in the person's everyday listening condition is recommended for postoperative comparison to the person's then everyday

TABLE II.
Minimum Speech Test Battery (MSTB).

Stimuli	Competing Signal	Aided Listening Condition			Appropriate Speech Recognition Measures
		Left	Right	Bilateral	
Monosyllabic words in quiet (60 dBA)		X	X		Consonant Nucleus Consonant (CNC)
Sentences in quiet (60 dBA)		X	X		AzBio Sentences
Sentences in noise (65 dBA)	Multi-talker speech babble +5 to +10 dB signal to noise ratio	X	X	X	AzBio Sentences in Noise; BKB-Sentences in Noise

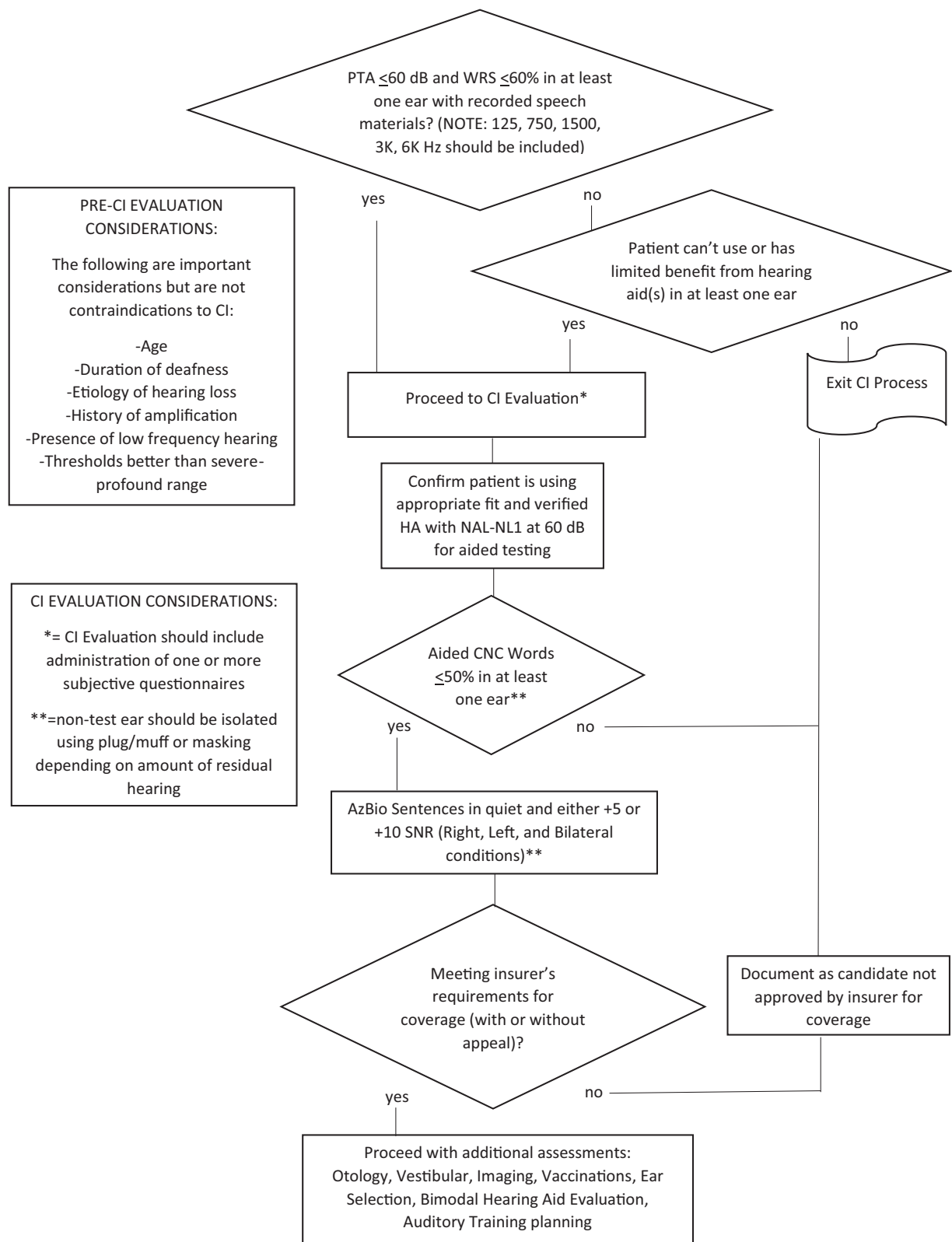


Fig. 2. Flowchart summarizing the protocol for cochlear implant candidacy testing in an adult with bilateral hearing loss.

listening condition. The everyday listening condition is defined as testing with the optimized hearing configuration typical of a patient's everyday listening

(e.g., unoccluded, unilateral or bilateral hearing aid(s), bimodal, unilateral or bilateral CI(s), EAS with contralateral HA).

Figure 2 summarizes the recommendations for determining CI candidacy using routine audiometry to screen potential candidates for referral, and aided speech recognition to verify candidacy and potentially coverage.

PREOPERATIVE MEDICAL EVALUATION

CI has proven successful in patients well into their eighth and ninth decades, and age alone should not preclude evaluation for CI or CI surgery if the patient is otherwise medically fit.^{100–102} In patients with terminal illness, chronic health conditions compromising the administration of safe anesthesia, or at the extremes of age (>95 years), best clinical judgement and shared decision making should be used when considering the provision of CI technology. In addition, numerous authors have published on the relationship between cochlear implantation and cognitive status in patients over the age of 65.^{103–105} Cognitive evaluations such as the mini mental status exam (MMSE) and Montreal Cognitive Assessment (MoCA), tests of verbally based stimuli and responses (i.e., digit span, Stroop), and comparable visually based tests such as the Brief Visuospatial Memory Test have been evaluated. While these tests may be helpful in assessing CI candidates and in tracking changes in cognition from pre- to post-CI, cognitive testing is not required prior to CI, and there are no recommendations for its inclusion during CI evaluation in this manuscript. Certain considerations must be given to circumstances unique to the aging person. These include possible degeneration of the central auditory system, declining cognitive status, diminished central receptive or expressive language function, and coexisting medical, fine motor, and psychosocial disorders. Although none of these issues are absolute contraindications to CI, they should be discussed with the candidate and their support system (friends, family, caregivers) during the evaluation process as they may impact both expectations and outcomes.^{103,106,107}

The medical history should include a thorough medical assessment of the candidate's comorbidities and cardiovascular health. Patients with chronic diseases such as diabetes, chronic obstructive pulmonary disease, kidney failure, atrial fibrillation, and coronary artery disease can safely undergo CI surgery. However, communication with the primary care physician or specialist is necessary to obtain surgical clearance and perioperative recommendations, which may include conscious sedation rather than general anesthesia.^{108–110} The evaluation must also include an otologic and neurotologic history and physical examination including microscopic otoscopy including an assessment of current and previous vestibular function. Up to 35% of adults over age 40 have vestibular dysfunction.^{111,112} Formal vestibular testing prior to CI has been advocated by some to help mitigate the risk of bilateral vestibular hypofunction following CI.¹¹³ This practice is not uniformly applied and is not mandatory.¹¹⁴ Furthermore, no consensus exists regarding who to test or which test(s) to perform. Pre-operative vestibular testing should therefore be performed at the discretion of the implant team and/or when warranted by the patient's history.

Like vestibular disturbance, the otologic history should also query for the presence of tinnitus. Although some data support the suppression of tinnitus following CI,^{115,116} the perception of tinnitus can persist following CI and reasonable expectations should be included as part of counseling.

Imaging

There is debate regarding the optimal imaging modality to assess cochlear, middle ear, and mastoid anatomy prior to CI surgery. High resolution computed tomography (HRCT) and/or magnetic resonance imaging (MRI) have both been used. Although the data suggest preoperative imaging rarely affects surgical decision making,¹¹⁷ imaging ordered in preparation for CI surgery remains at the discretion of the surgeon. Like any diagnostic tool, cost/benefit analysis and risk assessment must be considered in each case.

Ear Selection

The decision of which ear to implant is nuanced and creating a formulaic approach leading to specific recommendations is not possible. Often the decision is based on objective CI testing, but other factors can contribute such as patient preference, medical evaluation, preoperative imaging, duration of severe-to-profound hearing loss, amplification history, and audiometric findings.^{42,118,119} Although the poorer hearing ear was routinely selected in the past, dogmatic methodology should not take precedence in all cases over these other factors.^{118,120,121} This less rigid approach may lead to a recommendation for implantation of the better hearing ear in some cases when it also meets candidacy. For instance, when the examination indicates significant pathology in one ear, implantation of the uninvolved ear (which may be the better hearing ear) is often indicated. However, in cases with an unrevealing history, normal examination and imaging, and symmetric hearing thresholds, the poorer performing ear on CI candidacy testing is routinely selected for CI.

Vaccinations

It is important that the vaccination history of CI candidates is reviewed by the CI team. The Centers for Disease Control (CDC) recommends all adult CI candidates (≥19 years old) be immunized against pneumococcal meningitis. The Task Force recommendation is to follow CDC guidelines prior to (and subsequent to when relevant) cochlear implantation and these guidelines are summarized in Table III. Vaccination recommendations may differ between patients based on age, medical history, and/or previous vaccinations. Additional details regarding vaccination recommendations in CI patients can be found on the CDC website.^{122,123}

TABLE III.

Pneumococcal Meningitis Vaccination Recommendations for Adult CI Candidates and Adults Who Have Previously Received a CI.

Pneumococcal Meningitis Vaccine

19–64 years with no previous vaccinations/unknown vaccination history

Single dose PCV20

OR

Single dose PCV15 followed by single dose of PPSV23 at least 8 weeks later

≥65 years

Single dose PCV20

OR

Single dose PCV15 followed by single dose of PPSV23 at least 8 weeks later

*The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated.

≥ 1 dose of PPSV23 but no PCV13, PCV15, or PCV20

Single dose of PCV15 or PCV20 at least 1 year after last PPSV23 dose

*When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

Previous dose of PCV13 or PCV15 but not PPSV23

Single dose of PPSV23 at least 8 weeks after dose of PCV13 or PCV15

*The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series.

Note: Vaccination schedule should be completed 2 weeks or more before surgery.

PCV 13 = pneumococcal conjugate vaccine 13 valent (Prevnar 13™); PCV15 = pneumococcal conjugate vaccine 15 valent (Vaxneuvance™); PCV20 = pneumococcal conjugate vaccine 20 valent (Prevnar 20™); PPSV23 = pneumococcal polysaccharide vaccine (Pneumovax 23™).

COUNSELING AND THERAPY

Prior to surgery, the CI team must attempt to understand the patient's goals and expectations as well as those of the caregiver(s) and others involved in the candidate's support system. Data suggest a patient's expectations before CI may influence their postoperative QoL after surgery, with those who report lower performance expectations showing higher postoperative QoL.¹²⁴ Importantly, preoperative expectations do not appear to impact post-CI speech recognition scores.¹²⁵ Although there is no validated measure to assess expectations prior to CI surgery, many CI centers have developed their own pre-operative CI questionnaire that is administered to and discussed with the candidate and their support system during the evaluation process.

Patient-reported outcome measures (PROMs) assessing the real-world benefits and improvements in QOL following cochlear implantation have been popularized to complement the objective information gained from speech-centered outcome measures. Examples of these PROMs include Speech, Spatial and Qualities Questionnaire (SSQ),¹²⁶ and a version of the Cochlear Implant Quality of Life Profile (CIQOL-35 or CIQOL-10).¹²⁷ The CIQOL-35 has recently been validated and is more psychometrically sound and comprehensive than these other tests for assessing QOL in adult CI users.¹²⁸ Although preoperative CIQOL-35 scores are not correlated with objective outcomes following CI and are not used for candidacy determination, collecting these data using a standardized instrument will allow large-scale QOL studies in the future. Therefore, the authors suggest the CIQOL-35 be administered pre-operatively and at 3- and 12-months post-CI. CI satisfaction has been shown to correlate with self-assessed improvements in hearing disability, auditory perception, speech perception, and ease of communication. However, satisfaction following CI is not

exclusively related to objective determinants and may also be related to positive self-esteem, less severe symptoms of depression, and the use of humor.¹²⁹ Furthermore, measuring subjective benefit can guide counseling and aural rehabilitation and initiate changes in CI programming to be used in various real-life listening situations.

Aural Rehabilitation

During the CI evaluation process, it is important for the hearing health professional to discuss the importance of post-operative rehabilitation following CI. The candidate's motivation and support system to participate in rehabilitation services following implantation should be assessed. As more is learned about the patient's goals, an individualized listening therapy plan can be developed and could include referrals to additional specialists (e.g., speech language pathologist). Despite evidence suggesting aural rehabilitation training exercises improve outcomes in CI recipients,^{130,131} formal aural rehabilitation training programs not often incorporated as part of the follow-up care. Aural rehabilitation can occur through the CI clinic, guided by a speech pathologist or audiologist. For centers without these services, patients can be given the appropriate materials to use at home. For those patients with computer and internet access, self-directed computer-based training should be encouraged as research demonstrates that doing so results in improved speech recognition and CI-related QoL.¹³²

OTHER CONSIDERATIONS

Insurance Coverage

It is important to recognize that 'candidacy' and 'coverage' are not synonymous. As previously discussed,

clinical best practice dictates many candidates fall outside of FDA-labeled indications and CMS coverage policies. Although National Coverage Determination (NCD) policies published by CMS specify rigid guidelines for unaided audiometric thresholds and aided speech recognition testing, it is important to recognize these definitions may be more stringent than clinical best practice. In addition, because each state administers its own Medicaid program, differences exist in CI coverage for adults 21 years and older. As outcomes have improved and candidacy criteria continue to broaden beyond payer guidelines, policies and associated determination of candidacy serve to confuse the issue of candidacy versus coverage, which may restrict appropriate education and access.

Off-Label Considerations

Off-label use of a medical device is the application of the device for a purpose not included as an indication in the FDA-approved device labeling. Clinicians often recommend CI for patients falling outside of FDA-approved criteria when the advantages outweigh the disadvantages. Over 75% of CI surgeons in the US self-report that they perform “off-label” CI surgery.¹⁰ Off-label implantation requires the clinician be well informed about the product, its use on “firm scientific rationale and sound medical evidence”, keep the patient’s best interests at the forefront of the decision-making process, and use best knowledge and judgment.

SUMMARY/GUIDELINES FOR IDENTIFICATION OF CI CANDIDATES

1. Any patient with hearing loss who gains limited benefit from their current HA(s) and desires improvement in hearing should be referred for a CI evaluation. Referrals for borderline candidates, even if the candidate does not qualify, provides an opportunity for counseling and documents a baseline to monitor for future hearing loss progression.
2. CI should not be considered a “last resort”. Candidates should not wait for “something better”. CI is currently the most effective option for the management of sensorineural hearing loss not optimally managed by HAs.
3. The presence of residual acoustic hearing should not deter referral for CI candidacy evaluation. Residual hearing is not a contraindication for CI surgery, and if maintained following CI can lead to better speech understanding in noise, appreciation of music, and improved sound quality among other benefits. In addition, EAS listening strategies can be implemented post-operatively.
4. Ear-specific CI candidacy must be considered as many studies have demonstrated the benefit of CI in cases of UHL/SSD and AHL.
5. A “revised 60/60” criteria can be used as a clinical benchmark for referral for a CI evaluation whereby each ear is considered individually for CI rather than using the better ear as the reference point. If a patient has a PTA ≥ 60 dB HL and an unaided monosyllabic word recognition score $\leq 60\%$ in the worse hearing ear the patient should be referred for CI evaluation. It should be remembered patients falling outside the “traditional” 60/60 criteria or the “revised” 60/60 criteria may still qualify for CI and should not be excluded from CI evaluation.
6. Patient-specific factors must be considered in identifying appropriate CI candidates and can be helpful in counseling prior to surgery. These factors include demographic information, etiology of deafness, duration of hearing loss, HA history, and the candidate’s physical/mental/emotional support system. Although these factors deserve consideration during the evaluation process, they are rarely absolute contraindications for surgery.
7. CI candidacy testing begins with CNC monosyllabic word testing in each ear using optimized hearing aids. Candidacy is recommended by a score of $\leq 50\%$ in the ear-to-be implanted, regardless of performance in the contralateral ear. AzBio sentence recognition testing is then performed in the ear to be implanted and used to determine qualification for insurance coverage. “Best aided” should be interpreted as the score for the ear considered for CI fitted optimized hearing aids.
8. To determine if a candidate qualifies for insurer’s coverage for the CI surgery and device, best aided connected speech testing should be performed in the ear to be implanted using AzBio sentences played with a 10-talker babble in +10 dB SNR. To further evaluate hearing status and qualification of insurer’s requirements, the clinician should consider decreasing the adversity (sentences obtained in quiet at 60 dB A) or increasing the adversity (AzBio in +5 dB SNR with sentences presented at 65 dB A and noise presented at 60 dB A) of the listening condition as appropriate.
9. Appropriate recommendations for fitting hearing technology in the contralateral, non-implanted ear, should be discussed to allow for optimization of binaural hearing, use of compatible accessories, etc.
10. Hearing related disability can be assessed using a variety of QOL instruments. While optional and unrelated to behavioral outcomes post-CI, measuring subjective benefit can guide counseling and aural rehabilitation and initiate changes in CI programming based on various real-life listening situations. The CIQOL-35 is a validated questionnaire specific to CI patients, and administration is suggested pre-implantation and at 3-months and 12-months post-CI. The CIQOL-35 can be administered annually thereafter where appropriate to ensure the patient is progressing and meeting stated goals.
11. Patients not meeting current FDA labeling and CMS requirements should still be considered for a CI. Evidence-based medicine should guide clinical decision making by the multidisciplinary CI team. Consideration of insurance coverage should be included during counseling as a supplement to clinical recommendations but should not be used as deterrent for referral for a CI evaluation or for CI candidacy.

12. Implementation of an aural rehabilitation program must be encouraged as it is essential to maximize outcomes following CI.
13. There is no “bad” CI referral. Even if a patient does not initially qualify, the evaluation process can be educational for the patient, can provide a baseline for comparison in the future, and may result in optimization of HA technology and/or the provision of assistive listening devices.

CONCLUSION

Untreated and undertreated hearing loss can have negative effects on quality of life. Any patient unable to benefit from, or who perceives dissatisfaction with amplification should be referred for a formal CI evaluation. Currently, adult CI candidacy determination involves consideration of both medical and audiological criteria. Appropriate identification of CI candidates has been shown to lead to positive outcomes in multiple objective and subjective domains. Given the success of CI technology as a treatment for disabling hearing loss, it is imperative to expand access for all appropriate candidates. These evidence-based recommendations outline a standardized method for the identification of potential CI candidates, and for the pre- and post-operative evaluation of objective and subjective outcomes.

CONFLICT OF INTEREST STATEMENT

DMZ serves on the Surgical Advisory Boards for MED-EL Corporation and Advanced Bionics Corporation, is course director and faculty for Institute for Cochlear Implant Training and is a consultant for Cochlear Corporation. SMP is a consultant for Pipeline Therapeutics and faculty for the International Institute for Cochlear Implant Training. SAS is a consultant for and receives study funding from Cochlear Corporation, is on the advisory board for Envoy Medical, is course director and faculty for Institute for Cochlear Implant Training and is on the Editorial Board of the Hearing Journal. CCD serves on the Advisory Board for Cochlear Americas, MED-EL Corporation, Envoy Medical, and IotaMotion Inc., is a course director and faculty for Institute for Cochlear Implant Training, is a consultant for Advanced Bionics, and received grant funding from NIH/NIDCD and MED-EL Corporation.

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