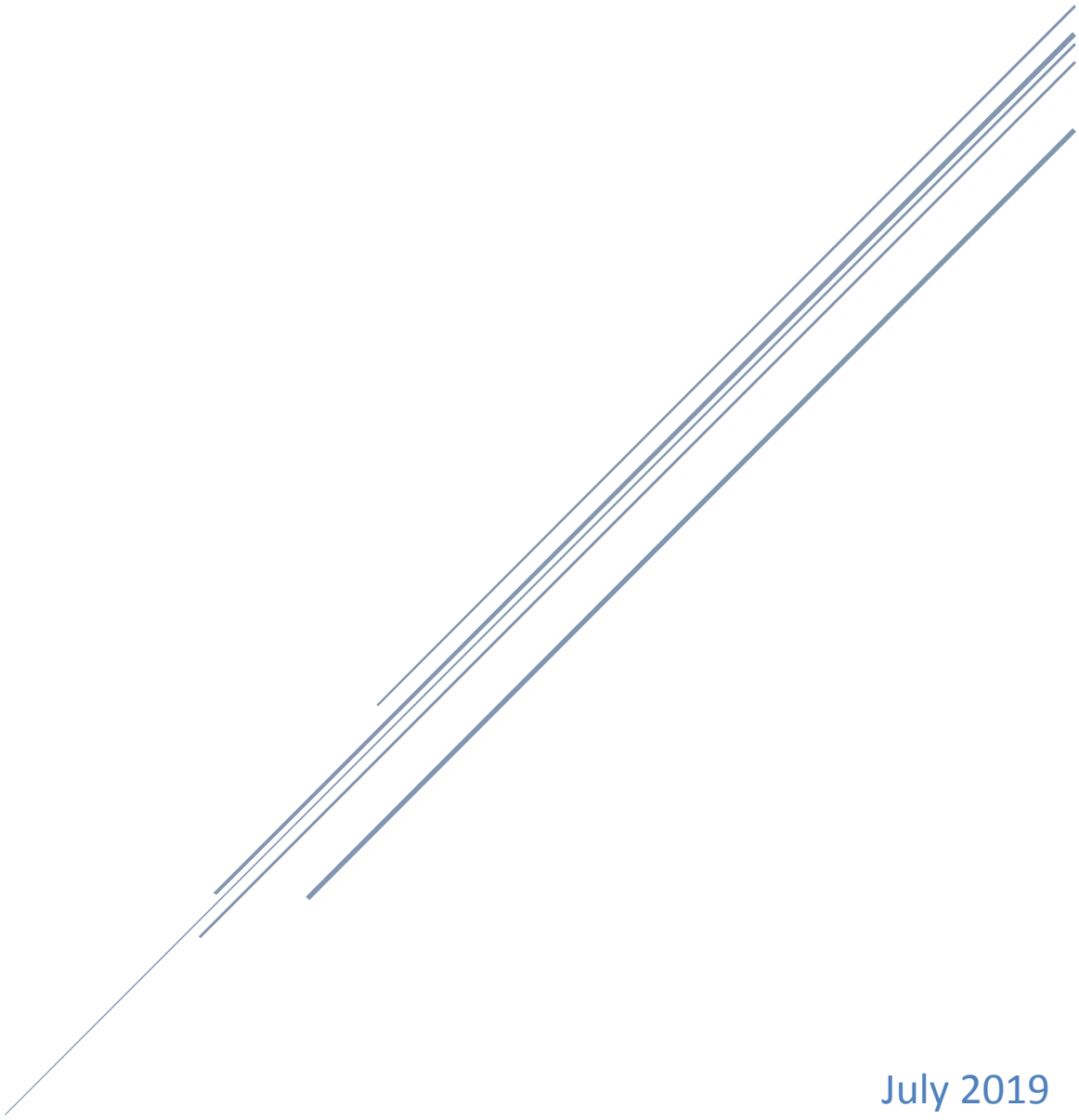
CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS



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Clinical Practice Guidelines: Cochlear Implants

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1. INTRODUCTION/DEVELOPMENT PROCESS

This document was prepared by the American Academy of Audiology (the Academy) Task Force on Cochlear Implant Practices. As is the goal of other practice guidelines provided by the Academy, the goal of this document is to provide a set of statements, recommendations, and strategies for best practices. This particular practice guideline document is specific to the evaluation for, and management of, cochlear implants. Statements and recommendations in this document were formed by initially reviewing the existing scientific evidence published in peer-reviewed and non-peer-reviewed journals. When direct evidence was not available, both indirect evidence and consensus practice were considered in making recommendations.

This guideline addresses the technical aspects of the cochlear implant candidacy evaluation, objective measurements, device programming, and follow-up care. This guideline is not intended to serve as a standard to dictate precisely how cochlear implants should be programmed. The guideline is meant to provide the evidence base from which the clinician can make individualized decisions for each patient. In addition, the guideline can help inform physicians, reimbursement agencies, government agencies, the hearing health-care industry, patients, families, and caregivers about what research evidence demonstrates as the current best practices related to cochlear implant care.

The process of developing this guideline was evidence-based when possible. Evidence-based practice integrates clinical expertise with the best available clinical evidence derived from systematic research. Where evidence is ambiguous or conflicting, or where scientific data are lacking, the clinical expertise of the task force was used to guide the development of consensus-based recommendations. The following areas are addressed within the document: signal processing, audiological candidacy criteria, surgery considerations for the audiologist, device programming, outcomes assessment and validation, follow-up schedule, and care beyond device programming.

In the literature search for the present document, task-force members first sought to identify studies at the top of the hierarchy of study types (see Table 1). Once definitive clinical studies that provided valid relevant information were identified, the search stopped. The search was extended to studies/reports of lower quality only if there were no higher quality studies. Traditionally, the highest levels of evidence include randomized controlled trials and systematic

reviews/meta-analyses of randomized controlled trials (Levels 1 and 2). Studies implementing a crossover design were labeled as Level 2 in this document. In this type of experiment, participants are first randomized into treatment groups and then, after experiencing the treatment for a specified period, each subject "crosses over" and receives the other treatment for a period of time. During searches, literature that was presented as a review article of published data but did not present the review as a meta-analysis or systematic review was not rated. These pieces of evidence are noted in evidence tables as CNR to represent could not rate. This approach has been used in previous Academy practice guidelines.

Table 1. Explanation of Levels of Evidence and Grades of Recommendation

Levels of Evidence
1. Systematic reviews and meta-analyses of randomized controlled trials
2. Randomized controlled trials
3. Non-randomized intervention studies
4. Descriptive studies (cross-sectional surveys, cohort studies, case-control designs)
5. Case studies
6. Expert opinion

Grades of Recommendation
A. Consistent Level 1 or 2 studies
B. Consistent Level 3 or 4 studies or extrapolations from Level 1 or 2 studies
C. Level 5 studies or extrapolations from Level 3 and 4 studies
D. Level 6 evidence or troubling inconsistencies or inconclusive studies at any level

Adapted from Cox, R. (2005). Evidence-based practice in provision of amplification. *Journal of the American Academy of Audiology, 16*(7), 419-438.

In addition to grading the evidence and assigning it a level (see Table 1), it was determined if the evidence was Efficacy (EF) or Effectiveness (EV). EF is evidence measured under "laboratory or ideal" conditions and EV is evidence measured in the "real world." Each section provides relevant background, a list of recommendations, and a table with each recommendation, the source (citation), level of evidence, grade, and an indication of support of efficacy and/or effectiveness (See Table 2 for an example table).

In some cases, recommendations are based on acoustic or physical facts where an empirical evidence base is not necessary and would not be expected. In cases where the

recommendation is based on a physical or acoustic fact (a First Principle), “acoustic fact” or “physical fact” is listed under “Source” in the evidence tables (See Table 2 for an example of the format of an evidence table).

Table 2. Sample Recommendations and Summary of Evidence Table

Rec.	Evidence	Source	Level	Grade	EF/EV

Please note: the recommendations made in this document are not referenced in the traditional manner, but all references are provided in full at the end of the section, following the Summary of Evidence table. Additionally, a complete reference list is available at the end of the guideline. This document will be reviewed in accordance with the American Academy of Audiology Guideline for Practice Guideline Documents, and modified, where appropriate, to incorporate new knowledge or clinical practice patterns.

Academy Task Force on Guidelines for Cochlear Implants

This document originated as an extensive review of literature prepared by the American Academy of Audiology Task Force on Guidelines for Cochlear Implants. Multiple individuals contributed to the creation of this document. The original task force initiated work on the document in 2015. The members of the 2015 Task Force included Holly Teagle, AuD (Co-Chair); William Shapiro, AuD (Co-Chair); Anne Beiter, MS; Laurie Eisenberg, PhD; Jill Firszt, PhD; Michelle Hughes, PhD; Geoff Plant; Amy Robbins; Tom Walsh; and Terry Zwolan, PhD.

In 2017, the composition of the task force changed. The members of the 2018 Task Force included Jessica Messersmith, PhD (Chair); Lavin Entwisle, AuD; Sarah Warren, AuD, PhD; and Michael Scott, AuD. The final document, while informed by the document created by the 2015 task force, represents an updated review of the evidence, which allowed for a comprehensive compilation of current knowledge in a format consistent with other Academy guidelines documents.

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2. OVERVIEW OF COCHLEAR IMPLANTS

The cochlear implant is an auditory sensory device designed for individuals with hearing loss who desire auditory input, but do not receive adequate benefit from acoustic amplification alone. For individual recipients of cochlear implants to gain optimal benefit from the device, the appropriate selection of recipients, optimized programming, auditory therapy, and routine follow-up care are needed. Depending on the age of the recipient, the timing of implantation, and other individual characteristics, intense auditory therapy may be necessary to gain full benefit from the cochlear implant.

The purpose of a cochlear implant is to represent acoustic stimuli as electrical impulses presented to the auditory nerve that can be perceived as sound by the recipient. When programming cochlear implants, goals include optimal audibility and speech understanding, as well as comfort with sound quality after extended device use. As improvements in cochlear implant technology and programming have occurred, goals have expanded to music appreciation and speech understanding in complex listening environments.

A cochlear implant functions by representing the auditory environment through electrical stimulation of the auditory nerve by operating within an electrical range that is sufficient for audibility, while not stimulating the auditory system in a manner that is damaging or perceived as intolerable by the user. The device bypasses the impaired cochlea and directly stimulates residual neural elements in the auditory nerve. For successful cochlear implant use, high residual neural survival is needed.

The surgically implanted internal components consist of a receiver/stimulator placed under the skin or within the temporal bone and an electrode array inserted into the scala tympani of the cochlea. The external components consist of a microphone, sound processor, transmitter, and power supply. The microphone collects the sound and sends the input to the sound processor. Within the sound processor, the signal is digitally analyzed, separated into frequency bands, and compressed into an electrical dynamic range. The transmitter then sends the signal across the skin to the internal component.

A magnet is situated in both the transmitter and receiver/stimulator so that the two components remain aligned, enabling the electrical signal to be conveyed across the skin via radio frequency. The internal receiver picks up the signal from the transmitter and delivers the signal to specific electrodes within the array that are arranged tonotopically. The selected electrode then stimulates the auditory nerve via discrete electrical pulses.

The rudimentary function and components of cochlear implants are largely the same across cochlear implant manufacturers. However, there are variations in electrode arrays, sound-processor designs, processing schemes, programming considerations, and pairing of assistive devices across cochlear implant models and manufacturers.

Cochlear implants should be considered for individuals whose hearing loss cannot be adequately addressed through acoustic amplification (e.g., hearing aids) alone. Since receiving Food and Drug Administration (FDA) approval in 1984, the criteria for cochlear implantation has expanded to include individuals of younger ages and those with more residual hearing and better speech-perception abilities. The use of cochlear implants now includes bilateral implantation (receipt of a cochlear implant in each ear), electroacoustic cochlear implants (some frequencies transmitted via acoustic amplification and other frequencies transmitted via electrical stimulation), and bimodal stimulation (receipt of a cochlear implant in one ear and use of a hearing aid in the contralateral ear).

Although not specifically covered under FDA approval, cochlear implants are being successfully used with individuals with unilateral deafness or asymmetric hearing loss where only the ear to be implanted meets cochlear implant criteria. Across the time period of FDA-approved cochlear implant use, the determination of appropriateness for cochlear implantation has become less centered on audiometric thresholds and performance with amplification (hearing aids) has gained greater importance.

Systematic advancements in cochlear implant technology and practices have resulted in improvements in communication outcomes. Today, the majority of individuals who use cochlear implants are able to understand speech in multiple situations and some may experience some degree of music appreciation. Further, the majority of children who use cochlear implants are able to develop excellent auditory skills and use spoken communication.

Despite this overall success, outcomes with this sensory device are characterized by wide variability that are attributed to many factors. The factors include, but are not limited to, age at onset of the hearing loss, stimulation of the auditory pathway prior to implantation, pre/post-lingual deafness, age at implantation, cochlear implant experience and auditory training, residual hearing, spiral ganglion cell survival in auditory pathways, cognitive abilities, patient/family personality and motivation, parental involvement and commitment, quality of device programming, and consistency of follow-up appointments.

The audiologist's role in the clinical management of recipients of cochlear implants spans from pre-implant assessment and determination of candidacy to ongoing post-implant care. The audiologist conducts the pre-implant audiological test battery for determining cochlear implant candidacy, which includes, but is not limited to, conducting assessments of auditory sensitivity, aided speech detection/reception, and spoken-word recognition and serves on the team determining candidacy. The audiologist also provides post-implant care critical to positive outcomes with a cochlear implant. Timely and consistent follow-up care and device programming are factors contributing to success with the cochlear implant that are within the scope of audiologists. These factors ensure appropriate counseling, care of the device, and provide the opportunity for optimized programming leading to increased access to the various acoustic cues needed for adequate speech perception and speech and language development.

The task force, when developing this document, realized the limitations in generalizing the programming and follow-up care needed for individual recipients of cochlear implants. As previously stated, outcomes achieved with a cochlear implant vary widely and are attributed to multiple factors. This variability will inherently result in deviations from standard audiological care and implementation of programming approaches.

For example, differences in care approach are likely to vary, based upon the individual user's auditory-skill development and their ability to provide perceptual reports of sound quality. While this document encompasses both adult and pediatric recipients of cochlear implants, these differences in care may warrant separate guideline documents for adult and pediatric recipients in the future. This document is to serve as a guide for making clinical decisions regarding the audiological management of recipients of cochlear implants, both pre- and post-operatively; however, it should not be a substitute for the practicing clinician's knowledge and interpretation of the evidence base when working with individual patients.

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3. SIGNAL PROCESSING

Objective

Cochlear implant signal processing provides the basis for cochlear implant programming and directly impacts the cochlear implant recipient's outcomes with the device. Decisions regarding signal processing are based upon the individual's listening needs, abilities and cognitive considerations, understanding of the physiology and function of the system, empirical evidence, and clinical expertise. These decisions target the goal of enhancing outcomes with the cochlear implant device. Although many aspects of signal processing may stabilize across the time period of using a cochlear implant, these aspects should be considered when changes in performance or device function occur or if the user's listening needs change. Determination of signal-processing parameters should be individualized to the user based upon appropriately validated evidence. Specific signal processing and the ability to manipulate signal-processing parameters are dependent upon the cochlear implant manufacturer used. As such, technical documentation from individual cochlear implant manufacturers should be consulted.

Recommendations for Cochlear Implant Signal Processing

The following signal processing parameters should be considered when fitting cochlear implants until sufficient data exists to exclude said parameter.

1) Impedance

a. Measurement of telemetry provides information about short and open circuits, contributes to the maximum output of the device, and consistent measures allow for evaluation of internal device function. As such, telemetry should be measured as frequently as possible, at least during appointments where a change to programming is made. Audiologists should not be concerned if impedance values change a few kOhm across electrodes, provided that:

   i. There is not a concomitant change in performance.

   ii. There are no out-of-compliance messages in the programming software.

b. If impedance changes are noted across consecutive sessions, a detailed history should be conducted with the recipient and consultation with the surgeon should occur.

c. It is possible for electrodes presenting with normal impedance intra-operatively to demonstrate either short or open circuits at later visits. Conversely, electrodes presenting with short or open circuits intra-operatively may spontaneously

resolve, presenting with normal impedance at later dates. This variability underscores the need to test impedance at the majority of visits.

i. Electrodes that intermittently present as short or open circuits should be deactivated for two reasons:
    1. Intermittency may be a sign of impending permanent electrode failure.
    2. If a normally functioning electrode with a history of short/open circuit returns to a short/open state in between regular clinic visits, the recipient may experience diminished perception with the device until reprogramming can be accomplished.

ii. Impedance is generally lowest at the intra-operative test interval and highest at the initial stimulation, with stabilization of values within the first few months of device use. Certain factors can cause additional impedance changes after stabilization, such as:
    1. Device or electrode non-use or reduced wear time.
    2. Re-implantation has occurred; impedance changes should be monitored within the same internal device.
    3. If stimulation beyond voltage compliance limits is occurring; overstimulation should not occur.
    4. Hormonal changes.
    5. Disease processes (e.g., otitis media, otosclerosis) or late onset inflammatory response.
    6. Electrode array migration.

iii. If impedance changes are observed and the above factors can be ruled out, this may indicate a device-related issue. Certain identifiable patterns, such as alternating high-low impedances across even- and odd-numbered electrodes or segments of the array with very low impedance (but not low enough to be flagged as short circuits), may result from damage to the silicone coating around the electrode lead. This condition typically occurs slowly over time, which is why it is extremely important to compare impedance measures across multiple post-operative intervals. If concomitant performance declines and/or adverse percepts are experienced, the audiologist should consult the manufacturer, and the following steps may be recommended:

1. Deactivate some of the electrodes with atypically low impedance (e.g., every second or third affected electrode)
2. Deactivate all of the affected electrodes
3. Consider re-implantation if device fault is determined

2) Directional microphones

a. Directional microphone processing should be considered for all patients.
b. Full-time directional processing is not necessary and should be used with caution in children.
c. Adaptive directional processing may provide additional benefits to listeners in noise with minimal significant consequence.

3) Electrical Dynamic Range (EDR)

a. The system should provide an adequately wide EDR.
b. Optimization of stimulus levels for both thresholds and loudness levels are primary factors contributing to outcomes.
c. Low scores on speech perception measures and poorer sound field thresholds occur as a result of overestimating and/or underestimating threshold and loudness levels (e.g., EDR).
d. Programming with equal loudness percepts across channels results in improved sound quality and speech recognition when compared to programs with unbalanced stimulation levels.
e. Perceived loudness of the stimulus is affected by multiple facets of the stimulus. The stimulus parameters that can impact loudness perception are: amplitude, pulse duration, number of electrodes stimulated, and stimulation rate. Clinicians should consider the effect of changes to stimulus parameters on loudness perception and modify stimulation levels appropriately, particularly if threshold and upper stimulation levels were set prior to the change in stimulus parameter.

4) Input Dynamic Range (IDR)

a. The lower end of the IDR should correspond to an input level of approximately 25 dB SPL.
    i. For children, the lower end of the IDR should not be increased, due to the need for access to soft speech in this population. Access to soft speech is needed for incidental learning, hearing sounds from a distance, and general access to the range of speech sounds.

ii. For adults, the lower end of the IDR may be increased slightly (5 to 10 dB) to address complaints for hearing in noise if other attempts to address hearing in noise are not adequate.

b. The upper end of the IDR should be set in accordance with manufacturer-specific allowance. Until such time that data are available to indicate otherwise, the size of the IDR should be adequately wide to provide optimum speech perception in quiet and noise, while providing a sound that is perceived as comfortable by the user.

5) Sensitivity

a. Increasing sensitivity may provide improved speech-perception performance in quiet, but may result in poorer speech-perception performance in sound environments with noise.
b. Conversely, decreasing sensitivity may be useful for controlling excessive background noise when necessary.

6) Rate

a. The per-channel and overall stimulation rate is dependent upon the specific cochlear implant manufacturer and device.
b. Cochlear implant recipients may demonstrate a perceptual preference and/or a performance difference across stimulation rates. The determination of the stimulation rate can be based upon recipient preference and assessments of benefit.
c. The rate of stimulation is directly related to pulse duration, as an increase in rate reduces the allowable duration of the pulse.

7) Pulse duration

a. Pulse duration should be balanced with pulse rate and stimulation level to obtain adequate loudness perception for the cochlear implant recipient.
b. Pulse duration may need to be increased if the cochlear implant user requires high current levels to elicit adequate loudness growth.

8) Processing/coding strategies

a. Because threshold and comfort levels can be affected by the speech encoding strategy used, it is important to set the speech encoding strategy prior to measuring threshold and loudness levels (i.e., establishing the EDR).
b. Use newer processing strategies, as they provide greater flexibility in programming options to optimize patient performance.

c. Stimulation mode: At the current time, monopolar stimulation is the recommended stimulation mode, however, multiple modes are available (e.g., bipolar and tripolar).
    i. Typically, a broader stimulation mode (monopolar) results in lower threshold values due to a larger physical separation between active and ground electrodes, which may, in turn, extend battery life.
    ii. The use of monopolar stimulation allows for a more consistent threshold value for adjacent electrodes, due to the broader spread of current. This consistency throughout the array can allow for interpolation of threshold and comfort level values of adjacent electrodes not obtained through actual behavioral testing. This can be especially beneficial where time is critical; i.e., programming with young children or individuals with multiple involvements.

9) Channels/Bands/Frequency Allocation Tables (FAT)

a. The system should provide different pitch perceptions for different channels for the recipient that are delivered by distinct electrical contacts in the electrode array placed in the cochlea. These electrical contacts are designed to deliver stimulation channels that are tonotopically organized, mimicking the natural organization of the healthy cochlea. Basally-placed electrodes correspond with higher frequencies that progress to lower frequencies as channels correspond to more apical areas.
b. Narrow bandwidths within channels are desired for better spectral representation.
c. More spectral information across channels may lead to improved performance with the device. Recognize, however, that realization of spectral information by the cochlear implant user is dependent on not only the device signal processing but also on spiral ganglion nerve survival in the auditory system and placement of the electrode array in the cochlea.
d. The use of virtual channels can increase the number of pitch perceptions and frequency coding realized by the cochlear implant user, which may, in turn, result in improved performance by the cochlear implant recipient.

10) Other processing features

a. Features such as digital noise reduction, wind reduction, and other adaptive signal-processing features may prove beneficial for some recipients of cochlear implants. The decision to use these features should be based upon patient preference and assessments of benefit.

Summary of Evidence for Cochlear Implant Signal Processing

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.	Measurement of impedance telemetry provides information about short and open circuits, contributes to the maximum output of the device, and a time line of impedance measures contributes to evaluation of internal device function.	Electrical and physical fact 8 17 22	 4 4 4	 B B B	EF/EV EV EV EV
2)a.	Directional microphone processing should be considered for all patients.	18 36 37	2 2 2	A A A	EF EF EF
2)b.	Full-time directional processing is not necessary and should be used with caution in children.	No published evidence available specific to children who use cochlear implants. Well documented in hearing aid literature. See the Academy's Pediatric Amplification Guidelines for review.			
3)b.	Optimization of stimulus levels is a primary factor contributing to outcomes.	3 29	3 4	A C	EF EF
4)b.	The size of the IDR should be adequately wide to provide optimum speech perception in quiet and noise, while	9	4	C	EF

	providing a sound that is perceived as comfortable by the user.	10 11 19 20 30 33 38	2 4 3 3 2 3 4	A B D D A B B	EF EF EF EF EF EF EF
5)a.	Increasing sensitivity may provide improved speech perception performance in quiet, but may result in poorer speech perception performance in sound environments with noise.	3 23 33	3 3 3	A B B	EF EF/EV EF
5)b.	Conversely, decreasing sensitivity may be useful for controlling excessive background noise when necessary.	No published evidence available. Current clinical practice.			
6)b.	Cochlear implant recipients may demonstrate a perceptual preference and/or a performance difference across stimulation rates. Determination of stimulation rate can be based upon recipient preference and assessments of benefit.	1 2 27 34	3 2 4 3	B A B B	EF/EV EF/EV EF EF
7)a.	Pulse duration should be balanced with pulse rate and stimulation level to obtain adequate loudness perception for the cochlear implant recipient.	Physical fact 7	 2	 A	EF/EV EF

8)a.	Because threshold and comfort levels can be affected by the sound encoding strategy used, it is important to set the encoding strategy prior to collecting threshold and loudness levels (EDR).	Physical fact 7 32	 2 6	 A D	EF/EV EF EF/EV
8)b.	Use newer processing strategies, as they have been shown to provide greater flexibility in programming options to optimize patient performance.	Physical fact			
8)c.i-8)c.ii.	Typically, a broader stimulation mode (monopolar) can allow for lower and more consistent threshold values, due to a larger physical separation of active and return electrodes. This allows for interpolation of threshold and comfort-level values of adjacent electrodes not obtained through actual behavioral testing, as well as extending battery life.	5 28	3 3	B B	EF EF
9)c.	More spectral information across channels may lead to improved performance with the device.	26 31 39	CNR 1 CNR	CNR A CNR	 EF
9)d.	Use of virtual channels can increase the number of pitch perceptions and frequency coding realized by the cochlear implant user which may, in turn, result in improved performance by the cochlear implant user.	4 6 12 14 16 24 25	3 2 1 3 2 3 3	B B A B A B B	EF/EV EF EF/EV EF EF EF EF

10)a.	Features such as digital noise reduction, wind reduction, and other adaptive signal-processing features may prove beneficial for some recipients of cochlear implants.	13	3	B	EF
		15	3	B	EF
		21	3	B	EF
		35	3	B	EF
		36	2	A	EF

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4. CANDIDACY CONSIDERATIONS FOR THE AUDIOLOGIST

Objective

The pre-operative evaluation is a dynamic and evolving aspect of the implant process. During the pre-implant process, and through continued periodic team meetings, cochlear implant team members work together to evaluate outcomes with available technologies to determine if surgical intervention with a cochlear implant will likely result in improved hearing for an individual. Candidacy is strongly influenced by the likelihood of improved hearing and evolving criteria. Thus, patient management depends on sound clinical judgment involving several different areas of audiology, including audiometric testing, electrophysiology, fitting and verification of amplification, speech perception, and a solid understanding of the impact of hearing loss on educational, vocational, and psychosocial outcomes, as well as speech and language skills. Additionally, the audiologist works closely with the surgeon and other team members in the pre-operative process to consider the effect that the patient's hearing history or radiographic findings may have on performance.

Cochlear implants are classified as a Class III medical device under the United States Food and Drug Administration (FDA). Therefore, the FDA oversees the sale, distribution, and marketing of cochlear implants, and determines the specific wording used in labeling, including information regarding indications for use. The FDA-approved indications for use for children and adults for contemporary cochlear implant systems vary, depending on the timing and construction of the clinical trial. Approved indications for contemporary devices are available on the FDA website (https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062882.htm).

Insurance providers, such as Medicare, may require specific criteria for assessment and determination of cochlear implant candidacy that must be followed if a patient is enrolled with that insurance provider. Presently, the Medicare criteria differ from those of the FDA. The Medicare criteria can be found on the Center for Medicare and Medicaid Services website (https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=134.). The team evaluating for, and determining, candidacy for cochlear implants should seek out this information for the individuals they serve.

Cochlear implants may be appropriate for individuals outside of the FDA-approved indications. The determination of the appropriateness of cochlear implants within and beyond FDA-approved criteria should be made by the team of professionals at the cochlear implant center, as well as by the individual, or family of the individual, who might receive the cochlear implant.

The determination of candidacy for a cochlear implant involves a series of tests conducted by professionals including, but not necessarily limited to, the cochlear implant surgeon, radiologist, audiologist(s), speech language pathologist(s), psychologist(s), parent/guardian(s) (if a pediatric recipient), and local educators and therapists. The aspects of the pre-operative process for determining candidacy for a cochlear implant are described below.

Recommendations for a Cochlear Implant Evaluation

1) Audiological evaluation

a. The audiometric test battery should include a comprehensive behavioral audiological evaluation of each ear that produces the following results:
    i. Audiological case history
        1. The case history will reveal important factors that may imply candidacy and may predict post-operative outcomes. These factors should be identified prior to testing and should be clearly documented. The factors may include, but are not limited to:
            (a) The potential presence of abnormal cochlear anatomy
            (b) Age at implantation
            (c) Perinatal problems such as meningitis, hyperbilirubinemia, and other etiologies associated with sensorineural hearing loss
            (d) Duration of deafness
            (e) Hearing aid use prior to implantation
        2. Individuals with special considerations should not be excluded from receiving a cochlear implant solely based upon their case history; however, realistic expectations should be addressed thoroughly through appropriate counseling for individuals who have additional confounding variables. Examples of such persons include, but are not limited to:
            (a) Prelingually deafened adolescents and adults
            (b) Adults or children with disabilities in addition to deafness
            (c) Elderly patients with medical and/or cognitive concerns

ii. Unaided air conduction thresholds determined using developmentally appropriate assessment measures
    1. Thresholds should be obtained for octave frequencies 125–8000Hz and inter-octave frequencies as indicated.
    2. Better pre-operative hearing thresholds are associated with better post-operative outcomes in children and pre-lingually deafened adults.

iii. Bone-conduction thresholds determined using developmentally appropriate assessment measures
    1. Thresholds should be obtained for octave frequencies 250–4000Hz.

iv. Auditory speech perception using appropriately fit amplification using developmentally appropriate assessment measures
    1. Appropriately fit amplification should be determined through completion of verification measurements, ensuring that the amplification used to evaluate speech-perception performance amplifies sound appropriately to maximize speech understanding and test results reflect the patient's best aided performance.
    2. Verification testing is performed either by probe microphone measurements or test box verification with patient-specific real ear to coupler difference (RECD) corrections (American Academy of Audiology Pediatric Amplification Protocol, 2013).
        (a) If such testing indicates the patient's personal hearing aid is not suitable, an appropriate hearing aid must be selected and used for the evaluation.
    3. Speech-perception testing should be performed in the sound field using recorded test materials at a presentation level of 60 dBA SPL to reduce variability.
    4. A test battery that is developmentally and linguistically appropriate should be used. Test materials should be sensitive enough to measure differences in hearing technologies and performance over time, especially considering the changing criteria used to identify candidates. Recommended speech-perception assessments can be found in Tables 3 and 4.
        (a) When testing adults, clinics should follow recommendations provided in the manual of the Minimum Speech Test Battery (MSTB)

(http://www.auditorypotential.com/MSTBfiles/MSTBManual2011-06-20%20.pdf).

(b) When testing children, audiologists should consider the speech-perception assessment hierarchy delineated in the Pediatric Minimum Speech Test Battery (PMSTB) (Uhler et al, 2017).

(c) Some FDA and Medicare guidelines base candidacy on "best aided" performance. Therefore, speech perception testing should be performed with each ear aided separately, as well as binaurally, to determine the patient's best aided condition. Testing each ear individually provides information that can be used to help determine which ear to implant in cases of unilateral cochlear implantation and also helps to determine if the patient demonstrates any binaural advantage or disadvantage when using two devices.

b. Tests of non-behavioral audiological function also may be part of the evaluation test battery, including:
    i. Assessment of peripheral auditory system and lower brainstem function through the use of otoacoustic emissions, immittance testing (including tympanometry and acoustic reflexes), and auditory brainstem response (ABR) and/or auditory steady state response testing (ASSR).
    ii. Vestibular assessment, which may affect the ear of choice for implantation, as well as identify patients who could be more susceptible to balance difficulties following cochlear implant surgery.
c. Objective measures and performance on speech perception measures are not always indicative of a recipient's perception of their individual performance. Assessment of subjective ability and determination of need should be documented as part of the candidacy process.
    i. Documentation of subjective ability can serve to:
        1. Assess the recipient's quality of life and provide the clinician with information that may be missed if assessed with objective testing alone.
        2. Establish the specific needs of the recipient and serve to aid in the counseling of realistic expectations of outcomes.
        3. Validate post-operative benefit from the device.
    ii. Many instruments exist to quantify recipients' subjective perception and communication needs. While most instruments were developed to assess

amplification need and/or benefit, they can be used in cochlear implant candidacy, as well. Assessments should be selected based on specific recipient characteristics. Recommended assessments of subjective ability can be found in Tables 3 and 4.

2) Medical evaluation

a. The pre-operative medical evaluation is performed by the surgeon, who is typically an otologist or neuro-otologist, and in some cases, the medical professional involved in the recipient's routine medical care. This evaluation typically involves a medical history, physical examination, and verification that the patient is current on all recommended immunizations.
b. Imaging may be included in the medical evaluation, at the discretion of the surgeon. Physicians should be aware that the presence of a cochlear implant can prevent optimal imaging of the head, which should be considered when providing medical clearance for cochlear implantation.

3) Additional non-audiological evaluations

a. Along with audiological and medical evaluations, additional evaluations provide valuable information in the candidacy process, including influencing determination of candidacy, establishing expectations for the potential candidate, and guiding rehabilitative recommendations. Examples of additional evaluations include:
    i. Speech and Language Evaluation
        1. A speech and language evaluation is useful in the adult candidacy process and critical in the pediatric candidacy process. This evaluation, performed by a speech-language pathologist with experience working with adults and/or children with hearing loss, will use standardized assessments to determine the individual's current level of communicative ability. These outcomes will inform candidacy decisions, indicate predictive outcomes post-implantation, and aid in setting appropriate intervention and goals following implantation.
    ii. Educational Evaluation
        1. Academic skills are indicators of language proficiency in children; educators may bring valuable information to the candidacy process. An education evaluation may be performed by a speech-language pathologist or an educator to assess the need for future educational support. The audiologist should be consulted or

included as part of the Individualized Education Plan (IEP) team involved in the design and implementation of the plan for a child with hearing loss.

iii. Psychological and/or Social Work Evaluation

1. An evaluation by a psychologist and/or social worker may be beneficial in some cases when determining cochlear implant candidacy. Hearing loss is associated with depression, reduced social engagement, and poorer health-related quality of life in children and adults. A psychological or social work evaluation may reveal underlying issues that could affect potential outcomes with cochlear implantation. Additionally, consulting with a psychologist and/or social worker can help to mitigate unrealistic expected outcomes for cochlear implant candidates. Assessments may include nonverbal assessment of social, emotional, behavioral, vocational, and adaptive abilities in order to help determine if factors other than hearing impairment are affecting auditory performance.
2. Cognitive evaluations may be of particular importance in older adults; cognitive screeners can be administered by any member of the cochlear implant team. A developmental psychological evaluation may be recommended in pediatric cases.

4) Pre-operative counseling

a. Counseling should be provided during the candidacy process by audiologists and other related providers to ensure that recipients and their support system (a caregiver, spouse, or other individual) have the knowledge and support needed for establishing appropriate expectations with the device, implementation of intervention strategies, and psychosocial well-being.
b. While many counseling topics, such as those related to the effects of hearing loss and appropriate treatment options are within the scope of the audiologist, there may be cases where the audiologist will refer to other allied health-care professionals for more extensive services that are outside of the audiologist's scope of practice.

Table 3. Candidacy Assessment Tools for Adults

Clinic/Laboratory	Source
Aided sound-field thresholds	
MSTB (MSTB, 2011)	MSTB (2011)
Consonant-Nucleus Consonant (CNC)	Peterson and Lehiste (1962)
AzBio Sentence Lists	Spahr et al (2012)
Real World/Subjective	**Source**
Questionnaires:	
Abbreviated Profile of Hearing Aid Benefit	Cox and Alexander (1995)
The Client-Oriented Scale of Improvement	Dillon, James, and Ginis (1997)
The Glasgow Hearing Aid Benefit Profile	Gatehouse (1999)
Hearing Handicap Inventory for Adults (HHIA)	Newman et al (1990)
Hearing Handicap Inventory for the Elderly (HHIE)	Ventry and Weinstein (1982)
Speech, Spatial, and Qualities of Hearing Questionnaire (SSQ)	Gatehouse and Noble (2004)

Table 4. Candidacy Assessment Tools for Children

Clinic/Laboratory	Source
Aided sound-field thresholds	
PMSTB (Uhler et al, 2017)	Uhler et al (2017)
Early Speech Perception Test (ESP)	Moog and Geers (1990)
Pediatric Speech Intelligibility (PSI)	Jerger and Jerger (1982)
Lexical Neighborhood Test (LNT)	Kirk et al (1995)
Multisyllabic Lexical Neighborhood Test (MLNT)	Kirk et al (1995)
Consonant-Nucleus Consonant (CNC)	Peterson and Lehiste (1962)
Bamford-Kowal-Bench sentences in noise (BKB-SIN)	Bench et al (1979) Etymotic Research (2005)
Pediatric AzBio Sentence Lists	Spahr et al (2014)
Real World/Subjective	**Source**
Questionnaires:	Meinzen-Derr et al (2007)
Auditory Skills Checklist (ASC)	Kuehn-Inacker et al (2003)
LittlEARS Auditory Questionnaire (LEAQ)	Obrycka et al (2017)
IT-MAIS	Zimmerman-Philips et al (2000)
MAIS	
Parents' Evaluation of Aural/Oral Performance of Children (PEACH)	Robbins et al (1991) Ching and Hill (2005)

Summary of Evidence for Candidacy

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.i.2.(a)	Presence of abnormal cochlear anatomy may impact candidacy and predict post-operative outcomes. Information should be documented clearly in the case history.	20	4	B	EV
1)a.i.2.(b)	Age at implantation may affect candidacy and predict post-operative outcomes. Information should be documented clearly in the case history.	4 5	3 1	B A	EV EV
1)a.i.2.(c)	Perinatal problems, such as meningitis, hyperbilirubinemia, and other etiologies associated with sensorineural hearing loss may affect candidacy and predict post-operative outcomes. Information should be documented clearly in the case history.	1 20 37	1 4 4	A B B	EV EV EV
1)a.i.2(d)	Duration of deafness may affect candidacy and predict post-operative outcomes. Information should be documented clearly in the case history.	4 17	3 4	B B	EV EV
1)a.i.2(e)	Hearing aid use prior to implantation may affect candidacy and predict post-operative outcomes. Information should be documented clearly in the case history.	6 17 27	4 4 4	B B B	EV EV EV
1)a.i.2.(a)	Prelingually deafened adolescents and adults may benefit from cochlear implantation and should not be excluded from candidacy. Families should be counseled regarding realistic expectations.	6 23 28 45 48	4 4 3 4 4	B B B B B	EV EV EF EV/EF EF
1)a.i.2.(b)	Children with disabilities in addition to deafness may benefit from cochlear	7	1	A	EV/EF

	implantation in quality-of-life outcomes and environmental awareness. These groups should not be excluded from candidacy. Families should be counseled regarding realistic expectations.	13	1	A	EV/EF
1)a.i.2.(c)	Elderly patients may benefit from cochlear implantation and should not be excluded from candidacy. Families should be counseled regarding realistic expectations.	46 47	CNR CNR	CNR CNR	
1)a.ii.2.	Audiometric threshold testing is used to determine candidacy; better pre-operative hearing thresholds are associated with better post-operative outcomes in children and prelingually deafened adults.	8 10 26	1 1 4	A A B	EV EV EV
1)a.iv.1	Audiologists should perform electroacoustic verification of amplification to ensure appropriate fit in order to determine the best-aided condition.	44	1	A	EF
1)a.iv.2.(a)	If the patient's hearing aid is determined not suitable, adjustments should be made or an appropriate hearing aid must be used for the evaluation.	No published evidence available. Current clinical practice.			
1)a.iv.3.	Speech-perception testing should be performed in the sound field using recorded materials at a level of 60 dBA SPL to reduce variability.	2 38	4 4	B B	EV EV
1)a.iv.4	Speech-perception material should be developmentally and linguistically appropriate. Test materials should be sensitive enough to measure differences in hearing technologies and performance over time.	43	CNR	CNR	

1)b.i.	Test of non-behavioral auditory function may also be part of the of the test battery, including assessment of the peripheral auditory function and lower brainstem function.	No published evidence available. Current clinical practice.			
1)b.ii.	Test of non-behavioral auditory function may also be part of the of the test battery, including assessment of the vestibular system. Vestibular disturbances may occur after implantation and should be discussed with the patient prior to surgery.	18	1	A	EV/EF
1)c.	Pre-operative assessments of subjective performance and quality of life can help to determine communication needs and can later be used to validate post-operative benefit.	9 11 14 16	4 3 4 4	B B B B	EF EF EF EF
2)a.	A pre-operative evaluation by the surgeon to determine candidacy is routine practice.	No published evidence available. Current clinical practice.			
3)a.i.1.	A speech and language evaluation may be recommended in adult candidacy evaluations and could be considered critical in pediatric candidacy evaluations.	No published evidence available. Current clinical practice.			
3)a.ii.1.	Pediatric cochlear implant recipients are at an educational disadvantage when compared to normal-hearing peers. An educational evaluation can bring	15 33	3 3	C C	EV EV

	valuable educational information to the candidacy process.				
3)a.iii.1.	Because of the increased risk of depression, reduced social engagement, and poorer health-related quality of life in individuals with hearing loss, a psychology and/or social work evaluation may be recommended for adults and children.	24 29 34	3 1 1	B A A	EV EV/EF EV
3)a.iii.2.	A cognitive evaluation or cognitive screener should be considered when evaluating older adults.	39 40 45	6 6 3	D D B	EV EV EF
4)a.	Counseling toward appropriate expectations should be done by the audiologist.	No published evidence available. Current clinical practice.			

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5. SURGICAL CONSIDERATIONS FOR THE AUDIOLOGIST

Objective

Although the surgical procedure is not within the purview of the audiologist, there are a number of issues surrounding surgery of which the audiologist needs to be aware. Knowledge of the procedure will allow the audiologist to guide the patient through the process and understand when to refer concerns to the surgeon. The overriding issue is the communication between the surgeon and the audiologist. This communication is critical pre-operatively when the patient asks the audiologist questions regarding surgical procedure, intra-operatively during device monitoring, and post-operatively as the patient is seen for device programming. This section will focus on the aspects of the surgical procedure where the audiologist will have an active role.

Recommendations Related to the Role of the Audiologist Regarding Surgery

1) Intra-operative measures for determining device function

a. Intra-operative testing, completed in-person in the operating room or remotely, can provide valuable information to the audiologist, as well as the surgeon and family, about the integrity of the device. Specifically, intra-operative testing can be used to verify function of individual electrodes, provide baseline measures of device and neural function, and provide information used to determine whether or not the use of a back-up device should be considered.

   Intra-operative testing, such as ESRT, NRT, ECAP, etc., is not a measure of the integrity of the device. As such, determination of when to use a back-up device is unclear in the current literature. Intra-operative testing should not be considered a replacement for information that can be gleaned from radiographics.

   While some aspects of device testing will not provide immediate guidance on exactly how to program the cochlear implant, several measures will provide the audiologist with information that may affect programming decisions post-operatively. The following steps are described in the typical order that might be attempted toward the close of the surgical procedure, but should not be

considered a strict schedule if certain test measures are found to be more valuable.

i. Impedance telemetry
    1. Impedance telemetry indicates whether or not the device can provide appropriate stimulation.
        (a) Normal impedance values do not imply a full insertion. Rather, this information indicates that electrodes are in contact with an electrically conductive medium.
        (b) Impedance values tend to be at their lowest in the operating room during surgery.
    2. Short circuits are identified as abnormally low impedance values as designated by each manufacturer.
    3. Open circuits are identified as abnormally high impedance values as designated by each manufacturer.
    4. Typically, a combination of electrode impedance measures, other objective measures (i.e., Electrically-Evoked Compound Action Potential or Electrically-Evoked Stapedial Reflex Threshold), and imaging are used to determine whether the use of a back-up device is necessary. However, there is no clear agreement in the current literature regarding when a back-up device should be used. The audiologist may want to advise use of a back-up device in cases when:
        (a) All intracochlear electrodes read as open circuits when tested in monopolar mode. This likely indicates an open circuit on the monopolar electrode. Troubleshooting steps should be taken in the operating room to resolve the open circuits. If the open circuits cannot be resolved, the device could be programmed in an alternative coupling mode (i.e., bipolar), however, this would limit options for processing strategies and other programming choices.
        (b) Half or more of the electrode array presents with abnormal impedance (short or open circuits), particularly if the surgical insertion was challenging.

ii. Electrically-Evoked Compound Action Potential (ECAP)
    1. Can be used:
        (a) as a tool for determining auditory nerve and device function.

(i) The presence of an ECAP indicates that the auditory nerve is responding to electrical stimulation and that the device is functioning. However, lack of an ECAP response does not necessarily indicate that the device is malfunctioning or that the auditory nerve is not functioning.

(b) to determine the need for further evaluation of electrode array placement in the cochlea (i.e., tip fold-over).

2. Intra-operative ECAP thresholds do not serve as the best predictor of post-operative settings (i.e., lower and/or upper stimulation levels). Intra-operative ECAP thresholds are typically observed at higher stimulus levels compared to thresholds obtained post-operatively.
3. ECAP is a unilateral peripheral response from the auditory nerve.

iii. Electrically-Evoked Stapedial Reflex Threshold (ESRT)

1. Can be used:
   (a) as a tool for determining device function and function of the peripheral/brainstem portion of the auditory pathway.
      (i) The presence of an ESRT indicates that the auditory nerve and stapedial reflex arc are responding to electrical stimulation and that the device is functioning. However, lack of an ESRT does not necessarily indicate that the device is malfunctioning or that the auditory nerve is not functioning.
2. Can be obtained intra-operatively through:
   (a) Visual observation of the contraction of the stapedius muscle by the surgeon.
3. Intra-operative thresholds do not serve as the best predictor of post-operative settings (i.e., upper stimulation levels). Intra-operative measurements are typically observed at higher stimulus levels compared to measures obtained post-operatively. Further, intra-operative measurements can be affected by anesthesia dosage.
4. The muscle contraction is a bilateral response, and therefore can be observed/measured in the contralateral ear.

2) Intra-operative measures for monitoring hearing preservation

a. Emerging evidence exists for the use of intra-operative testing to monitor hearing preservation and acoustic trauma during insertion of the electrode array. Specifically, the use of electrocochleography (eCochG) during electrode array insertion can provide real-time information regarding cochlear function. Changes in cochlear function observed during surgery may affect outcomes, specifically residual hearing, post-operatively.

3) Post-operative care

a. Following surgery, patients must have sufficient time for the implant site to heal before initial activation is to occur. This time frame is ultimately up to the surgeon and poses an area where adequate communication for clearance is required. Please see the follow-up care section for further information regarding post-operative follow-up care.

Summary of Evidence for Surgery

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.	Intra-operative testing, completed in-person in the operating room or remotely, can provide valuable information to the audiologist, as well as to the surgeon and family about the integrity of the device. However, determination of when to use a back-up device is unclear in the current literature.	3 5 8 14 19	4 4 4 4 3	B B B C B	EV EV EF/EV EV EV
1)a.i.1	Telemetry indicates whether or not the device can provide appropriate stimulation.	5 8 18 20	4 4 3 3	B B C B	EV EF/EV EV EF/EV
1)a.i.1.(a)	Normal impedance values do not imply a full insertion. Rather, this information indicates that electrodes are in contact with an electrically conductive medium.	8 20	4 3	B B	EF/EV EF/EV

1)a.i.1.(b)	Impedance values tend to be at their lowest in the operating room during surgery.	1 12 20	3 3 3	B B B	EF/EV EF/EV EF/EV
1)a.i.2.	Short circuits are identified as abnormally low impedance values as designated by each manufacturer.	Physical fact			
1)a.i.3.	Open circuits are identified as abnormally high impedance values as designated by each manufacturer.	Physical fact			
1)a.ii.1	ECAP can be used as a tool for determining auditory nerve and device function. Lack of an ECAP threshold does not necessarily indicate that the device is malfunctioning or the auditory nerve is not functioning.	2 4 9 10 14 20	3 4 3 2 4 3	B B B A C B	EF/EV EV EF/EV EF EV EF/EV
1)a.ii.2	Intra-operative ECAP thresholds do not serve as the best predictor of post-operative settings (i.e., upper stimulation levels). Intra-operative measurements are typically observed at higher stimulus levels compared to measures obtained post-operatively.	9 12 20 21	3 4 3 4	B B B B	EF/EV EF/EV EF/EV EF/EV
1)a.iii.1	ESRT can be used as a tool for determining device function. Lack of an ESRT threshold does not necessarily indicate that the device is malfunctioning, or the auditory nerve is not functioning.	9 14	3 4	B C	EF/EV EV
1)a.iii.2	ESRT can be obtained intra-operatively through:	9 15	3 3	B C	EF/EV EF

	(1) Change in the static admittance of the middle ear as recorded in the ear canal using an immittance bridge. (2) Visual observation of the contraction of the stapedius muscle by the surgeon.	16 18	3 3	B C	EF/EV EV
1)a.iii.c	Intra-operative ESRT measurements do not serve as the best predictor of post-operative settings (i.e., upper stimulation levels). Intra-operative measurements are typically observed at higher stimulus levels compared to measures obtained post-operatively. Further, intra-operative measurements can be affected by anesthesia dosage.	2 6 13 22	3 2 4 3	B B C B	EF/EV EF EF/EV EF
2)a.	Emerging evidence exists for use of intra-operative testing to monitor hearing preservation and acoustic trauma during insertion of the electrode array. Specifically, the use of eCochG during electrode array insertion can provide real-time information regarding cochlear function. Changes in cochlear function observed during surgery may impact outcomes, specifically residual hearing, post-operatively.	7 11 17	3 3 3	B B B	EF EF EF
3)a.	Following surgery, patients must have sufficient time for the implant site to heal before initial activation is to occur. This time frame is ultimately up to the surgeon and poses an area where adequate communication for clearance is required.	No published evidence available. Current clinical practice.			

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6. DEVICE PROGRAMMING

Objective

Device programming is one of the most critical elements of a recipient's success with a cochlear implant and is heavily influenced by the programming audiologist's knowledge and experience with cochlear implants. This section provides recommendations outlining the possible procedures that can be followed or performed when programming a recipient's cochlear implant after surgery. Over time, objectives and procedures for device programming may change as the recipient gains more experience with their cochlear implant and adapts to electrical stimulation. See the management and follow-up section of this document for a brief outline and time line of typical or expected procedures.

Goals of Device Programming

1) **At initial stimulation:**
    a. Acceptance of the device
    b. Comfort and audibility of the stimulation provided

2) **At subsequent programming appointments:**
    a. Establish a dynamic range that:
        i. Is accepted by the recipient
        ii. Provides audibility across a broad spectrum
        iii. Is wide enough to provide the mapping of sounds that are perceived as soft, moderately loud, and loud
    b. Document/monitor performance with the device

Recommendations for Device Programming

1) **Review operative/intra-operative report**
    a. Prior to the initial stimulation, it can be helpful for the audiologist to obtain a copy of the imaging, operative and/or intra-operative monitoring report.
        i. The report(s) can provide useful information regarding the number and the integrity of electrodes inserted into the cochlea.
        ii. Avoid stimulation of extra-cochlear electrodes (i.e., those that are not fully inserted) during the initial stages of programming to prevent non-auditory side effects in order to provide a smoother transition to the use

of the device.

2) Discuss progress or changes that have occurred with the recipient since his/her last appointment

3) Check skin flap

a. Check skin flap (i.e., skin between the headpiece and the internal magnet) integrity to ensure no irritation or tissue breakdown.
    i. Magnets that are too tight can lead to skin necrosis under the magnet.
    ii. During the first few weeks of device use, it is not uncommon for the headpiece to fall off due to post-surgical swelling, and the recipient gains comfort and ease with wearing/placing the device.

4) Measure electrode impedances

a. Electrode impedances should be measured as frequently as possible, at least during appointments where a change to programming is made, and compared across multiple visits to evaluate any sudden or slow changes in electrode function over time.
b. Electrodes that intermittently present as short or open circuits should be programmed out of the map, as this may be a sign of impending permanent electrode failure. Current literature available regarding the number of inactive electrodes required to consider revision surgery is unclear.
c. A normally functioning electrode with a history of short/open circuit may return to a short/open state in between regular clinic visits. The recipient may subsequently experience diminished perception with the device until reprogramming can be accomplished. See the signal-processing section of this document for more detailed information regarding impedance telemetry measurements.

5) Select strategy/parameters

a. Because threshold (T) and upper stimulation levels can be affected by the processing/coding strategy used, it is important to set the processing/coding strategy prior to obtaining information used to establish the electrical dynamic range.

6) Establish the electrical dynamic range (EDR) on selected electrodes[1]

a. Setting the EDR can be done through measurement of all or a subset of electrodes using a combination of psychophysical and objective measures. Common clinical practice varies regarding measurement of all or a subset of electrodes for creation of an adequate program.
    i. Obtaining accurate psychophysical measures of loudness and pitch is likely to improve recipient performance with the cochlear implant.
    ii. Several measures can be completed to obtain psychophysical responses from the recipient. These measures include: 1. behavioral judgment of threshold stimulation levels (T-levels), 2. behavioral judgment of upper stimulation levels, 3. loudness balancing, and 4. pitch scaling.
        1. Behavioral measurement of threshold (T) stimulation levels
            (a) T-levels should be established using procedures similar to those used when performing threshold audiometry.
                (i) Visual reinforcement audiometry, conditioned play audiometry, and traditional audiometry techniques should be used as appropriate for the individual needs of the cochlear implant recipient.
            (b) Considerations for setting T-levels:
                (i) If T-levels are set too low, the recipient may not be provided with sufficient audibility of soft sounds.
                (ii) If T-levels are set too high, the recipient may experience a greater level of ambient noise, as well as a restricted EDR. For CIS strategies, the user may report a static or frying sound.
                (iii) Measurement of T-levels should be completed routinely for those who use cochlear implant devices that require measurement of T-levels.
                (iv) Some devices allow for setting T-levels at a value related to the electrical dynamic range or upper stimulation level. For those who use cochlear implant devices that do not require measurement

[1] May change default parameters (strategy, rate, pulse duration, etc.) if poor responses are obtained (example: inadequate loudness growth due to voltage compliance issues). Depending on the device manufacturer, changes to default parameters may require re-measurement of the EDR.

of T-levels, deviation from default T-levels may be warranted to improve performance.

2. Behavioral measurement of upper stimulation levels
    (a) Considerations for setting upper stimulation levels:
        (i) Underestimating upper stimulation levels may negatively impact speech recognition, sound quality, and ability to monitor the sound of one's voice.
        (ii) Overestimating upper stimulation levels may result in discomfort and aversion to the device, as well as negatively impacting speech recognition and sound quality.

b. Objective measures used in device programming
    i. Both prelingually deafened adults and young children may demonstrate a limited ability to provide reliable behavioral feedback necessary to establish the electrical dynamic range. Therefore, programming may need to rely more heavily on objective measures to ensure proper device function and appropriate sound-processor settings. Common objective measures include: 1. ESRT measures and 2. ECAP measures.
        1. ESRT measures
            (a) Because the stapedial reflex occurs bilaterally, ESRTs can be measured from either the ipsilateral or contralateral ear to the cochlear implant.
            (b) ESRT should be obtained using the same stimulus used during behavioral programming.
            (c) Several studies have shown strong correlations between ESRT and upper stimulation levels. However, findings are mixed in regard to how often ESRTs underestimate, approximate, or overestimate map upper stimulation levels.
            (d) Normal tympanometric findings are required in order to proceed with ESRT measurement. Even in situations with normal tympanometric findings, ESRT may not be measurable in all cochlear implant recipients.
            (e) ESRTs can be helpful for setting upper comfort levels for prelingually deafened children, who often lack the concept of "loud" and may be less likely to demonstrate adverse

reactions to loud sounds, as well as for adults who provide inconsistent reports of loudness.

2. ECAP measures
    (a) ECAP thresholds and program stimulation levels are only moderately correlated.
    (b) ECAP thresholds generally occur within the electrical dynamic range, although they may exceed upper comfort levels for some recipients. ECAP thresholds almost always occur above behavioral T level. ECAP thresholds therefore represent a level that should be audible to the recipient.
    (c) The presence of an ECAP indicates that the auditory nerve is responding to electrical stimulation and that the device is functioning. However, lack of an ECAP response does not necessarily indicate that the device is malfunctioning or that the auditory nerve is not functioning.

7) Optimize program

a. Loudness balancing
    i. Programming with equal loudness percepts across channels results in improved sound quality and speech recognition when compared to programs with unbalanced stimulation levels.
b. Pitch scaling
    i. Electrodes that are enabled should provide increasing pitch perception as the electrode location progresses from apical to basal cochlear place. Electrodes that are reported by the recipient as deviating from this organization and/or those that are not perceived as differing in pitch may be considered for deactivation in programming.

8) Go live to ensure comfort and audibility

a. Informal speech testing, e.g., Ling sounds[2] should be performed to ensure that the recipient has access to various frequencies across the speech domain.

[2] Ling, D. (1976). Speech and the hearing-impaired child: Theory and practice. Washington, DC: Alexander Graham Bell Association for the Deaf.
Ling D. & Ling A.H. 1978. Aural Habilitation. The foundation of verbal learning in hearing–impaired children. Washington, USA: The Alexander Graham Bell Association for the Deaf, Inc. p. 98.

9) Load program(s) into sound processor

a. When placing programs in the sound processor memory, the most effective program is the one that requires minimal manipulation.
b. Progressively louder programs (i.e., progressively larger electrical dynamic range) may be warranted at initial stimulation, based upon the recipient's initial reaction and acceptance of the device. However, this should be done with caution to avoid overstimulation.

10) Counsel

a. Counseling may include, but is not limited to:
    i. Discussion of external device care, including proper use and maintenance of all components of the external equipment (i.e., processor, cable, coil, battery, remote, etc.).
    ii. Discussion of changes made to programs compared to the previous visit.
    iii. Discussion of different programs provided (if applicable) and when they should be used.
    iv. Discussion of importance of aural rehabilitation.
    v. Discussion of consistent device use and realistic expectations.

Summary of Evidence for Device Programming

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.i.	Prior to the initial stimulation, it can be helpful for the audiologist to obtain a copy of the operative and/or intra-operative monitoring report. The report(s) can provide useful information regarding the number and the integrity of electrodes inserted intracochlearly.	16	6	D	EF/EV
3)a.	Check skin flap (skin between the headpiece and the internal magnet) integrity to ensure no irritation or tissue breakdown.	No published evidence available. Current clinical practice.			
4)a.	Electrode impedances should be measured as frequently as possible, at least during appointments where a	2 9	4 4	B B	EF/EV EF

	change to programming is made, and compared across multiple visits to evaluate any sudden or slow changes in electrode function over time.				
4)b.	Electrodes that intermittently present as short or open circuits should be programmed out of the map, as this may be a sign of impending permanent electrode failure. Current literature available regarding the number of inactive electrodes required to consider device failure and subsequent revision surgery is unclear.	2 16 19	4 6 4	B D B	EF/EV EF/EV EF/EV
5)a.	Because threshold and upper stimulation levels can be affected by the processing/coding strategy used, it is important to set the processing/coding strategy prior to obtaining information used to establish the electrical dynamic range.	Physical fact			
6)a.	Establish electrical dynamic range on all or a selected subset of electrodes via psychophysical measurements of threshold (T) and upper stimulation level and/or physiological measurements (i.e., ECAP and ESRT). Some research suggests a measurement of a subset of electrodes is adequate. Common clinical practice varies.	14	3	B	EF
6)a.i.	Obtaining accurate psychophysical measures of loudness and pitch is likely to improve the recipient's performance with the cochlear implant.	3 16	3 6	C D	EF EF/EV
6)a.ii.1.(b)(i)	If T-levels are set too low, the recipient may not be provided with	18	6	D	EF/EV

	sufficient audibility of soft sounds.				
6)a.ii.1.(b)(ii)	If T-levels are set too high, the recipient may experience a greater level of ambient noise, as well as a restricted EDR.	18	6	D	EF/EV
6)a.ii.2.(a)(i)	Underestimating upper stimulation levels may negatively impact speech recognition, sound quality, and ability monitor the sound of one's voice.	18	6	D	EF/EV
6)a.ii.2.(a)(ii)	Overestimating upper stimulation levels may result in discomfort and aversion to the device, as well as negatively impacting speech recognition and sound quality.	18	6	D	EF/EV
6)b.i.1.(c)	Several studies have shown strong correlations between ESRT and map upper stimulation levels. Findings are mixed in regard to how often ESRTs underestimate, approximate, or overestimate map upper stimulation levels.	1 7 8 11 12 13 17	4 3 4 4 4 5 4	C B C B C C B	EF EF EF EF EF EF EF
6)b.i.1.(d)	ESRT may not be measurable in all cochlear implant recipients. Normal tympanometric findings are required.	1 10 11 12	4 6 4 4	C D B C	EF EV EF EF
6)b.i.2.(a)	ECAP thresholds and program stimulation levels are only moderately correlated.	4 15	1 4	A B	EF EF

6)b.i.2.(b)	ECAP thresholds generally occur within the electrical dynamic range, although they may exceed upper comfort levels for some recipients. ECAP thresholds almost always occur above behavioral T level. ECAP thresholds therefore represent a level that should be audible to the user of the CI.	4	1	A	EF
6)b.i.2.(c)	Lack of an ECAP threshold does not necessarily indicate a device malfunction.	Physical fact			
7)a.	Programming with equal loudness percepts across channels will likely result in improved sound quality.	3 16	3 6	C D	EF EF/EV
7)b.	Electrodes that are enabled should provide increasing pitch perception as the electrode location progresses from apical to basal cochlear place. Electrodes that are reported by the recipient as deviating from this organization and/or those that are not perceived as differing in pitch should be disabled in programming.	5 6	4 3	B B	EF EF
8)a.	Go live after establishment of the EDR to ensure comfort and audibility. Informal speech testing, e.g., Ling sounds (Ling, 1976; Ling, 1989) should be performed to ensure that the patient has access to various frequencies in the speech domain.	16	6	D	EF/EV
9)a.	When placing programs in the sound processor memory, the most effective program is the one that requires minimal manipulation.	No published evidence available. Current clinical practice.			
9)b.	Progressively louder programs may	18	6	D	EF/EV

	be warranted at initial stimulation based upon the recipient's initial reaction and acceptance of the device.				

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7. OUTCOMES ASSESSMENT AND VALIDATION

Objective

Outcomes assessment is a critical component of cochlear implant follow-up care and evidence-based best practice. This section will discuss qualitative and quantitative measures that can serve as methods of validation for both adult and pediatric cochlear implant recipients.

Recommendations for Outcome Assessment

Outcomes assessments can help provide documentation of benefit derived from use of a cochlear implant, help identify potential programming parameters that need to be adjusted during routine programming, as well as determine the need for any additional recommendations outside of the purview of the programming audiologist. Therefore, outcomes assessment should be performed at regular intervals after initial stimulation of the device. Please see the follow-up/timeline section of the document for a more in-depth discussion regarding when outcomes assessment(s) should be performed post-operatively.

1) Use of validated assessment tools

a. All cochlear implant recipients should complete measures of speech perception to further assess performance outcomes and treatment efficacy. Assessment protocols have been created and validated for both adult and pediatric cochlear implant recipients. The Minimum Speech Test Battery (MSTB) has been designed for adults and the Pediatric Minimum Speech Test Battery (PMSTB) has been developed as the pediatric counterpart.

   Both protocols aim to help serve as guidelines for the appropriate selection of speech-perception testing materials for cochlear implant recipients, both pre and post-operatively. Post-operatively, these assessment tools can be used as part of the comprehensive outcome assessment test battery, which also may include cochlear implant sound-field thresholds, various questionnaires, and/or objective measures (i.e., ECAP, ESRT). Together, these measures play an important role in documenting and validating that the recipient's current programming parameters are appropriate. This is an important consideration for pediatric recipients who also are developing speech and language skills.

i. Tables 3 and 4 in the Candidacy section outline current outcomes assessment tools available for adult and pediatric cochlear implant recipients, respectively. These resources serve as guidelines in terms of what tools generally may be appropriate for assessing outcomes and treatment efficacy.

2) Use of subjective input

a. Subjective input from the recipient and those who regularly interact with the recipient (i.e., spouse, parent, guardian, teacher, speech-language pathologists, auditory-verbal therapist, special education instructor, etc.) should be considered when determining the effectiveness and benefit derived from a cochlear implant. This information can be collected interview-style during appointments, through informal questionnaires created by the cochlear implant center, or informally during team meetings, with the recipient and other health-care providers involved in the recipient's care plan.

3) Consideration of appropriate modifications to outcomes assessment battery

a. Audiologists must consider what assessment tools are most appropriate on a case-by-case basis. Modifications to components of the outcomes assessment test battery (specifically speech-perception testing) may be necessary.
    i. The recommended speech-perception test materials outlined by the MSTB may be too difficult for some recipients with low language skills or developmental delays. In these cases, other materials may be more appropriate. It is important to note that, in order to appropriately compare performance post-operatively with the cochlear implant to pre-operative performance with the patient's previous device, the same speech-perception test battery should be administered. Additionally, audiologists should be aware of ceiling effects and adapting the test battery appropriately over time. Longitudinal retrospective data within the recipient and clinic should be used to establish and change protocols.
    ii. For pediatric cochlear implant recipients, many of the assessment materials outlined by the PMSTB are not normed for children with hearing loss. In attempts to account for differences between children with normal hearing and children with hearing loss, the recommended age ranges provided for each of the assessment materials outlined in the PMSTB differs from age ranges originally provided by each of the test manuals. However, these age ranges should be considered flexible, depending on the development and needs of the child.

iii. In the cases mentioned above, as well as in many other cases, the audiologist should use their best clinical judgment to make appropriate modifications to the outcomes assessment test battery on an individual basis. See Uhler et al (2017) and Gifford, Shallop, and Peterson (2008) for more detailed information regarding selection of appropriate speech-perception test materials.

4) Addressing poor performance in the sound booth

a. Poor performance during validation testing in the sound booth warrants further investigation into potential factors that may be impacting performance with a cochlear implant (i.e., device wear time or programming parameters). However, audiologists should recognize that expected outcomes for individuals vary and, as such, performance in the sound booth should be considered with respect to perceived benefit, quality of life, and psychosocial outcomes.

i. Cochlear implant sound-field thresholds may be related to speech recognition at soft speech and conversational levels.

1. For example, cochlear implant sound-field thresholds poorer than 30-40dBHL, and/or significantly poorer performance on appropriate measures of speech perception compared to pre-operative or most recent validation testing may warrant further exploration into optimal device programming and device use.

Summary of Evidence for Outcomes Assessment of Adult Cochlear Implant Recipients

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.	Adult cochlear implant recipients should complete measures of speech perception outlined by the MSTB to assess performance outcomes and treatment efficacy.	8	CNR	CNR	
2)a.	Subjective input from the recipient and those who regularly interact with the recipient should also be considered when determining the effectiveness and benefit derived from a cochlear implant.	4 5 8 9	4 4 3 3	B B B B	EV EV EV EV

3)a.	Audiologists must consider what assessment tools are most appropriate on a case-by-case basis.	3	3	B	EF
4)a.	Poor performance during validation testing in the sound booth warrants further investigation into potential factors that may be impacting performance with a cochlear implant.	2 6	4 4	B B	EF EF

Summary of Evidence for Outcomes Assessment of Pediatric Cochlear Implant Recipients

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.	Pediatric cochlear implant recipients should complete measures of speech perception outlined by the PMSTB to further assess performance outcomes and treatment efficacy.	12	CNR	CNR	
2)a.	Subjective input from the recipient and those who regularly interact with the recipient should also be considered when determining the effectiveness and benefit derived from a cochlear implant.	7 10 11 13	4 4 4 4	B B B B	EV EV EV EV
3)a.	Audiologists must consider what assessment tools are most appropriate on a case-by-case basis.	12	6	D	EV
4)a.	Poor performance during validation testing in the sound booth warrants further investigation into potential factors that may be impacting performance with a cochlear implant.	1	2	B	EF

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8. FOLLOW-UP SCHEDULE

Objective

Regardless of age, accurate mapping of the electrical dynamic range (i.e., electrical thresholds [T] and upper stimulation [M/C] levels) is a main contributor to post-operative performance. Frequent appointments are necessary in the first year following activation of the cochlear implant in order to optimize programming and maximize audibility. Continued device management, monitoring of surgical site, and monitoring of progress with the device are necessary to ensure auditory access and appropriate fitting across time.

Recommendations for Management and Follow-up Schedule

1) Pediatric follow-up schedule

a. For children, the following follow-up schedule is recommended for the first year of device use:
    i. Initial activation: Typically occurs 1-4 weeks post-operatively, in accordance with the recommendation and approval of the surgical team
    ii. 1 week post initial activation
    iii. 2 months post initial activation
    iv. 3 months post initial activation
    v. 6 months post initial activation
    vi. 9 months post initial activation
    vii. 12 months post initial activation

b. The follow-up schedule after the first year of device use should be dependent upon the progress the child has made with the device and the caregiver's comfort and skill in maintaining equipment.
    i. For children who are not reliable in reporting sound quality or for those whose caregiver has not developed skill in maintaining equipment, follow-up appointments may be warranted every 3 months.
    ii. Children who are reliable in reporting sound quality and whose caregiver has developed competence in maintaining equipment may be seen for follow-up appointments less frequently.
        1. For example, biannually (e.g., every 6 months) for school-aged children or annually for adult-like children (e.g., adolescents).

2) Adult follow-up schedule

a. For adults, the following follow-up schedule is recommended for the first year of device use:
    i. Initial activation: Typically occurs 1-4 weeks post-operatively, in accordance with the recommendation and approval of the surgical team
    ii. 1 week post initial activation
    iii. 1 month post initial activation
    iv. 3 months post initial activation
    v. 6 months post initial activation
    vi. 12 months post initial activation
b. The follow-up schedule after the first year of device use should be dependent upon the progress the individual has made with the device. For most adults, follow-up appointments can occur biannually (e.g., every 6 months) or annually.

3) Situations necessitating additional programming sessions

a. For both children and adults, additional programming sessions should be scheduled if certain changes in the patient's auditory responsiveness or speech production occur. These changes include, but are not limited to:
    i. Changes in auditory discrimination
    ii. Increased request for repetition
    iii. Omission of sounds
    iv. Prolongation of vowels
    v. Change in vocal quality or volume
    vi. Intermittency
    vii. Fluctuation in hearing with device
    viii. Balance issues
    ix. Head trauma
    x. Infection or other medical concerns for the cochlear implant site
    xi. Technology updates

Summary of Evidence for Follow-Up Schedule

Rec	Evidence	Source	Level	Grade	EF/EV
1)a.	Follow-up schedule for children for the first year of device use. a. Initial activation: Typically 1-4 weeks post-operatively, in accordance with	1 2	6 4	D B	EF/EV EV

	recommendation and approval of the surgical team b. 1 week post initial activation c. 1 month post initial activation d. 3 months post initial activation e. 6 months post initial activation f. 9 months post initial activation g. 12 months post initial activation	3 4 5	6 4 4	D B B	EF/EV EV EV
1)b.	For children, the follow-up schedule after the first year of device use should be dependent upon the progress the child has made with the device and the caregiver's comfort and skill in maintaining equipment.	3	6	D	EF/EV
2)c.	For children who are not reliable in reporting sound quality or for those whose caregiver has not developed skill in maintaining equipment, follow-up appointments may be warranted every 3 months.	2 4	4 4	B B	EV EV
1)d.	Children who are reliable in reporting sound quality and whose caregiver has developed competence in maintaining equipment may be seen for follow-up appointments less frequently. For example, biannually (e.g., every 6 months) for school aged children or annually for adult-like children.	2 3 4	4 6 4	B D B	EV EF/EV EV
2)a.	Follow-up schedule for adults for the first year of device use. a. Initial activation: Typically 1-4 weeks post operatively, in accordance with recommendation and approval of the surgical team b. 1 week post initial activation c. 1 month post initial activation d. 3 months post initial activation e. 6 months post initial activation f. 12 months post initial activation	3 5	6 4	D B	EF/EV EV

2)b.	For adults, the follow-up schedule after the first year of device use should be dependent upon the progress the individual has made with the device. For most adults, follow-up appointments can occur biannually (e.g., every 6 months) or annually.	3 5	6 4	D B	EF/EV EV
3)a.	For both children and adults, additional programming sessions should be scheduled if certain changes in the patient's auditory responsiveness or speech production occur. These changes include, but are not limited to: i. Changes in auditory discrimination ii. Increased request for repetition iii. Omission of sounds iv. Prolongation of vowels v. Change in vocal quality or volume vi. Technology updates	3	6	D	EF/EV

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9. COMPONENTS OF FOLLOW-UP APPOINTMENTS

Objective

As previously stated, accurate mapping of the electrical dynamic range (i.e., electrical thresholds [T] and upper stimulation [M/C] levels) is a main contributor to post-operative performance. Through continued device management, adequacy of device fitting and benefit with the device can be tracked and necessary changes to device fitting made as needed. Additional components included in the ongoing care of an individual with a cochlear implant may include informational and adjustment counseling, connection with educational and vocational rehabilitation resources (where appropriate), development of self-advocacy skills, and assurance of patient support for continued cochlear implant use. Combined, these components of follow-up appointments contribute to the benefit recipients gain from use of their cochlear implant.

Recommendations for ongoing care of individuals with a cochlear implant

1) Assurance of equipment fit and function

a. Assurance of equipment function is critical for device use and benefit.

2) Measure of telemetry/impedance

a. Telemetry/impedance measures should be completed at most follow-up appointments, particularly those where changes are made to device programming.
b. Telemetry/impedance should be compared across multiple visits to evaluate sudden or slow changes in electrode function. See the signal-processing section within this document for a discussion of application of telemetry/impedance measures.

3) Assessment of the electrical dynamic range (EDR)

a. Ongoing evaluation/assessment of the recipient's EDR is necessary to ensure appropriateness as well as program optimization.
b. Electrical thresholds (T) and upper stimulation levels that are based upon the recipient's report of loudness can fluctuate, particularly during the first year of cochlear implant use.

c. Appropriateness of the electrical dynamic range can be evaluated through multiple means. The recipient's behavioral reports of threshold and loudness, physiological measures, and outcome and validation measures should all contribute to determination of appropriateness of electrical dynamic range across follow-up appointments.

4) Optimization of programming

a. Performing loudness balancing and/or pitch scaling during device programming can further optimize sound quality and improve speech recognition ability by deactivating electrode(s) that do not provide appropriate or expected percepts.
b. Identification of aberrant electrodes that produce poor sound quality or do not produce growth in loudness with increased current levels. Deactivation of these electrodes may be considered.

5) Physiological measures of auditory system response to electrical stimulation

a. ECAP thresholds and ESRT measurements in adults typically do not change significantly across time. Therefore, it is recommended that ECAP and ESRT measurements be obtained across the electrode array at an early visit to establish a baseline of auditory function. If performance declines at a later time, ECAP and ESRT measures can be repeated and compared to the baseline. Substantial increases in threshold or degraded waveform morphology, in the case of the ECAP, may indicate diminished auditory nerve function.

6) Validation measures

a. As discussed in the outcome assessment and validation section of this document, validation measures should be consistently implemented through follow-up appointments. At least one validation assessment should be included in each follow-up appointment.
b. Assessment of audibility through the cochlear implant (e.g., sound-field thresholds or Ling sounds) and speech perception performance should be evaluated at multiple appointments during the first year of device use.
    i. For adults, evaluation of audibility and speech perception performance after the first year of device use should be evaluated at least annually or sooner if concerns of a decline in performance arise.
    ii. For children, evaluation of audibility and auditory, speech, and language development should be conducted routinely throughout development. More frequent monitoring of progress is warranted in those children who are in the period of developing language and auditory skills.

7) Counseling

a. Informational and adjustment counseling should be provided to ensure that recipients (both children and adults) and their support system (caregiver, spouse, or another individual) have the knowledge and support needed for consistent device use, implementation of intervention strategies, and psychosocial well-being. Review of data logging, including wear time, program usage, and sound environment settings, provide beneficial information for areas of needed counseling.

8) Conducting appropriate referrals

a. Refer the recipient for additional evaluation, intervention, and/or support as needed. These referrals include but are not limited to:
    i. Referral for medical care with the cochlear implant surgeon if concerns such as skin flap-breakdown, extrusion of internal components, incision-site infection, or the like arise.
    ii. Referral for concerns for neurological problems.
    iii. Referral to social work for development of support systems.

9) Early intervention and educational support

a. For children, facilitation of accessing and using early intervention and educational support in compliance with local, state, and federal regulations should be included in routine follow-up care.

10) Hearing Assistive Technology (HAT)

a. Discuss listening environments the user experiences and the use of hearing assistive technology (HAT). Support and optimization for the HAT should be included if the cochlear implant user implements this technology. Further recommendations regarding HAT can be found in the Care Beyond Device Programming section of this guideline document.

11) Other outside supportive resources

a. Discussion of support resources and peer support groups (e.g., parent-to-parent groups for children who use cochlear implants and adult groups for adult recipients) should be included in routine follow-up care.

Summary of Evidence for Components of Follow-Up Appointments

Rec	Evidence	Source	Level	Grade	EF/EV

1)a.	Assurance of equipment function is critical for device use and benefit.	No published evidence available. Current clinical practice.			
2)a.	A measure of telemetry/impedance should be completed at most follow-up appointments, particularly those where changes are made to device programming.	4 18 20 27	4 3 4 4	B B B B	EV EV EV EF/EV
3)a.	Conduct ongoing evaluation/assessment of the individual's electrical dynamic range to ensure appropriateness as well as program optimization.	11 20	4 4	B B	EV EV
3)b.	Electrical thresholds and upper stimulation levels determined based upon patient report of loudness can fluctuate, particularly during the first year of cochlear implant use.	16 17	3 6	B D	EV EF/EV
3)c.	Appropriateness of the electrical dynamic range can be evaluated through multiple means. The user's behavioral reports of threshold and loudness, physiological measures, and outcome and validation measures should all contribute to determination of appropriateness of electrical dynamic range across follow-up appointments.	8 9 10 13 16 22	4 3 4 3 3 3	B B C B B B	EF/EV EV EF/EV EV EV EV
4)a.	Optimization of programming should include performance of	5	3	C	EF

	loudness balancing and pitch ranking.	6 7 17	4 3 6	B B D	EF EF EF/EV
4)b.	Optimization of programming should include identification of aberrant electrodes that produce poor sound quality or do not produce growth in loudness with increased current levels. Deactivation of these electrodes may be considered.	2 21	4 2	B A	EF EF
5)a.	ECAP and ESRT thresholds should be obtained across the electrode array at an early visit to establish a baseline of auditory function.	8 10 12 15	3 4 4 4	B C B C	EF EF EF EF
6)a.	Validation measures should be consistently implemented through follow-up appointments. At least one validation assessment should be included in each follow-up appointment.	19 20	4 4	B B	EV EV
6)b.	Assessment of audibility through the cochlear implant and speech perception performance should be evaluated at multiple appointments during the first year of device use.	17 19	6 4	D B	EF/EV EV

6)b.i.	For adults, evaluation of audibility and speech perception performance after the first year of device use should be evaluated at least annually or sooner if concerns of a decline in performance arise.	20	4	B	EV
6)b.ii.	For children, evaluation of audibility and auditory, speech, and language development should be conducted routinely throughout development. More frequent monitoring of progress is warranted in those children who are in the period of developing language and auditory skills.	3 17 19	6 6 4	D D B	EF/EV EF/EV EV
7)a.	Informational and adjustment counseling should be provided to support consistent device use, implementation of intervention strategies, and psychosocial well-being.	17 20 26	6 4 4	D B C	EF/EV EV EV
8)a.	Refer the recipient for medical care with the cochlear implant surgeon if concerns arise.	3 17	6 6	D D	EF/EV EF/EV
9)a.	For children, facilitate access and use of early intervention and educational support in compliance with local, state, and federal regulations.	14 17	2 6	B D	EV EF/EV
10)a.	Discuss listening environments the user experiences and the use of hearing assistive technology (HAT). Support and optimization for the HAT should be included if the cochlear implant user	23 24 25	3 3 6	B B D	EF EV EF/EV

	already implements this technology.				
11)a.	Discussion of support resources and peer support groups (e.g., parent-to-parent groups for children who use cochlear implants, and adult groups for adult recipients) should be included as part of routine follow-up care.	1 26	4 4	C C	EV EV

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10. CARE BEYOND DEVICE PROGRAMMING

Objective

To realize maximum benefit from the device, cochlear implant recipients require consistent follow-up and intervention beyond cochlear implant programming. The use of HAT in addition to the cochlear implant device may be required in challenging listening environments. This is true of patients at all ages and durations of deafness, albeit with a variety of approaches required. This section will outline recommendations outside of device programming that should be considered in order to maximize individual outcomes for cochlear implant recipients.

Recommendations

1) Opportunity for implementation of HAT(s)

a. All individuals who use a cochlear implant should be considered as a potential candidate for HAT. HAT(s) are beneficial for individuals communicating in complex listening environments (e.g., noise, car travel, large reverberant rooms, day-care environments, communicating from a distance) and should be specifically considered with school-age children.

   i. The American Academy of Audiology published clinical practice guidelines (CPG) for remote microphone HAT and classroom audio distribution systems. These documents are available at: https://www.audiology.org/publications-resources/document-library/hearing-assistance-technologies.

   ii. With the rapid evolution of remote microphone technology, clinicians should identify evidence supporting how this technology is applied. This supporting evidence should not be manufacturer-generated (e.g., not a manufacturer white paper).

2) Feedback and use of intervention to further optimize device programming

a. The objective of intervention is to develop auditory skills through a variety of activities and to provide the audiologist who programs the cochlear implant with feedback on what the recipient is hearing (or not hearing) in order to optimize device settings.

i. Intervention for adults may focus on auditory training. The specific intervention needs may vary based upon factors known to affect outcomes. Auditory training may include analytic exercises, synthetic exercises, and/or speech tracking. These interventions may occur within the clinical environment, at home, or in group settings.

ii. For children, intervention should focus on the holistic developmental process with the goal of auditory access and meaningful integration of sound. Auditory development of children with normal hearing can serve as a basis of comparison for children with cochlear implants, however it cannot be used as an exclusive guideline for three primary reasons. First, children with cochlear implants do not receive the device(s) at birth and are therefore delayed in listening by the time their device is activated. Second, even optimally programmed cochlear implants do not replicate normal hearing, placing children with cochlear implants at a disadvantage in their listening development. Third, a large percentage of children with hearing loss have additional disabilities.

    1. Considerable variability exists in the performance of children with cochlear implants. Auditory goals should be individualized, taking into consideration the unique characteristics of the child and family. Engaging family members in therapy and coordinating efforts among therapists and educators is believed to result in the best outcomes for children and families.
    2. Because cochlear implants typically provide access to sound across the speech spectrum and allow for the development of listening and spoken-language skills, many families choose an aural/oral communication mode. However, for a variety of reasons, including the family culture and characteristics of the child, visual support for communication in the form of American Sign Language (ASL), Signed English, or Cued Speech may be a part of the communication approach used by families. Parents should be provided with information about the range of communication options for children who are Deaf/deaf/hard of hearing (D/HH), from highly auditory, such as an auditory-verbal approach, to highly visual, such as the use of American Sign Language.
    3. Successful recipients of cochlear implants may be found in children using every mode of communication. However, evidence suggests that the likelihood (not guarantee) of a child gaining high benefit in the areas of speech perception, speech production, and

spoken language increases when more emphasis is placed on listening and spoken language in the child's home and educational setting.

4. High performance has been linked to full-time use of the cochlear implant(s) in home and school environments. Educational settings that do not encourage the meaningful use of audition, where listening skills are not promoted, and/or where children are not encouraged to wear their cochlear implants may be considered high-risk or even a contraindication for placement of children using cochlear implants.
5. Cochlear implant recipients can realize success in using multiple languages (i.e., bilingual). Factors that correlate with favorable outcomes are the same as in any child with the exposure to rich, complex models of both languages.

3) Language models for pediatric recipients

a. The amount and quality of language used by parents/caregivers of children with hearing loss has a strong influence on these children's linguistic development, just as it does in children with normal hearing**.** Research links high parent engagement with better communication outcomes for children with hearing loss and specifically for children using cochlear implants.

4) Training for enhancement of music appreciation

a. Materials targeting music perception and appreciation are available and are shown to be beneficial and should be implemented with recipients who wish to improve music-perception abilities with their cochlear implant.

5) Considerations for children with comorbidities

a. For children with mild cognitive impairment who receive cochlear implants, auditory skills may progress in a sequence similar to that of children without additional conditions who use a cochlear implant, but at a slower rate. For children with severe or profound additional disabilities, some may realize a traditional scope and sequence of skill development following receipt of a cochlear implant. For others, their progress needs to be measured by criteria that are unique to them and that reflect the goals of the family.

6) Considerations for activities of daily life

a. Considerations for activities of daily life and safety should be made for all recipients. These other needs may include vocational considerations, social support, telephone use, alarms, and alerting devices.

7) Implementation of bilateral stimulation

a. Bilateral stimulation should be considered for all recipients. A hearing aid should be used in the non-implant ear in individuals with acoustic hearing that is aidable. For those individuals who do not benefit from a hearing aid in the non-implant ear, bilateral cochlear implants should be considered if not contraindicated.

Summary of Evidence for Care Beyond Device Programming

Rec.	Evidence	Source	Level	Grade	EF/EV
1)a.	All individuals who use a cochlear implant should be considered as a potential candidate for hearing assistive technology; particularly those who experience complex listening environments and school-aged children.	42 50	1 4	A B	EF EF
2)a.i.	Intervention for adults may focus on auditory training. The specific intervention needs may vary based upon factors known to affect outcomes.	28 43 44	1 1 4	A A B	EF EF/EV EF/EV
2)a.ii.	For children, intervention should focus on the holistic developmental process with the goal of auditory access and meaningful integration of sound.	6 15 21 24 31	CNR 1 2 3 1	CNR A A A A	 EF EF EF EF

2)a.ii.1.	Engaging family members in therapy and coordinating efforts among therapists and educators is believed to result in the best outcomes for children and families.	1 11 36	4 4 3	B B B	EV EF/EV EF
2)a.ii.2.	Parents should be provided with information about the range of communication options for children who are D/HH, from highly auditory, such as auditory-verbal, to highly visual, such as American Sign Language.	Standard clinical practice.			
2)a.ii.3.	The likelihood of a child gaining high benefit in the areas of speech perception, speech production, and spoken language increases when more emphasis is placed on listening and spoken language in the child's home and educational setting.	7 8 12 17 19 20 22 23 31 38 47 48	3 3 5 1 3 3 4 3 1 3 3 3	B B C B B B B B A B B B	EF/EV EF EF EF EF EF EV EF EF/EV EF EF/EV EF

2)a.ii.4.	High performance in children who use a cochlear implant has been linked to full-time use of the cochlear implant in home and school environments.	14 33	4 3	B B	EV EF/EV
2)a.ii.5.	Individuals who use cochlear implants can experience success in using multiple languages.	3 4 18 34 45	3 3 3 4 3	B B C B B	EF EF EF EF EF
3)a.	The amount and quality of language used by parents/caregivers of children who use cochlear implants has a strong influence on these children's linguistic development.	11 35 36 40 47	3 3 3 3 3	B B B B B	EF/EV EF EF EF/EV EF
4)a.	Materials targeting music perception and appreciation should be implemented with individuals who wish to improve music-perception abilities with their cochlear implant.	25 39	1 1	B B	EF/EV EF/EV
5)a.	The progress of individuals with special needs should be measured by criteria that are unique to them and that reflect the goals of the family.	27 29 49	4 3 4	B B B	EV E EV
6)a.	Considerations for activities of daily life and safety should be	2	3	B	EF/EV

	made for all individuals who use a cochlear implant. These other needs may include vocational considerations, social support, telephone use, vibrotactile alarms, and alerting devices.	5 46	3 4	B B	EF/EV EF/EV
7)a.	Bilateral stimulation should be considered for all individuals who use a cochlear implant, if not otherwise contraindicated.	9 10 13 16 26 30 32 37 41 42	3 3 3 3 4 3 1 1 3 1	B B B B B B A A B A	EF EF EF EF/EV EF EF/EV EF EF EF EF

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11. BILLING

The American Academy of Audiology recommends consulting your institution, reimbursement advisor, legal counsel, and/or payor representative to ensure compliance with local, state, and national guidelines and regulations regarding billing and coding for cochlear implant-related goods and services.

12. COMPLETE REFERENCE LIST

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