

# American Cochlear Implant Alliance Task Force Guidelines for Determining Cochlear Implant Candidacy in Children

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This article summarizes the available evidence on pediatric cochlear implantation to provide current guidelines for clinical protocols and candidacy recommendations in the United States. Candidacy determination involves specification of audiologic and medical criteria per guidelines of the Food and Drug Administration. However, recommendations for a cochlear implant evaluation also should maintain flexibility and consider a child's skill progression (i.e., month-for-month progress in speech, language, and auditory development) and quality of life with appropriately fit hearing aids. Moreover, evidence supports medical and clinical decisions based on other factors, including (a) ear-specific performance, which affords inclusion of children with asymmetric hearing loss and single-sided deafness as implant candidates; (b) ear-specific residual hearing, which influences surgical technique and device selection to optimize hearing; and (c) early intervention to minimize negative long-term effects on communication and quality of life related to delayed identification of implant candidacy, later age at implantation, and/or limited commitment to an audiologic rehabilitation program. These evidence-based guidelines for current clinical protocols in determining pediatric cochlear implant candidacy encourage a team-based approach focused on the whole child and the family system.

**Key words:** Candidacy, Children, Cochlear implants, Interdisciplinary.

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## PURPOSE

This document aims to provide professionals and consumers with current, evidence-based criteria for determining cochlear implant (CI) candidacy for the pediatric population. Evidence-based practice involves integration of external evidence from systematic scientific research, internal evidence from clinical expertise, and individualized evidence from fully informed patients' unique values, preferences, and goals (Sackett et al. 1996; Culbertson & Jones 2005; Dang & Dearholt 2018).

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The strength of scientific research follows levels of evidence, with the strongest recommendations coming from systematic reviews, meta-analyses, and randomized controlled trials, and the lowest recommendations emerging from expert opinion (see Appendix A, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>). Clinical expertise of the task force supplemented research evidence in developing these guidelines.

Pediatric CI candidacy is a rapidly changing and evolving process due to new research and technological advancements. Some candidacy recommendations have gained approval from country-specific entities (e.g., Australian Therapeutic Goods Administration, Belgian Federal Government, British CI Group, Danish National Board of Health, European CE Marking, US Food and Drug Administration [FDA]), whereas others reflect guidelines from individual CI companies or evidence-based practice before official change in approved guidelines. Most guidelines worldwide agree on pediatric implantation for profound bilateral hearing loss (HL), but differences arise relative to age at implantation, level of residual hearing, speech recognition, or auditory status of the contralateral ear (National Institute for Health and Clinical Excellence 2009; British CI Group 2017; and the Belgian Federal Government, described in Bruijnzeel et al. 2017). Still, protocols for candidacy determination for children vary greatly across CI centers. This document intends to mirror contemporary evidence-based practices in pediatric CI candidacy to provide professionals and consumers guidelines for current clinical protocols, individualized patient decisions, and support for insurance and peer-to-peer review discussions. This document fills the need for separate CI candidacy guidelines for the pediatric population (Messersmith et al. 2019) with the intent for regular updates based on research evidence and clinical expertise every 18 to 24 months.

## BACKGROUND

The United States FDA approved the first multichannel CI as medically safe for use in children with bilateral profound sensorineural HL in 1990. Early research showed children who received an implant at a younger age outperformed children with similar degrees of HL using hearing aids in sound detection and auditory perception skills (Tobey 1994; Fryauf-Bertschy et al. 1997; Snik et al. 1997; Nikolopoulos et al. 1999; Kirk et al. 2000). Certain factors contribute to age at implantation, including the advent, acceptance, and implementation of early hearing detection and intervention programs, subsequent earlier initial hearing aid fitting (Cupples et al. 2018; Yoshinaga-Itano et al. 2018), plus research consistently supporting the positive influence of earlier implantation on speech perception (Ching et al. 2013, 2018; Dettman et al. 2021) and spoken language (Geers

& Nicholas 2013; Percy-Smith et al. 2013; Tobey et al. 2013; Dettman et al. 2021, 2016b; Ching et al. 2017; Yoshinaga-Itano et al. 2018). The combination of these factors lead to FDA approval of CIs in children with profound HL ( $\geq 9$  or 12 mo, depending on manufacturer) or severe to profound HL ( $\geq 25$  mo). Recently, the FDA approved implantation for children ( $\geq 5$  years) with single-sided deafness (SSD) (FDA, Reference Note 1).

The FDA lowered the age at implantation over the past 30 years, but pediatric CI candidacy guidelines could benefit from further expansion based on current research. Twenty years elapsed since the age-based criterion decreased from 12 to 9 mo. This delay in FDA approval occurred even though numerous studies published in that time frame supported significantly improved outcomes and adequate safety before age 12 mo (Waltzman & Roland 2005; Roland et al. 2009; Houston & Miyamoto 2010; Vlastarakos et al. 2010; Colletti et al. 2012; Holman et al. 2013; Leigh et al. 2013; Dettman et al. 2016b; Miyamoto et al. 2017; Hoff et al. 2019; Karltorp et al. 2020; Teagle et al. 2019).

In addition, published research and clinical outcomes support implantation in children who do not meet FDA-supported guidelines. These “off-label” applications yield successful treatment of children with younger chronologic age ( $< 9$  or 12 mo), more residual hearing (i.e., severe to profound HL younger than 25 mo, low-frequency residual hearing), asymmetric hearing (i.e., appropriate auditory technology for each ear when hearing thresholds differ between ears), and SSD (i.e., typical hearing in one ear, severe to profound HL in the contralateral ear) (Dettman et al. 2007; Roland et al. 2009; Leigh et al. 2011; Colletti et al. 2012; Cadieux et al. 2013; Carlson et al. 2015; Friedmann et al. 2016, 2020). “Off-label” applications of CI technology may not match current FDA criteria, but they do not violate licensure or certification regulations. Clinicians can go beyond FDA-approved criteria to support nontraditional CI candidacy based on medical appropriateness, as evidenced by systematic research and clinical experience, to benefit individual patients (see Off-Label Considerations).

In addition to considering research evidence, shifts in pediatric CI candidacy should consider recommendations of the Joint Committee on Infant Hearing. Multiple statements of the Joint Committee on Infant Hearing (2007, 2013, 2019) focus on issues important to early identification, intervention, and ongoing care of infants and children with HL. The medical team and interventionists should have expertise managing infants and children with HL. To emphasize the importance of earlier fitting of auditory technology and early intervention, the most recent position statement advocates hearing screening by 1 mo, identification of HL by 3 mo, and enrollment in early intervention by 6 mo (i.e., 1-3-6 benchmarks for management of pediatric HL) (Table 1). However, the 2019 Joint Committee on Infant Hearing position statement encourages early hearing detection and intervention

programs to strive to meet 1-2-3 benchmarks: Screening by 1 mo, identification by 2 mo, and enrollment in intervention by 3 mo.

Younger ages at hearing aid fitting afford the opportunity to evaluate progress with hearing aids—or lack thereof—resulting in referrals to CI centers for candidacy evaluation within the first year of life. Many children complete the CI candidacy evaluation before the FDA-labeled minimum age for implantation (Carlson et al. 2018). Barriers to early implantation include delays in insurance approval, presence of residual hearing or medical comorbidities, family indecision, and geographical location (Armstrong et al. 2013; Fitzpatrick et al. 2015). This disparity in age at CI evaluation and the FDA-approved implantation age may not be in the best interest of young children with significant degrees of HL.

### CI CANDIDACY CONSIDERATIONS

The question arises as to when to refer a pediatric patient for CI candidacy evaluation, especially because referral criteria vary by device manufacturer and child age. CI candidacy extends beyond audiometric criteria to include speech recognition and functional assessment. Insufficient benefit from appropriately fit amplification (i.e., lack of month-for-month progress in attaining speech, language, or auditory developmental milestones) and/or poorer quality of life also factor into candidacy decisions. Several instruments evaluate quality of life in children as young as 4 years through self-report or parent proxy, but most measures focus on generic aspects of life satisfaction (Starfield et al. 1993; Ravens-Sieberer & Bullinger 2000; Varni et al. 2002, 1999; Riley et al. 2004) rather than HL-specific well-being (Archbold et al. 2008; Patrick et al. 2011; Umansky et al. 2011; Hoffman et al. 2019) (see Appendix B, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>). Thus, assessing functional outcomes based on parent and clinician feedback on a child’s auditory awareness, auditory responsiveness, and progress in acquiring language skills should become fundamental considerations for implant candidacy.

Figure 1 offers guidance for when clinicians should refer a child for a CI evaluation. These recommendations mimic momentum in adult implantation to streamline referrals for candidacy evaluation to include patients with unaided pure-tone average (mean of thresholds at 500, 1000, and 2000 Hz)  $\geq 60$  dB HL and aided monosyllabic word scores  $< 60\%$  correct in the ear to be implanted (Zwolan et al. 2020). When applied retrospectively to a large sample of adult implant candidates, these 60/60 screening guidelines yielded a 96% sensitivity rate (i.e., candidates met both word recognition and threshold criteria), a 65% specificity rate (i.e., noncandidates did not meet the 60/60 criteria), and a 76% positive predictive value (i.e., probability of meeting both traditional CI candidacy and the 60/60 guidelines). Based on the work of international clinical researchers,

**TABLE 1. Early hearing detection and intervention benchmarks for management of infants who are deaf or hard of hearing**

Early Hearing Detection and Intervention Benchmark	Stipulation	Current Guidelines (Joint Committee on Infant Hearing 2019)	Recommended Guidelines (Joint Committee on Infant Hearing 2019)
Hearing screening	(all infants)	By 1 mo chronologic age	By 1 mo chronologic age
Comprehensive audiologic and medical evaluation	Referral on hearing screening	By 3 mo chronologic age	By 2 mo chronologic age
Amplification fitting	Confirmed diagnosis as deaf or hard of hearing	Within 1 mo of identification	Within 1 mo of identification
Enrollment in appropriate therapeutic intervention	Confirmed diagnosis as deaf or hard of hearing	By 6 mo chronologic age	By 3 mo chronologic age

we recommend a 50/70+ guideline for referral to pediatric CI candidacy (Fig. 1). That is, clinicians should refer pediatric patients for evaluation if they meet any of the following criteria: appropriately selected word recognition scores  $<50\%$  correct (Dettman et al. 2004; Bittencourt et al. 2012); unaided pure-tone thresholds  $>70$  dB HL (Davidson 2006; Fitzpatrick et al. 2009; Leigh et al. 2011, 2016; Bittencourt et al. 2012; Leal et al. 2016); or poor functional performance, limited progress in language or auditory development, or poor quality of life (Mondain et al. 2002; Lazaridis et al. 2010; Vickers et al. 2016).

In summary, clinicians should consider audiometric criteria, speech perception, and functional outcomes when referring a child for a CI candidacy evaluation. If the CI team determines the child is a good candidate, they can proceed with implantation. If not, the team can continue to monitor the child's progress to ensure provision of opportunities to maximize communication.

### The CI Team

Several factors play a role when identifying a pediatric CI candidate, including the onset and duration of HL, duration and consistency of hearing aid use, interactive communication among family members, access to postimplant therapy, and an educational setting that supports the development of formal communication methods. HL that results in candidacy for pediatric implantation might occur at birth or at any time thereafter. Continued monitoring of hearing status and outcomes from amplification is essential to provide the child the best (re)habilitation. This point is particularly cogent for genetic and acquired causes of HL, which can result in progressive losses that may require a shift in auditory technology (i.e., transitioning from hearing aids to CIs) (Fitzpatrick et al. 2015; Zwolan & Sorokin 2016). These decisions occur with input from parents and professionals involved in the child's care based on a holistic approach. Clinicians should think beyond rigid guidelines of hearing aid versus CI candidacy to embrace auditory technology as a continuum to allow a child to access necessary auditory information.

The CI team includes an interdisciplinary array of professionals, each of whom contributes information necessary to assess the appropriateness of a CI for a particular child with HL (Fig. 2). These professionals may include but are not limited to a physician, audiologist, speech-language pathologist, teacher of the deaf, early intervention specialist in children who are Deaf or Hard of Hearing, and counselor/psychologist/social worker (Bathgate et al. 2013; Martin & Raine 2013; Moeller et al. 2013; Athalye et al. 2015; Madell & Flexer 2019). The National Deaf Children's Society and the British CI Group recommend a team of at least seven different professionals, with the possibility of more professional involvement based on the child's unique situation (e.g., ophthalmologist, cardiologist) (Archbold et al. 2015). The caretaker(s) of the child are essential members of the CI team (Athalye et al. 2015). The CI team should aim for timely, coordinated services among team members to maximize the chance that children with significant HL can reach their individual potential (Martin & Raine 2013; Athalye et al. 2015). The rest of this document details the pediatric CI candidacy process.

### Demographics/Lifestyle

Audiometric and medical criteria provide guidance for when to discuss pediatric implantation, but the CI team also should take a holistic approach considering the family's lifestyle, goals, and expectations for the child (Moeller 2000; Moeller et al. 2013; Dettman et al. 2016b). Nonaudiologic factors such as the child and family's quality of life, availability of resources, history of family involvement, assurance of consistent device use during all waking hours, and realistic expectations afford a well-rounded perspective of a child's prognosis for CI outcomes (Moeller 2000; Nikolopoulos et al. 2004; O'Brien et al. 2010; Park et al. 2019a; Wiseman et al. 2021).

First, a child's success with a CI depends on the parent/guardian's available resources for the child. For example, higher socioeconomic status can affect a child's age at implantation, speech, language, and auditory-based outcomes (Kirkham et al. 2009;

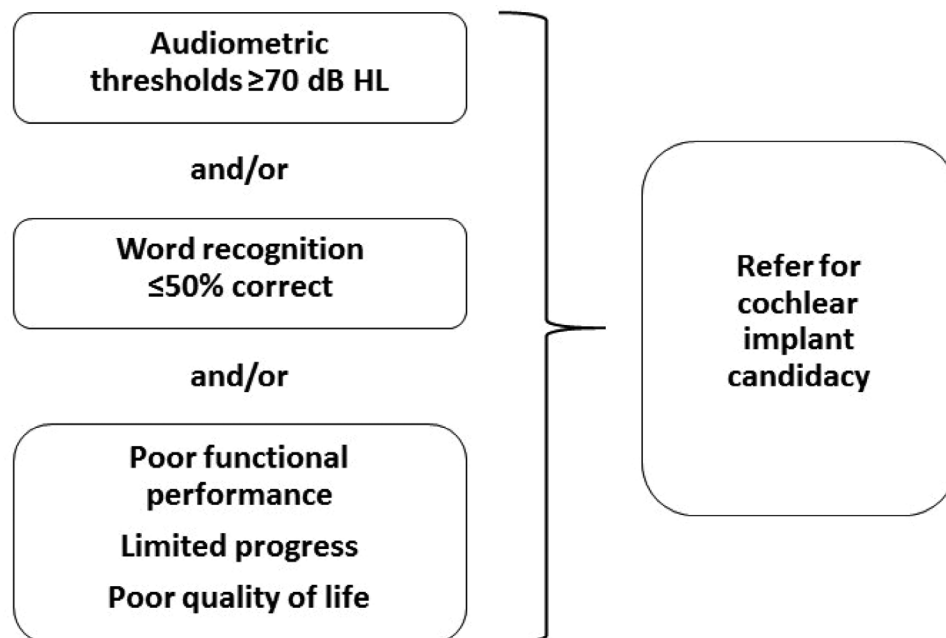


Fig. 1. Schematic for determination of CI candidacy. CI indicates cochlear implant.

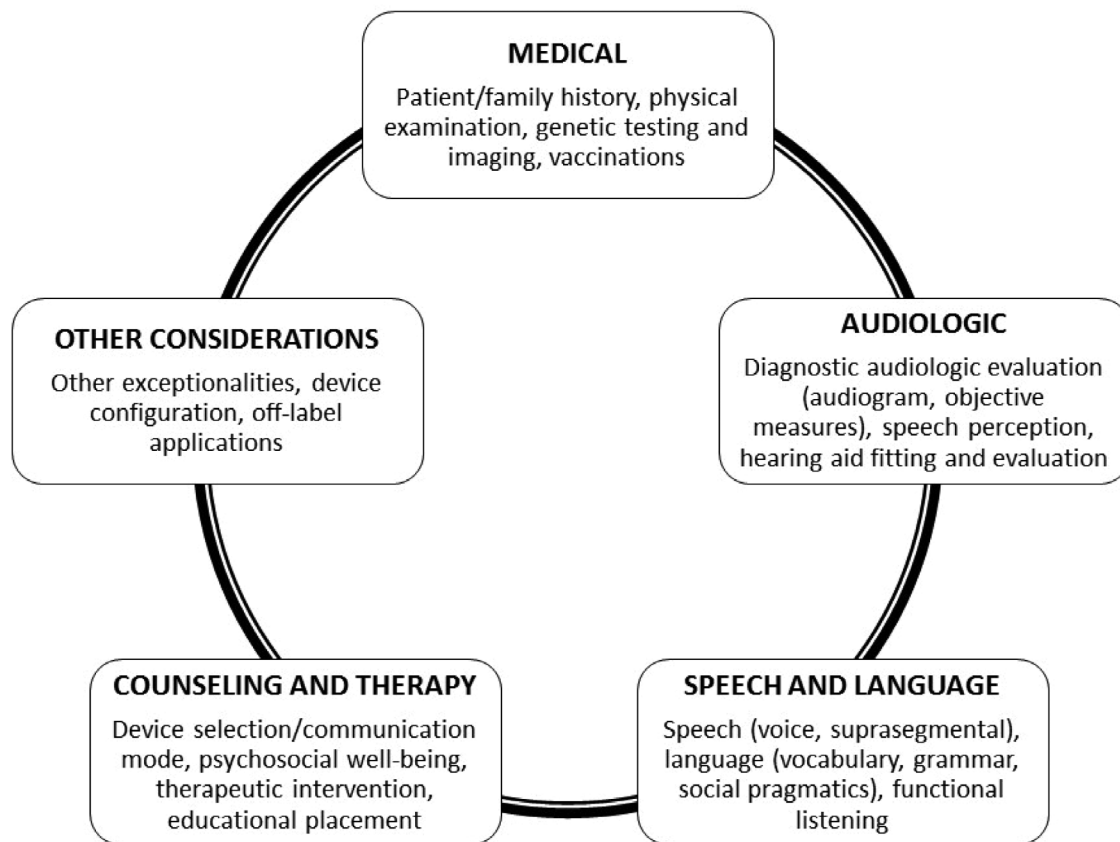


Fig. 2. Professionals associated with a multidisciplinary team to determine pediatric CI candidacy. CI indicates cochlear implant.

Niparko et al. 2010; Jeddi et al. 2012; Wu et al. 2015; Dettman et al. 2016a; Sharma et al. 2017). In addition, access to a support system (e.g., connection with other families with children with CIs, support groups) influences outcomes such that families with stronger support systems better navigate their child's hearing healthcare and have lower parental stress (Kluwin & Stewart 2000; Zaidman-Zait et al. 2016; Haddad et al. 2019; Ravi & Gunjawate 2020). A family's financial and support resources do not negate the decision to implant, but they might highlight the need for additional support and resources from professionals.

Subjective validation questionnaires can identify areas of strength and areas of concern to guide counseling and (re)habilitation for the child and family. For example, clinicians can use questionnaires to assess condition-specific quality of life (Archbold et al. 2002, 2008; Hoffman et al. 2019) and family-related factors such as family stress levels (Friedrich et al. 1983; Meadow-Orlans 1990; Abidin 1995; Quittner et al. 2010, 1990), self-efficacy (Desjardin 2003; Guimond et al. 2008), and family involvement and support (Dunst et al. 1984; Moeller 2000; Desjardin 2003) (see Appendix B, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>).

Second, child and family commitment are crucial to not only preimplantation evaluation and surgery, but also postimplantation (re)habilitation. The CI team should examine adherence to scheduled appointments and clinical recommendations because family involvement significantly contributes to early language skills in children with HL (Moeller 2000). Clinicians also should consider proximity of the patient to a qualified (re)habilitation provider because greater geographical distance to the

clinic could reduce participation (Lai et al. 2014; Sharma et al. 2017). Sharma et al. (2017) explored teletherapy for speech and language services for patients who live farther from the clinical facility—a more feasible option with broader implementation of remote appointments during the coronavirus disease 2019 pandemic (Dimer et al. 2020; Tohidast et al. 2020).

Third, the CI team should reflect on the child's hearing aid retention and daily device use preimplant. The Outcomes of Children with HL study found children wearing their devices at least 10 hr per day learn language faster than children with less daily device use (Tomblin et al. 2015). Recent evidence supports the link between mean daily CI use and early auditory skills (Wiseman et al., 2021), speech recognition (Fryauf-Bertschy et al. 1997; Spencer et al. 2004; Wie et al. 2007; Easwar et al. 2018), and language abilities (Park et al. 2019a; Busch et al. 2020; Gagnon et al. 2020). The literature lacks a daily dose recommendation for pediatric implant users, although Park et al. (2019a) report better receptive and expressive language in children wearing their devices at least 80% of age-appropriate "hearing hours" (accounting for differences in sleep patterns by age). The positive effect of consistent use of auditory technology on communication outcomes persists regardless of device type. However, clinicians should acknowledge some children may resist wearing their hearing aid consistently because they do not perceive benefit from it, and this may not have a direct correspondence with consistent use of a CI.

#### **Audiologic Evaluation**

**Hearing History** • An accurate, comprehensive hearing health history underlies not only diagnosis, but also prognosis relative

to progression of HL, appropriateness of implantation, expectations for postimplant development, and counseling. Key components of a hearing health history include onset of HL, duration of profound HL, duration of hearing aid use (including current hearing aid use or lack thereof), and etiology of HL (Wolfe 2018). Poorer postoperative outcomes in children coincide with longer duration of deafness (Fryauf-Bertschy et al. 1997; Dowell et al. 2002; Vincenti et al. 2014), inconsistent hearing aid use (Teagle & Eskridge 2010), presence of syndromic or genetic etiology (Eze et al. 2013; Busi et al. 2015; Cejas et al. 2015), perinatal problems (e.g., cytomegalovirus, kernicterus, hypoxia) (Philippon et al. 2010; Kang et al. 2016), and atypical cochlear anatomy—especially narrow internal auditory canals and common cavity malformations (Busi et al. 2015; Kang et al. 2016).

**Diagnostic Audiologic Evaluation** • The audiologic evaluation provides valuable information regarding a child's unaided hearing capability, but should not serve as the sole determining factor when considering candidacy. Assessment of residual hearing in the ear under consideration and the contralateral ear (should hearing sensitivity differ between ears) affords information important for device and electrode selection as well as possible bimodal hearing solutions (see Off-Label Considerations).

Diagnostic hearing assessments should include age-appropriate measures necessary to characterize HL. Objective electrophysiological measures using frequency-specific stimuli (i.e., tone burst auditory brainstem response [ABR] or auditory steady state response) can provide estimates of type and degree of HL with completion of both air and bone conduction testing. These results facilitate hearing aid fitting at an early age (Baldwin & Watkin 2013; Hang et al. 2015; Leigh et al. 2019). A strong correlation exists between click ABR and tone burst/auditory steady state response thresholds and subsequent behavioral hearing thresholds from 1000 to 4000 Hz (Johnson & Brown 2005; McCreery et al. 2015). However, ABR thresholds can overestimate the best pure-tone threshold by more than 20 dB at some frequencies, justifying the need to obtain a behavioral audiogram (Picton et al. 2005; Baldwin & Watkin 2013; McCreery et al. 2015; Leigh et al. 2019). Even when a child has no response on diagnostic ABR testing, clinicians should seek confirmation of hearing thresholds with behavioral testing (Hang et al. 2015).

Other objective measures such as tympanometry should be completed at each visit to rule out middle ear dysfunction (e.g., otitis media), which can delay the implantation process without proactive management (Hang et al. 2015). Clinicians also should test acoustic reflexes and otoacoustic emissions as a cross-check for degree of HL (Jerger & Hayes 1976) and diagnosis of auditory neuropathy spectrum disorder (ANSD) (Berlin et al. 2010).

Evaluations also should include the following behavioral measures: parental questionnaires about auditory skills (e.g., LittlEARS, Auditory Skills Checklist), ear-specific unaided air and bone conduction threshold testing to determine hearing levels and to cross-check electrophysiological results, and speech recognition abilities, if possible (see Speech Recognition Testing). Ideally, audiologists with specific experience working with children will conduct the behavioral testing in a CI evaluation. Clinicians should be aware of the importance of obtaining ear-specific information required for selection of device configuration (e.g., ear selection for implantation, consideration of bimodal fitting; Bruce et al. 2014; Davidson et al. 2019) and documentation for insurance authorization (see Other considerations).

**Speech Recognition Testing** • Use of a uniform test battery for children with HL facilitates continuity of care, assists in clinical decision-making (e.g., transition from hearing aids to CIs or addition of remote microphone technology), and allows clinicians and researchers to define benchmarks for an aggregate clinical population—as evidenced by the Minimum Speech Test Battery for adults (Luxford 2001; Minimum-Speech-Test-Battery 2011; Spahr et al. 2012; Holder et al. 2018; Prentiss et al. 2020).

The Pediatric Minimum Speech Test Battery (PMSTB) by Uhler et al. (2017) includes a hierarchical organization of perceptual tasks ranging from prelexical instruments (e.g., parental questionnaires and speech discrimination testing) to lexically-based word and sentence tests administered in quiet and/or noise (Peterson & Lehiste 1962; Bench et al. 1979; Jerger & Jerger 1984; Moog & Geers 1990; Kirk et al. 1997; Etymotic Research 2005; Spahr et al. 2014) (see Appendix C, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>). The PMSTB recommends tests, in quiet and in noise, as a function of chronologic age and language age (e.g., receptive and expressive language skills), and provides guidance for when to move from one test to another. Figure 4 displays a skeleton version of the PMSTB protocol (see Uhler et al. 2017 for the full battery). Ideally, each testing session should yield a measure of word recognition, sentence recognition in quiet, and sentence recognition in noise. However, clinicians must be realistic in assessing a child's ability to complete a variety of tasks within a single session and recognize the need to schedule a follow-up testing session.

**Functional Listening Assessment** • Although audiologic testing identifies which sounds a child hears, functional listening assessments determine what meaning the child derives from the detected sounds through a diverse range of skills (see Appendix D, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>). This testing can be performed by an audiologist, speech-language pathologist, early intervention specialist, or teacher of the deaf, but should be completed by a professional with experience in treating children with HL.

Functional listening assessments may include analysis of suprasegmental features (e.g., duration, intensity, pitch) which form the basis for rhythm, timing, and stress in language (Moog & Geers 1990; Moog et al. 1995; Zimmerman-Phillips et al. 2000; Stredler-Brown & Johnson 2004a, b; Wilkes & Children 2001; Ertmer 2003). These assessments also may examine the child's ability to hear distinctive features necessary to identify vowels and consonants (Ling 1976, 1989; Ertmer 2003, 2015; Meinzen-Derr et al. 2007; Walker 2009; Sindrey 2014) or identify speech sounds, words, or sentences (Moog & Geers 1990; Robbins et al. 1991; Moog et al. 1995; Zimmerman-Phillips et al. 2000; Wilkes & Children 2001; Ertmer 2003; Kuehn-Inacker et al. 2003; Ching & Hill 2007; Meinzen-Derr et al. 2007). Functional listening assessment may include how a child's listening changes with noise and distance to provide real-life examples of how a child truly performs with the current amplification in noisy environments such as classrooms, community locations, and home (Johnson & VonAlmen 1997).

**Hearing Aid Fitting and Evaluation** • Figure 3 summarizes clinical practice guidelines on pediatric amplification from the American Academy of Audiology (2013). These guidelines support use of prescriptive formulae with targets based on pediatric, not adult, hearing needs in programming hearing aids to optimize

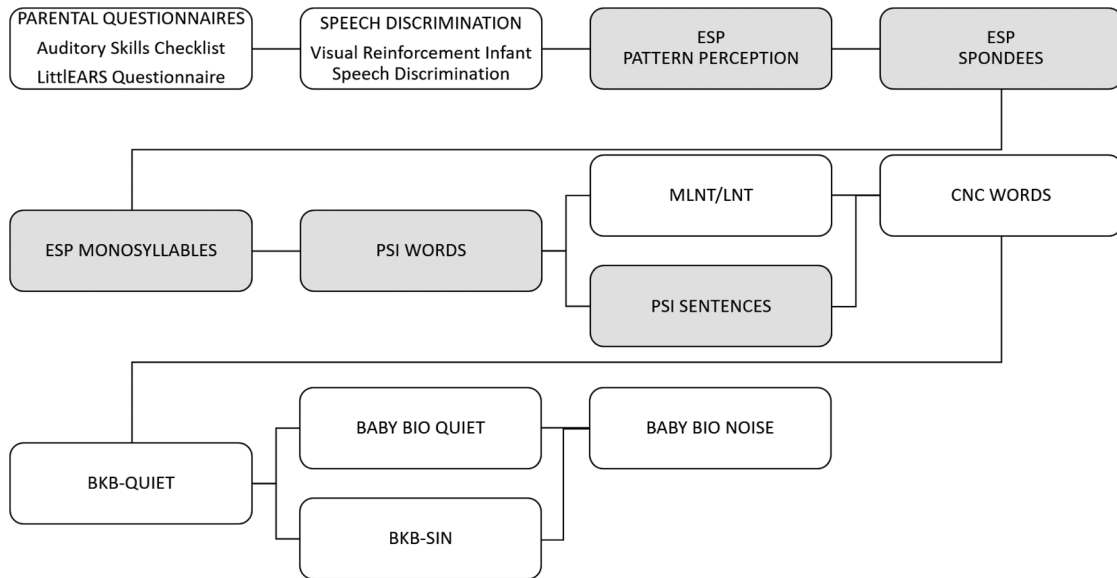


Fig. 3. Speech perception measures that comprise the Pediatric Minimum Speech Test Battery by Uhler et al. (2017). Gray boxes indicate closed-set measures. Baby Bio indicates Pediatric AzBio test; BKB-Quiet, Bamford-Kowal-Bench test in quiet; BKB-SIN, Bamford-Kowal-Bench Speech-in-Noise test; CNC, Consonant-Nucleus-Consonant test; ESP, Early Speech Perception test; LNT, Lexical Neighborhood test; MLNT, Multisyllabic Lexical Neighborhood Test; PSI, Pediatric Sentence Intelligibility test.

auditory access. Verification of hearing aid fittings—objective measures that ensure device settings afford maximum audibility across a wide frequency range at a comfortable level without over-amplification—should occur via real ear measurements or real ear to coupler difference measurements, which accommodate individual differences in ear canals based on anatomy, size, and/or chronologic age to ensure provision of adequate amplification. Validation of hearing aid fittings denotes subjective measures that quantify perceived cost and benefit or changes in quality of life relative to use of auditory technology. This typically involves aided testing, aided speech awareness and recognition testing in the best aided condition and in the ear to be implanted for older children, and parent/caregiver questionnaires for younger children. Aided testing should be completed after optimization of hearing aid fitting and confirmation of full-time device use.

However, aided testing should not be the sole source of validation nor used in isolation to make candidacy decisions.

Not all implant candidates fit a typical audiometric profile. Children who do not make the expected progress with hearing aids to achieve auditory, speech, or language milestones, despite full-time use and participation in intervention, should be referred for evaluation.

**Medical Evaluation/Status**

**Patient and Family Medical History** • The medical professional evaluating CI candidacy for a child should consider both family and individual history. Family history affords a detailed assessment of the presence of premature, severe to profound, syndromic or nonsyndromic HL. A child’s individual history specifies perinatal history (e.g., cytomegalovirus, prematurity,

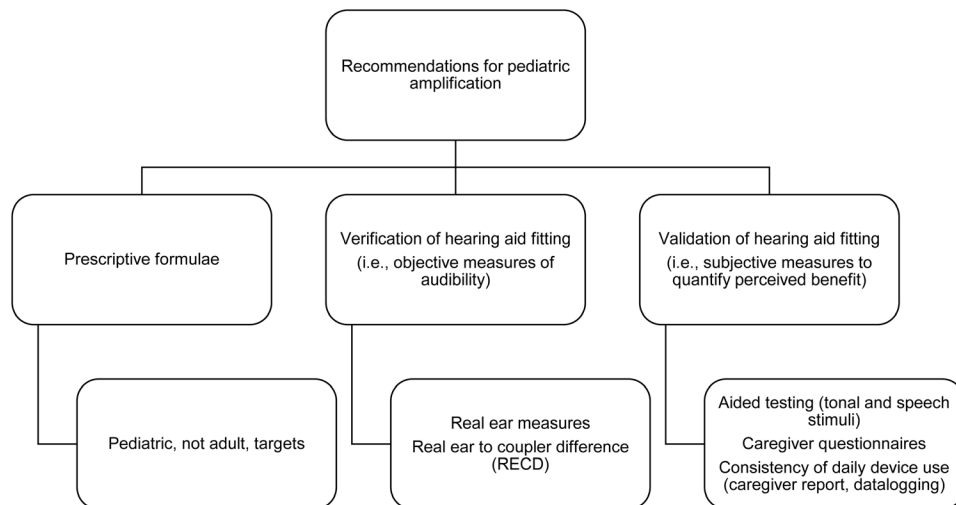


Fig. 4. Summary of guidelines for pediatric amplification. This figure is adapted from the American Academy of Audiology (2013) practice guideline on pediatric amplification, focusing on prescriptive formulae, verification, and validation of hearing aid fittings.

kernicterus, hypoxia) and otologic history (e.g., noise exposure, ototoxic medications, chronic ear disease, ear surgery, trauma). A child's medical, demographic, and otologic history contribute to determination and prognosis of candidacy, but few absolute contraindications exist in pediatric implantation.

**Physical Examination** • Consideration of medical candidacy for CI surgery may require input from several disciplines (e.g., otolaryngologist, neurotologist, neuroradiologist, genetic counselor, CI team). Physical evaluation of a pediatric implant candidate should include otologic and neurotologic examination, otomicroscopy, and assessment of syndromic features to a cranial nerve examination, and assessment of neurologic findings.

**Additional Assessments: Genetic Testing and Imaging** • Genetic testing is recommended for all children identified with HL. For imaging, both high resolution computed tomography and magnetic resonance imaging provide important information about anatomy, which influences the candidacy decision. Appropriate imaging allows the surgeon to ascertain the presence of cochleae and cochlear nerves, cochlear malformations and caliber of cochlear nerves, and the presence of other anatomic factors that might affect surgical planning. Thus, when selecting an imaging technique, physicians should use their discretion while also assessing cost, benefit, and risk on a case-by-case basis (Adunka et al. 2007; Vincenti et al. 2014; Digge et al. 2016).

**Vaccinations** • The Centers for Disease Control recommend pediatric CI candidates receive two of the standard childhood vaccines and one additional vaccination at age 2 years to protect against meningitis (see Appendix E, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>; details about recommended vaccinations are available at <https://www.cdc.gov/vaccines/vpd/mening/public/dis-cochlear-faq-gen.html>).

### Speech and Language Evaluation

A determination of pediatric candidacy for implantation should include frequent speech and language assessments to determine if a child is making a month's progress in the same amount of time. Implant candidates typically demonstrate deficits in speech and/or spoken language due to insufficient access through appropriately fit and consistently worn hearing aids. Children with SSD, progressive, steeply sloping, or later onset HL (i.e., after developing spoken language) may have age-appropriate speech and language, so the CI team should consider signs of skill regression, the risk for future delays in speech and language, cognitive or listening fatigue, and the added time needed for processing auditory information through an impaired auditory system (Tharpe & Gustafson 2015).

Speech and language testing ought to be completed by a therapist with experience managing children with HL, particularly those with CIs, to afford comprehensive discussion of expectations and appropriate setting of goals (Tharpe & Gustafson 2015). When the goal for the child is age-appropriate speech and spoken language, then tests standardized on children without HL are appropriate to use. Specific assessment batteries may vary by age, but should include speech, language, and functional listening assessments (see Appendices D and F, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>).

**Speech Assessment** • Speech production evaluations encompass the quality and quantity of speech sounds produced (see Appendix F, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>). For preverbal children, this may include

analysis of suprasegmental features (duration, intensity, and pitch) and vowels, consonants, and syllable combinations produced by the child (Goldman & Fristoe 2015; Fudala & Stegall 2017). Speech assessments advance from production of isolated sounds to measures at the word level and conversational intelligibility (i.e., how well the child is understood). For all children, clinicians can evaluate fluency, resonance, and voice quality of productions.

Children with severe to profound HL without CIs often have predictable speech patterns due to unclear hearing of phonemes and poor auditory feedback for their own productions. These speech differences include slower speaking rate, higher occurrence of prolonged vowels, hypernasality, centralized vowels, and restricted consonant repertoires (e.g., more labial and stop consonants) (Blamey et al. 2001; Warner-Czyz & Davis 2008; Baudonck et al. 2015; Sebastian et al. 2015; Jafari et al. 2016).

**Language Assessment** • Children with HL may demonstrate deficits in spoken language, which could reflect inadequate amplification, inappropriately fit hearing aids, decreased hearing sensitivity, inadequate daily device use of hearing aids, or additional diagnoses (Berger 2011; Hewitt et al. 2012; Madell et al. 2019). Pediatric CI candidates show delayed spoken language milestones (e.g., later babbling onset, restricted receptive, and expressive vocabulary) compared with age-matched peers with typical hearing via both informal criterion-based measures and formal standardized measures (Niparko et al. 2010; Penna et al. 2014, 2015). In addition, children with HL show differences in grammar, social pragmatic skills, and figurative language on standardized measures (see Appendix F, Supplemental Digital Content 1, <http://links.lww.com/EANDH/A884>).

### Counseling and Therapy

**Parent Alignment With Goals and Clinical Techniques** • The strength of the family-practitioner relationship largely determines how well caregivers understand and follow through with team recommendations. Informed consent of the family is critical; parent engagement serves as a primary predictor of outcomes in children enrolled in early intervention (Moeller 2000). The parents' answers to two foundational questions drives much of the team's decision-making and counseling with the family:

1. What are your goals for your child?
2. What are your goals in seeking CIs for your child?

**Device Selection and Communication Mode** • During candidacy evaluation, professionals should discuss the range of available options for CI devices. Device selection includes not only the manufacturer, but also the speech processors, external accessories, and connectivity of the implant system.

Audiologists and speech-language pathologists also should discuss the spectrum of communication options ranging from reliance on visual language to spoken language (e.g., American Sign Language, Bilingual-Bicultural, Listening and Spoken Language) and, when possible, introduce the family to deaf mentors or families successfully using various communication modalities (Robbins 2009; Tharpe & Gustafson 2015; Humphries et al. 2020). This discussion may span multiple sessions from multiple professionals on the CI team to ensure parental understanding and informed choice of communication options. The CI team should highly value parent choice. Parents also should be aware that the child's communication modality may change as a function of the child's progress and preferred

mode of communication. Also, depending on the child's age relative to critical windows for auditory and language development, switching to a CI does not guarantee fluent use of spoken language, but that does not negate other potential benefits such as increased environmental sound awareness and general well-being. Regardless of communication modality, counseling should incorporate discussions with the family about use of appropriate amplification during all waking hours and realistic expectations of how a CI may support the child.

Helping families understand the degree to which each option emphasizes and reinforces auditory input will help guide discussions on realistic expectations and motivation for a CI (Robbins 2009; Tharpe & Gustafson 2015). Although each method of communication has at least some children who perform at high levels, the likelihood of achieving strong spoken language skills increases substantially in more auditory-based programs (Robbins 2009; Geers et al. 2017).

**Psychosocial Well-Being** • CI candidacy evaluations benefit from inclusion of a social worker, clinical psychologist, counselor and/or therapist to assess the child's cognitive function and general development and evaluate the family's support, commitment, and motivation (Bathgate et al. 2013; Madell & Flexer 2019). These professionals can evaluate the family's commitment to not only undergoing surgery, but also engaging in the intense follow-up appointments and aural (re)habilitation protocol required to maximize outcomes postimplantation (Heman-Ackah et al. 2012).

Acknowledgment and management of potential barriers to family participation also underlie a child's success after implantation. A social worker could help facilitate accommodations such as arrangement of transportation or daycare, assistance with paperwork, or coordination of appointments. A psychologist's evaluation of a child's level of functioning and mental well-being can direct family-based discussions on realistic expectations (Bathgate et al. 2013). First, nonverbal intelligence consistently predicts communication outcomes in children with CIs (Geers et al. 2002, 2003; Phillips et al. 2014; Park et al. 2015), though these relationships may be confounded by language skills. Second, assessment of psychological factors (e.g., emotions, internalizing and externalizing behaviors) may benefit a candidacy evaluation due to higher rates of aggression, anxiety, and attention deficits in children with HL (Theunissen et al. 2014; Saki et al. 2019). Third, examination of social factors (e.g., peer relationships, family circumstances, and cultural issues) provides a framework for intervention (Bathgate et al. 2013). Family socioeconomic characteristics may not affect the decision to implant (Brkic et al. 2010), but children from families with lower socioeconomic status, maternal education, and caregiver support tend to have poorer outcomes postimplantation (Niparko et al. 2010; Geers & Sedey 2011; Ching & Dillon 2013) so the family may need additional support to minimize barriers.

The team should consider and respect each family's home language and culture (e.g., multilingualism, hearing and deaf community involvement) because these issues may influence decisions, including the type of therapeutic intervention to pursue for a child. Use of a language other than English in the home is never a reason to exclude a child from CI candidacy. Finally, engagement with a professional trained in counseling or therapy can connect families with appropriate public and private resources (e.g., Department of Developmental Disabilities,

community and online support groups) to reduce stress in all areas, including financial planning.

**Therapeutic Intervention** • Speech, language, and listening therapy forms an essential component of (re)habilitation pre- and postimplantation. Selection of the therapist should emphasize the skill set (i.e., expertise in working with children who are deaf or hard of hearing), not the degree designation of the professional providing the services (e.g., speech-language pathologist, audiologist) (Tharpe & Gustafson 2015). In addition, practitioners have different exposure in different communication modalities. For example, a certified auditory-verbal practitioner can provide services promoting listening and spoken language; other clinicians have experience guiding families with sign language in combination with oral language. It is important to find a professional who can provide services in a specific child's preferred mode of communication.

**Therapy Before Cochlear Implantation** • By receiving speech and language services with appropriately fit hearing devices before implantation, the CI team can establish whether the child is making adequate progress with their hearing aids or has potential to perform better with a CI. Most children with HL have some unaided or aided access to sound and speech; thus, therapy should begin soon after identification of HL and receipt of hearing devices. Therapy while waiting for a CI allows development of early auditory, functional listening, speech, and language skills to the best of the child's ability. Involving caregivers in therapy sessions prepares them to serve as the child's primary teacher for ongoing communication skill development and advocacy skills.

**Educational Placement** • Depending on the child's age, professionals should discuss realistic expectations for educational environments. This involves assessing the child's educational needs in their own environment, at home, and at school; available services in the child's school district (e.g., auditory technology, sign language interpreter, teacher of the deaf); and guiding families through the process to obtain such services to maximize future use of the CI at home and at school.

## Other Considerations

**Presence of Other Exceptionalities** • The presence of secondary disabilities other than HL occurs in one-third of children with HL (Birman et al. 2012; Roush & Wilson 2013; Archbold et al. 2015; Cupples et al. 2018). The most common comorbid conditions include intellectual disabilities, learning disabilities, and developmental delay. Although children with HL and other exceptionalities often have lower mean performance levels, slower rate of skill acquisition, and greater variability in communication outcomes compared with those without other exceptionalities, additional conditions should not automatically preclude cochlear implantation.

Due to the unpredictability and variability in communication outcomes in children with HL who have additional disabilities, professionals and parents may need to define progress differently relative to speech, language, and hearing milestones. Understanding the family's reasons, expectations, and goals for their child's future with a CI is critical. Clinicians may need to examine nontraditional factors such as the child's use of amplification or changes in the child's affect and social engagement while using auditory technology (Clark et al. 2007; Meinzen-Derr et al. 2010; Hayward et al. 2016).



Children with ANSD, a heterogeneous group, constitute ~10% of children with HL (Ching et al. 2013). Children with ANSD often exhibit inconsistent response to sound, which can make it difficult to determine adequacy of hearing aid fitting preimplantation and CI fitting postactivation (Berlin et al. 2010; Teagle et al. 2010). Children should be evaluated as potential CI candidates based on their speech perception scores, parent questionnaires, and therapist reports even if audiometric threshold results do not meet typical candidacy guidelines (Rance & Barker 2008). ANSD often presents with disproportionately poor speech recognition abilities—particularly in noise—relative to degree of HL (Rance & Barker 2008; Berlin et al. 2010).

**Device Configuration** • Professionals and families must decide on the configuration of auditory technology (i.e., unilateral CI, bilateral CIs, or bimodal with a CI on one side and a hearing aid on the contralateral ear). Bilateral CIs or bimodal configurations take advantage of binaural benefits such as improved localization and better speech perception in noise (Litovsky 2011; Schafer et al. 2011; Litovsky & Gordon 2016). Bimodal configurations capitalize on residual hearing in the contralateral ear, which contributes to improved speech perception in noise, better music perception, and possibly better speech production (especially suprasegmental quality) compared with other device configurations (Nitttrouer et al. 2012; Wenrich et al. 2017; Davidson et al. 2019). However, binaural configurations may not be suitable for all children with HL, including those with absent/abnormal cochleovestibular anatomy, additional exceptionalities (e.g., to reduce sensory stimulation), or SSD. In cases of unilateral or bimodal configurations, audiologists should regularly monitor the auditory status of the nonimplanted ear to determine the potential need for a second implant.

**Insurance Coverage** • FDA labeling and Medicaid coverage for CIs defines candidates more conservatively than current practices throughout the United States (FDA 2000, 2019, 2020a, b, c; Medicaid, 2021; Services 2005). Centers for Medicare and Medicaid Services last updated their Decision Memo for cochlear implantation in 2005 (<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=134>), and deemed CIs a covered benefit for Medicaid recipients up to age 20 years (<https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>). Because each state administers its own Medicaid programs, differences exist in determination of CI candidacy requirements. Thus, children with the same degree of HL and speech perception scores may meet eligibility requirements for an implant through some state Medicaid or private insurance programs, but not others. This position paper aims to reduce such candidate inconsistency. If consistent candidacy guidelines (e.g., 50/70+ protocol) were adopted by the FDA and Centers for Medicare and Medicaid Services, children across the country would have equal opportunities to receive a CI if they were deemed a candidate by their implant team.

**Off-Label Considerations** • While standard FDA CI candidacy approvals exist, clinicians often use cochlear implantation for children outside these guidelines (i.e., younger age at implantation, better speech perception, more residual hearing) when they feel the advantages significantly outweigh disadvantages—also known as “off-label” implantation. More than three-fourths of surgeons in the United States currently implant off-label (Carlson et al. 2018). The FDA has released statements regarding responsible use of off-label

devices in certain circumstances (see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices>).

**Age at Implantation** • The FDA approved age of implantation at 9 and 12 mo; however, hundreds of children have received devices at earlier ages. For example, if a child sustained profound HL due to meningitis and imaging provides evidence of fibrosis and ossification, the child should receive a CI as soon as possible because a completely ossified cochlea might prohibit full insertion of the electrode array, likely resulting in a poor outcome (Rotteveel et al. 2005; Roland et al. 2008; Nichani et al. 2011; Black et al. 2014; Liu et al. 2015). In addition, many centers routinely implant infants (6 to 9 mo) if they feel confident in the behavioral and physiologic testing results. The literature supports the efficacy and safety of this approach, with no higher risk of implantation in a child at 6 versus 12 mo of age (Roland et al. 2009; Heman-Ackah et al. 2012; Friedmann et al. 2020). Moreover, children implanted before 12 mo exhibit better speech, language, and auditory outcomes than those implanted after 12 mo, supporting the benefit the brain receives from meaningful auditory information at a younger age (Waltzman & Roland 2005; Vlastarakos et al. 2010; Leigh et al. 2013; Nicholas & Geers 2013; Mitchell et al. 2019; Dettman et al. 2021).

**Speech Recognition Skills** • Speech recognition abilities represent another boundary pushed by off-label implantation. Current FDA guidelines base pediatric candidacy on speech perception skills (when measured). The criteria indicate sentence comprehension, but do not specify the measure, stimulus intensity, or listening condition (quiet or noise). Clinicians increasingly rely on word versus sentence recognition to reduce confounding effects of cognitive factors (e.g., working memory, top-down processing) on speech perception skills.

**Presence of Residual Hearing** • Current practice also challenges the traditional implantation criteria of severe to profound HL. Low-frequency residual hearing in both the implanted and nonimplanted ear has been used as a valuable tool to predict speech perception outcomes in pediatric implant recipients (Chioffi & Hyppolito 2017). Preservation of residual hearing is possible (Skarzyński et al. 2002; James et al. 2005; Rajan et al. 2018; Park et al. 2019b) and can lead to better speech perception in noise (Dettman et al. 2004; Mok et al. 2010; Wolfe et al. 2017; Park et al. 2019b), appreciation of music (Gfeller et al. 2006; Yüksel et al. 2019), psychoacoustics (i.e., pitch perception) (Yüksel et al. 2019), and improved sound quality (James et al. 2005). The presence of residual hearing should not be a deterrent to implantation, but should influence surgical technique, electrode choice, and consideration of acoustic plus electric hearing in the implanted ear.

**Electroacoustic Stimulation** • Electroacoustic stimulation (EAS) devices represent an emerging technology for children with no more than a moderate HL in the low frequencies and a severe HL in the high frequencies. EAS devices include an acoustic component in the low frequencies and an electric CI component in the high frequencies. At present, all three FDA-approved manufacturers have EAS options with ear-level processors, but no EAS options have received FDA approval for use in children. Recent outcomes with hearing preservation, electrode technology, and surgical techniques during pediatric implantation detail superior results, especially with hearing in noise and

music appreciation (Dettman et al. 2004; Gfeller et al. 2006; Mok et al. 2010; Wolfe et al. 2017; Park et al. 2019b; Yüksel et al. 2019). However, low-frequency residual hearing in a child has a higher risk of degradation over time than in adults with stable low frequency hearing. Therefore, surgeons should consider a longer electrode array to accommodate conversion from EAS to electrical stimulation only over time. The audiologist, in tandem, can fit the acoustic component of a sound processor with the presence of residual and usable low-frequency hearing.

**Single-Sided Deafness** • Many children with SSD struggle despite hearing aid or osseointegrated amplification. Children with unilateral HL have increased risk for speech, language, social, and academic difficulties (e.g., 10 times more likely to repeat a grade than peers with typical hearing) (Bess & Tharpe 1988; Kenworthy et al. 1990; Tharpe 2008; Lieu et al. 2012; Anne et al. 2017; Mahomva et al. 2021). Children with SSD receiving CIs show positive outcomes similar to adults (e.g., speech recognition in noise, localization, and confidence) compared with other technology options (e.g., contralateral routing of sound hearing aid, bone-anchored hearing aid) (Vlastarakos et al. 2014; Friedmann et al. 2016; Greaver et al. 2017; Polonenko et al. 2017; Sladen et al. 2017a, b; Zeitler et al. 2019), and the FDA recently approved implantation for children ( $\geq 5$  years) with SSD (FDA, Reference Note 1) (Greaver et al. 2017; Zeitler et al. 2019). Implantation for SSD has gained momentum in young children, especially in patients with conditions that put the better-hearing ear at risk (e.g., cytomegalovirus) (Friedmann et al. 2016). Magnetic resonance imaging forms a crucial component in the consideration to proceed with implantation in children with SSD to determine the status of the cochlear nerve and the cochlea (Friedmann et al. 2016). Nearly half of children with SSD have cochlear nerve deficiency or no cochlear nerve on the affected side (Buchman et al. 2006). The presence of inner ear malformations (e.g., common cavity, enlarged vestibular aqueduct) in the poorer-hearing ear increases the urgency to implant to combat negative cascading effects associated with longer durations of deafness. Thus, the implant team should discuss with parents and caregivers the option of implanting a child with SSD at a young age to reap the benefits of this technology.

### SUMMARY/GUIDELINES FOR IDENTIFICATION OF CI CANDIDATES

1. Numerous factors influence pediatric CI candidacy. This document specifies audiologic (i.e., severe to profound sensorineural HL) and medical criteria. However, an unsuccessful hearing aid user who does not achieve month-for-month progress in speech, language or hearing; who has poor functional listening due to HL; and/or who has reduced quality of life should be considered for referral.
2. Evidence suggests ear-specific consideration in cases of asymmetric HL.
3. Cochlear implantation should not be a last resort. Earlier implantation leads to better outcomes in children.
4. Residual hearing in both the implanted and nonimplanted ear can lead to better speech understanding in noise, music appreciation, and sound quality. The presence of residual hearing should not be a deterrent to implantation, but should influence surgical technique, electrode choice, and consideration of acoustic plus electric hearing in the implanted ear.

5. Implementation of and commitment to an aural (re) habilitation program is necessary and required.
6. FDA and Medicaid guidelines do not necessarily align with best clinical practice. The CI team should use evidence-based practice to guide clinical decision-making and should not rely on payer policies to determine candidacy. Rather, consideration of coverage should be included in counseling to supplement clinical recommendations.
7. When an individual is determined to be a CI candidate, consideration should also be given to the nonimplanted ear to allow for appropriate recommendations for hearing technology for optimization of overall hearing and use of compatible accessories.
8. There are no inappropriate referrals for a CI. If a patient does not meet candidacy criteria, the evaluation will provide an opportunity for counseling and a baseline for monitoring progression. Early intervention in the form of implantation or improved amplification is paramount, but missing an opportunity to improve a patient's auditory access and quality of life can be extremely detrimental to their long-term hearing health.
9. While medical, demographic, and otologic history deserve consideration in determining candidacy, they are rarely absolute contraindications.

### CONCLUSIONS

Professionals working with children who have HL should closely monitor the development of communication skills with hearing aids to determine if and when they should refer a child with HL for a comprehensive evaluation by the CI team. Research findings and clinical expertise often precede changes in FDA, necessitating attention to ever-changing standards of evidence-based practice for pediatric cochlear implantation. Finally, adoption of a team-based approach will facilitate optimization of candidacy decisions and communication outcomes for each individual child.

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