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Pediatric CI 3-60 Guideline: When to Refer Children for a Cochlear Implant Candidacy Evaluation

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Objectives: Despite the success of cochlear implants (CIs) in providing access to sound for children with significant hearing loss, only approximately 50% of children with severe-to-profound sensorineural hearing loss in the United States receive this treatment option. One contributing factor to this underutilization is uncertainty surrounding the appropriate time to refer for a CI candidacy evaluation. The purpose of this study was to analyze hearing evaluations captured from children with known hearing losses at three progressive, major CI centers to develop updated guidelines for referral to pediatric CI evaluation.

Design: Retrospective data were collected at the three participating centers. The most recent hearing evaluation for 1179 children younger than 14 yrs of age with known hearing losses was captured during a 2-yr period (January 2020–December 2021). Hearing evaluations included standard hearing evaluations to monitor hearing loss of all degrees, as well as CI candidacy evaluations. The following data points were collected: hearing device configuration, age, referral recommendation for CI evaluation, CI recommendation, audiogram thresholds (four-frequency pure-tone average, 4FPTA), unaided and aided word recognition scores (WRS), and unaided and aided speech intelligibility index (SII).

Results: Of the 348 children (531 ears) referred for CI candidacy evaluation, a CI was recommended for 84% of them. Nearly half of the ears recommended for implantation attained a 4FPTA better than 90 dB HL with 96% of them having a 4FPTA of 60 dB HL or greater. When evaluating aided SII (252 ears), 94% of the ears recommended for implantation had an SII ≤0.60. For those with aided WRS available (99 ears), 96% had WRS scores ≤60% correct. Only 23% of children (22% of ears) undergoing CI evaluation could complete aided open-set speech recognition testing, highlighting the need to rely on objective measures such as aided SII to determine CI candidacy in children. Overall, 94% of ears met at least one of the following criteria: unaided 4FPTA thresholds ≥60 dB HL, aided SII ≤0.60, or WRS ≤60% correct. Note that 36% of children recommended to receive a CI did not meet U.S. Food and Drug Administration criteria (i.e., asymmetric hearing loss, better than severe-to-profound hearing loss, WRS >30%, or younger than the age limit).

Conclusions: Pediatric CI candidacy considerations require a holistic approach that incorporates evidence-informed decision-making to accommodate age-related limitations in behavioral testing. These data-driven recommendations support a three-faceted referral guideline for CI evaluation, called CI 3-60: unaided 4FPTA ≥60 dB HL, aided SII ≤0.60, or WRS ≤60% correct (when available) in the ear to be implanted. This pediatric referral recommendation is consistent with current adult CI candidacy evaluation referral guidelines but adds consideration of aided SII to compensate for pediatric limitations in completing open-set speech recognition tasks. While not all children referred for an evaluation ultimately undergo implantation, these guidelines (a) capture a high proportion who would benefit more from a CI than hearing aids, and (b) frame CIs as part of a continuum of hearing technology for children who are deaf or hard of hearing.

Key words: Cochlear implant, Pediatric candidacy, Referral guidelines.

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INTRODUCTION

Despite the success of cochlear implants (CIs) in providing access to sound for children with significant hearing loss, only approximately 50% of children with severe-to-profound sensorineural hearing loss in the United States receive this treatment option (Bradham & Jones 2008; Sorkin & Buchman 2016). The low utilization rate persists in the United States even after the expansion of criteria for approval by the U.S. Food and Drug Administration (FDA) and diverges from estimates of uptake around the world. For example, more than 90% of eligible pediatric patients receive a CI in the United Kingdom, Australia, and Sweden, and 65% of eligible children receive a CI in Germany (Sorkin & Buchman 2016). Factors affecting the rate of pediatric CI uptake are complex and multifaceted, and include socioeconomic status (e.g., insurance type) (Wiley & Meinzen-Derr 2009; Lester et al. 2011; Armstrong et al. 2013; Yang et al. 2018), race (Liu et al. 2021; Omar et al. 2022), geographical location (Bush et al. 2014; Fujiwara et al. 2022), and referral patterns (Chundu et al. 2013). While hearing health recommendations cannot change some patient-related variables (e.g., socioeconomic status, race, geographical location), other factors have the potential for malleability (e.g., referral patterns, referring provider's knowledge of current pediatric CI recommendations). The current article uses clinical data to generate evidence-based recommendations to change referral patterns and, subsequently, referring provider's identification of potential CI candidates beyond FDA-approved indications.

In the United States, the FDA has approved cochlear implantation in children with bilateral severe-to-profound hearing loss over the age of 7 mo and in children with single-sided deafness over the age of 5 yrs. As CI technology continues to develop, children are benefiting from cochlear implantation outside of FDA guidelines, known as "off-label implantation." Examples of off-label implantation include chronologically younger children (i.e., <7 mo with bilateral hearing loss and <5 yrs for single-sided deafness), children with asymmetric hearing loss (Dettman et al. 2004; Leigh et al. 2011; Cadieux et al. 2013; Carlson et al. 2015), and children with better residual hearing (e.g., electric acoustic stimulation; less severe hearing levels) (Bruce et al. 2014; Leigh et al. 2016; Carlson et al. 2017; Rajan

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et al. 2018; Park et al. 2019; Holder et al. 2021). For example, research shows that children implanted before 9 mo achieve speech discrimination, language comprehension, and vocabulary skills on par with typical hearing peers and significantly better than children implanted at 12 mo of age or later (Colletti et al. 2012; Karltorp et al. 2020; Cottrell et al. 2024). Although research supports less stringent criteria for cochlear implantation, discrepancies between the FDA indications and evidence-based research findings can result in provider uncertainty regarding when to refer a child for a CI candidacy evaluation.

US FDA indications, clinical guidelines, research, and professional associations (e.g., American Academy of Otolaryngology-Head and Neck Surgery; American Cochlear Implant Alliance; American Speech-Language-Hearing Association) agree that bilateral CI reflects the standard of care for children with profound bilateral sensorineural hearing loss (Litovsky et al. 2006; Asp et al. 2012; Sarant et al. 2014; Guideline on Cochlear Implants 2019; Gifford 2020; Farrell 2021; American Cochlear Implant Alliance, n.d.), yet ambiguity arises for children with less severe and asymmetric hearing losses. Most recently, the American Cochlear Implant Alliance Task Force provided guidelines for when a child should be referred for a CI candidacy evaluation based on the integration of evidence from published scientific research and clinical expertise of the task force. The task force recommended that children be referred for a CI candidacy evaluation if they meet any of the following criteria: word recognition scores ≤50% correct, unaided pure-tone thresholds ≥70 dB HL, or limited progress in speech, language, or hearing development with appropriately fit and consistently worn hearing aids. Their guidelines also emphasize the importance of ear-specific consideration for candidacy evaluations and caution against using CI as an intervention of last resort. This document filled a major gap in the literature offering evidence-based guidelines to clinicians surrounding pediatric CI evaluations, but as the article highlights, regular updates to these recommendations are needed every 18 to 24 mo to keep up with technological updates and current research evidence. Warner-Czyz and Uhler (2023) further expanded the guidelines for pediatric CI candidacy evaluation by including measures of hearing aid verification based on newly published research (Park et al. 2022). The additions specified the inclusion of aided Speech Intelligibility Index (SII), the proportion of audible speech weighted by importance of the frequency region, ≤0.68 with appropriately fitted hearing aids (Wiseman et al. 2023) and root mean square error, the difference between the hearing aid output and the prescribed target output, >5 dB (Bagatto et al. 2023; McCreery et al. 2017).

While the American Cochlear Implant Alliance Task Force guideline reviewed key studies contributing to CI referral guidance (Dettman et al. 2004; Fitzpatrick et al. 2009; Leigh et al. 2011, 2016; Bittencourt et al. 2012; Leal et al. 2016), the literature lacks a large-scale assessment of children undergoing pediatric CI candidacy evaluation at leading centers to further inform referral guidelines. Zwolan et al. (2020) published the highly referenced "60/60" guideline for adults, which recommends that adults be referred for CI candidacy evaluation when their unaided pure-tone average (PTA) is ≥60 dB HL and unaided word recognition is <60% correct (Zwolan et al. 2020; Hunter & Tolisano 2021). Similar to 20/20 vision, the 60/60 guideline was intended to be memorable and easy to implement for referring clinicians—intentionally employing measures (i.e., PTA and unaided word recognition) routinely administered during hearing tests. A similar tool is needed for the pediatric population to improve referral patterns (Park et al. 2021), especially for children with more residual hearing and asymmetric hearing losses, which are considered off-label implantation cases. Off-label implantation is fairly routine in the CI space with 78% of surveyed neurotologists reporting completion of off-label implantation in 2018 (Carlson et al. 2018). Since off-label implantation is so common, clinicians cannot rely solely on labeled indications to guide best clinical practice.

The purpose of the present study was to provide specific guidance for referral for a CI candidacy evaluation based on data collected from three progressive, major CI centers. When considering which assessments to include as part of the criteria, priority was given to measures typically performed by referring clinicians with an existing evidence base in the literature. Three measures were chosen for inclusion: (1) Four-frequency pure-tone average (4FPTA): A PTA was included based on the study of Leigh et al. (2016), which showed that 75% of children with CIs have better word recognition than hearing aid users with unaided 3-frequency PTA of 60 dB HL or poorer. We added 4000 Hz to the average due to the importance of high-frequency audibility for speech and language development in children (Stelmachowicz et al. 2001, 2004, 2007; Pittman 2008; Walker 2023) as well as speech understanding (Eisenberg et al. 2000). (2) Aided SII: Aided SII was chosen for inclusion based on evidence of the correlation with speech recognition (Stiles et al. 2012) and language outcomes (Tomblin et al. 2015; Wiseman et al. 2023) in addition to its clinical availability in the hearing aid verification system already being employed for this patient population (Leal et al. 2016). (3) Aided word recognition scores (WRS): Aided WRS were included, given congruence with the adult population and inclusion in current FDA guidelines for CI candidacy (Carlson et al. 2015).

The aim of this study was to leverage multicenter hearing evaluation data to inform updated guidelines for referral of children to CI evaluation. Our hypothesis was that our guidelines would support more relaxed referral criteria (e.g., less severe levels of audiometric thresholds and better speech recognition scores than current FDA-labeled indications) for pediatric patients, and that these data-driven guidelines would align with recommendations for referral for CI candidacy evaluation set forth for the adult population.

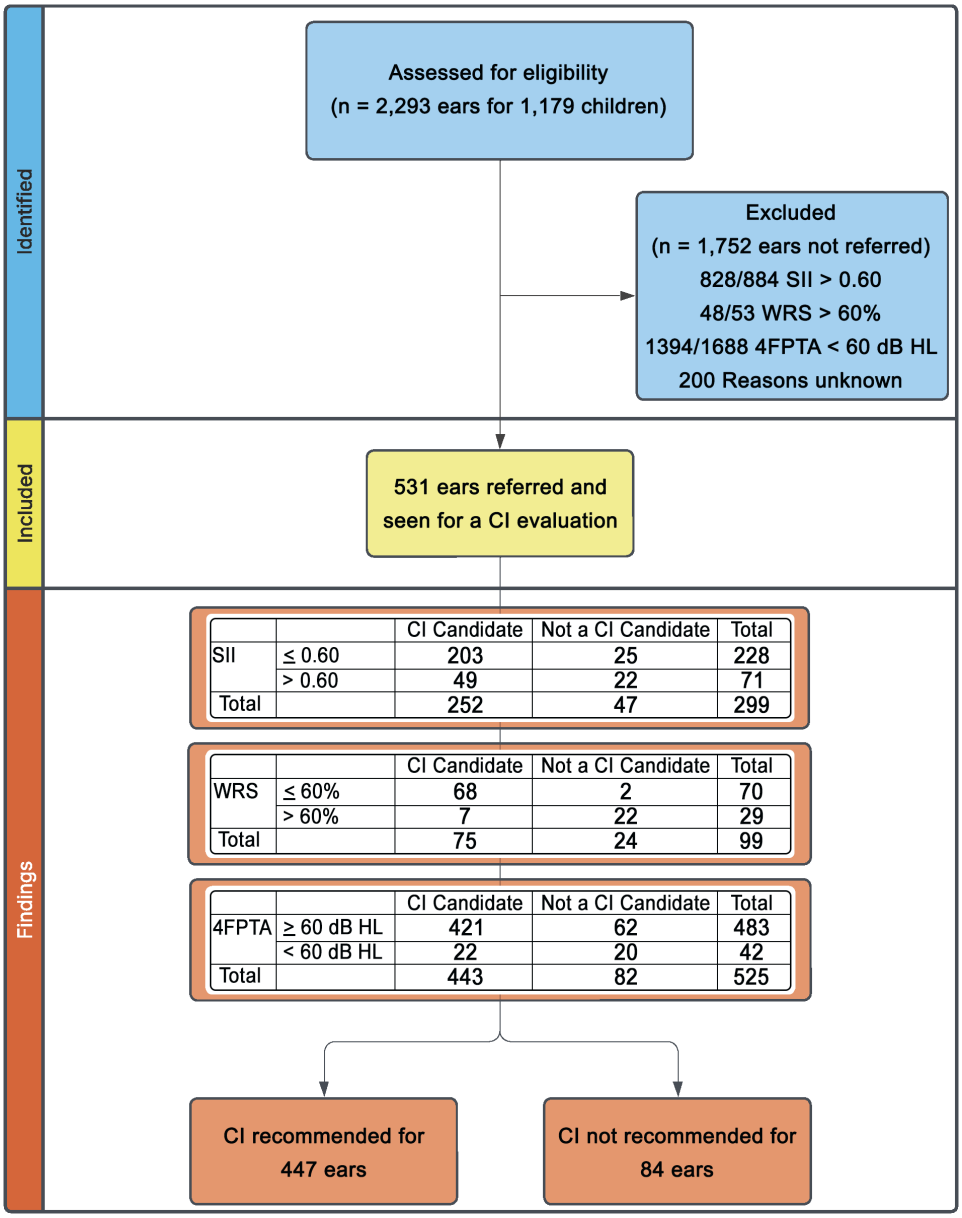
MATERIALS AND METHODS

Before data collection, institutional review board approval was obtained from all participating universities. Retrospective data were collected from medical charts at the three participating centers and stored in REDCap (Harris et al. 2009). Data from the most recent hearing evaluation for children younger than 14 yrs of age with known hearing losses were captured during a 2-yr period (January 2020–December 2021). These hearing evaluations included standard hearing evaluations to monitor hearing loss of all degrees, as well as CI candidacy evaluations. The following data points were collected: Hearing device configuration used at time of testing (i.e., traditional hearing aid, bone conduction hearing aid, bone-anchored hearing implant, typical hearing, unaided), age in years at time of hearing test, recommendation for referral for a CI candidacy evaluation; CI recommendation (i.e., if the patient was

referred and a CI candidacy evaluation was conducted, was a CI recommended?); audiogram (air conduction 125 to 8000 Hz; bone conduction 500 to 4000 Hz); unaided and aided word recognition (including material, presentation type, and presentation level); and unaided and aided SII as reported by the hearing aid verification system. WRS measures varied across participants, including both closed-set (i.e., Early Speech Perception test, NU-Chips, Word Intelligibility by Picture Identification test) and open-set measures (e.g., CID W-22, Consonant-Nucleus-Consonant test, Lexical Neighborhood Test, Multisyllabic Lexical Neighborhood Test, NU-6, Phonetically Balanced Kindergarten word list). Only open-set measures were included in the analysis. Participants most commonly completed the CNC (51%) or PBK (13%) speech recognition tests for aided WRS. The vast majority (95%) of aided WRS testing was completed at 60 dBA. We used these data to assess whether the subject would qualify for cochlear implantation under FDA criteria.

Subjects

A subject flow diagram can be found in Figure 1, and details for the patient pool can be found in Table 1. Hearing evaluations from 1179 pediatric patients were collected between January 1, 2020, and December 31, 2021. Each ear being evaluated was treated as a separate subject, for a total of 2293 subjects. Age at testing ranged from 4 mo to 13 yrs 11 mo. At the time of the assessment, most of the full sample used traditional hearing aids (64%), with a smaller proportion of ears having either typical hearing or unaided hearing (14% each), and <10% using a bone conduction hearing aid (6%) or bone-anchored device (2%).



		CI Candidate	Not a CI Candidate	Total
SII	≤ 0.60	203	25	228
	> 0.60	49	22	71
Total		252	47	299

		CI Candidate	Not a CI Candidate	Total
WRS	≤ 60%	68	2	70
	> 60%	7	22	29
Total		75	24	99

		CI Candidate	Not a CI Candidate	Total
4FPTA	≥ 60 dB HL	421	62	483
	< 60 dB HL	22	20	42
Total		443	82	525

Fig. 1. Flowchart of subject selection. The "Findings" section includes confusion matrices for each of the three referral criteria. 4FPTA indicates four-frequency pure-tone average; CI, cochlear implant; SII, speech intelligibility index; WRS, word recognition scores.

TABLE 1. Pediatric patient information

	Full Sample (n = 2293 ears)	Referred for Evaluation (n = 531 ears)	Recommended to Receive a CI (n = 447 Ears)
Age at hearing evaluation			
Mean; SD	7.6; 3.7	5.0; 3.9	4.7; 3.8
Range	0.3–13.9	0.3–13.7	0.3–13.7
Hearing device			
Hearing aid	1,473	422	361
Normal hearing	329	0	0
Unaided with HL	312	106	84
Bone conduction aid	141	3	1
Bone-anchored hearing implant	38	0	0
Unaided PTA (dB HL)			
Mean; SD	50.8; 31.3	90.0; 20.9	91.9; 19.5
Range	–2.5 to 125.0	28.8–125.0	28.8–125.0
N	2214	525	443
Unaided SII			
Mean; SD	33.8; 31.7	5.0; 11.0	3.8; 9.2
Range	0–100	0–68.0	0–59.0
N	1289	324	277
Aided SII			
Mean; SD	71.0; 22.0	46.0; 19.0	44.0; 19.0
Range	0–100	0–92.0	0–82.0
N	1185	299	252
Aided WRS (% words correct)			
Mean; SD	53.6; 31.2	40.0; 27.5	29.4; 20.8
Range	0–100	0–96.0	0–72.0
N	152	99	75

CI, cochlear implant; HL, hearing loss; PTA, pure-tone average; SII, speech intelligibility index; WRS, word recognition score.

Statistics

Estimates of the sensitivity and specificity of unaided 4FPTA, aided SII, and WRS of predicting CI candidacy (both individually and in two- and three-variable combinations) were calculated in RStudio (R Core Team 2021) using the pROC package (Robin et al. 2011). Sensitivity, or true positive rate, was calculated as (true positives)/(true positives + false negatives). Specificity, or true-negative rate, was defined as (true negatives)/(true negatives + false positives).

RESULTS

As shown in Table 1, 531 (23%) of the full sample received a referral for a CI candidacy evaluation. Of the ears referred for a CI candidacy evaluation, 447 (84%) received a recommendation to proceed with the CI process. Figures 2–4 illustrate the cumulative percentage of ears recommended for cochlear implantation with an unaided 4FPTA, aided SII, and WRS, respectively, across the range of scores. For example, in Figure 2, 3% of the CI candidates had an unaided 4FPTA ≥120 dB HL, 56% had an unaided 4FPTA ≥90 dB HL, and 96% had an unaided 4FPTA ≥60 dB HL. Similarly, Figure 3 shows that 19% of the CI candidates had an aided SII between 0 and 0.20, 56% between 0 and 0.40, and 94% between 0 and 0.60. Finally, Figure 4 shows cumulative percentages for aided WRS, which includes data from 75 ears (17% of the CI candidates). Sixty-two percent of WRS for the CI candidates were ≤30% correct (i.e., scores ranged from 0 to 30% correct) and 96% were ≤60% correct (i.e., scores ranged from 0 to 60% correct). At least 94% of ears recommended for cochlear implantation had a 4FPTA of ≥60 dB HL, an aided SII of ≤0.60, or a WRS of ≤60%. The high proportion of ears meeting at least one of these criteria and receiving a CI recommendation supports their use as reference values for a referral for CI evaluation.

Receiver operating characteristic (ROC) curves are shown in Figure 5, with the CI 3-60 reference values marked along their respective curves. Using a 4FPTA of ≥60 dB HL as a screening tool yielded a sensitivity of 95%, indicating most subjects referred for a CI evaluation who met this criterion were candidates for a CI. Specificity was 24%, meaning that only one-quarter of the subjects who were referred but not considered CI candidates had a 4FPTA better than 60 dB HL.

Aided SII was slightly less sensitive. An aided SII of 0.60 or lower yielded a sensitivity of 81%. The specificity was slightly higher than the 4FPTA, such that 47% of subjects referred for a CI candidacy evaluation who were not candidates had an aided SII ≤0.60.

Aided word recognition was highly predictive. Sensitivity of referral for subjects with aided WRS of 60% or poorer was 91% and specificity was 92%. Of note, only one-quarter of the subjects referred for CI evaluation could complete open-set aided word recognition.

If two or more metrics were required to meet the "60" criteria, specificity was very high for combinations that included WRS in both two-variable combinations (i.e., 92% for WRS + 4FPTA, 100% for WRS + aided SII) and the three-variable combination (100% for WRS + aided SII + 4FPTA). False positives were rare when WRS was 60% or poorer and almost nonexistent when another metric also met the 60 threshold. This was a tradeoff, however, as combining metrics typically resulted in poorer sensitivity. Sensitivity for WRS + aided SII was 54%, WRS + 4FPTA was 84%, 4PTA + aided SII was 74%, and WRS + aided SII + 4FPTA was 53%. It should also be noted that only

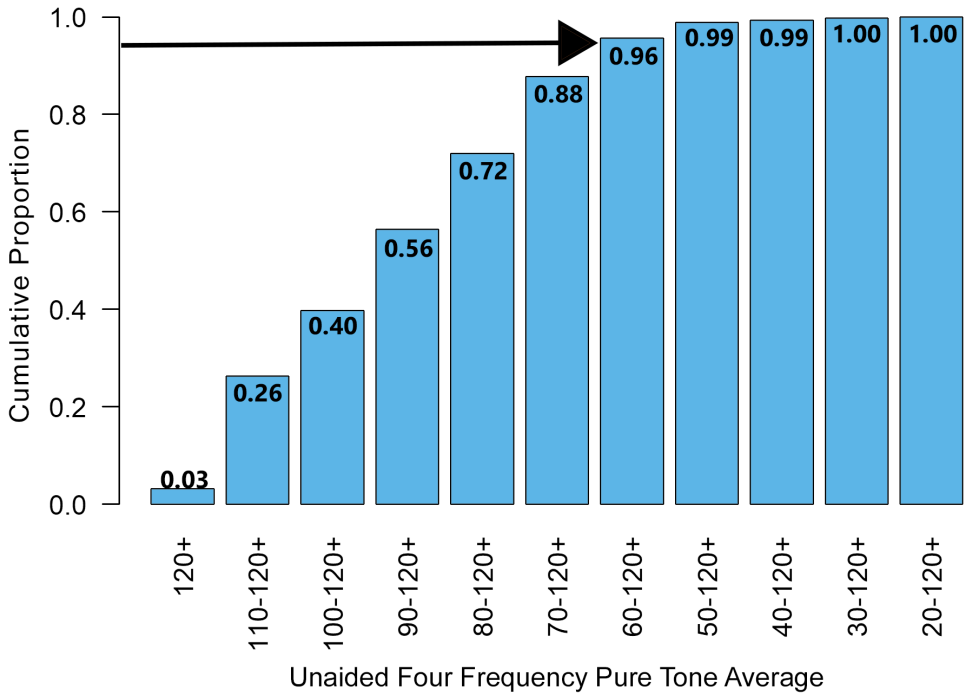


Fig. 2. Cumulative frequency graph displaying the proportion of CI candidates whose four-frequency PTA (500, 1000, 2000, and 4000 Hz) fell into the specified range. The horizontal arrow highlights the large proportion of CI candidates (96%) captured in the bin with a PTA of 60 dB HL or greater. CI indicates cochlear implant; PTA, pure-tone average.

slightly more than half (56%) of those referred had 4FPTA and aided SII available, 19% 4FPTA and WRS, and 16% had WRS + SII or all three measures available. These findings reflect the heterogeneity of children who are deaf or hard of hearing and support the importance of considering each metric individually rather than in combination.

A CI was recommended for 297 children (447 ears), which constituted 84% of ears referred for a CI evaluation. In contrast, only 64% of the ears recommended for implantation met FDA candidacy criteria, which are determined by chronological age, degree of hearing loss, and aided word recognition ability specific to each laterality classification.

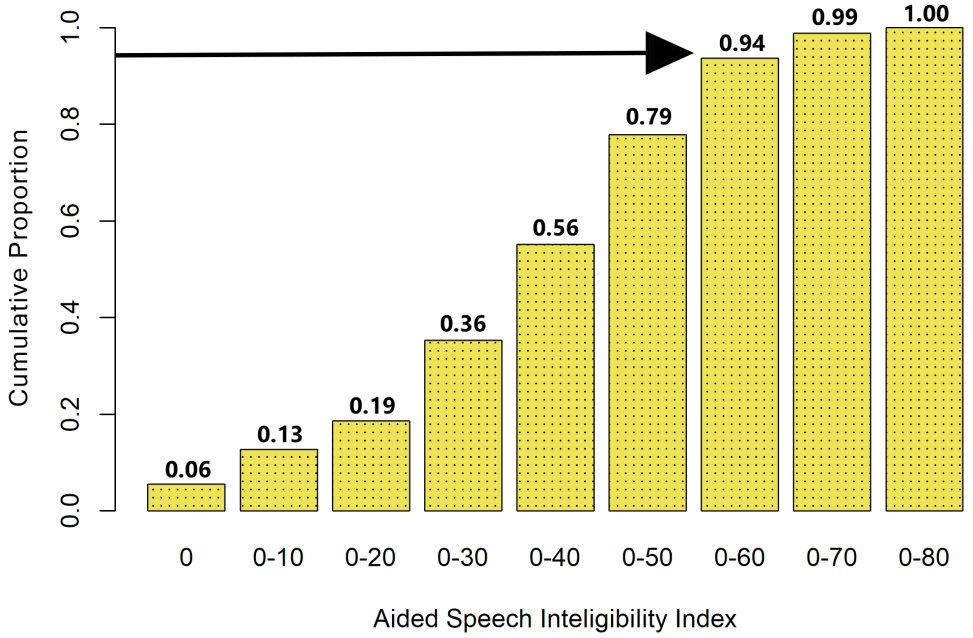


Fig. 3. Cumulative frequency graph displaying the proportion of CI candidates whose aided SII fell into the specified range. An SII ≤0.60 captured 94% of the CI candidates, as highlighted by the horizontal arrow. CI indicates cochlear implant; SII, speech intelligibility index.

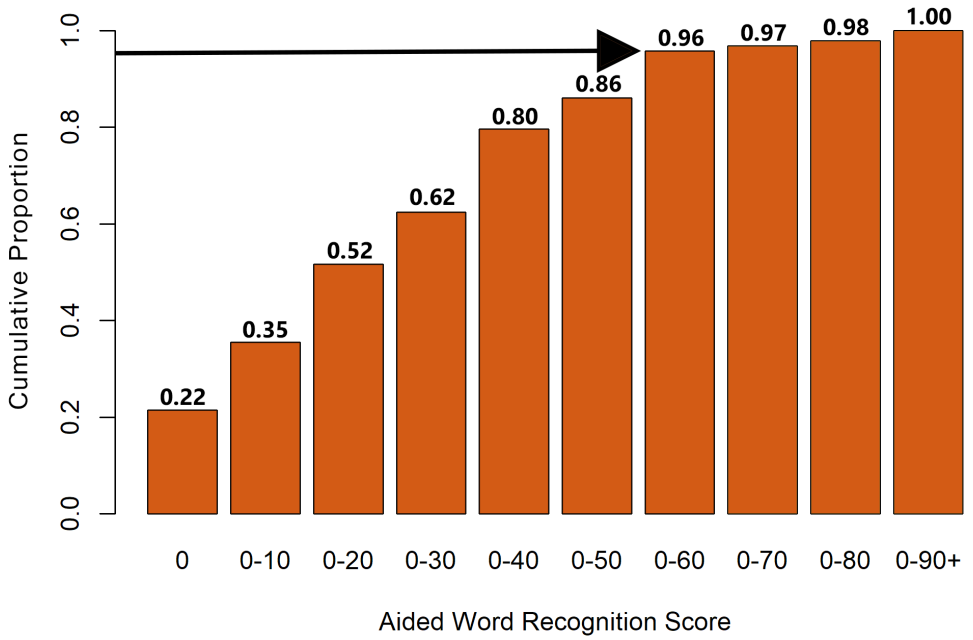


Fig. 4. Cumulative frequency graph displaying the proportion of CI candidates whose aided WRS fell into the specified range. As shown by the horizontal arrow, 96% of the CI candidates had an aided WRS ≤60%. CI indicates cochlear implant; WRS, word recognition score.

DISCUSSION

Hearing healthcare professionals in the United States frequently see children who are deaf or hard of hearing who may not benefit adequately from hearing aids but do not qualify for cochlear implantation based strictly on FDA-based criteria. In the United States, the discrepancy between FDA indications and best clinical practice guidelines per published research (Park et al. 2022; Warner-Czyz et al. 2022; Warner-Czyz & Uhler 2023) creates ambiguity as to when to refer a child for a CI candidacy evaluation. Although three-fourths of neurotologists in the United States perform off-label implantation (Carlson et al. 2018), other surgeons and CI centers adhere strictly to the FDA indications leading to under-referral for evaluation. The present study collated data from more than 2000 ears of children who are deaf or hard of hearing to determine evidence-based recommendations for referral for a CI evaluation. Sensitivity analyses support more relaxed guidelines for pediatric CI evaluation referrals, with the specific recommendations including unaided 4FPTA ≥60 dB HL, aided SII ≤0.60, or WRS ≤60% correct (when available) in the ear to be implanted.

The recommendation for a CI candidacy evaluation for patients with an unaided PTA ≥60 dB HL and unaided WRS ≤60% correct mirrors recommendations for adults (Zwolan et al. 2020; Hunter & Tolisano 2021). Hunter and Tolisano (2021) found using 60% correct on a word recognition task as the referral threshold had 83% sensitivity in correctly identifying CI candidates and 64% specificity in appropriately excluding non-CI candidates for adults. Zwolan et al. (2020) reported even higher sensitivity (96%), similar specificity (66%), and a false-positive rate of 34% when the referral guideline accommodated both unaided PTA and unaided word recognition in the better ear. Similarly, Leigh et al. (2016) used an evidence-based approach to pediatric CI referral guidelines by evaluating speech recognition outcomes in 142 children (4 to 16 yrs) diagnosed as deaf or hard of hearing. Results indicated a 75% chance of improvement in word recognition scores with a CI compared with a hearing aid for an equivalent PTA of 60 dB HL, suggesting pediatric CI users could attain speech recognition abilities like that of children with moderate hearing levels using hearing aids. Thus, Leigh et al.'s findings align with the PTA-based recommendations for referral for CI candidacy evaluation in adults by Hunter and Tolisano and Zwolan et al. as well as the results of this study.

The audiometric thresholds considered for evidence-based adult CI evaluation and candidacy (Zwolan et al. 2020; Hunter & Tolisano 2021) and pediatric CI evaluation and candidacy (Leigh et al. 2016) thus far specify a three-frequency PTA, which could miss children whose thresholds worsen at frequencies higher than 2000 Hz. Inclusion of 4000 Hz in the PTA reflects its importance for speech information, including /s/ and /z/ morpheme audibility, which underlies acquisition of plurals, possessives, and auxiliary verbs (Flexer 1999; Stelmachowicz et al. 2004; Pittman 2008; Walker 2023). Moreover, speech information available at 4000 Hz supports the acquisition of third person, questions, and past perfect verbs. Hearing aids often do not have adequate bandwidth to provide auditory access to high-frequency speech sounds, particularly for female speakers (Stelmachowicz et al. 2004). Inaccessibility of high-frequency information could lead to difficulties discriminating similarly sounding consonants that differ in their third formant (e.g., /n/ and /m/) or fourth formant values (e.g., /s/ and /sh/) (Anderson 2012). Reduced access to high-frequency sounds can also negatively affect a child's ability to monitor their own speech production, potentially resulting in poorer articulation and, subsequently, poorer speech intelligibility (Anderson 2012). Moreover, Pittman (2008) reported that children produced sentences with 5 to 6 dB lower intensity for frequencies greater than 2000 Hz compared with adult productions of the same stimuli. The combination of lower intensity of child productions

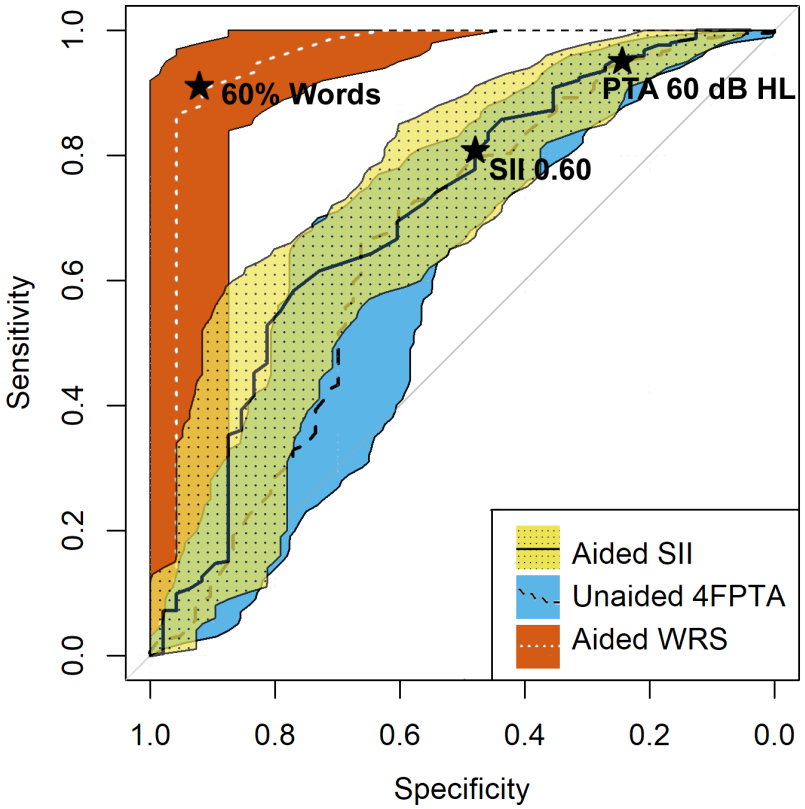


Fig. 5. Receiver operating characteristic curve illustrating the sensitivity and specificity of each referral variable on the y and x axes, respectively. The diagonal line indicates random classification. The stars indicate the sensitivity and specificity thresholds of each of the CI 3-60 variables. Shaded areas represent 95% confidence intervals. 4FPTA indicates four-frequency pure-tone average; PTA, pure-tone average; SII, speech intelligibility index; WRS, word recognition score.

and inaccessibility of high-frequency cues for speech, language, and hearing development could have a compounded adverse effect on peer social communication skills of children who are deaf or hard of hearing, which often corresponds to poorer quality of life in children who are deaf or hard of hearing (Dammeyer 2010; Theunissen et al. 2014; Haukedal et al. 2018; Zaidman-Zait & Most 2020; Aanondsen et al. 2023). Therefore, audiometric-based considerations for CI evaluation and candidacy should incorporate high-frequency information, like the 4FPTA, to capture the importance of that frequency region for speech, language, and hearing development. That being said, the 4FPTA yielded excellent sensitivity (95%) and poorer specificity (24%) for correctly identifying and rejecting children as CI candidates, respectively. The poorer specificity for 4FPTA likely resulted from children with lesser degrees of hearing loss getting referred for a CI evaluation only when they did not make progress with auditory development using appropriately fit hearing aids (e.g., children with auditory neuropathy spectrum disorder). In the current study sample, a four-frequency PTA captured nine more ears for referral for a CI candidacy evaluation than a three-frequency PTA.

The recommended CI evaluation referral criteria of aided SII ≤0.60 garnered an acceptable sensitivity value (81%) and a poorer specificity value (47%), indicating its usefulness in correctly identifying CI candidates. This value also aligns with previous research relative to the amount of audibility needed for appropriate access to sound for spoken language development (i.e., receptive vocabulary, syntax, pragmatics) in children with hearing aids (aided SII ≤0.65 to 0.71; Stiles et al. 2012; Tomblin et al. 2015; Wiseman et al. 2023) and in reframed recommendations for CI candidacy in children (aided SII ≤0.68; Warner-Czyz & Uhler 2023). In fact, Wiseman et al. (2023) reported pediatric hearing aid users with mild to severe hearing loss with a mean better-ear aided SII at average output lower than 0.61 (95% confidence interval = 0.53 to 0.68) have an increased risk of language delay compared with those with better-ear aided SII higher than 0.61. Because SII accounts for the percentage of audible speech weighted by the importance of that frequency region, it provides complementary information to the audiogram itself by accounting for hearing loss configuration and the impact of hearing loss on speech audibility—including high-frequency sounds crucial for spoken language development.

Pediatric CI evaluation referral criteria of WRS scores ≤60% correct resulted in excellent sensitivity and specificity (91% and 92%, respectively). The sensitivity of this speech recognition level falls squarely in the range for adult CI candidacy referral recommendations (83 to 92%; Zwolan et al. 2020; Hunter & Tolisano 2021). In addition, delineation of 60% correct on a word recognition measure approximates the median score for CI users in Leigh et al. (2016). However, only one-fourth of our sample completed speech recognition testing as part of the candidacy evaluation, likely due to consideration for a CI prior to an age and language level at which they can complete this type of testing, as in Leigh et al. Thus, speech recognition measures provide value when available, but they cannot be conducted in young infants and children, as well as children with comorbid conditions. This necessitates the recommendations of "or"

versus "and" when considering 4FPTA ≥60 dB HL or aided SII ≤0.60 or WRS ≤60% correct.

STRENGTHS AND LIMITATIONS

This study has multiple strengths to support its generalizability to a broader population of children who are deaf or hard of hearing. First, analyses included a large, diverse sample of children who are deaf or hard of hearing from three CI centers spread across the nation. Second, all three recommendations based on 4FPTA, aided SII, and WRS yielded sensitivity values >0.80, meaning these metrics correctly identify children as appropriate CI candidates. Third, more relaxed guidelines for referral for the evaluation of CI candidacy—including consideration of individual ears and nontraditional candidates for CI (e.g., more residual hearing, better word recognition relative to FDA indications)—align with criteria used worldwide (Dettman et al. 2004; Leigh et al. 2016; Rajan et al. 2018; Park et al. 2021, 2022; Warner-Czyz et al. 2022). Using the referral guidelines outlined in this article may provide a more direct path to recommending a CI evaluation for children who are deaf or hard of hearing and may result in reaching more children who are candidates for CIs (Sorkin & Buchman 2016; Park et al. 2021). Improved referral patterns, particularly, may have a positive effect in the United States, which shows a market penetration rate of 50% compared with 90% in Australia, England, and New Zealand (Sorkin & Buchman 2016; Zombek & Wolfe 2023). Finally, the use of sensitivity and specificity as guidelines for recommendations for referrals for a CI candidacy evaluation mirrors techniques used in previous studies focused on adults who are deaf or hard of hearing (Zwolan et al. 2020).

This study also has limitations. First, both 4FPTA and aided SII had acceptable to excellent sensitivity, but relatively poor specificity (24% and 47%, respectively), suggesting that relying on these metrics alone may result in over-referral of children for a CI evaluation. Over-referral in healthcare may lead to increased costs to families and insurance companies and increased anxiety in patients and families. However, children with false-positive scores, in which they may meet some but not all the criteria for a specific diagnosis or treatment recommendation, represent an at-risk population needing special considerations by their health care provider. For instance, Glascoe (2001) found that children with one or more false-positive scores who were over-referred for a developmental screening performed significantly more poorly (i.e., 9 to 14 points lower on standardized measures with means of 100 and SD of 15) and had higher relative risk on adaptive behavior, language, intelligence, and academic achievement measures compared with children with true-negative scores. Applied to recommendations for children who are deaf or hard of hearing, we can consider over-referral for evaluation of CI candidacy as a way of introducing CIs as part of the continuum of care versus adopting a wait-and-see approach reliant on a child's failure to progress with hearing aids (Warner-Czyz & Uhler 2023). Second, inclusion of a word recognition measure yielded excellent sensitivity and specificity, but only 23% of CI candidates in our study could complete this testing—a striking contrast from the adult population, where most patients complete speech recognition as part of the CI candidacy evaluation protocol (Dunn et al. 2024). The limited availability of speech recognition metrics as part of pediatric CI candidacy evaluations reflects the chronological and language age of children undergoing evaluation rather than omitting speech recognition measures as part of evaluation protocols (Park et al. 2022; Warner-Czyz et al. 2022).

This study was also limited by the populations that were not included in the sample. Data were selected based on behavioral testing, hence infants or children with comorbidities who could not provide valid behavioral results were not included. The study by Hang et al. (2015) suggests that children with "no response" frequency-specific auditory brainstem response testing are CI candidates. Leigh et al. (2019) challenge their findings, suggesting that click-auditory brainstem response and auditory steady state response tests are not sensitive enough to determine candidacy. Future studies should focus on identifying highly specific objective test methods for children who cannot perform reliable behavioral audiometry. We agree with Leigh et al. that this population warrants multifaceted assessment and recognize that an experienced pediatric CI program may be the best place for comprehensive evaluation.

Children who were referred for behavioral testing but did not attend an evaluation were not included in the referred group as their outcomes were unknown. We also did not collect data on why a referral or CI was not recommended. Some children may have been audiologic candidates but not medically cleared for surgery. Finally, in line with the purpose of this article to identify evidence-based criteria to refer a child who is deaf or hard of hearing for a CI candidacy evaluation, we did not evaluate the uptake of CI recommendation or the appropriateness of the CI candidacy decision. Future studies should investigate the uptake of CI and candidacy considerations in children who are deaf or hard of hearing.

CONCLUSION

This large-scale evidence-based approach to CI referral guidelines for children supports more relaxed criteria than outlined in FDA indications and previous recommendations for CI candidacy for children (Leigh et al. 2016; Park et al. 2022; Warner-Czyz et al. 2022). These data-driven, evidence-informed guidelines for pediatric CI evaluation referrals are comprised of three independent but related components: Unaided 4FPTA ≥60 dB HL, aided SII ≤0.60, or aided WRS ≤60% correct (when available) in the ear to be implanted. The 60/60/60, or CI 3-60 guidelines, echo the 60/60 guidelines for referring adults for CI candidacy evaluation, thereby affording consistency in recommendations across the lifespan. Moreover, these three metrics individually have sensitivity ratings in the acceptable to excellent range, suggesting each can correctly identify children as CI candidates. Not all children referred for a CI evaluation will undergo implantation, but these revised guidelines (a) capture a high proportion of children who would experience more benefit from a CI than a hearing aid and (b) begin the conversation of CIs as part of a continuum of hearing technology for children who are deaf or hard of hearing.

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