

Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Candidacy Evaluation

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Objective: To evaluate the effectiveness of a 60/60 referral guideline for identifying patients who should be referred for a cochlear implant candidacy evaluation (CICE), which states patients should be referred if they demonstrate a best ear unaided monosyllabic word score less than or equal to 60% correct and if they demonstrate an unaided pure-tone average in their better ear that is greater than or equal to 60 dB HL.

Study Design: Retrospective review of data from adults who participated in a CICE.

Setting: A single tertiary medical facility.

Patients: Five hundred twenty-nine patients who participated in a CICE.

Intervention: CICES included unaided threshold assessment, unaided speech recognition, and aided word and sentence testing.

Main Outcome Measure: Ninety-five percent of patients who met traditional indications for a cochlear implant

($n = 250$) had a pure-tone average that was greater than or equal to 60 dB, while 92% had a better ear unaided monosyllabic word score that was less than or equal to 60%.

Results: If used as a screening measure, the 60/60 measure resulted in a 96% detection rate and a 34% false-positive rate for identifying adults who would meet traditional indications for a cochlear implant.

Conclusions: Hearing professionals should consider referring patients for a CICE when they meet the 60/60 guideline. It is hoped that provision of this guideline will result in greater numbers of adults being referred for CICES, improving access to cochlear implants for patients who may benefit from this important technology. **Key Words:** CI referral—Cochlear implant candidacy—Cochlear implant candidacy evaluation.

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Numerous investigators report that access to cochlear implantation is poor, particularly for adults, and that less than 10% of adults who qualify for a cochlear implant actually receive one (1–4). Proposed reasons for this are numerous and include lack of hearing screening for adults, lack of familiarity with cochlear implant (CI) candidacy criteria amongst primary care physicians, audiologists, and the general population (1,3), and lack of referral guidelines for audiologists who dispense hearing aids. Additional reasons cited include a need for improved communication between hearing aid and CI clinics (5) and weak to moderate positive correlations between data typically collected by referral sources (earphone audiometrics) and aided speech recognition scores that are used to determine candidacy (6).

Although a few investigators have published evidence-based criteria for recommending a CI (7–9), very few have examined criteria for when patients should be referred for testing to evaluate CI candidacy. Gubbels et al. (10) examined the medical records of patients who were seen at their clinic over a 5-year period and found that 86% of patients with monosyllabic word recognition scores at or below 32% met criteria for a CI. They concluded that patients with a pure-tone threshold average (PTA) (250, 500, 1000 Hz) of ≥ 75 dB and/or a monosyllabic word recognition test score of $\leq 40\%$ have a high likelihood of meeting candidacy criteria for a CI. In their study, candidacy decisions were based on AzBio Sentences (11) or older test materials, such as HINT sentences (12), which have been found to lack the sensitivity needed to appropriately measure benefit with either hearing aids or cochlear implants (13). If more contemporary test measures had been used, it is likely their data would have revealed that a higher monosyllabic word score or lower PTA could be used to predict candidacy.

In 2018, our team analyzed unaided word scores for 84 subjects who met candidacy requirements for a CI (14) using a procedure similar to that of Gubbels et al. (10) and found that 86% of the patients who qualified for a CI at

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our facility obtained a best unaided monosyllabic word score of 60% or less; this is much higher than the 32% monosyllabic word score obtained by the subjects in their study. We elected to expand our analysis to include all patients who were seen over a longer period of time and to additionally evaluate the PTA of the better hearing ear since current CI indications include requirements regarding unaided audiometric hearing and speech recognition.

The purpose of this study was to evaluate the preoperative unaided audiometric characteristics of patients who qualified for a cochlear implant to develop referral guidelines for a CI. These referral guidelines are based on preoperative data for patients who met traditional indications for a contemporary cochlear implant (15) when candidacy was based on contemporary sentence measures administered in quiet and/or noise. It should be noted that these guidelines do not apply to patients who may receive a cochlear implant outside of traditional indications, such as those with asymmetric hearing loss (AHL), single-sided deafness (SSD), or those who receive a recommendation for a CI off-label.

To be clinically useful for referring clinicians, this study focused on preoperative measures typically performed by such clinicians, and included analysis of the unaided three frequency PTA of the better hearing ear as well as analysis of the highest preoperative unaided monosyllabic word recognition score obtained when scores for the right and left ears were compared.

METHODS

Subjects

Six hundred sixty one adults were observed for a cochlear implant candidacy evaluation (CICE) at our facility between January 1, 2016 and September 30, 2019. Of these patients, 250 met traditional indications for a cochlear implant, 279 did not meet traditional indications, and 132 were removed from the analysis for a variety of reasons, including non-English-speaking patients; presence of cognitive impairment that was determined to affect the outcome of the evaluation; inappropriate referrals, such as patients with mild or moderate hearing losses who had never tried hearing aids; patients who presented with different prosthetic needs, such as those with conductive or mixed losses; and patients referred specifically for off-label implantation, such as those with asymmetric hearing losses or SSD. Records were reviewed to identify preoperative unaided audiometric air and bone conduction thresholds, unaided pure-tone averages (average of the threshold at 500, 1000, and 2000 Hz) for each ear, and unaided monosyllabic word recognition for each ear. This information was provided by a clinic that referred the patient for a CICE, or was obtained at our clinic as part of the CICE.

Unaided Monosyllabic Words

Unaided monosyllabic word tests conducted at the outside facilities varied and included NU-6 Monosyllabic Words (16), CNC Monosyllabic Words (17), and CID W-22 Words (18). Unaided word testing was typically performed using a variety of presentation formats (either monitored live voice or recorded) and used various presentation levels that depended on the patient's hearing loss. For unaided word testing, there were several cases for which the audiogram indicated that testing

could not be completed by the audiologist (typically due to degree of hearing loss and/or no responses at the limits of the audiometer). When this occurred, a word recognition score of 0% was entered for that particular ear for data analysis. Although including data collected on a variety of measures and presentation formats created variability in the dataset, we included this information as it represents typical test procedures and outcomes used by many audiologists who refer patients for CICEs.

As part of the CICE, audiometric data was examined to determine if patients met the traditional criteria of a bilateral moderate to profound sensorineural hearing loss in the low frequencies and a profound hearing loss in the mid to high-speech frequencies (15). A low-frequency PTA was calculated based on an average of the unaided thresholds obtained at 250 and 500 Hz and was considered to be bilaterally moderate if the PTA was 40 dB or greater in each ear. The high-frequency thresholds (2 kHz and beyond) were examined for each ear and were considered to be bilaterally profound if at least one threshold was 90 dB or greater in each ear. If no response was obtained at the limits of the equipment, a value of 130 dB HL was entered for data analysis for each specific frequency at which this occurred. Additionally, speech recognition data obtained during the CICE was used to determine if they met the criteria of a best aided sentence score of less than or equal to 60%.

Aided Sentence Recognition

Before the start of the CICE, patients' hearing aids were examined and tested to determine if they were working properly and to determine if they met NAL NL2 targets. If they did not meet targets, clinic hearing aids were programmed to meet targets and those aid(s) were used in the CICE. Patients' hearing aids were used in the evaluation if they met targets and if they were functioning properly. On occasion, testing was performed twice, once with the patient's aid(s) and once with the clinic aid(s) to ensure the best aided performance was determined. The preoperative speech recognition battery used in the CICES included AzBio sentences in quiet (11), AzBio sentences at a +10 signal-to-noise ratio, and CNC Monosyllabic words (16) in quiet, all presented at a level of 60 dB SPL to a soundfield at zero degrees azimuth (19). Scores obtained on AzBio sentences presented in either quiet or noise with the right ear aided, left ear aided, and both ears aided were compared. Patients were considered to meet traditional indications if they obtained a score less than or equal to 60% correct in the condition that yielded the best aided score in noise. Typically, testing at a +10 signal-to-noise ratio was performed if the patient obtained a score greater than or equal to 40% in quiet. If noise scores were not available, candidacy was based on the best AzBio sentence score obtained in quiet.

Patients who participated in a CICE that did not result in a recommendation for a CI were typically encouraged to return annually for a CICE. Thus, some patients were observed up to three times during the time period mentioned. In such cases, data for each visit was included in the analyses.

The primary goal of this study was to develop referral recommendations that apply to measures typically performed by clinicians who may refer patients for a cochlear implant, and included analysis of the unaided PTA of the better hearing ear as well as the highest unaided word recognition score obtained preoperatively when scores for the right and left ears were compared. These two values were examined for patients who did or did not meet traditional indications for a cochlear implant.

TABLE 1. Demographic information for the candidates and non-candidates who participated in a cochlear implant candidacy evaluation

	Age	Preoperative PTA (dB HL) Better Ear	Preoperative Best Unaided Word Score (%)	Preoperative Best Aided Word Score (%)	Preoperative Aided AzBio Sentences in Quiet (%) Best Aided	Preoperative Aided AzBio Sentences in Noise (%) Best Aided
Candidates						
Mean (SD)	65.4 (17.7)	87.15 (17.6)	25.47 (23.0)	16.88 (17.1)	30.10 (27.6)	33.72 (15.6)
N	250	250	196	219	250	75
Min-max	19-98	33-no response	0-88	0-76	0-96	0-59
Non-candidates						
Mean (SD)	70.38 (13.7)	58.53 (13.9)	56.25 (23.9)	48.31 (24)	76.44 (23.7)	65.28 (22.6)
N	279	279	195	203	270	220
Min-max	19-94	28-110	0-100	0-100	1-100	0-98

Indications for Medicare beneficiaries to receive a CI are stricter than those of the FDA. In addition to requiring a bilateral moderate to profound sensorineural hearing loss, patients with Medicare insurance are required to demonstrate “test scores of less than or equal to 40% correct in the best-aided listening condition on tape recorded tests of open-set sentence recognition” (20). A secondary objective of this study was to determine if the 60/60 referral guideline would be appropriate for use with Medicare-eligible patient.

RESULTS

Traditional Candidates

Of the 661 adult patients who were observed for a CICE, 250 (38%) presented with a bilateral moderate-to-profound sensorineural hearing loss and demonstrated a score less than or equal to 60% correct in their best aided condition and met traditional indications for a cochlear implant. Two hundred seventy-nine patients (42%) who were seen for a CICE did not meet one or both of the criteria listed above and, therefore, were not considered to meet traditional indications for a cochlear implant. Demographic information for both groups is provided in Table 1.

Candidates: Unaided Better Ear PTA

The preoperative unaided PTAs obtained for the better ear for all 250 patients who qualified for a cochlear implant are provided in Figure 1. This group of subjects demonstrated a mean better ear PTA of 87 dB HL ($n = 250$; range = 33–130 dB). Figure 1 provides (A) a summary of the cumulative percentage of patients who obtained various PTAs in their better hearing ear as well as (B) the cumulative percentage of patients whose better ear PTA fell into various decibel ranges. Figure 1A indicates that 95.1% of the 250 subjects who met traditional CI indications had a preoperative PTA in their better hearing ear that was 60 dB HL or greater, while Figure 1B demonstrates that very few candidates demonstrated a PTA less than 60 dB HL and that most candidates had a better ear PTA between 70 and 89 dB HL. It should be noted that we included one patient with Auditory Neuropathy Spectrum Disorder in our subject group. This subject presented with an atypical audiogram with a better ear PTA that fell between 30 and 39 dB HL, even though she met the criteria of a moderate low frequency hearing loss and a profound high frequency hearing loss (e.g., reverse-u-shaped audiogram).

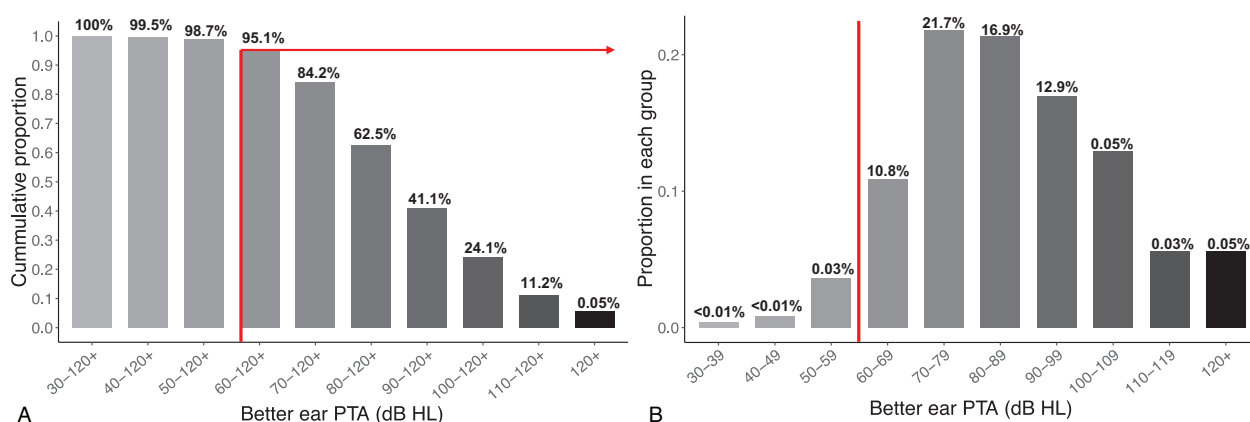


FIG. 1. Bar graph of the cumulative proportion of traditional cochlear implant candidates who presented with a preoperative pure-tone average (PTA at 500, 1000, and 2000 Hz) in dB HL for the better-hearing ear, within the specified range (in dB HL) shown along the x axis. For example, 100% of patients presented with preoperative PTA in their better ear between 30 and 120+ dB HL while only 41.1% of patients demonstrated a PTA between 90 and 120+ dB. Red lines and arrow highlight the percentage of patients (95.1%) who presented with better ear PTA between 60 and 120+ dB HL. B, It shows the proportion of candidates who presented with better ear PTA at different dB HL levels, broken down into ranges of 10 dB.

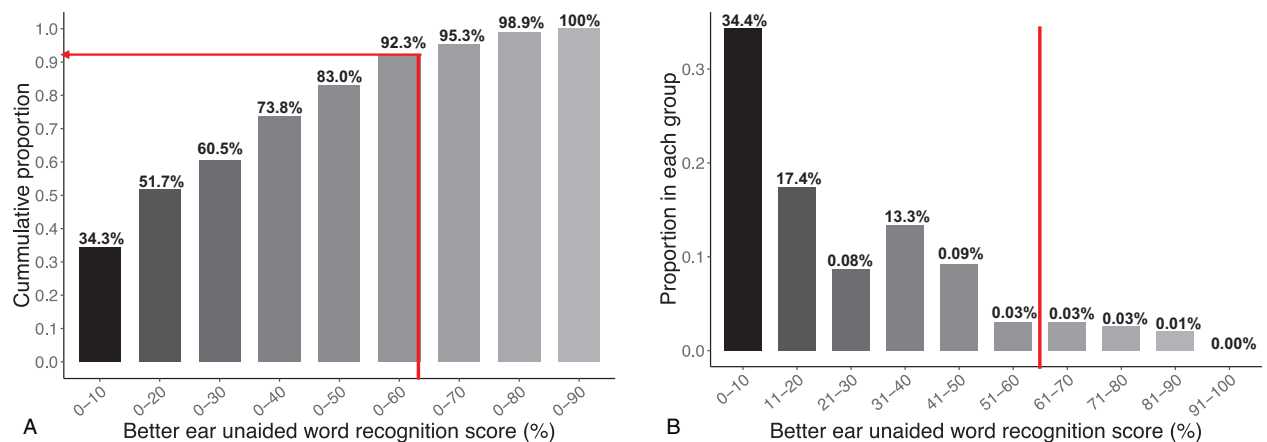


FIG. 2. This is similar to Figure 1, but for preoperative unaided word recognition in the better ear. *A*, It provides a bar graph of the cumulative proportion of traditional cochlear implant candidates who presented with a preoperative unaided word recognition score in the better ear, within the specified range (%) shown along the *x* axis. For example, 100% of patients presented with preoperative word recognition score in their better ear between 0 and 90%, while only 60.5% presented with a score that was 30% or less. Red lines and arrow highlight the percentage of patients (92.3%) who presented with better ear unaided word recognition scores between 0 and 60%. *B*, It shows the proportion of candidates who presented with better ear unaided word recognition scores at different performance levels broken down into ranges of 10%.

Candidates: Unaided Best Monosyllabic Word Recognition

The group of patients who met traditional indications for a cochlear implant demonstrated a mean unaided best monosyllabic word score of 25% correct ($n=196$; range = 0–88%). Their scores are further broken down in Figure 2, which provides (*A*) a summary of the cumulative percentage of patients who obtained a variety of monosyllabic word recognition scores in their better hearing ear as well as (*B*) the cumulative percentage of patients whose best unaided monosyllabic word score fell into various percentage ranges. Figure 2*A* indicates that 92.3% of the 197 subjects who met traditional CI indications, and had an unaided monosyllabic word score available, had a score in their better ear that was 60% or lower. Figure 2*B* demonstrates that very few of our traditional candidates (7.7%) demonstrated an unaided monosyllabic score greater than 60%. A large portion of the candidates (34.4%) had a better ear unaided word recognition score that was less than or equal to 10%.

Referral Guidelines

Based on the data obtained in this study, patients are highly likely to qualify for a CI if they demonstrate a PTA in the better ear that is greater than or equal to 60 dB HL. More than 90% of the patients in our study who qualified for a CI met this indication. Additionally, of the

candidates for whom a better ear unaided monosyllabic word score was available ($n=198$), 183 (92%) demonstrated a score less than or equal to 60%.

Using 60/60 as a Screening Tool

Although better ear PTA information was available for all patients, better ear unaided word scores were not always available. Of the 545 patients included in our two groups, both better ear PTA and better ear unaided monosyllabic words scores were available for 220 of the candidates and for 195 of the non-candidates (415 patients total). Data was used from the 415 patients with both data points to determine if the 60/60 guideline would be suitable for use as a screening tool to determine if a patient should be referred for a CICE. Results of this evaluation are shown in Table 2. Of the 220 candidates with both PTA and better ear unaided word recognition, 212/220 met both components of the 60/60 referral indication, resulting in a sensitivity rate of 96%. The eight patients who did not meet both guidelines met the better ear monosyllabic word guideline of 60% or less but demonstrated PTAs that were less than 60 dB HL. In contrast, only 67/195 of the non-candidates met both components of the 60/60 referral guideline while 128/195 (65%) did not, resulting in a specificity index of 65.6%. For this group of patients, the guideline had a positive predictive value, or PPV of 76%, indicating a 76%

TABLE 2. When examined as a screening tool for cochlear implant candidacy, the 60/60 referral guideline demonstrated a sensitivity (detection rate) of 96.3%, a specificity rate of 65.6% (false-positive rate of 34%), a positive predictive value of 76%, and a negative predictive value of 94%

	Candidate	Non-candidate	Total	
Meets 60/60	212	67	279	PPV = 76%
Does not meet 60/60	8	128	136	NPV = 94%
Total	220	195	415	
	Sensitivity: 212/220 = 96.3%		Specificity: 67/195 = 65.6%	

probability of meeting traditional CI candidacy if they meet the 60/60 guideline. The 60/60 guideline had a negative predictive value, or NPV of 94%, indicating a 94% probability that a patient will not meet traditional indications for a CI if they have a best ear unaided speech recognition score greater than 60% combined with a better ear pure-tone average that is less than 60 dB HL.

Medicare-eligible Beneficiaries

A large percentage of patients seen in our clinic during the past several years for a CICE are 65 years of age or older. Such patients, if enrolled in straight Medicare, are required to meet stricter indications than those outlined in this study for traditional CI candidacy. Although both indications require a bilateral moderate to profound hearing loss, Medicare requires the best aided sentence score to be less than or equal to 40%, which is stricter than the criteria of less than or equal to 60% used in this study. We analyzed data for all patients who were Medicare-eligible (65 yr of age or older) at the time of their CICE. The results of this analysis are provided in Figure 3. Of the 661 patients who participated in a CICE during the time frame of this study, a total of 392 (59.3%) were 65 years of age or older. Of these 392 patients, 144 (37%) met traditional FDA indications of a bilateral moderate to profound sensorineural hearing loss and a best aided sentence recognition score of 60% or less. Of these 144 patients, 93 had unaided word recognition scores available. Of these 93, 79 (85%) met the 60/60

guideline for referral. Additionally, 107/144 (74%) of these patients also met Medicare's indication of a score less than or equal to 40% on an open-set sentence recognition test. Unaided word scores were available for 66/107 of the Medicare candidates. Of these 66 patients, 62 (94%) met the 60/60 guideline for referral. Based on these findings, the 60/60 referral guideline seems to be appropriate for use with Medicare-eligible beneficiaries.

Based on these findings, we recommend professionals refer a patient for a CICE to evaluate their candidacy for a traditional cochlear implant if they present with a PTA of 60 dB or greater in the better hearing ear and if they demonstrate a best unaided monosyllabic word recognition score that is 60% or less.

DISCUSSION

One possible reason for under-referral of adults for CICES may be the difference in test procedures used by referring professionals and by audiologists who perform CICES. Audiometric testing performed by referring audiologists rarely includes aided sentence recognition. In our review of 661 records of patients referred for a CICE, we did not locate a single record where aided sentence recognition testing had been performed by the referring audiologist. Because the relationship between word and sentence recognition is not straightforward, it remains difficult for referring professionals to know when a patient should be referred for a CI when aided sentence testing has not been performed.

Our recommendations differ from those of Gubbels et al. (10), who concluded that patients with PTAs (250, 500, 1000 Hz) ≥ 75 dB and/or a monosyllabic word recognition score $\leq 40\%$ have a high likelihood of meeting candidacy criteria. Although we agree with their findings, we think patients with lower PTAs and better monosyllabic word scores should be referred for a CICE. Differences between our findings are likely due to the fact that we used more contemporary test methods to determine candidacy.

Professionals have indicated to us that they prefer to recommend patients participate in a CICE when they are fairly certain a CI will be recommended. This is especially true when the CI center is located a great distance from the patient's home due to concerns about the time and money spent by the patient to travel for the evaluation. We are hopeful the results of this study will be used by clinicians since the patient's PTA or unaided word recognition score can be compared with the data provided here to inform patients about the likelihood that they may or may not meet traditional indications for a CI.

It is interesting to note that many of the patients (34.3%) seen in our clinic for a CICE demonstrated an unaided word recognition score in their better ear that was less than 10%, and many (38%) demonstrated a better ear PTA that fell between 70 and 89 dB HL. It is highly likely that many of these individuals would have qualified for a CI if a CICE had been recommended or

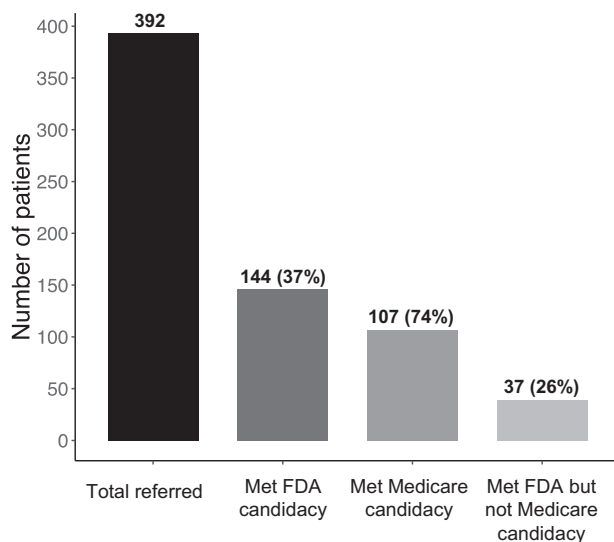


FIG. 3. Bar graph showing referral and candidacy statistics for patients who are Medicare-eligible (≥ 65 yr old) at the time of the candidacy evaluation. The y axis shows the number of patients who fell within each category shown on the x axis. Percentages (number of patients who met the specific criteria shown on the x axis label for the second column, divided by the total number of patients evaluated in the first bar (392)) are also shown in the second bar. For bars/columns 3 and 4, these percentages were derived by dividing the total number of patients who met the description provided on the x axis, divided by the total number of patients who met FDA candidacy and were at least 65 years of age (second column/bar, $n = 144$).

performed sooner. Dowell (21) reported that recipients' chances of a good outcome are significantly better if implantation occurs relatively soon after onset of severe hearing loss and before the loss of all functional auditory skills. Thus, timely referrals are important.

In this study we determined that the 60/60 guideline would be appropriate for use with patients over the age of 65 years; 94% of the patients with unaided word scores available who met the stricter Medicare criteria for a CI also met the 60/60 referral criteria. It should be noted that many Medicare-eligible patients are enrolled in Medicare managed-care plans and many are covered by traditional insurance beyond the age of 65 years. When this occurs, their insurers may have requirements that are less strict than Medicare's current indications. Because of this, we recommend practitioners consider using the 60/60 referral guideline for all adult patients, even if a patient is enrolled in Medicare. Use of the guideline does not seem to result in a higher number of non-candidates even though the indications are stricter.

It is extremely important for referring professionals to keep in mind that many insurers will consider providing preauthorization for a cochlear implant even when patients fail to meet traditional indications. This not only includes patients with slightly better hearing than traditional indications allow, but also includes patients with AHL or SSD. Recent FDA approval of the MedEl device for patients 5 years of age and older who meet AHL or SSD indications (22) demonstrates a strong change in the audiometric configurations that are being considered for cochlear implantation. In such cases, we recommend the referring clinician consult with their local CI clinic to discuss a potential referral as many clinics are providing CIs to patients outside traditional indications, such as due to participation in an approved research study or clinical trial, or due to their willingness to seek off-label implantation for someone they consider to be a good candidate for a CI.

Use of the 60/60 guideline will not guarantee that all patients who meet the referral guideline will receive a recommendation for a cochlear implant. Additionally, use of the 60/60 guideline may miss some patients who are CI candidates; some patients who presented with PTAs less than 60 dB or with scores greater than 60% on an unaided monosyllabic word test still met our traditional indications for a CI. Similarly, some non-candidates met one or both components of the guideline. Thus, professionals should consider referring patients for a CICE if they fall outside these referral recommendations and are experiencing significant difficulties with their hearing. Although this study focused on traditional indications, CI candidacy is typically based on several factors that are considered along with the patient's audiometric test results. These factors include the general health and well-being of the individual, status of the cochlea, patient motivation, and the insurer's willingness to provide coverage for this life-changing procedure. We are confident that provision of this evidence-based 60/60 referral guideline will increase the number of referrals

for CICEs as it decreases some of the uncertainty that currently exists regarding when a patient should be referred for a CICE.

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