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## 1. ACKNOWLEDGEMENTS

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We appreciate the willingness of Auditory Potential, LLC to license an extended subset of AzBio sentences in support of this project. Additional sentence testing materials for pediatrics and for Spanish speaking patients can be purchased at their website: <https://www.auditorypotential.com/index.html>

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Some portions of this manual are modified extractions from the User Manual for the Minimum Speech Test Battery for Adult Cochlear Implant Users (2011) <sup>1</sup>.

## 2. INTRODUCTION

In 2022, the Institute for Cochlear Implant Training (ICIT) recruited a panel of expert audiologists to update and revise the MSTB. This panel utilized a modified Delphi consensus process to revise the test battery and to improve its applicability, taking into consideration recent changes that have occurred in clinical care related to cochlear implants (CIs). This resulted in the MSTB-3, which includes test protocols for evaluating traditional CI candidates (bimodal and bilateral), as well as candidates for electric-acoustic stimulation (EAS), and those with single-sided deafness (SSD) or asymmetric hearing loss (AHL). The MSTB-3 provides information that supplements the earlier versions of the MSTB, such as recommendations of when to refer patients for a CI evaluation, recommended patient reported outcome measures (PROMs), considerations regarding the use of cognitive screeners, and sample report templates for clinical documentation of pre-and post-operative care. Electronic versions of test stimuli, along with all the materials described above, will be available to clinicians via the ICIT website ([cochlearimplanttraining.com/mstb](https://cochlearimplanttraining.com/mstb)). The goal of the MSTB-3 is to be an evidence-based test battery that will facilitate a streamlined standard of care for adults with hearing loss.

The purpose of this manual is to guide clinicians on how to use the MSTB-3 to evaluate candidacy for a CI and to post-operatively evaluate performance. It includes several different sections that will aid in these tasks. It is hoped that clinicians working with patients who utilize other types of hearing technology, such as hearing aids or auditory osseointegrated devices will also find the MSTB-3 useful for evaluating patient performance over time.

### ***EVOLUTION OF THE MSTB-3***

Hearing loss is a disability affecting millions of individuals in the United States <sup>2</sup>. Multichannel cochlear implants were first recognized by the Food and Drug Administration (FDA) as a safe and effective treatment for significant hearing loss in adults in 1984. The MSTB was originally introduced in 1996 as a tool to guide clinicians in their determination of CI candidacy. It was later revised in 2011. Numerous changes have taken place in clinical care of CI patients since 2011, making this update necessary.

Approvals have been granted by the FDA for several commercially available devices since they were first introduced. Notable changes in FDA-approved indications have taken place since 2011, when the last version of the MSTB was published. This includes approval of the Nucleus Hybrid device in 2014 and approval of the MED-EL EAS device in 2016, both of which expanded indications to include patients with greater preoperative residual hearing. In 2019, the FDA approved the MED-EL device for use in patients with Asymmetric Hearing Loss (AHL) and Single Sided Deafness (SSD) and in 2022 approved the Cochlear device for use in patients with SSD. All 5 of the indications mentioned above use CNC



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Monosyllabic Word scores<sup>3</sup>, rather than a sentence score, as one of the primary determinants of CI candidacy. Additionally, the Center for Medicaid and Medicare services (CMS) approved a long-awaited expansion of its indication for CI in 2022, which now indicates adults who score up to 60% on an open-set sentence test may be considered a CI candidate. These expansions have improved access to CI for adults and have broadened the way clinicians think about and evaluate patients for CI candidacy.

Unfortunately, FDA indications for more traditional adult candidates (those with significant bilateral sensorineural hearing loss) have not changed significantly in more than 20 years. Considering that technological advances have resulted in improved outcomes, and in order to keep up with the above-mentioned expanded indications, clinical testing of traditional candidates has broadened to include presentation of test materials in conditions that are more reflective of patients' real-world experience<sup>4</sup>, including administration of sentence materials in the presence of background noise. The amount of noise used in testing often varies; some clinicians choose to present sentences in mild levels of noise, such as a +10 signal-to-noise ratio (SNR), while others choose to present sentences in a moderate amount of noise, such as a +5 SNR. This has led to inconsistency regarding test protocols currently being used to determine CI candidacy, and has led to confusion amongst clinicians, patients, and payers regarding who should be considered a candidate for a CI. Clearly defined test protocols are needed in order to guide clinicians in this important decision-making process.

## ***USING CNC SCORES AS A FIRST STEP IN DETERMINING CI CANDIDACY***

Although the CNC Monosyllabic Words Test was included in both previous versions of the MSTB, clinicians in the United States have not typically placed great emphasis on word scores when determining CI candidacy. This was likely due to the historical use of sentences in FDA and insurer indications. However, the trend towards CNC words as the primary metric in recent FDA-approved indications impacted the decision to prioritize the use of CNC words in the MSTB-3. During the consensus process, several benefits of using CNC Words to evaluate candidacy were discussed, including the finding that word tests are less likely to demonstrate postoperative ceiling effects than sentences<sup>5,6</sup>, and that word tests are a more reliable gauge of peripheral hearing since they contain fewer contextual cues and are less susceptible to the influence of higher level, top-down processing than sentence tests<sup>6</sup>. Additionally, the use of word scores will bring the United States closer to the indications used by most other countries<sup>7</sup>. Thus, a decision was made to use the CNC Words test as the primary measure for a clinical determination of CI candidacy.

## ***DEFINING BEST-AIDED***

One important addition of the MSTB-3 is the definition of "best-aided" when evaluating CI candidacy. This was influenced by recent FDA-approved indications that place greater emphasis on the ear to be treated and less emphasis on scores obtained in the contralateral/untreated ear. Importantly, this impacted the consensus panel's decision to define the patient's "best aided" listening as the score obtained for an individual ear when the patient uses a hearing aid that has been optimized for that ear. Because recent approvals include patients with greater hearing in the contralateral ear, the MSTB-3 reminds clinicians that the test ear must be appropriately isolated during speech recognition testing.

## ***DETERMINATION OF INSURANCE COVERAGE BASED ON SENTENCE SCORES***

The MSTB-3 recognizes that many insurers continue to use sentence scores as the primary criteria for CI coverage. Therefore, the MSTB-3 protocol includes a recommendation to evaluate sentence recognition in the patient's best aided listening condition, if the patient meets the clinic's recommendation for a CI based on their best aided CNC score. Although the MSTB-3 defines "best-aided" as the score obtained for an individual ear when the patient uses a hearing aid that has been optimized for that ear, insurers may require specific testing parameters for determination of coverage and may have their own definition of "best aided". For example, if the insurer defines "best aided" as the score obtained when the patient is using bilateral hearing aids, then testing under the bilateral aided condition should be used to



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determine if the patient qualifies for coverage. Clinicians are also reminded that insurers often require patients to demonstrate a certain level of hearing loss to qualify for coverage. One such example is Medicare, which states that patients must demonstrate a “bilateral moderate to profound sensorineural hearing loss.” Because of this, Medicare patients are not currently eligible to receive coverage for a CI if they have SSD. It is recommended clinicians refer to the specific indications provided by the patient’s insurer to determine if additional tests or conditions need to be included in the evaluation, and to determine if a CI will be covered if one is recommended.

## **WHAT ELSE IS DIFFERENT ABOUT THE MSTB-3?**

The recommendation to use CNC words to determine clinical candidacy and the revised definition of “best aided” are two significant ways the MSTB-3 differs from the earlier versions. Other changes include the following:

1. The MSTB-3 focuses on clinical decision-making and does not recommend additional testing for the purpose of research.
2. The AzBio Sentences<sup>8</sup> and CNC Monosyllabic Words are available as downloadable audio files.
3. The MSTB-3 recommends sentences be administered at a level of 65 dBA in noise (versus 60 dBA in quiet) to represent the increased vocal effort that is typically used by a talker when speaking in the presence of background noise.
4. The provision of test protocols to guide clinicians through the evaluation process.
5. A recommendation to perform post-operative testing less frequently if the patient is performing at an expected level (3 and 12 months versus the previous recommendation to test at 1, 3, 6, and 12 months).
6. Recommendations regarding patient reported outcome measures.
7. Report templates to foster consistency among clinicians in reporting evaluation results.

In summary, the MSTB-3 represents a concerted effort to update and improve the test protocols being used in clinics to evaluate CI candidacy and to post-operatively evaluate performance. Every attempt has been made to develop a truly minimum test battery that will be sufficient for use with most patients. However, it should be noted that determination of CI candidacy is a complex process that includes more than just an examination of speech recognition. Thus, the MSTB-3 should be viewed as part of a larger, comprehensive battery that evaluates other factors that contribute to CI candidacy, including the results of the medical evaluation, audiometric testing, and patient expectations, motivation, and support.

## **3. COMPONENTS OF THE MSTB-3**

### **B. REFERRAL GUIDELINE**

Limited guidance exists in the literature to help referring providers determine when they should refer patient for a CI evaluation. Recently, Lee et al<sup>9</sup> compared sensitivity and specificity, Youden’s J statistic, negative and positive predictive value (NPV and PPV, respectively), and likelihood ratios when five CI candidacy evaluation referral screening tools were applied to their database of 248 CI candidates<sup>10-14</sup>. They concluded their analysis “supports the use of the “60/60” guideline developed by Zwolan et al.<sup>14</sup> as the best performing tool of the ones studied, balancing overall performance across sensitivity, specificity, PPC, and NPV” and that the 60/60 guideline “...offers a pragmatic strategy for hearing professionals to use when considering referral to a CI candidacy evaluation<sup>9</sup>.”

Following Likert statement review, the MSTB-3 consensus panel agreed to incorporate current clinical practice and recommend a referral guideline that modifies the 60/60, which utilized a restrictive definition of CI candidacy based on the patient’s better hearing ear. The referral guideline of the MSTB-3 places greater emphasis on the ear to be treated and includes the recommendation that patients with sensorineural hearing loss (SNHL) be referred for a CI evaluation when they present with an unaided PTA of 60 dB HL or greater and an unaided word score of 60% or less in the ear to be implanted (evaluated under earphones at a presentation level the audiologist deems appropriate to achieve the



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maximized unaided word score for the individual's hearing loss). The consensus panel additionally agreed there is no upper age limit for referring an individual for a cochlear implant evaluation. Additionally, referral sources should consult with members of the CI team before denying a referral for medical reasons as the CI team will communicate with other specialties as indicated (the primary care physician, anesthesiology, internal medicine, cardiology, geriatrics, etc.) to obtain medical clearance when needed for this surgical intervention.

It is important that the following information is included in community referrals:

1. Patient's contact information
2. Referring clinic's contact information
3. Patient's demographic and insurance information
4. Clinical notes regarding patient's hearing history, pertinent medical records, previous and current audiograms, unaided and aided speech perception test results

The hearing aid referral guideline described above places emphasis on **the ear to be treated**. Thus, it will apply to patients who present with SSD, AHL, and single sided significant hearing loss, including those who may qualify for treatment with electroacoustic or hybrid devices. Referring clinicians are encouraged to be aware that not all insurance providers will cover all FDA-approved indications (e.g., traditional Medicare does not cover SSD). Providing patient insurance information to the CI clinic enables the clinic to discuss such issues with the patient before they schedule a formal evaluation.

## B. CALIBRATION

### OVERVIEW

A certified equipment calibration specialist/company should complete regular calibration of all test equipment. Accurate soundfield calibration is essential to ensure that:

1. test results are comparable over time as patients gain experience with their hearing device(s) and,
2. to assure that outcome measures are valid and comparable across clinics.

The sound room, audiometer, and loudspeaker(s) are calibrated before administration of any tests. The sound room must be large enough for a chair to be placed in the center of the room and for the loudspeakers to be at least a meter from a reference point corresponding to the center of a seated listener's head. The minimum room size required is 1.83 x 1.83 meters or 6 x 6 feet.

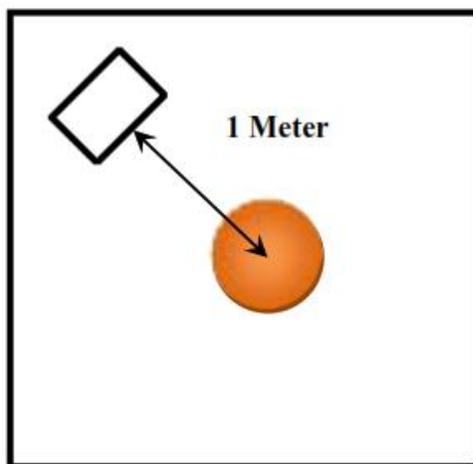
Preferably, the chair should be facing a corner away from any window or door. The primary loudspeaker, from which the target stimuli are presented, should be positioned at the level of a typical listener's head (approximately 86 centimeters or 39 inches from the floor) directly at the front of the chair (0° azimuth). With this arrangement, both the speech and noise signals will be presented from the same loudspeaker when testing in noise is performed. At least one additional loudspeaker is required to assess bilateral or bimodal performance with speech and noise presented from separate loudspeakers.

Calibration is a two-step process. First, the 1000-Hz tone is used to calibrate the level at the input to the audiometer (i.e., setting the VU meter to peak at 0 dB). Second, the calibration noise is used to measure the output, in dBA, from the loudspeakers in the soundfield using a sound-level meter (SLM). Ideally the SLM is mounted on a tripod or handheld with the microphone positioned at the reference point referred to above, corresponding to the center of a seated listener's head. Both calibration steps must be performed to ensure that the test stimuli are presented at the desired level. It is considered good clinical practice and assumed that a sound-level meter is available for speech perception

testing in the soundfield. Ideally, calibration of soundfield presentation levels should occur at each test session, with a minimum of once per day. Calibration of each outcome measure to be used, in this case CNC Words and AzBio sentences, is essential to ensure consistency across testing centers.

**CALIBRATION RECOMMENDATIONS:**

1. Present 1000 Hz calibration tone (this will be a track on the recorded test materials) and adjust the VU meter to zero on EXT A and EXT B.
2. Present speech-shaped calibration noise (a track on the recorded test materials) through the loudspeaker intended for testing.
3. Situate the sound level meter (SLM) in the location to approximate a patient's head when seated, one meter from the speaker at 0 degrees azimuth.
4. Set SLM to "A-weighted" and "Slow" setting.
5. Present the calibration noise from the desired loudspeaker.
6. Adjust the HL dial on the audiometer until the sound level meter reads desired presentation level (e.g., 60 dBA).  
Note: The HL dial level reading is irrelevant, provided that the VU meter is not clipping, and the sound level meter reading equals 60 dBA in response to speech-shaped calibration noise.
7. Consider presenting a couple of words and sentences to ensure that the presentation levels for the target stimuli match the measurement with calibration noise (switch from a slow to a fast setting on SLM to capture the rapid fluctuations in running speech).



**Figure 1.** Sound-field test set up.

## **AIDED THRESHOLD CALIBRATION**

Adult hearing clinics are typically calibrated for sound field presentation at 0° whereas pediatric clinics are often calibrated for sound field presentation at 45° or 90° with the latter allowing for a full head turn response during visual reinforcement audiometry (VRA). Note that there are frequency-specific corrections that should be applied if you will be completing CI-aided sound field audiometry with a loudspeaker orientation that is different from that used for calibration (ISO 82532: 2009). For example, if your loudspeakers were calibrated for 0° and you will be measuring CI-aided thresholds with the loudspeaker at 45° or 90°, you would add the corresponding correction factor shown in **Table 1.** to your measured threshold. Alternatively, if your loudspeakers were calibrated at 45° or 90° and you are measuring CI-aided thresholds with the speaker at 0°, you would subtract the corresponding correction factor shown from your measured threshold. If unsure about calibration details, consult your audiometer calibration certificate or acoustical engineer.

**Table 1. Frequency-specific corrections for 45° and 90° azimuth sound field audiometry for loudspeakers calibrated at 0° azimuth.**

Frequency (Hz)	45°	90°
125	0.5	1.0
250	1.0	2.0
500	3.0	4.5
750	3.5	3.0
1000	4.0	5.5
1500	1.5	0.0
2000	3.0	2.0
3000	5.0	2.5
4000	4.0	-0.5
6000	7.5	9.5
8000	5.5	8.5

## **C. TEST MATERIALS**

### **i. CNC WORD TEST**

The CNC word test consists of lists of monosyllabic words with equal phonemic distribution across lists. Each list exhibits approximately the same phonemic distribution as the English language<sup>15</sup>. The original CNC lists were revised to eliminate relatively rare words and proper nouns<sup>3</sup>. The resulting ten lists of 50 words each contain monosyllabic words with a frequency of occurrence of greater than four per million as calculated in the Thorndike and Lorge word frequency tables<sup>16</sup>.

### **CNC TEST MATERIALS**

The CNC test consists of 500 test words organized into 50-word lists. Each word is preceded by the carrier word “Ready.” There are three practice words at the beginning of each list. The words within each list are separated by approximately two seconds of silence.

### **CNC TEST PROCEDURES**

#### Setup

1. Make sure your audiometer and booth are calibrated for the appropriate test materials.
2. Seat the listener in the chair facing the loudspeaker through which the words will be played. Instruct the listener to maintain an upright head position and not to lean forward or to turn his or her head.
3. Instruct the listener with the following written or oral instructions:  
 “This is a test of your ability to understand speech. You will hear a man say the word “READY” followed by a test word. Your task is to repeat each test word you hear the man say. I will stop after each word to allow you to repeat what you heard. Please repeat anything you hear, even if it is only part of a word. It is all right to guess. I will play each word only once.”

## Test Protocol

1. Adjust Channel 1 to the HL setting that corresponds to 60 dBA from the loudspeaker and direct Channel 1 output to the desired speaker. (Channel 2 should be turned off)
2. PLAY the first carrier and practice word, then press PAUSE as needed to allow time for a response. Continue through all 50 words, pausing when needed to give the listener time to respond.
3. Record the response on the score sheet. If the word was repeated correctly, make an “X” in the Phonemes Correct column, under the column labeled ‘3’ (for three phonemes correct) in the fourth column. If the word was repeated incorrectly, record the number of phonemes correct in first, second or third columns, under the columns ‘0’, ‘1’, or ‘2’. There are three phonemes per word. If preferred, record the whole-word response under ‘Whole Word Response (Optional)’ and calculate the number of phonemes correct at the end of the test.

## Calculation of Word and Phoneme Scores in Percent Correct (Figure 2)

1. Total the ‘X’s for each column under ‘# Correct Phonemes.’
2. Record these totals in the worksheet section in the bottom right of the score sheet and calculate the total number of phonemes correct.
3. Enter the total number of phonemes calculated as the ‘Grand Total;’ this is the total number of phonemes correct (in the example shown, 114/150).
4. Enter the number of words with 3 phonemes correct at the bottom of the sheet; this is the number of whole words correct (in the example shown, 20/50).

### ii. AZBIO SENTENCES

The AzBio sentences are spoken by multiple male and female talkers using a conversational rather than deliberate speaking style. In addition, the sentences have limited contextual cues that make it difficult for a listener to “fill in” unintelligible words. The lists were equated for intelligibility by presenting the sentences to normal-hearing listeners through a 5-channel cochlear implant simulator<sup>17</sup>.

### AZBIO TEST MATERIALS

The AzBio sentences on the MSTB consist of 23 lists of 20 sentences that range in length from 4 to 12 words. Each list of 20 sentences consists of 10 sentences spoken by two male talkers and 10 sentences spoken by two female talkers (5 sentences per talker). Continuous 10 talker babble is recorded on channel 2 for assessment of performance in noise.

**Monosyllabic Word Test Key (CNC, List 1)**  
**MSTB CD**  
**Track 09 (Channel 1)**

Score all words for a beginning consonant sound, a nucleus (vowel) sound and an ending consonant sound.  
(Total phoneme count per word = 3. Phonemes must be in the appropriate order.)

Practice Items	1. DUCK			2. BOMB			3. JUNE			
	Test Items	Whole Word Response (Optional)	# Correct Phonemes	Test Items	Whole Word Response (Optional)	# Correct Phonemes	Test Items	Whole Word Response (Optional)	# Correct Phonemes	
		0	1	2	3		0	1	2	3
1. GOOSE					X	26. WRECK				X
2. NAME					X	27. ROUT		X		
3. SHORE	<u>chose</u>			X		28. BOAT			X	
4. BEAN	<u>bin</u>			X		29. RIPE		X		
5. MERGE				X		30. WHEEL			X	
6. DITCH				X		31. DEAD			X	
7. SUN	<u>some</u>			X		32. SOB			X	
8. TOUGH				X		33. MESS			X	
9. SEIZE	<u>size</u>			X		34. WISH			X	
10. LEASE	<u>least</u>			X		35. CHORE			X	
11. HOME				X		36. WOOD			X	
12. JAR				X		37. KING			X	
13. PAD				X		38. TOAD			X	
14. FALL	<u>sale</u>		X			39. CHECK			X	
15. VAN	<u>fan</u>		X			40. LOOP			X	
16. JUG	<u>jump</u>		X			41. LAG			X	
17. YEARN	<u>earn</u>		X			42. SALVE			X	
18. MAKE	<u>mate</u>		X			43. DIME			X	
19. GALE			X			44. HULL			X	
20. TOOTH	<u>toot</u>		X			45. THIN		X		
21. PATCH			X			46. SHIRT			X	
22. BOIL	<u>foil</u>		X			47. ROSE			X	
23. HATE	<u>gate</u>		X			48. FIT			X	
24. PICK	<u>sick</u>		X			49. KITE			X	
25. KNIFE	<u>nice</u>		X			50. CAPE			X	

Sum of boxes checked for: 0 4 25 20  
0 1 2 3

**Grand Total:**

1 Phoneme Correct:	<u>4</u>	X 1 =	<u>4</u>
2 Phonemes Correct:	<u>25</u>	X 2 =	<u>50</u>
3 Phonemes Correct:	<u>20</u>	X 3 =	<u>60</u>

# Words with 3 Phonemes Correct = 20 / 50 Words      **Grand Total: 114 / 150 Phonemes**  
(.20 x 100 = 40% or 2 x 20 = 40%)      (.76 x 100 = 76%)

**Figure 2. Example score sheet for the CNC Monosyllabic Words Test (used with permission from Auditory**

## AZBIO TEST PROCEDURES

### Setup

1. Ensure your audiometer and booth are calibrated for the appropriate test materials.
2. Seat the listener in the chair facing the loudspeaker through which the stimulus will be played. Instruct the listener to maintain an upright head position and not to lean forward or to turn his/her head.
3. Instruct the listener with the following written or oral instructions:  
 “This is a test of your ability to understand speech. You will hear a man or a woman reading a list of sentences. Your task is to repeat all of the words in each sentence. Please repeat everything that you hear, even if it is only part of a word or part of the sentence. It is all right to guess. I will stop after each sentence to allow you to repeat what you heard. I will play each sentence only once.”

### Test Protocol in Quiet

1. Adjust Channel 1 to the HL setting that corresponds to 60 dBA and direct Channel 1 output to the desired speaker. (Channel 2 should be turned off)
2. PLAY the sentence. Continue through all 20 sentences, pausing when needed to give the listener time to respond.
3. On the score sheet, circle the words repeated correctly in the sentence. Record the number of words correctly repeated in each sentence in the column marked Score.

### Test Protocol in 10-Talker Babble

1. Instruct the listener with the following written or oral instructions:  
 “This is a test of your ability to understand speech in a noisy situation. You will hear a man or a woman reading a list of sentences in a background of noise that sounds like many people talking in a crowded room. Your task is to repeat all of the words in each sentence. Please repeat everything that you hear, even if it is only part of a word or part of the sentence. It is all right to guess. I will stop after each sentence to allow you to repeat what you heard. I will play each sentence only once.
2. Adjust Channel 1 to the HL setting that corresponds to 65 dBA and direct channel 1 output to the desired speaker.
3. Adjust channel 2 to the HL setting that corresponds to the desired level of noise (e.g., 55dBA for +10 SNR or 60dBA for +5 SNR) and direct channel 2 output to the desired speaker.
4. PLAY the sentence. Continue through all 20 sentences, pausing when needed to give the listener time to respond.
5. On the score sheet, circle the words repeated correctly in the sentence. Record the number of words correctly repeated in each sentence in the column marked Score.

**AzBio Sentence Test  
List 1  
MSTB CD – Track 01  
(Channel 1 = Speech, Channel 2 = Noise)**

Sentence	Text	Poss	Score
1	I could hear another conversation through the cordless phone.	9	3
2	She relied on him for transportation.	6	4
3	He was an ordinary person who did extraordinary things.	9	7
4	How long has this been going on?	7	7
5	His class was on Saturday.	5	5
6	She was entitled to a bit of luxury occasionally.	9	8
7	The vacation was cancelled on account of weather.	8	6
8	The salon is not open on Mondays.	7	3
9	She had a way to justify any of her wrongdoing.	10	6
10	I feel sorry for my brother.	6	6
11	On numerous occasions they left early.	6	4
12	In private she let her hair down.	7	5
13	A mother always has something better to do.	8	4
14	You should be used to taking money from ladies.	9	7
15	Who would lie about cancer for attention?	7	5
16	Hang the air freshener from your rearview mirror.	8	6
17	You can use your computer to make greeting cards.	9	6
18	I guess you know what you're doing.	7	7
19	You must live in a gingerbread house!	7	4
20	The cat was born with six toes.	7	7
		<b>Words Correct</b>	<b>110</b>
		<b>Words Possible</b>	<b>151</b>
		<b>Percent Correct</b>	<b>72.8</b>

**Figure 3. Example score sheet for the AzBio Sentences.**



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## Calculate the Sentence Recognition Score (Figure 3)

Count the number of words correct for each sentence. Total the number of words correct for all of the sentences in the list and divide by the total number of words in the list. The number of words per list is given on the score sheets. For each list, multiply by 100 the ratio of words correct divided by the total words to obtain the score in percent correct.

CNC and AzBio test materials and scoresheets can be downloaded from the ICIT website:

[cochlearimplanttraining.com/mstb](http://cochlearimplanttraining.com/mstb)

### **iii. PATIENT REPORTED OUTCOME MEASURES (PROMS)**

Patient reported outcome measures provide clinicians with relevant disease-specific subjective information on how cochlear implant candidates and recipients are affected by hearing loss. The information derived from such measures supplement the medical and audiological information gathered during the evaluation process and facilitate relevant referrals and recommendations for improved care. Areas that may be important to evaluate using such measures include quality of life, cognition, mental health, spatial hearing, and tinnitus.

The consensus process for the MSTB-3 resulted in a recommendation to include patient questionnaires in the pre-operative evaluation as well as to have them administered as part of the formal post-operative evaluations conducted 3- and 12-months following surgery. Scores obtained pre-operatively can guide discussions with the patient regarding difficulties they are experiencing when using their current hearing technology and the impact that a CI may or may not have on such listening experiences. They can be used both pre- and post-operatively to guide discussions regarding the expectations of the patient and their family members and comparison of pre- versus post-operative scores can be used to document changes in the areas measured by the questionnaire that were impacted by the intervention. Finally, the results of PROMs can be included in reports to insurers as they yield information regarding how the hearing loss impacts the patient's ability to function in their daily life and often support the recommendation that a CI will result in improvements in hearing, daily function, and quality of life.

Questionnaires recommended by the MSTB-3 include the Cochlear Implant Quality of Life (CIQOL-10 Global) and the Speech, Spatial and Qualities of Hearing Scale 12 (SSQ-12). Downloads and links to these questionnaires are available on the ICIT MSTB-3 website ([cochlearimplanttraining.com/mstb](http://cochlearimplanttraining.com/mstb)).

The Cochlear Implant Quality of Life (CIQOL-10 Global)<sup>18-20</sup> provides a comprehensive assessment of functional outcomes in adults with cochlear implants. Additional information about this measure is available at: <https://medicine.musc.edu/departments/otolaryngology/research/cochlear-implant/instruments>

The Speech, Spatial and Qualities of Hearing Scale 12 (SSQ-12)<sup>21</sup> was designed for use with individuals presenting with hearing loss and focuses on features that are typically negatively impacted by hearing loss. In addition to asking the patient about speech perception and quality of hearing, questions regarding spatial hearing are also included as this is critical for safety awareness, environmental understanding of sound, and for incidental learning. The three domains that the SSQ assesses are valuable and all are recommended for use during cochlear implant evaluations to allow for a more complete understanding of an individual's hearing needs and deficiency<sup>22</sup>.

The Tinnitus Handicap Inventory (THI) questionnaire<sup>23</sup> is recommended for inclusion in evaluations when the patient reports tinnitus, which can be a debilitating condition that negatively impacts a person's overall quality of life<sup>24</sup>. Tinnitus is often present in patients with hearing loss and is commonly present in patients with single sided deafness (SSD) or



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asymmetric hearing loss (AHL). The THI provides information regarding the impact that tinnitus has on an individual and can assist with medical decisions, such as the preferred ear for implantation.

Additional questionnaires may be needed to supplement the information obtained from patients and that may facilitate individualized care. The General Anxiety Disorder-7 (GAD-7)<sup>25</sup> and the Patient Health Questionnaire-9 (PHQ-9)<sup>26</sup> are mental health screeners that can help identify patients who are at increased risk for anxiety and depression. While most audiologists encounter patients with mental health concerns<sup>27</sup> it is important to incorporate screening measures in the clinical environment to help the clinician determine if a referral for additional assistance is needed.

#### **iv. COGNITIVE EVALUATION CONSIDERATIONS**

Literature regarding the link between cognition and hearing continues to emerge. Although, the MSTB-3 panel did not specifically recommend the completion of a cognitive screener for all adult patients, members of the panel agree it is important for clinicians to recognize the link between cognition and hearing.

The Likert statements related to inclusion of cognitive screening when evaluating adults that did reach consensus are provided below.

- a) Information regarding hearing and cognition should be included in the MSTB-3 document.
- b) A cognitive screening tool, if used, should be chosen based on validity, specificity and sensitivity, sensitivity to Mild Cognitive Impairment (MCI), and should address attention, memory, and executive function.
- c) Results of the cognitive screening are not designed to exclude a patient from cochlear implantation.
- d) Audiologists should participate in training and/or certification of selected screening tool.
- e) And lastly, cognitive screening should be conducted in a quiet, well-lit environment

Thus, the MSTB-3 recommends that decisions regarding administration of a cognitive screener be left to the discretion of the clinician. Additional information regarding cognitive screening may be found in the Supplemental Literature Reviews section.

## **D. PREOPERATIVE PROTOCOL FOR DETERMINING CI CANDIDACY**

### **i. TRADITIONAL CANDIDATES**

For the MSTB-3, the term “Traditional Cochlear Implant Candidate” refers to patients who demonstrate a significant hearing loss in each ear. Many traditional candidates will qualify for a CI in both ears due to the significant nature of their bilateral hearing loss.

### **UNAIDED AUDIOMETRIC TESTING**

Implant centers may opt to perform audiometric testing if testing has not been performed within the past six months, if the clinician has any concerns regarding the reliability of previous test results, and/or if there are concerns regarding a change in hearing since the patient was last tested. It is recommended clinicians follow the [“Guidelines for Manual Pure-Tone Threshold Audiometry”](#), as published by the American Speech-Language-Hearing Association, when performing unaided audiometric testing. Additionally, pre-operative unaided word recognition testing using recorded materials should be performed when possible.

Audiometric testing should include the test frequencies of 250-8000 Hz. Clinicians should consider including threshold assessment at 125 Hz if the patient is a potential candidate for an acoustic amplifier post-implant if hearing is preserved. Testing should include tympanometry, acoustic reflexes (ipsilateral and contralateral) and OAEs, as warranted.



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Unaided audiometric test results are an important part of the assessment as they will be used for verification of the patient's hearing aids and because insurers often include audiometric requirements in their qualifications for a cochlear implant.

## **HEARING AID VERIFICATION**

Prior to performing aided speech recognition testing, hearing aid verification is performed to ensure that the hearing aids used for testing meet targets or audibility as closely as possible to achieve best aided results. If best aided results can be better achieved using clinic hearing aid(s) rather than with the patient's personal aids, clinic hearing aids should be programmed, verified, and used for aided testing.

## **AIDED SPEECH PERCEPTION TESTING**

The CNC Monosyllabic Word test is used to evaluate each ear separately in the best-aided condition (see above definition) and is a basis for determining a clinical recommendation for a CI. Clinical recommendations for candidacy are based on CNC word scores obtained in the "best aided" listening condition, which is defined as the speech recognition scores for the ear to be implanted using an optimized hearing aid. This is a change from prior methodologies where the best aided condition typically referred to binaurally aided listening.

Procedures for evaluating CI candidacy are recommended below and are outlined in **Figure 4**.

1. Administer one recorded 50-word list of CNC Words to the right ear aided alone at 60 dBA in quiet.
2. Administer one recorded 50-word list of CNC Words to the left ear aided alone at 60 dBA in quiet.
3. Examine the score for each ear to determine if it meets the clinic's requirement for CI Candidacy
4. If neither ear meets candidacy, consider recommending the patient return in one year for re-evaluation, or sooner should they note a drop in hearing.
5. If both ears meet the clinic's requirement for CI candidacy, follow the steps below:
  - a) Administer one list of AzBio sentences to the right ear aided alone at a +10 dB SNR (signal presented at 65 dBA, noise presented at 55 dB A). Both the signal and the noise should be presented from the front speaker (SONO).
  - b) Administer one list of AzBio sentences to the left ear alone at a +10 SNR (signal presented at 65 dBA, noise presented at 55 dB A), both from front speaker (SONO).
  - c) Examine the scores obtained for each ear to determine if there is a preferred ear for implantation or if a bilateral CI will be recommended.
  - d) If the clinician is interested in obtaining additional information to help in the determination of candidacy, consider administering an additional list of AzBio sentences. If the patient performed poorly, consider administering a list of AzBio sentences to the ear to be implanted in quiet. If the clinician is interested in determining how the patient does in a more demanding situation, consider administering AzBio sentences to the ear to be implanted in a +5 SNR (signal presented at 65 dBA, noise presented at 60 dBA), both from the front speaker (SONO).
  - e) To obtain additional information regarding how the patient is performing, the clinician can consider administering AzBio sentences in the person's everyday listening condition (testing with the optimized hearing configuration typical of a person's everyday listening i.e., unilateral, or bilateral hearing technology, unaided/unoccluded).
  - f) Evaluate the insurer's requirements to determine if additional testing is needed (see below for additional information).



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6. If the best aided CNC score for only ONE EAR meets the clinic's requirement for CI candidacy, follow the steps below:
  - a) Administer one list of AzBio sentences to the ear that meets candidacy in an aided alone condition at a +10 SNR (signal presented at 65 dBA, noise presented at 55 dB, with both signal and noise presented from the front speaker (SONO)).
  - b) If the clinician is interested in obtaining additional information regarding the suitability of the ear to be implanted for implantation, consider administering an additional list of AzBio sentences to the ear to be implanted. If the patient performed poorly, consider administering a list of AzBio sentences to the ear to be implanted in quiet. If the clinician is interested in determining how the patient does in a more difficult listening situation, consider administering AzBio sentences to the ear to be implanted in a +5 SNR (signal presented at 65 dBA, noise presented at 60 dBA), both signal and noise presented from the front speaker (SONO).
  - c) To obtain additional information regarding how the patient is performing in their everyday listening situation, the clinician can consider administering AzBio sentences in the person's everyday listening condition (testing with the optimized hearing configuration typical of a person's everyday listening i.e., bilateral hearing technology or unaided/unoccluded). This may not be needed if the patient utilizes a unilateral hearing aid in the ear that has already been tested. The clinician should consider administering this list of sentences using the same SNR as the most difficult test situation used above when the ear to be implanted was tested alone.
  - d) Evaluate the insurer's requirements to determine if additional testing is needed (see below for additional information).

It is up to individual clinics to determine the CNC cut-off score that will be used to determine CI candidacy. A review of the literature revealed recommended cut-off scores of 40%<sup>6</sup>, 50%<sup>28</sup>, and in some instances, 60%<sup>29</sup>. Clinicians are encouraged to review the studies cited above to help them determine their clinic's cut-off score for CI candidacy.

## **EXAMINATION OF INSURER'S REQUIREMENTS**

As indicated previously, it is important for clinicians to determine if a patient qualifies for insurance coverage of a CI based on a review of the insurer's requirements. These requirements often include statements regarding audiometric, radiologic, and medical findings. Additionally, some insurers may require patients participate in a hearing aid trial. Some insurers may specify test parameters that need to be used when determining if a patient qualifies for coverage, i.e., specifying that best aided is reflective of a score obtained in a bilateral aided condition. Some insurers may require patients demonstrate hearing thresholds poorer than a specific pure tone average (PTA) to receive coverage for the CI. Clinicians must carefully review the insurer's requirements to determine if additional tests or conditions need to be included in the evaluation, and to determine if the patient qualifies for coverage based on their insurer's requirements.

## **PATIENT REPORTED OUTCOME MEASURES**

Next, clinicians are encouraged to administer and score patient reported outcome measures as described previously.

## **DOCUMENTATION OF FINDINGS**

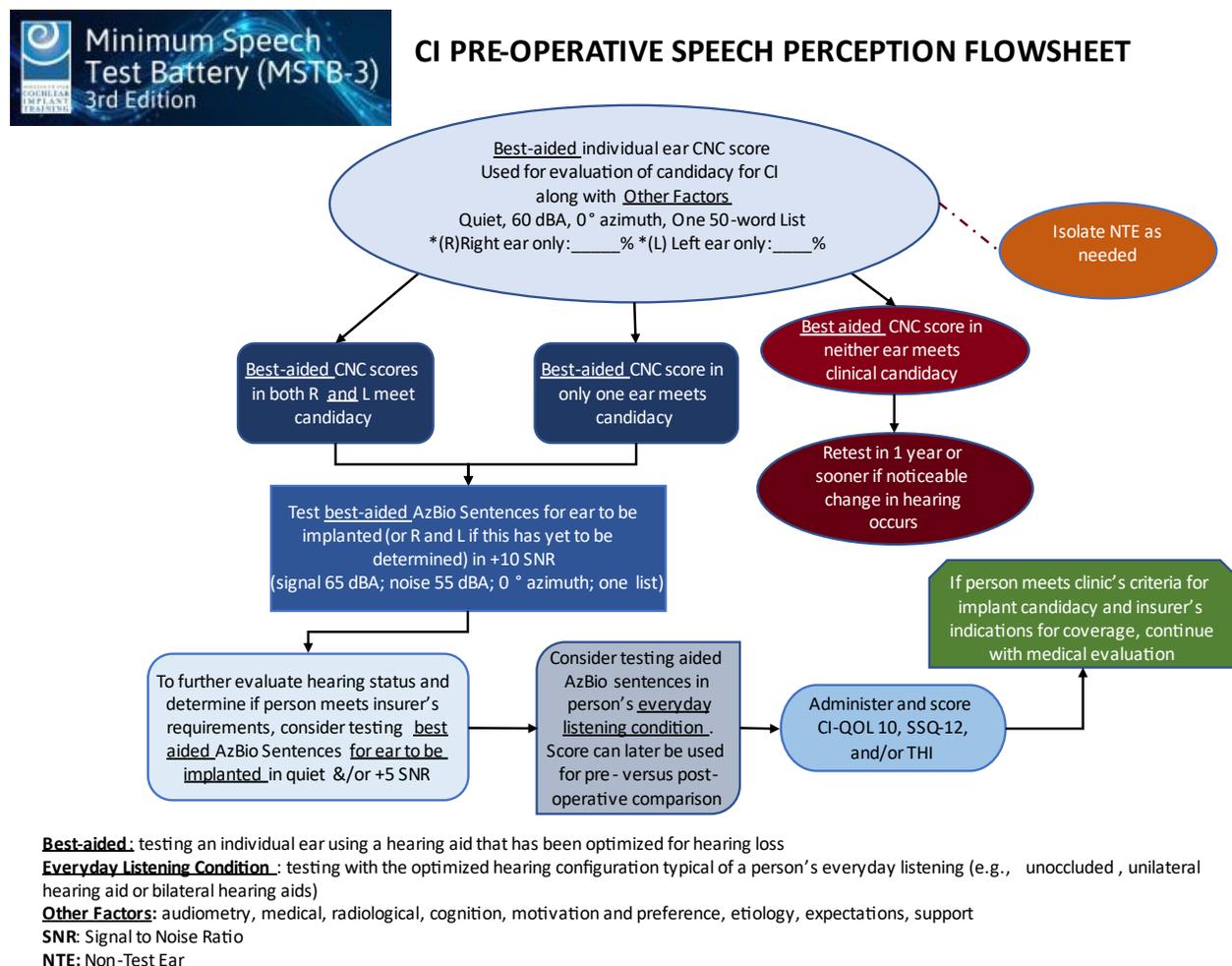
An essential component of the evaluation is documentation of the results. Upon completion of testing, clinicians should follow a standardized approach to reporting outcomes. This should include a comprehensive patient history, and description of the testing that was performed and clear delineation of the scores. The report should conclude with a statement regarding if a CI is recommended and if the patient qualifies for a CI based on their insurer. To assist with this

important aspect of care, the MSTB-3 provides sample templates for pre- and post-operative evaluation of outcomes. Such documentation serves as a means for communicating with other professionals regarding outcomes and recommendations. Additionally, a sample patient summary report is also included in the MSTB-3. Such a report can be provided to patients to ensure they understand the results of the evaluation and that they understand items that were discussed during the appointment.

### REFERRAL FOR MEDICAL EVALUATION

Once testing has been completed, the patient is referred to the CI surgeon. Copies of reports are provided, and the patient determines if the patient is a medically suitable candidate for a CI.

The pre-operative protocol described above is described graphically in **Figure 4**.



**Figure 4. Speech perception flow chart with steps to determine candidacy and qualification for insurance coverage for cochlear implantation. CNC Monosyllabic Word scores and other factors are used as the clinical basis for determining candidacy. Other measures and test conditions could be considered for further evaluation and insurance qualification.**



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## **ii. ELECTRO-ACOUSTIC STIMULATION**

Electric-acoustic stimulation (EAS) is the term typically used to describe the joint provision of electrical stimulation along with low-frequency acoustic stimulation for cochlear implant recipients who have normal hearing sensitivity to moderate hearing loss in the low-frequency portion of the speech frequency range (i.e., 1000 Hz and below). EAS is possible when low-frequency acoustic hearing is preserved after cochlear implantation.

Research has shown EAS is most likely to be beneficial for recipients whose low-frequency audiometric thresholds are better than 70 to 75 dB HL<sup>28,30-34</sup>; however, research has demonstrated benefit for individuals with low-frequency audiometric thresholds >80 dB HL (e.g.,<sup>30,31,35,36</sup>). If a patient demonstrates pre-operative hearing in this range, and the clinician feels the patient may be a suitable candidate for use of an acoustic amplifier, this information should be included in the patient report as doing so will alert the surgeon that the patient is a candidate for hearing preservation during surgery.

The MSTB recommends use of the test protocol described for traditional candidates above when evaluating patients who may be candidates for post-operative use of electroacoustic stimulation if their low frequency hearing is preserved.

## **iii. SINGLE SIDED DEAFNESS (SSD) AND ASYMMETRIC HEARING LOSS**

There are unique considerations clinicians need to be aware of when evaluating patients with SSD or AHL. For example, it is important for clinicians to ensure the patient has received appropriate medical evaluation and treatment, if indicated, for their unilateral hearing loss prior to being evaluated for a CI. Such treatment may include steroids if the patient experienced a sudden hearing loss in the affected ear. Additionally, radiographic testing is essential to rule out the possibility of a tumor or structural abnormality of the hearing nerve which may complicate a recommendation for a CI.

### **AUDIOMETRIC TESTING**

Like traditional candidates, testing of patients with SSD or AHL should begin with audiometric testing, if indicated, and verification of the hearing aid to be used in best aided testing. Special attention should be taken to ensure that appropriate masking levels are used throughout all test procedures used with patients with SSD or AHL.

### **BEST-AIDED CNC WORD TESTING AND ISOLATING THE NON-TEST EAR**

Determination of the best aided individual ear CNC score for the ear being considered for a CI should be completed using a 50-word recorded list presented to the soundfield in quiet at a level of 60 dBA. It is up to the clinician to determine the preferred method for isolating the poorer ear during testing. Options include the plug and muff approach<sup>37</sup>, presentation of masking via an insert earphone to the better ear<sup>38</sup>, application of masking in combination with circumaural earphones placed over the better ear<sup>39,40</sup>, and use of direct audio input or direct connect to the hearing device<sup>37</sup>.

If the best aided CNC score for the ear being considered for a CI exceeds the clinic's cut off score for candidacy, a recommendation should be given for the patient to return in one year for retesting, or sooner should they note a change in hearing. If the score for the ear being considered for a CI meets the clinic's cut off score for candidacy, additional testing should be performed.

### **AZBIO SENTENCES IN THE BEST AIDED CONDITION**

Although FDA indications for SSD and AHL typically place emphasis on a monosyllabic word score as the determinant for CI candidacy, many insurers require patients to demonstrate a minimal sentence score to qualify for coverage.



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Additionally, if a CI is not covered by a patient's insurer, but the clinician plans to ask the insurer for coverage, sentence scores are often helpful at demonstrating the impact the unilateral or asymmetric hearing loss has on speech recognition. The MSTB-3 recommends the preferred test condition for determining CI candidacy is SONnh or SONB and includes delivery of sentences at a 0 SNR (both signal and noise presented at 65 dBA) with the signal delivered from the front speaker (S0) and noise coming from the speaker situated near the patient's normal (NH) or better ear (NB).

## ***TESTING IN THE EVERYDAY LISTENING CONDITION***

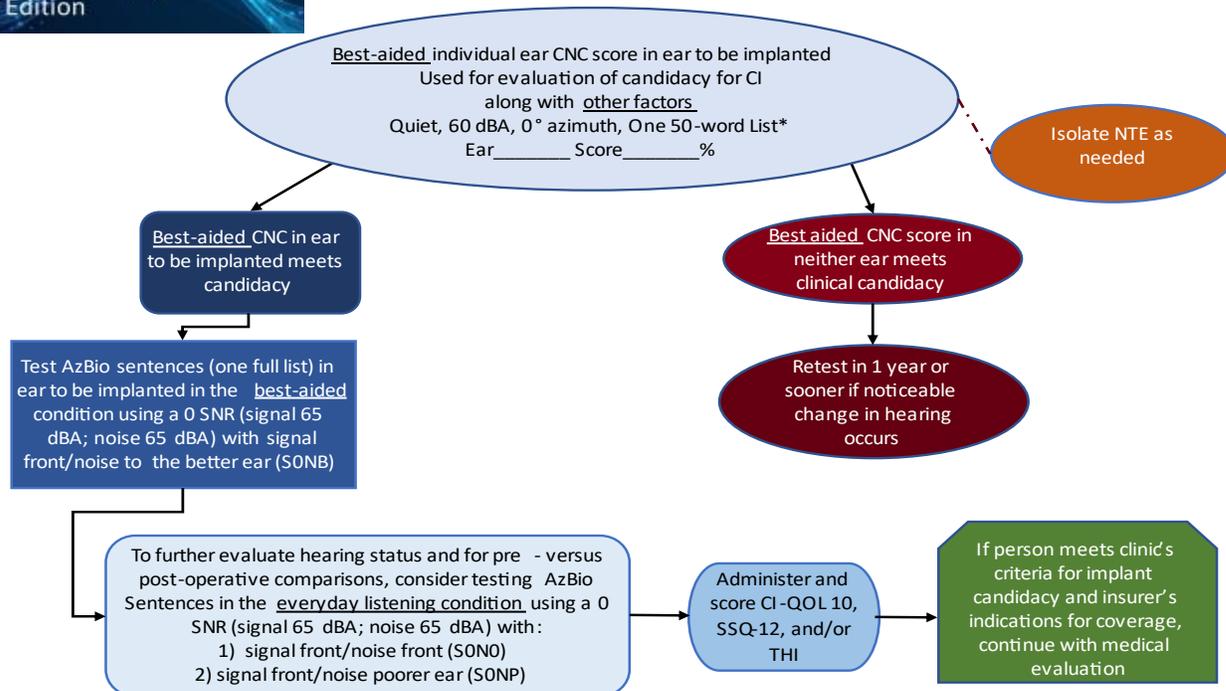
Clinicians often choose to administer additional sentence lists in a variety of configurations to evaluate and document the difficulties patients with SSD or AHL have in different listening conditions, including testing in the everyday listening condition. In this condition, an additional list may be administered using a 0 SNR (both signal and noise presented at 65 dB A) with the signal and the noise both delivered from the speaker located at 0 degrees azimuth (SON0) or presenting a list where the signal is presented from the front and noise is presented to the poorer ear (SONP).

## ***PATIENT REPORTED OUTCOME MEASURES***

Patients who present with SSD often report severe tinnitus in the ear to be treated. If tinnitus is present, the MSTB-3 recommends the Tinnitus Hearing Index (THI) be used to evaluate the impact that tinnitus has on the patient's daily life. This is in addition to the CI-QOL and SSQ-12 that are recommended for all CI candidates. Clinicians often choose to include the results of the THI in the report to the insurer when seeking coverage of a cochlear implant, since an added benefit of a CI often includes post-operative reduction in tinnitus.

The pre-operative protocol for determining CI candidacy in patients with SSD is provided in **Figure 5**.

## CI PRE-OPERATIVE SPEECH PERCEPTION FLOWSHEETSSD



**Best-aided:** testing an individual ear using a hearing aid that has been optimized for hearing loss

**Everyday Listening Condition:** testing with the optimized hearing configuration typical of a person's everyday listening (e.g., unoccluded, unilateral hearing aid or bilateral hearing aids)

**Other Factors:** audiometry, medical, radiological, cognition, motivation and preference, etiology, expectations, support

**SSD:** Single-Sided Deafness

**SNR:** Signal to Noise Ratio

**NTE:** Non-Test Ear

**Figure 5. Speech perception flow chart with steps to determine candidacy and qualification for insurance coverage for patients with single-sided deafness (SSD). CNC Monosyllabic Word scores and other factors are used as the clinical basis for determining candidacy. AzBio sentences could be administered in a variety of test conditions to supplement information for candidacy consideration and insurance qualification.**

## E. POSTOPERATIVE TEST PROTOCOLS

### i. RECOMMENDED TEST INTERVALS

Like pre-operative testing, the MSTB3 provides a detailed protocol to guide clinicians in their post-operative testing of CI recipients, as outlined in **Figure 2**. Unlike previous versions of the MSTB, the MSTB-3 recommends post-operative testing be performed on all patients 3- and 12-months post-implant. If the patient is not performing optimally at 3 months, the clinician should consider additional testing prior to the 12-month post-activation timeframe to ensure the patient is making adequate progress with the device.



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## ii. CALIBRATION, ROOM SET-UP AND TEST PREPARATION

Particular care needs to be taken to ensure that all patients are tested using standardized test procedures. This includes ensuring that the test room is appropriately set up and that all equipment has been calibrated. See section B above for a detailed description regarding calibration.

Prior to conducting post-operative testing, the clinician should ensure that devices (hearing aid(s) and/or cochlear implant(s)) are working properly, sound quality has been checked, and that all devices have been verified and/or optimized. If a hearing aid is used when testing patients in a bimodal condition, hearing aid verification should be performed on the aided ear. If an acoustic amplifier is used as part of an EAS sound processor, the acoustic amplifier should be optimized and verified prior to testing. Other considerations include use of appropriate test measures to isolate the test ear when needed (as previously described above for pre-operative testing), and use of recorded sentences in a patient's native language, when possible, when testing non-English speaking recipients.

## iii. AUDIOMETRIC TESTING

For unaided audiometric testing, pure tone thresholds should be determined for the implanted ear post-operatively if functionally audible thresholds were present prior to implantation. If an acoustic amplifier is being used, unaided audiometric testing of the implanted ear should be performed prior to each appointment where programming of the sound processor occurs. For the non-implanted ear, threshold testing should be performed annually, as well as during any appointment where concerns are expressed about a recent change in hearing in that ear.

## iv. HEARING AID VERIFICATION

Hearing aid verification should be performed on each aided ear prior to performing speech recognition testing. This includes verification of the hearing aid on the contralateral ear or verification of the acoustic amplifier if used in conjunction with the sound processor on the implanted ear. If optimal results cannot be achieved with the patient's hearing aid, the clinician should consider using a clinic hearing aid that has been optimized for the patient's hearing loss prior to conducting speech recognition testing of that ear, particularly if the non-implanted ear is being considered for a cochlear implant. If optimal results cannot be achieved with the patient's acoustic amplifier, the acoustic amplifier should be replaced, optimized, and verified to meet prescriptive targets.

## v. SOUNDFIELD THRESHOLD TESTING

Soundfield threshold testing should be performed for the patient's primary sound processor program whenever a formal evaluation of speech recognition is performed, as well as if concerns arise regarding the accuracy of the patient's sound processor program. Such testing should include determination of thresholds warbled pure tones ranging from 250-6kHz are presented to the soundfield. Aided thresholds with a well fit CI typically fall between 20-30 dB HL. If detection is not optimal, the clinician should troubleshoot the patient's equipment to ensure it is working properly and should also consider reprogramming the device prior to performing speech recognition testing.

## vi. SPEECH RECOGNITION TESTING

### **CNC MONOSYLLABIC WORD TESTING**

Post-operative speech recognition testing (**Figure 6**) begins with administration of the CNC Monosyllabic Words Test in quiet for the implanted ear(s). This includes administration of one 50-word list in the patient's best aided condition where the signal is presented to the implanted ear(s) in quiet at a level of 60 dBA.



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## ***AZ BIO SENTENCE TESTING***

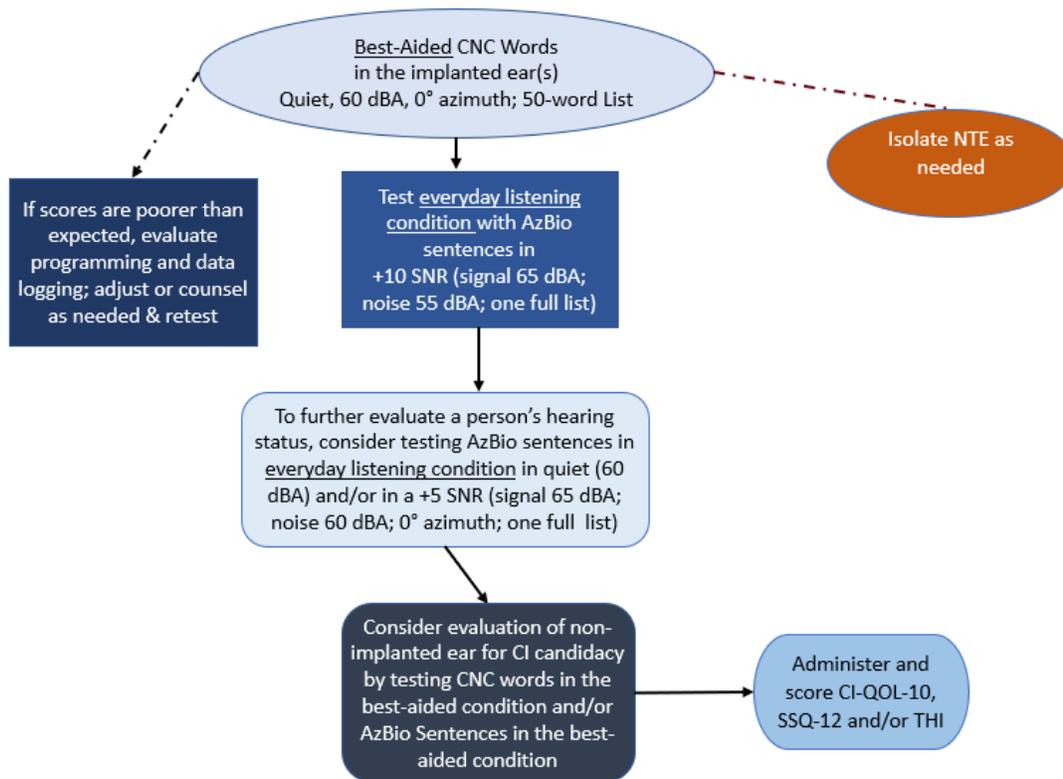
To evaluate pre- versus post-operative comparison of speech recognition, the clinician should consider administering one list of AzBio Sentences at +10 signal-to-noise ratio (SNR) (sentences presented at 65 dBA, noise at 55 dBA) in the person's everyday listening condition (bimodal, bilateral, unilateral). For additional information regarding the patient's performance, the clinician can consider presenting an additional list of AzBio sentences in quiet (sentences presented at 60 dBA), if the +10 SNR was not used pre-operatively. If the more difficult test situation of +5 SNR was used preoperatively, the clinician can consider administering one list of AzBio sentences at a +5 SNR (sentences presented at 65 dBA, noise at 60 dBA). The clinician may also choose to administer one list of AzBio sentences to the implanted ear only if additional information is desired.

Clinicians are reminded to apply effective masking to the non-test ear if indicated during post-operative speech recognition testing. If scores are poorer than expected, the clinician is encouraged to check factors that may impact performance, such as the number of hours of device use (datalogging) as well as check to make sure the device is optimally programmed. The patient should be counseled appropriately, and performance should be monitored over time to ensure the patient is making adequate progress.

For patients with SSD, the default presentation condition used pre-operatively to determine CI candidacy included AzBio sentences presented to the front with noise presented to the side of the normal hearing ear [SONB or SONnh]. Thus, this should be the preferred test condition for comparing pre- versus post-operative performance. Additional conditions that could be administered, particularly if they were administered pre-operatively, include presentation of the signal and the noise to the front [SON0] or presentation of the signal to the front and noise to the implanted ear [SONci]. When testing in noise, clinicians are reminded to present the signal at 65 dBA while the noise should be presented either 10 dB (for a +10 SNR) or 5 dB (for a +5 SNR) lower than the presentation level used for the signal.

## CI POST-OPERATIVE SPEECH PERCEPTION FLOWSHEET

Completed at 3 months, 12 months, and Annually thereafter



**Best-aided:** testing an individual ear using an optimized acoustic amplifier as needed based upon functionally aidable residual hearing.

**Everyday Listening Condition:** testing with the optimized hearing configuration typical of a person's everyday listening (e.g., bimodal, unilateral CI, bilateral CIs, EAS with contralateral HA; testing should be completed best-aided when a HA/acoustic amplifier is used).

**SNR:** Signal to Noise Ratio

**NTE:** Non-test ear

**Figure 6. Post-operative test protocol to evaluate performance with a CI.**

### vii. EXAMINATION OF BIMODAL BENEFIT

If the patient is performing appropriately on CNC words with the CI, the clinician can compare scores obtained using the CI alone on AzBio sentences in a +10 SNR (SON0) and compare that to the score obtained when the patient utilizes a hearing aid on the non-implanted ear in conjunction with the CI (bimodal hearing). Subtraction of the score obtained with CI alone from the score obtained using CI+HA can be as an indicator of bimodal benefit the patient receives from using both devices. Little or no difference between scores obtained on these two test conditions may indicate reduced bimodal benefit and may signal a need to further evaluate the non-implanted ear as a possible candidate for a CI.

### viii. EVALUATION FOR A BILATERAL CI

If a bilateral CI is being considered, the clinician may choose to administer CNC words to evaluate the non-implanted ear for CI candidacy. If the ear meets the clinic's cut off score for a CI, a recommendation to complete the pre-operative test protocol to evaluate CI candidacy should be considered. If such an evaluation occurs, the clinician needs to perform



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unaided testing of the non-implanted ear to determine if the hearing aid is appropriately optimized based on verification results. If time does not allow for such testing, the clinician may ask the patient to return for a CI candidacy evaluation.

## ix. PATIENT REPORTED OUTCOME MEASURES

Finally, the MSTB-3 recommends that patient questionnaires be administered in conjunction with speech recognition testing to derive additional information regarding the patient's overall hearing performance. Pre- and post-operative scores obtained on such measures can be compared to further evaluate benefit derived from the use of the CI. The results of the questionnaires should be evaluated to determine areas of listening that the patient is excelling or struggling with. Results should be reviewed with the patient, and recommendations should be provided regarding areas of difficulty.

## x. EAS PATIENTS

Post-operatively, several steps are recommended for EAS patients:

1. the clinician should check the audiometric test results of the implanted ear no later than 1 month following device activation to determine the viability of providing a map to the patient that utilizes both electric and acoustic stimulation.
2. During subsequent appointments, unaided pure-tone audiometry (AC) is completed for the implanted ear prior to CI programming at each clinic visit to determine whether additional programming and verification of the acoustic component should be completed.
3. Speech perception testing is minimally conducted in the CI-ear alone (CI+ipsilateral HA) and in the bilateral condition (CI+ipsilateral HA + contralateral HA) 3-, and 12-months following activation.
4. After the first year of EAS use, speech perception testing is completed in the EAS ear and bilateral (EAS or EAS + contralateral hearing aid) condition at least annually following unaided audiometry and HA verification.
5. EAS ear performance is assessed with the non-implanted ear occluded either via EAR foam plug or fully occluding earmold with the HA turned off.
6. For EAS patients, unaided pure-tone audiometry (AC & BC) is completed for the non-implanted ear 1) annually, 2) following reports of hearing changes to guide hearing aid (HA) verification via probe-microphone measures, and/or 3) to help determine CI candidacy for that ear.
7. For EAS patients, aided speech perception testing for the non-implanted ear alone is completed annually to help determine CI candidacy for that ear.
8. Because EAS benefit is driven at least in part by access to low-frequency interaural timing difference (ITD) cues provided by binaural acoustic hearing, the acoustic or HA component should not attempt to provide amplification above 1000 Hz in the implanted ear irrespective of the unaided thresholds in the high-frequency range as the implant will transmit information in this frequency region.

## F. REPORT TEMPLATES

The MSTB-3 consensus group recognizes the significant role that consistent and thorough documentation plays in evaluation and treatment of patients with cochlear implants. Members of the consensus panel provided samples of the reports they use in clinical care. These samples were then used to create report templates for the MSTB-3, including a report template for pre-operative evaluation of CI candidacy and post-operative programming. A sample patient After Visit Summary (AVS) is also provided to ensure patients are provided with written information regarding the results of the CI evaluation and summarizes what was discussed during the appointment. Additional information regarding the value of clinical documentation may be found in the Supplemental Literature Review section and the report templates may be found in the Report Template section.

## 4. SUPPLEMENTAL LITERATURE REVIEWS

### A. COGNITION

Literature regarding the link between cognition and hearing continues to emerge. Although, the MSTB-R does not specifically include the completion of a cognitive screener in standard practice, contributors to this document believe in the importance of our role in supporting the link between cognition and hearing. We have a better understanding that hearing loss is positively associated with a risk of dementia, especially in patients aged 45 to 64 years<sup>41</sup>. Hearing protection, screening, and treatment may be used as strategies for mitigating this potential risk factor<sup>41</sup>. As providers, we need to consider the larger impact that good hearing health and early identification may have on overall public health and the healthcare costs. The Lancet Commission on dementia prevention, intervention, and care suggests that addressing modifiable risk factors might prevent or delay up to 40% of dementia cases<sup>42</sup>. According to the Alzheimer's Association<sup>43</sup>, the number of individuals aged 65 years and older with Alzheimer's disease (AD) is expected to exceed 13 million by 2050, becoming one of the greatest burdens on the United States health care system. Cognitive screening is an important public health issue to try and mitigate the risk factors for cognitive decline, hearing loss being one of the most prominent<sup>41,42,44</sup>.

As audiologists, we do not receive formally trained regarding cognitive decline. It is imperative that we learn about the stages of cognitive decline and how this information can be utilized to provide holistic, patient centered care and ensure appropriate, timely referrals. The precursor to dementia is Mild Cognitive Impairment (MCI). The Alzheimer's Association reports that MCI is an early stage of memory loss or other cognitive ability loss (such as language or visual/spatial perception) in individuals who maintain the ability to independently perform most activities of daily living. However, mild cognitive impairment (MCI) occurs five times more frequently than dementia in the older population<sup>45</sup>. It is reported that 10-15% of individuals with MCI will progress to Alzheimer's in 5 years<sup>46</sup>. Mild cognitive impairment is commonly undiagnosed. Studies show that 80% of patients in primary care have undiagnosed MCI and among those patients, 60-80% have Alzheimer's disease<sup>47 43</sup>. Screening can prompt early diagnosis of the patient for reversible causes of memory loss. Healthcare professionals who serve an aging population, audiologists are likely to encounter undiagnosed cases of cognitive impairment<sup>47</sup>. In order to provide timely referral for medical assistance as well as an optimized individual outcome of audiologic interventions, audiologists should be trained to recognize abnormality in cognitive status<sup>45</sup>.

Although contributors did not reach full consensus on cognitive screening as a part of the MSTB-R, several Likert statements reached consensus:

- a) Information regarding hearing and cognition should be included in the MSTB-R document.
- b) A cognitive screening tool should be chosen based on validity, specificity and sensitivity, sensitivity to Mild Cognitive Impairment (MCI), and address attention, memory, and executive function.
- c) Results of the cognitive screening are not designed to exclude a patient from cochlear implantation.
- d) Audiologists should participate in training and/or certification of selected screening tool.
- e) And lastly, cognitive screening should be conducted in a quiet, well-lit environment.

Cognition plays a critical role in listening and communication, especially impacting speech-in-noise perception. Listening is more demanding for listeners with auditory impairment and/or poor cognitive abilities<sup>48</sup>. Differences in cognitive processing abilities most likely explains different audiological outcomes despite similar audiograms. Cognitive abilities are associated with speech-in-noise performance, which is the most representative of a patient's real-world performance. As the severity of the hearing loss increases the impact of cognitive processing abilities on understanding speech-in-noise increases<sup>49</sup>, suggesting that individuals being considered for a cochlear implant will be more reliant on cognitive processing. Cognition must be considered to optimize treatment/management outcomes<sup>45</sup>. Cognitive



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screening will help to assess target areas for functional auditory rehabilitation (i.e., speech-in-noise), which in addition to enhancement of auditory perceptual abilities, may need to include enhancement of language and memory domains as well <sup>49</sup>. Understanding cognitive processing abilities will help audiologists devise an effective management plan and assist in counseling regarding expectations post-implantation, particularly in background noise. In a recent study by Walia et al <sup>50</sup>, the inclusion of the MoCA had the greatest impact on the prediction of AzBio +10 dB SNR postoperative performance, accounting for more variance in speech perception performance in noise than duration of deafness, age, or electrode placement. The culmination of research suggests that, as providers, we should be exploring the place of a cognitive screener within our practice.

Looking forward, we will continue to explore the literature as it relates to screening tool recommendations and outcomes measures demonstrating the benefit of hearing aid and cochlear implantation on cognitive performance. As we implement a cognitive screener within our practices, we must remember that cognitive screenings are not diagnostic tools and should not be used to diagnose cognitive impairment <sup>51</sup>. Utilization of a cognitive screener will require us to consider appropriate patient and professional communication, define the appropriate referral process, increase patient and physician outreach regarding the link between hearing loss and cognitive decline, determine appropriate follow-up screening protocol, learn how to use screening results to improve patient care, and continue as a profession to increase our knowledge of normal cognition and signs of decline.

## **B. DOCUMENTATION**

### **i. BACKGROUND**

Clinical documentation is an essential component of any medical or audiologic practice. Clinical documentation serves multiple purposes including record-keeping for the managing provider, communication to referring and co-managing providers for continuity of care, support for the diagnosis, justification of treatment recommendation for reimbursement and/or implant candidacy determination, and historical tracking for patients. Regulatory requirements have continued to increase around quality of care provided to patients and the quality of care is often assumed to be based on the quality and thoroughness of clinical reports <sup>52</sup>. Providers tend to think of clinical note-writing as a necessary step to capture the key aspects of the visit and to protect oneself should future concern be raised for interventions provided. However, this application of clinical note review is perhaps the least commonly utilized. More commonly, clinical notes are used to aggregate results and assess outcomes, compel insurance providers to accurately review a submission for coverage benefits, and communicate decision-making. Thus, the clinical note represents a prime opportunity to not only retroactively document clinical activity but also to proactively guide behaviors and decision-making, enhance quality of care provided, reduce burden for providers, and improve clinic efficiency.

The development of electronic health records (EHR) was intended to streamline the documentation process, while enhancing detail and quality of note-writing. Quite the inverse result has been repeatedly noted, however. The process of using EHR has been cited as a leading cause of provider burnout <sup>53</sup> adding time to administrative duties with variable impact on quality, reimbursement, and outcomes. Often, this inefficiency and stress is due to lack of standardized templates and documentation requirements. Furthermore, most approaches do not take advantage of clinical decision support measures to guide clinician practices <sup>54</sup> which results in a compounding effect of both evolving care and enhancing documentation. In recent years, various tools and techniques have been developed to improve documentation quality and reduce the associated time commitment <sup>52</sup>.

Cochlear implant providers face the additional challenge of practice inconsistencies which this most recent version of the Minimum Speech Test Battery attempts to address. Prentiss et al <sup>55</sup> reported considerable variability in preoperative testing methods, result interpretation, and determination of candidacy and suggested that “this lack of standardization



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in the delivery of care may increase the risk for health care inequities, specifically in access to care for adults with clinically significant hearing loss<sup>7</sup>. Additionally, inconsistent clinical practices limit advancement of the field because data are difficult to aggregate making trends nearly impossible to identify.

In addition to the benefits of a standardized battery proposed by the updated Minimum Speech Test Battery, an accompanying standardized template offers the following benefits:

1. Standardized approach to clinical measures guides better quality of outcomes;
2. Ability to compare results across providers and centers and aggregate data for research studies;
3. Reduced burden for providers and increase clinic efficiency;
4. Reduced inconsistency of candidacy determination;
5. Reduced insurance denials due to completeness of data.

## ***STANDARDIZED APPROACH TO CLINICAL MEASURES GUIDES BETTER QUALITY OF OUTCOMES***

Standardized clinical templates often include the integration of decision support by incorporating the recommended questions of a comprehensive patient history and minimum guidelines for key objective and subjective measures. Having clinically relevant aids presented during the note-writing process itself prompts clinicians to include queries and assessments they might not otherwise consider<sup>54</sup>. For example, a focused and clinically organized template could help remind the provider to ask about duration of hearing loss or likelihood of progression based on etiology, options the provider might otherwise have overlooked. Ebbers et al<sup>52</sup> reported that structured and standardized recording leads to an increase in the quality of the notes recorded in the EHR. They cited the consistency of repetition that standardized notes provide as an effective training tool for the inclusion of relevant visit components. Parikh et al<sup>56</sup> similarly noted routine aspects of an appointment that are important to quality care were more frequently documented with standardized templates and increased inclusion of uncommon factors. Lastly, delay in time to treat may be reduced when standardized templates are utilized<sup>57</sup>.

## ***ABILITY TO COMPARE RESULTS ACROSS PROVIDERS AND CENTERS AND AGGREGATE DATA FOR RESEARCH STUDIES***

There is increasingly interest in using electronic medical records to develop patient registries, which are data repositories rich with information that can be retrospectively analyzed. Registries are “patient-centered, purpose-driven, and designed to derive information on defined exposures and health outcome” which contrasts with the transactional nature of the electronic medical records<sup>58</sup>. Nevertheless, registries and EHRs are interdependent; successful registries rely on consistent documentation of data over time and across providers.

## ***REDUCED BURDEN FOR PROVIDERS AND INCREASE CLINIC EFFICIENCY***

While widespread practice is to document in free text, there are numerous benefits of using discrete data. In addition to seamlessly extracting data for registries, minimizing free text decreases the time spent inputting data, particularly after repeated exposure to standardized templates<sup>52</sup>. “Note bloat” refers to the increased length and redundancy of notes observed in recent years<sup>59</sup> which impacts provider experience and reduces readability and therefore effective communication. The use of optimized note templates may not only improve efficiency in documentation but also may increase provider satisfaction<sup>60,61</sup>.

## ***REDUCED INCONSISTENCY OF CANDIDACY DETERMINATION***

Although not well explored in the literature, the value of standardized templates for earlier identification of need for surgical intervention and reduction in treatment delays has been documented<sup>57,62</sup>. Determination of cochlear implant candidacy is often impeded by varying approaches to aided speech testing inclusion and result interpretation. Use of a



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standardized template that encourages a universal approach to test administration and candidacy determination may act as a guide to encourage more consistency across centers and providers.

## **REDUCED INSURANCE DENIALS DUE TO COMPLETENESS OF DATA**

Clinical documentation that supports clinical decision-making and justification of treatment recommendations is essential to the determination of coverage by payers. In addition to meeting compliance requirements, thorough documentation that demonstrates an assessment aligned to best practices and accurately reflects the care provided increases the likelihood of meeting the burden of evidence required by insurance. This may ultimately improve reimbursement for services<sup>63</sup>.

## **ii. CONCLUSIONS**

Clinical documentation is an essential component of any visit, but for reasons beyond compliance and historical record-keeping. The utilization of well-written standardized templates can deliver numerous benefits ranging from improving provider satisfaction to achieving optimal clinical outcomes. Cochlear implant programs have a unique opportunity to leverage a documentation tool that is standardized across programs. Using consistent, optimal documentation that includes clinical decision support, communicates common factors for determination of candidacy, and facilitates aggregation of data may encourage increased utilization of cochlear implants across CI programs.

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