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Modern Approach to Evaluating Speech Perception with the Minimum Speech Test Battery – Revision 3

Presenter: Camille Dunn, PhD; Terry Zwolan, PhD

Hello everyone, and thank you for joining us on our audiology online modern approach to evaluating speech perception with the MSDB three and our learning outcomes. So after this course, participants will be able to describe the process of consensus that was used to develop the MSDB three, define the MSDB three test battery for both pre and post operative candidates and recipients, and explain how to apply case study examples to assist with decision making processes for cochlear implant candidacy and postoperative follow up.

I'd like to begin by acknowledging the MSDB three team, especially my colleague and friend Camille Dunn. It was really a pleasure to work with Camille on the MSDB three, but if we look at this group of experts that put together the MSDB three, when I talk about the MSDB three, I say it was really one of the most impactful things that I've worked on in my career. Look at that group of professionals. To be able to work with them to try to develop a test protocol that could be used for both pre and post operative testing was really quite an amazing experience for me. These people are all brilliant and outspoken, so we had great discussions, but I think you'll be happy to hear all about the MSDB three.

That was our final result that we ended up with. The MSDB three was funded by the cochlear implant manufacturers, advanced bionics, cochlear and meddle. And they do like to mention that although they provided partial funding for this project, sometimes there is a discussion about off label in talking about cochlear implant candidacy, and they do not endorse any off label use of their products. Next slide, please. So why a new test battery?

The minimal speech test battery has been around for a very long time, since the late 1990s, and the most recent version was introduced in 2011, which, gosh, that's 13 years ago. And we know that CI candidacy has changed so much in the last 13 years, probably more in the last 13 years than it ever has before. Because during that time,

hybrid and eas and asymmetric hearing loss and single sided deafness all have received FDA approval. And that has really changed who our cochlear implants are to this day. And what's happened is that that led us to a disconnect between clinical recommendations of who clinicians feel are good candidates for a cochlear implant, and what the FDA or the insurers are telling us is a cochlear implant candidate.

So as we changed our testing, we saw that clinics became inconsistent regarding the test measures used to evaluate and determine candidacy. So with the introduction of sentences in noise, we all started with a plus ten and some clinics went to plus five, some clinics went to zero signal to noise and we were really inconsistent across clinics regarding how we were determining candidacy. And this really has led to confusion amongst so many of us. Amongst our referral sources. Our refers might say, you know, if I send my candidate to clinic a, they'll probably be identified as a candidate, and if I send this person to clinic b, they might say that they're not a candidate and how do I know which one is right?

And so our referral sources were confused and that's really impacted referrals. CI professionals within, in clinics, some would say, I like to use a plus five signal to noise ratio and other ones said, I only feel comfortable with a plus ten. So even within our clinics, sometimes professionals were confused and that really led to confusion for our patients as well. And importantly, what we've seen with those recent FDA approvals, especially single sided deafness and asymmetric hearing loss, those, the FDA utilized real world evidence to make decisions about those FDA approval. And we know if in the future the FDA or Medicare or insurers are going to come to us as clinicians to utilize real world evidence, it will be much better if we're all on the same page and using similar test materials to determine candidacy and evaluate postoperative performance.

Next slide, please. So the purpose of the MSDB three, when we all got together, we said we really wanted to develop an evidence based, streamlined test batteries that would be widely and consistently used to determine preoperative candidacy and to perform postoperative assessment of adult cochlear implant patients.

Next slide. So the goals, we really wanted our test materials to be in an electronic format, no more CDs. And with that, with the electronic format that we can now download the materials, we're able to offer 15 additional AZ bio sentences. That was sort of a plus that came with the development of the MSDB three. We wanted streamlined test batteries for all patients, not just for our traditional CI candidates, because our candidacy has changed.

So we really wanted to provide information that applied to all candidates, including single sided deafness, asymmetrical and those who utilize electroacoustic stimulation. We wanted it to be a minimal battery that applied to most patients. If we look at the previous version of the MSDB, we saw that they gave us a pretty lengthy test battery and they said, if you're running short on time, use this minimal battery. Well, we wanted to do the opposite. We wanted to start with a minimal battery and then provide additional tools if needed to aid in that important decision about candidacy.

And we know that a lot of our patients that we see for an evaluation are very straightforward, and we can utilize that minimal battery with them to make a good decision. But in those cases where we need more information, then that information is there as well. And we know that candidacy is so much more than just an audiogram and just speech recognition testing. So we've provided recommendations for functional test measures, questionnaires that are recommended. The actual questionnaires are available on the website.

There's information about scoring and how to utilize them. And there are also recommendations for if and when to use a cognitive screener to supplement your decision making, and when to provide additional referrals for care. Importantly, if we're all going to utilize this real world evidence, it's important for us to report them in similar manners. So there are templates to streamline report writing and really increase our efficiency and our consistency among clinics. And then there's also this inclusion of recommendations for pre and postoperative care.

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So how is the MSDB three developed? Well, let's go into that briefly because it was such a nice process. We'd like to take you just briefly through those steps which are displayed on this slide. So we had our group of leading experts and they participated in a modified Delphi consensus to develop the MSDB three. And we started by breaking them off into pairs of two, and those pairs would perform a rigorous literature review regarding their topic.

So someone was assigned single sided deafness, another pair was assigned traditional, and they would use specific research guidelines in order to perform that literature review. They then utilized that literature review to develop test protocols that they presented to the team. And we discussed the various protocols. And then they went away and wrote Likert statements that were generated to describe each of their protocols. So an example of a Likert statement would be CNC monosyllabic word should be the primary measure used to determine clinical candidacy for a cochlear implant.

And if the group came to consensus and we all agreed with that statement, then that statement would be incorporated into the protocol. If it wasn't agreed upon, then they'd have to go back to the drawing board. We would discuss it until we were able to

finish all of the protocols based on approved Likert statements. So the protocol sections were eventually developed based on 56 approved Likerts, which are all posted on the CI website. And then we presented the finalized protocols to our stakeholders.

We were a little bit worried about this because there were a lot of important stakeholders and we were worried. They want us to make many changes, but it went really smoothly. They were all very supportive, and I think they were all really happy that we finally had sort of standardized protocols that were being recommended and used. And then finally, the MSDB three has been submitted for publication. We're in the process of getting that published, but the protocols and all of the resources are available on the CI website.

Next slide, please. So, before we get into what the MSDB three is, we should mention a few things that it is not because these differ from previous versions. So first and foremost is it is not a research protocol. We had to remind each other through all of our discussions about the protocol that it's not a research protocol. And there were a lot of researchers on that development team, so we had to remember that this was really primarily based on clinical care.

It focuses on clinical care and provides clinicians with the minimal test needed to make a clinical decision about candidacy. Certainly some of the tests in the protocol can be used for research purposes, but we felt like it was really important to focus on clinical care. The second point that the group really agreed on is that it's not designed to align with current FDA or insurer indications. The early discussion really focused on the fact that many clinicians felt as though when we're seeing an implant candidate, there was too much focus being placed on first determining if they meet their insurer's indications, and maybe that clinical judgment about are you a good candidate? Was lost in that decision process.

So the MSDB three really focuses on making clinical decisions first, looking at the patient, looking at all of these factors, looking at their audiogram, looking at their speech recognition, and specifically their CNC to begin with, to determine if we think they're a good clinical candidate for an implant. And then once that clinical decision is made, additional tests can be administered to determine if the patient qualifies for an implant based on their insurer's indications. And we were all really proud about that because we feel as though it was time to sort of bring back that clinical decision making to the clinician rather than first, starting with insurer indications. And importantly, it's not a guideline of test scores to determine candidacy. Along with those clinical decisions come that decision of what is going to be your clinic's cutoff score.

That's going to help guide you in your determination of who's a good clinical candidate for this technology. Next slide.

So a few things have changed that we'll mention. The first and foremost is best aided. We looked at current indications and best aided, and we see oftentimes that it's not really clearly defined. So this group wanted to embrace this ability to give a clear definition of what best aided is. So for the MSDB, three, best aided is defined as testing using a hearing aid that has been optimized for hearing loss in the ear to be implanted.

So traditionally, best aided has sometimes been the ear to be implanted, but more often it's been based on a bilateral score. And the group felt that bilateral best aided was oftentimes impacted by the better ear, and the better ear was not the ear that we were going to treat or be implanted, and that oftentimes kept patients away from receiving an implant. So we had this ear that wasn't even all that great, but it was too good for an implant, but it was keeping our patients away. And personally, I'm sad about the patients that were turned away because the ear we weren't going to treat impacted their candidacy decisions. This was also impacted by recent FDA approvals

of EAS and also SSD and asymmetric, where we have learned to place greater emphasis on the ear to be implanted and place less emphasis on the contralateral ear.

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So this best dated really represents evolution of clinical care. And when I think back on all the years that I've been doing implants, I think about how our clinical care has evolved and how with each of these steps, clinicians, it took us a while to embrace these changes. So, for example, years ago, we used to present our test stimuli at 60 decibels, at 70 decibels rather than 60 decibels. And Jill first did a great publication where she demonstrated that 60 decibels was more effective because it more aligned with what our patients are experiencing, their daily life. So clinicians embraced that.

We looked at indications and they oftentimes don't state what the stimuli is. Stimuli needs to be what the presentation level needs to be. A big one was transition of our sentences years ago. We utilized very easy CID sentences, and then we transitioned to hint sentences, and then we transitioned to AZ bio sentences. And if, for example, we look at the Medicare indications, they say that patients need to obtain a certain score on sentences, but they don't state what sentence material, which left us room for clinical evolution of making a clinical decision about which sentence would be used.

Another perfect example is how when we started to present sentences in noise versus quiet, I think that was a hard one for clinicians. As we started to do that. They said, well, I think people meant in quiet, but it wasn't specifically stated. And we really needed to start looking at noise because that truly represented the difficulties that our patients were experiencing. And again, all of these were impacted by recent FDA approvals that impacted our clinical care and our clinical decision making.

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So we also, if we focus on best aided, we didn't want to just focus on that ear to be implanted. We wanted our primary focus to be there. But we also want to know how our patients are hearing in their everyday situations. So the MSDB three includes an everyday listening condition, which is testing with the optimized hearing configuration typical of the patient's everyday listening. Now, that's changed over time, too.

Traditionally, it used to be bilateral hearing aids. Well, now it might be a unilateral hearing aid. If we have someone with an asymmetric hearing loss with one deaf ear and one ear with a hearing loss, they might only be wearing one hearing aid. We might have some SSD patients that aren't wearing a hearing aid on either ear. So they would be bilateral, unaided, occluded.

So we decided it was important to include that in the test battery. And then lastly, we've included a focus on CNC words. We've had CNCs in the MSDB for a very long time, but sometimes they were even an afterthought. Okay, I'm going to do CNCs as well. Well, as you'll see when Camille goes through this, we start with CNCs, and we look at aided individual ear CNC scores to determine and guide us if these ears will meet initial.

Initial clinical determination of CI candidacy. So we might wonder, why would we use CNC words? Well, we know that our recent FDA approved indications, all four of them, utilized c and C word scores to determine candidacy. So the group saw a trend. We said, hmm, that trend is going towards CNC words.

Lots of investigators support the use of CNC words as an ideal measure for use with cochlear implant patients because they're less likely to demonstrate ceiling effects post implant. Then sentences are. And several have mentioned that they're a cleaner test of hearing because they often, well, they're not usually presented in background noise,

and they don't bring memory into the mix, which can sometimes be an issue with our older patients. So if we're putting our older patients and basing our clinical decisions on a sentence test that requires memory, and we're adding noise in, we're adding all these factors in where the CNC is more of a cleaner test. Recently, Jill Furst and her colleagues found that patient age impacted AZ bio scores, but not CNC scores.

And that really helped foster all of this information towards moving towards CNCs. On the next slide, we'll talk about the CNC scores. So big question might be what CNC score equals candidacy? And you'll see when Camille goes through this, that we start with CNC scores. Well, it's up to individual clinics to determine their clinical cutoff score.

So instead of providing you with a score, we're providing you with resources that we'd like you to read, that we'd like you to review so your clinic can make a decision about their individual cutoff score. And the advantage of this is if, let's say, you decide to start at 40%, maybe a year from now, you'll clinically evolve to a different score and change that to 50%. But again, that's embracing the clinician's ability to make these important decisions about candidacy. So with that, I'm going to hand it over to Camille, and she'll take us through the decision tree. All right, thank you, Terry.

Great job setting this next slide up. One of the things, when we were developing this revised MSDB, as we were going through it, everyone kept saying, I wish we had a flowchart. I wish we had a way that we could work through step by step in a nice, easy manner for us to be able to determine candidacy. So that's what we did. We worked really hard on trying to come up with a way that you could follow a flowchart.

As Terry mentioned, we start off with CNC words. This flowchart is assuming we're starting after we've done an audiogram, after we've verified the hearing aids to the best that we possibly can. Fitting the patient with a longer hearing aid. If they're hearing aids

that they came in with, are not appropriately fitted, then we would fit them with longer hearing aids. So we're at the point where we know the patient is fitted with the best hearing aids possible.

We're going to test them with CNC words in the right ear and in the left ear. That's going to be one of the first ways that we're going to think about is this patient a cochlear implant candidate? We do that along with what we call other factors. And if you look down at the bottom of the screen, it defines what other factors are audiometry. So we know that certain insurance are going to say, you have to have bilateral, moderate or profound hearing loss.

Doesn't say it has to be symmetrical. It just says that it has to be bilateral, moderate to profound. So we have to think about audiometry, other medical indications, radiology, their cognition, what are their expectations? What motivated them to come to our office and seek out a cochlear implant? So we do that to determine candidacy along with CNC words, because we know that patients that come in, there are a lot of things that hearing history that may affect outcomes.

So we don't want to lose track of some of those other factors. Once we have our CNC word score in both of our ears, there's really three different scenarios that can fall into place. One is the best aided c and C score in neither ear meets cochlear implant candidacy. And so maybe for that reason, we'd say to that patient, you know what? We're really glad you came into our clinic today.

We have a great baseline, but right now, you're just really not a candidate. Maybe their hearing aids weren't fitted appropriately, so we recommend they go back to their audiologist and maybe have a tune up. Maybe we recommend they go back to their hearing aid audiologist and start utilizing accessories or kind of just shape up, maybe how they're hearing with in their everyday listening condition with their current hearing

aids. Another scenario is that maybe the best aided c and C scores in both of the ears meet candidacy. Again, both scores could meet candidacy, but perhaps there's one ear that's poorer than the other.

Or maybe at this point, we talk to the patient about their preferences. Do you have a preference if you're sitting in the car and you are the primary driver, maybe you prefer to have your right ear implanted if both meet candidacy. So we kind of go through those scenarios. But if that isn't enough to determine which ear you want to implant at this point, you could also do aZ biosensors in the right and left ear if you already know up above based on the preferences, or a poorer or better ear with the CNC word scores, you could just move on at this point and test them in the ear to be implanted, starting with a plus ten signal to noise ratio. You'll notice that our signal is 65 dBA.

When we're testing patients in backgrounds of noise versus previously, we've always used a 60 dBA. When we test patients and noise, we're still using in quiet 60 dBA for AZ biosensors. But if we're putting patients in a background of noise, we have raised that target presentation level because, as you guys know, when we're in backgrounds of noise, we raise our voice. And so this represents, based on, again, some evidence in the literature that when we're presenting it in background noise, we switch to a 65 and then we have either a plus five plus ten, you know, a zero signal to noise ratio, if that is most appropriate, and we can test that ear to be implanted after we do that, you know, you can kind of evaluate at that point, do I need to change the signal to noise ratio? So if I started off in a plus ten and I think about the insurer requirements, or if I want to get a little bit more information from that patient, maybe I need to switch it to a plus five signal to noise ratio.

But on the reverse, maybe I also need to put that AZ bio sentence and test them in quiet. What if they're doing pretty poorly with that plus ten and you don't want the patient to have a floor effect or you want to determine how they do with a Z biosensors

in quiet. You can switch to a 60 dBA, test them in quiet, and then you've kind of covered all your bases as far as that. So one of the first things, as Terry and I have been presenting this information to multiple people for a while, one of the comments that we often get is, well, if we're changing the signal to noise ratio, making a little bit harder, aren't we making this patient a cochlear implant candidate? And really we're not right at this point, we're determining if that patient qualifies for coverage under their insurer requirement.

The step one, we tested CNC words, and that, along with our other factors, is what determined if that patient is a cochlear implant candidate. So we've really tried to separate out the concepts between are you a cochlear implant candidate? And based on that, will you qualify for coverage under your current insurer?

Another scenario that might come up are best stated CNC word scores and only one year meets candidacy. So this might be somebody who has really pretty asymmetric hearing loss between their two ears. And so maybe only one ear meets candidacy. Again, at this point, you really need to take into account other factors. What if the patient comes in and you do CNC word scores and that ear maybe had a vestibular schwannoma and so maybe they weren't able to preserve the auditory nerve?

That would be a scenario where you'd say, well, you know what? I need to take into account the other factors. I know you don't score well with your CNC words in that ear. But here's what your medical indications indicate. So we need to think about that.

But maybe they do just have a poor ear over another. And so one ear meets candidacy. In that scenario, you would just go right in, test that ear to be implanted, start with the plus ten, test them for qualification. At that point you're seeing do they qualify for coverage with their insurer. And if you need to adjust that signal to noise ratio, we pop in right here.

Another reminder that if you need to switch it to a quiet situation or a little bit harder noise situation, you can do that at this point. So from there, Terry brought up testing them in their everyday listening condition. This is really important and so we want to bring to make you aware that testing in the everyday condition is important for getting an understanding of how they are performing with both their ears together. But it also can be really useful if you want to compare their pre op score to post operative comparisons. So this is a good stopping point for you to think about testing them with their everyday listening condition, really with both CNC words and az biosensors, if that is something you want to do.

Again, this is a minimal test battery. So I always think about from candidacy, everything I do when they're here for their evaluation, once they get their cochlear implant, I can't go back and get that same test condition again. So if I say I don't have time to test their everyday listening condition today at their candidacy, you can't get that test back versus postoperatively. If you test them in that condition in their everyday at twelve months and you say at 24 months, hey, I maybe don't have time for that, or they just popped in for one reason or another, you can test them again the next time they come in and get that everyday listening condition. But when you're testing for candidacy, you can't.

And so that's just something I want to bring up and remind all of our listeners here today that this is kind of your time point to think going forward what you might want, what kind of information is important for you. We also went through the Leichardt process and it came to the CI quality of life and the SSQ twelve are two subjective questionnaires that really tell us how this patient is functioning, maybe in their real life. And so we are promoting giving the CI quality of life and the SSQ twelve at preoperatively and then following that postoperatively, as you'll see when we get to that point. And finally, once you've done all this, you can talk with a candidate and they

can move on and go through with the medical evaluation and take the next step to go on and get their cochlear implant. So that is kind of our flow sheet.

You can go our flow chart, you can go through each of those scenarios, and it just kind of leads you to the point where they're ready to move on to the next step. We also have protocols that we have on the CI website that takes you through calibrating to set up your room. How you do that, what's recommended for unaided testing goes through our aided speech test battery that we just went through. And so all of these are really nicely outlined and provided so that you don't really have to think about what you're going to do, how you're going to do it. It's all put together nicely in a package for you to try to streamline and make things a little easier.

So the next thing we're going to do, based on this information, we're going to walk through some case studies and just kind of try to apply what we've learned today to some actual patients that came through either Terry or my clinics. So this is patient number one. He was referred for a cochlear implant evaluation when they first came in. We often will do the audiogram first, and then we sit down and try to gather what those other factors are. And you can see that this patient had pretty long history of bilateral profound hearing loss.

He had chemotherapy when he was pretty young, at two years and at six years of age. But his hearing loss was actually identified before he had that first segment of chemotherapy. He doesn't really think that there's much family history, but, you know, he had some pretty realistic hearing goals. He wanted to enhance his hearing in his work environment, understand more when he wanted to communicate with his coworkers and his family. And he just felt like he wanted to try to improve his general quality of life.

And so those are very, very reasonable things that a lot of our patients, that's what drives them in, is an improvement in their quality of life. So you can see his ears had a little bit more hearing in the left ear, but pretty symmetrical, really, between the two. So we sought out, the first thing we're going to do is start out, we fitted the hearing aids. We're going to test those CNC word scores in both the left and right ears. The right ear he got 36%, and the left ear he got 26%.

In our clinic, we're using the clinical recommendation of 50% or less. And so at this point, my first thought is, wow, he really is a candidate in both ears. There's a little bit of difference between the left and right ear. And so I was kind of thinking that maybe we want to go with the left ear, keep that right ear continuing to use a hearing aid. So discuss that with the patient.

And sure enough, they kind of felt that same way. So our next step is we're going to test some AZ bio sentences. And I know I want to implant the left ear. That's kind of what I discuss with the patient. So I start out with a plus ten, and that patient scores 19%.

And so right now I know that that ear meets clinical recommendations for a CI, and I'm wondering if I should consider some additional testing in a plus five. And that's where the next bubble on our flowchart gives us that option. Do you want to get a plus five or do you want to test them in quiet to see how they do in that scenario?

So the next step is we want to test them with their everyday listening condition. So, because we tested them with a plus ten before, got that 19%, and we decided to move on with that same signal to noise ratio, we're going to test their everyday listening condition in a plus ten as well. And so that's what we did here. And we can see that that patient got a little bit of boost when we added in that right hearing aid. They got 28% in that scenario.

So we kind of have that patient set up from the speech perception testing we move through, give them their quality of life questionnaires and the SSQ, then we move that patient on for his medical evaluation. So what if only one ear meets candidacy? Let's go through a scenario where we have that, and in this situation, we have a patient coming in and they have. We score them, they get 12% in the right ear, but in their left ear, they're really getting 54%. And remember, in our clinic, we're using 50% or lower as kind of our cutoff for whether we determine if a patient's a cochlear implant candidate.

So right now, it's kind of set up after I have gone through the other factors, audio metrical tested them, fit them with hearing aids, I know that that right ear is probably a good ear for cochlear implantation, and then certainly keep that left ear amplified through hearing aids. So I test them. The next step is to test that right ear with our AZ biosensors. I started out with a plus ten and that patient dropped down to an eight, 8%. And that's pretty low.

And maybe I want to, again, think about, do I want to change that to AZ Bios? And quiet, do I want to change it to an AZ bio one plus five? Probably not, because we already know they're probably going to get 0%.

And so in this scenario, we do want to take into consideration when we do their everyday listening condition that that left ear was doing pretty good. And so in this scenario, we're going to go on and test the AZ Bios in a plus five with that everyday listening condition. Excuse me. Because we know when we want to do postoperative comparisons. Excuse me.

That right ear that gets the cochlear implant is really going to probably enhance the left ear. When we think of postoperative comparisons, we probably really want to take into

consideration that down the road, we're probably going to need that plus five scenario. That's how we test their everyday listening condition. We, we put them in a plus five and assuming that they're going to have some nice postoperative benefit.

So step four, we administer our questionnaires and refer that patient on to the surgeon.

All right. The one thing I also wanted to bring up was on our CI website under the MSDB, we developed templates that are really nice for your evaluation. It goes through and gives you things maybe you want to talk to the patient about preoperatively. Do they have tinnitus? Do they have dizziness?

You might want to talk about their medical history, get their duration of deafness, their etiology, what they worn for hearing aids in one or both years. And then it gives you your speech operative testing. And this is a really nice model to be able to put in your medical records. And so we develop these, and it gives you options based on how you tested them, how you should report it. And it makes it really easy then, postoperatively to be able to go back and compare improvements in scores over time.

All right, so MSDB provides an improved ability to cross check candidacy. So we're going to go on and talk about another case study where we have a traditional candidate. This is a 76 year old male. You can see his audiogram. He's worn hearing aids regularly for the past five years.

He has traditional Medicare. His goals are pretty realistic. Again, he wants to improve his quality of life. His wife really encouraged him to come to our center and be evaluated, but she did express some concerns regarding his hearing, his inability to pay attention in different situations, and his memory. And so that was something we were going to kind of tuck in the background when we went and did our testing.

We were going to really think through that, knowing that his wife kind of gave us a little bit of information that could be important when it comes to counseling. So his previous testing for candidacy, his AZ biosensors with bilateral, excuse me, bilateral hearing aids in a plus ten signal to noise ratio, he got a 42%, and the patient was deemed a candidate and proceeded with a CI. But based on our MSDB testing. Sorry, I was messing this up. Based on the way we tested previously in our MSDB, we would have given them AZ bio sentences with both ears, tested them in a plus ten, and he would have got 42%.

Based on Medicare guidelines of 60% or poor, we would have said, hey, you are a candidate. Let's move you through the pipeline. But with our new MSDB testing, this is where it really becomes important to think about. Even though we were so excited to have cms changed their guidelines up to 60%, we didn't want to lose track of some of the things that that wife kind of clued us in on. What about those other factors that might be important?

And so, in our MSCB, that's what we did. We focused on our CNC words when it was presented in quiet and there was no long sentences that that patient had to remember. His right ear got 60, 68% and his left ear got 66%. So right here is a red flag. What made that patient drop so much when we presented speech and backgrounds of noise?

Is the cochlear implant something that's going to help that patient improve in that background noise, or does the patient have good hearing? And maybe some of these other factors going on are causing that patient to really plummet when we put them in noise. With this patient, we did not recommend a cochlear implant. We recommended instead a cognitive screener, which was administered. And we talked to the patient about coming back maybe in a year or two if his CNC scores declined, because this is an example of that cross check where, you know, we have a patient that if we would

have tested them in noise and they scored within that 60% or under, we moved them through the pipeline.

This is where CNC really shows up as an important factor we need to consider for these patients.

Okay, I'm going to switch it back to Terry. Okay. And thanks, Camille. I'll mention that we do have a speech perception protocol for single sided deafness. We've gotten a lot of questions about this, and it's a nice addition.

I won't take you through the entire decision tree just due to time, but you basically will start with one ear that you're considering for candidacy. Because we know that in SSD we have one normal hearing ear and one ear that's typically profound. A couple of people have asked, why do we recommend sentence testing? Well, even though the FDA indication really states a word score, not all insurers, although many do approve single sided deafness, sometimes they don't. And the audiologist really wants to have additional information about the difficulties that the patient is experiencing.

So, similar to the previous decision tree, you'll start off with CNC scores, and if you feel as though that ear is not a good candidate, you'll recommend they come back in a year. If you feel as though this is a good candidate for an implant, you'll take them down this left hand side of the tree. And one thing that we do note is we want to demonstrate the difficulties this person is experiencing in their everyday listening condition. So it would typically be a hearing aid on the deaf ear and occluded, unaided normal hearing ear in a zero signal to noise ratio. A difficult situation where they've got noise at their good ear, signal at their bad ear, and how much they struggle to hear in that situation.

That, of course, as well as the CNC score, helps determine candidacy for SSD. And there's lots of more information in the MSDB three manual about SSD. On the next slide, we'll take you through just a sample case quickly that shows you this typical audiogram. And her hearing goals were really to improve speech understanding at work and social settings. Because noise is a trouble, is a problem, we see that they meet the indication they've got a score of 2% in the left ear and 100% in that right ear.

So then we went on to the next testing where AZ bio sentences are presented at a zero decibels signal to noise ratio. You all know that that means that the signal and the noise are at the exact same level. There's no difference between the two of them, so they would both be presented at 65 decibels. When that happened, this person demonstrated a score of 10%. And that really shows how much this person can struggle in everyday listening conditions when they have just one functioning ear, depending upon their situation and where the noise is.

Next slide, please.

So we then go on to administer questionnaires. In this case, a lot of times our patients with SSD have tinnitus, and so sometimes we recommend a tinnitus handicap questionnaire as providing data in the insurance letter to support that implantation of that deaf ear with a cochlear implant can really help benefit and reduce the tinnitus, as well as provide improved detection of sounds around them in their environment. Improved speech recognition, as we see with many patients with SSD. But we then administer those questionnaires and move them on for the medical evaluation like we did in the previous examples. Next slide, we're going to take you through the postoperative protocol.

There's a lot of detail in the protocol. What's different? Well, there's fewer evaluations recommended. We just recommend you do testing at three and twelve months. There's a streamlined test battery.

Again, no more research studies. We want to focus on clinical care. What is needed to make a decision about is this patient doing well or do we need to look at their programming? Do we need to counsel them more?

Is there a reason that they're not, not meeting the gains that we expected? And in this battery we have an enhanced consideration of the non implanted ear. Oftentimes if we implant in adults one ear first, that ear does so well, we're kind of forget about that second ear. But the MSDB three reminds clinicians to look at it. And the way that we look at that is the best aided CNC.

We have that from before the first ear was implanted. We recommend that that be looked at at three and twelve months later in both ears, in the implanted ear as well as in the contralateral ear. If the contralateral ear meets the clinic's candidacy decision for an implant, you're also going to look at their bimodal benefit. So if, let's say they have an implant in one ear and a hearing aid in the other, and the implant alone scores 80%, the implant plus the hearing aid takes them up to 96%. That's nice.

Bimodal benefit. We're going to say that they're getting benefit from that hearing aid, but if they score 80% in the implant alone and 80% when you add that hearing aid on and that aided ear is a candidate for an implant, that gives us more information that will help us determine if we should recommend a bilateral implant. So there's pointers like that in the postoperative follow up as well. Next slide, please. So this just shows you the protocol and I've starred the different conditions that we're going to look at.

The one on the far left, that red star just reminds clinicians that if a score is poorer than expected at three months, don't send them away for nine months, make sure they come back, look at their data logging, look at their programming, determine why they're not meeting your expected outcome, and do everything you can to bring those scores up to bring up that patient satisfaction. And the other star reminds us to not forget that contralateral ear in terms of potential candidacy for a bilateral cochlear implant. Next slide.

Lots of protocol listed, just like there was for the pre op protocol, step by step, where you can use a checklist, and we just won't go into all those details today. So after this, I'm passing it back to Camille to take us home.

All right. Okay, so we're going to go through some postoperative case studies based on what Terry just kind of went through with you guys. So we have the first patient, he's a traditional case study, a sequential patient that came in and wanted to see if maybe that contralateral ear is something we should be considering for an implant. So we verified that hearing aid that he had in the non implanted ear. We tested his best aided c and C word scores, and in that right ear, he got 6%.

When we had evaluated that patient for his first ear that he got implanted, that ear was actually getting 19%. So we know that ear is continuing to decrease and performing a little bit poorer, and so is the patient a candidate based upon what we know right now. We've considered the other factors, we've looked at his best aided c and C score, and that patient really is. So we wanted to consider him a candidate in that right ear for sequential evals. So when we move on, we're going to test that best aided AZ bio sentence score now.

So we're going to go right into the right ear. They got 9%. We started out in quiet in this scenario, just because we knew with his CNC word scores that probably putting in the

noise wasn't going to give us much information. So we wanted to go right to the quiet. And does this patient meet ensure qualifications?

Yeah, he sure did. We wanted to test postoperative comparisons, so we tested this patient in the bimodal condition, AZ biosensors and quiet. That patient's getting 63%. So doing fairly well with. When you add in that cochlear implant on the opposite ear.

When we test that same scenario with CNC words, he's getting 52%. So that's a quite big improvement from that cochlear implant. We administer our functional questionnaires, we provided our CI evaluation, and we move that patient forward for his medical evaluation. At this point, point.

So this is our case study, postoperative speech perception. So the patient in the first ear, the implant ear, or the ie implant ear, the right ear preoperatively was getting 6%. At three months, that ear was getting 44%. Now, the first implanted ear that we implanted twelve months ago was getting 42%. So you can see that right ear went from six to 44%.

That's a huge improvement. And he's doing better, or nearly the same as what he was doing in his ear that was implanted quite a while ago. When we look at the everyday condition previously, when we tested that patient bimodally at twelve months, he was getting 52%. Now adding that cochlear implant. So he now has cochlear implants on both ears, that patient is getting 66%.

So that is a huge improvement. A nice way to look at the importance of evaluating patients for that sequential cochlear implant. When we look at AZ biosensors in quiet, because we did that preoperatively and we didn't put them in noise, which, thinking back, would have probably been a really good idea for that case. The everyday

situation, when they were bimodal, that patient was getting 52%. Now, three months after being sequential, they've improved their score to 79%.

So almost by 30%. When we look at that ear with AZ bio sentences, 85 or 75% at three months. So a lot of times we start out implanting patients with a poor ear and leave them with a bimodal or hearing aid on the opposite ear. And that's a really good scenario for that patient. But if we start noticing that contralateral ear dropping, you can see catching it early really helps improve the patient's outcomes.

And that's certainly what we did in this scenario. Here's 84 months. Now that first ear is 31 months out, and that patient's second ear is twelve months out, and you can see an additional bump about 5%. And the implanted ear on the right, that second ear is doing pretty amazing. Went from 9% to 82% when we're testing that situation.

And quiet with sentences. So some closing thoughts. The MSDB really took a step back, like Terry said, from the research perspective, to try to move the emphasis back to clinical decision making. And I think all of us, like Terry said, it's really hard when you have a patient that meets candidacy in one ear, but because of our interpretation of the guidelines, we're telling them they're not a candidate for a cochlear implant or they don't qualify for coverage. And so I think for a lot of years, I made the mistake of telling a patient when they had a poor ear, 23% on one ear and 57% on the other.

I'm sorry, you're not a cochlear implant candidate? Well, they were a cochlear implant candidate, but based on the interpretation of the guidelines, they didn't qualify for cochlear implantation. And so really taking that approach and thinking it through in a different way really brought that decision making back to the audiologist and the hearing professionals that seeing that patient. We know candidacy begins with a clinical decision before determining if patient meets their insurer indication. So we're

not making somebody a candidate that's made before we determine if they meet their insurer indications.

Clinicians, it's really important that we determine all aspects of the MSDB and embrace it as an evolving part of our clinical care. Terry pointed out some wonderful observations of how that's changed over time, and it hasn't changed over time because we felt like we wanted the patient to become a cochlear implant candidate. It changed over time because we knew, based on research and evolving evidence, that we had supporting evidence to make that change. The CNC cutoff score, it gives the clinician the ability to do with what they feel comfortable. So if 50% is too high for you, maybe 40%, you feel more comfortable, and that's okay.

The aspect of the MSCB that you will embrace, just remember, it evolves, and it evolves because of the clinical care we give our patients.

And finally, we really want to point out that the MSDB three is not just for those of us who are seeing patients for a cochlear implant. I think it would be great if all clinicians use the same type of material. I think having that part of our tool belt, that part of our clinical care, if we tested CNCs when they have their hearing aids, we can see as they change when they become a cochlear implant candidate. And that's really going to speed up the changes in that patient's hearing audibility. And I think that's what we want to do.

We want to provide our patients with the ultimate care. We don't want them to get a cochlear implant before they're ready for a cochlear implant or they're a candidate for a cochlear implant. But when they are, we want clinicians to feel confident that that patient will qualify and send them for cochlear implant evaluation. So talk with your colleagues about using CNCs to monitor performance with hearing aids over time. All of this is available on the MSDB website.

I'm going to show you the website link for that. You can go on there. You can log in, you create an account. It doesn't cost you anything to create an account. Once you get into the MSDB three, you're going to see test better, the test battery, you're going to see referral guidelines, calibration information, functional outcomes, all of those templates that we talked about earlier.

You're going to find the flowchart. And then once we get our publication published, that'll go on there so it's easy access to you. But we also have our test manual that provides all of this wonderful information so that you have it at the tip of your fingers. So the next step, as Terry mentioned, the manuscript is submitted. I hope we're on our last revision of that, so hopefully it'll become available to you soon.

This is the website. So if you go to [cochlear implanttraining.com](http://cochlearimplanttraining.com), it'll pop up and you can go to the MSDB suite and log in and create that account. And lastly, we really want to thank you for tuning in today, for listening, and hopefully having some great questions that we can open the floor up to answer. Now, if you think of something later, don't hesitate to reach out to myself or Terry, or you can even put a question in the info at [cochlear implanttraining.com](http://cochlearimplanttraining.com), and that will get to us.

Do we have any questions already in the q and a? So I've been answering a few along the way, Camille, but we do have one that says, do we have data showing average aided c and C scores at three, six, and twelve months? And I think this is a great suggestion. It says we could use this for counseling during a CI evaluation or even hearing aid appointment where they're talking to someone about being referred for a cochlear implant, about expected average improvement with CI versus where they currently are with a hearing aid. And I know I did that a lot of times with my patients.

I would show them what the average is. And I think with the patient that you mentioned, where we did not recommend an implant for that patient, he was already scoring above those average scores. So both in the Medicare expansion study as well as in the 532 study led by Craig Buckman, the average CNC score at six and twelve months is about 62%. So that's really what's guiding a lot of clinics in choosing their CNC score that some are choosing 50% as recommended by ACIA. Some are going a little bit lower, a little bit more conservative, down to 40%.

But I think that's an excellent suggestion, is to look at those average scores. And I think, Camille, you'll agree with me, most of the patients coming in for implantable valves, their CNC scores are probably less than 20. Would you say that as well? Yeah, absolutely. And so when you think about that and they go from 20% up to 50 or 60%, that's a huge improvement.

And I think as we continue to implant patients above that 20%, that average that you just reported will probably go up. But until we have that information, you know, it's really hard to talk about it in this case, but I think that's a really good scenario. I was at a meeting last weekend and doctor Gifford presented some data over time at three and twelve months that she had pulled from their database. And, you know, so I. I think that there is data out there to show those averages.

We may just need to put some of that together. I agree. And I was communicating with someone in the Q and a earlier about just that, that because our patients are scoring so low now, our post op scores are a little bit lower. If we start to catch people sooner when they become candidates, maybe if they're scoring in the thirties or even 40% on CNCs, those are the people that typically are scoring 80, 90% on CNCs post op. And so those average scores are really not going to go up until we start catching candidates sooner, and then our outcomes will be better.

So it's one of those catch alls where we have to really do the work in order to show the score post implant. But we have to find people sooner and provide them with the technology they need it at the time they need it to get those average scores up.

All right. And I don't see any other questions. I think Christy wanted us to show that last slide.

All right, so on here, please remember to complete the exam once this is the presentation is done. The exam will be available for ten to 15 minutes after the conclusion. So log into your account, go to pending courses, choose take exam, and you'll complete the exam. I think for live credit has to be done within seven days. So you might have to wait a few minutes after this, but it'll be up for seven days.

Great. And thanks so much to everyone for attending. We really hope you embrace the MSDB three. Even if you're not working in an implant program. Go look at the materials they're really available for all of our patients, not just patients with implants.

There's a lot there that can be used with your hearing aid patients as well. So we encourage you to take a look and download the CNCs and start using them in your aided testing with your patients as well.