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What Happens During a Cochlear Implant Candidacy Evaluation?

Presenter: Terry Zwolan, PhD; Tracy Murphy, AuD

- I would like to welcome you to today's course presented by Cochlear and say thank you all for participating in this year's Industry Innovation Summit. We would like to thank our title sponsor, CareCredit and all of the companies who are joining us this year. It is my great pleasure and honor to turn the microphone over to our moderator today, Ms. Mary Beth O'Sullivan from Cochlear Americas.

- Thank you, Melissa. Welcome everyone, I am Mary Beth O'Sullivan. I'm a clinical marketing manager at Cochlear. And welcome to our course What Happens During a Cochlear Implant Candidacy Evaluation? There are a few handouts for you, including a PDF of the slides and if we don't get to your questions today, we will follow up with you after the course. So please put into chat anything you would like to get more clarification on throughout the presentation. Dr. Terry Zwolan and Dr. Tracy Murphy have created an excellent course with case examples from Dr. Murphy's practice, North Shore Audio-Vestibular Lab. So Dr. Murphy, I'll hand it over to you to introduce yourself.

- Great, thank you, Mary Beth. My name is Tracy Murphy. I am a clinical audiologist in private practice in the North Shore suburbs of Chicago. After having countless patients reach their limit with hearing aids and/or move on with cochlear implants elsewhere, I joined the Cochlear provider Network in 2019 so that I could help my patients more and provide additional support. I hope today to show you maybe how I approach cochlear implant candidacy and evaluations differently since I've become a Cochlear provider network member, Terry.

- Thank you, Tracy. And I'll just say that it's really my pleasure to present with you today, Tracy. So we're gonna team up on this and we're going to talk today about what happens during a cochlear implant candidacy evaluation. My name is Terry Zwolan. I joined Cochlear Americas a little bit over a year ago and prior to that I spent over 30 years at the University of Michigan as their director of their cochlear implant program.

So we're hopeful today to tell you what happens during a cochlear implant candidacy evaluation. Alright, so these are our financial disclosures for myself and Dr. Murphy. We have three learner outcomes. We're really going to talk about, we're going to describe the FDA approved indications for patients with single-sided deafness as well as other indications.

We're hoping that afterwards participants will be able to list procedures typically used in a cochlear implant candidacy evaluation and that participants will be able to describe importantly to their patients what will happen during a cochlear implant candidacy evaluation. At Cochlear, we typically start with our slide that states our mission, where we help people hear and be heard. We empower people to connect with others and live a full life. Today we're gonna focus on how we transform the way people understand and treat hearing loss and we innovate and bring to life or bring to market a range of implantable hearing solutions that deliver a lifetime of hearing outcomes. So most of you're very familiar with cochlear implants.

They've been around for a long time. They were first approved by the FDA for use in adults in 1985 and for children in 1990. Since that time, many changes have taken place including improvements in technology, changes in implant candidacy, and really importantly changes in procedures used to determine candidacy. So we're gonna try to shed some light on that today. So we're going to use some case studies just to demonstrate procedures that your patients will go through if you refer them for a cochlear implant candidacy evaluation. And we're going to include traditional patients, so those with bilateral moderate to profound sensory neural hearing loss as well as those most recently able to receive a cochlear implant such as those with single-sided deafness.

So we'll start with those more traditional patients. The adult indication for nucleus cochlear implants are a moderate to profound hearing thresholds in the low frequencies

for both ears, profound meaning greater than 90 dBHL in the mid to high frequency range. We've defined limited benefit from amplification as a score of 50% or less in the ear to be implanted on recorded sentences and 60% or less in the best aided condition. I'm really happy to state that previously Medicare was misaligned with the FDA approved indications, but in September of 2022, Medicare changed their policy after a lot of work, but they changed their policy to better align with those of the FDA. So now our Medicare beneficiaries can obtain a cochlear implant if they obtain a sentence recognition score less than or equal to 60% correct.

So that's an exciting change that's come about in our field more recently. If we look at hybrid indications, which back in 2014 the Hybrid L24 implant was approved by the FDA. And the big thing about this, if we look at that audiogram, look at all that low frequency hearing that opened up for our implant candidates. And so these patients, the FDA indications state that someone can have a severe to profound high frequency hearing loss, which would be a 75 dBHL pure average for two, three, and four kilohertz. But they can have normal low frequency hearing. So that really changed the look of the audiogram, especially in those low frequencies. They need to have limited benefit from amplification defined as a score of 10 to 60% on a word score.

So that's different from the previous one, which was a sentence score, but a 10 to 60% aided word score in the ear to be implanted and up to 80% word score in the opposite ear. Big, big change for us in the implant world to be able to offer this technology to different groups of patients. And what was beautiful about this is it enabled us to see how patients do with more low frequency hearing because devices then became available where if they preserve that low frequency hearing, they can use an acoustic component for the lows and continue to use electrical stimulation for the highs. So that electroacoustic stimulation that many of our patients use today is because of the result of this FDA approved indication that came about for the hybrid.

And even more recently we're still excited, more changes, even better was approval for single-sided deafness. So single-sided deafness is FDA approved for children as young as five years as well as older. In the ear to be implanted, candidates need to have a severe to profound sensory neural hearing loss defined as a pure tone average at five, one, two and for that's greater than 80 dB and then aided CNC word score or developmentally appropriate word test less than or equal to 5%. So from that audiogram you can see their contralateral ear can have completely normal hearing where in the ear that we're going to treat, they need to have a significant hearing loss. And what I love about this approval as well as that hybrid approval is it was really the first time we saw in our field a tendency to move towards focusing on the ear to be treated.

If we look at our traditional indication, it's more based on sort of both ears together, but not anymore. We're really moving our field to place greater emphasis on the ear that we're actually going to treat or provide a cochlear implant to. So what has happened with all these indications is they've evolved over time. Clinical care has evolved over time. Those audiograms are different and it becomes confusing as to when to send one of your patients for a cochlear implant candidacy evaluation. So in our next presentation that will take place on February 20th, we're going to go into more detail about that, give some guidance on when to consider a cochlear implant evaluation for your adult patients.

We're gonna talk about it a tiny bit today. Tracy's gonna talk about it in some of of those cases that were referred based on the 60:60. So I just wanna review that with you briefly. This was a study that we did at the University of Michigan because we identified that our referral sources were confused. They would come up to me at a meeting and they would say, "So when should I refer?" And I didn't really have a good answer. So we looked at data for over 500 patients and developed the 60:60. And really what the 60:60 tells us is that a patient is good to be referred for a cochlear

implant evaluation if they have a pure tone average in their better hearing ear for more traditional patients.

But a lot of people have said, "Don't focus on the better ear, focus on the ear to be treated." But if you look at an ear that has a pure tone average that's 60dB or greater, and if that ear has a word recognition score, an unaided word recognition score less than 60%, they're likely a very good candidate for a cochlear implant in that ear. Oftentimes these patients experience difficulties such as struggling to hear on the phone. They have difficulty understanding unfamiliar speakers, they withdraw from social events and often need others to repeat themselves. So this is just something for you to keep in mind and that we'll go into more depth in our next presentation. So what happens during an adult cochlear implant evaluation?

If you send your patient to a CI clinic, what's going to happen? Well, really the goal of the appointment is to determine if average benefit from a cochlear implant is better than the individual's benefit that they're currently receiving from a hearing aid. And we have lots of data to support that we can look at, what is the average performer doing now and with a cochlear implant and we can compare that to what our patients are doing with appropriately fit hearing aids. We also need to look at the individual and talk to them about their goals and their motivation, what difficulties are they having and what would they like to improve upon. And at the end of the appointment, we really wanna determine if a cochlear implant will be recommended in order to improve their hearing.

So what's included? We do aided speech perception testing using optimized hearing aids. When we do that testing, it's always using recorded materials presented in a sound field at a conversational level, mostly at 60dB SPL. And again, we have to look at how that hearing loss is impacting their function. So we have both objective and subjective measures. So the patient, we wanna know from them. So we ask them in

the form of questionnaires, "How are you doing?" So the results are a treatment recommendation. Either you're a good candidate for a cochlear implant or you're not a candidate for a cochlear implant and maybe we need to send them back to their hearing aid audiologist for possibly new hearing aids.

If they are a candidate, we discuss the next steps with them, which usually includes a medical evaluation. We talk about their device choice and we put them through for insurance authorization for the procedure. And of course we provide them with lots of resources because they come in with lots of questions and it's very important that we provide them with guidance through this journey. One of the last few slides I'll have before I send it over to Tracy is, Tracy's gonna be talking about the CNC Words test as well as the AzBio Sentences test. So I thought I'd put these up here just to familiarize people with this. So the CNC Words, the word is preceded by a ready prompt.

So for example, you would hear "Ready, goose, ready name", and we can do either a word score or we can score them according to correctness for the individual phonemes. And we take that into consideration when we recommend an implant. The AzBio Sentences have four different speakers, two female and two male speakers. They're nice sentences, they're kind of representative of a rate that we would hear in our everyday conversations. And frequently clinics will present these in background noise to more replicate a real world listening situation. So after this I'm gonna pass it over to Tracy and she's gonna take you through what patients go through in that candidacy eval.

- Thank you, Terry. I wanna emphasize something you said when you talked about the 60:60, and it'll come up with this first case is that referring patients for a candidacy evaluation doesn't mean that they're definitely getting a cochlear implant. And I think it's important to underscore that to patients because when they first hear that they might be a candidate for a cochlear implant, I think sometimes they're caught off

guard. My first case is a longstanding patient of my practice, a great guy. As you can see from his unaided audiogram, he's got a lot of hearing loss bilaterally. If we went by the 60:60 rule, his word recognition scores in quiet are actually 36% for the right ear and 56% for the left ear.

So based on pure tone average being greater than 60dB and the word recognition scores being less than 60%, he technically by that guideline could be referred for a cochlear implant eval for either ear. One of the other things that I think is important to consider when referring patients is to not get caught up in the age of the patient. 87, you know, you would never guess this man is 87 years old. But a lot of people think, oh, 87 years old, I don't wanna go under, you know, anesthesia for surgery. I have seen patients well into their nineties get implanted with cochlear implants and do quite well. So as you think about your patients and how they're functioning, don't get caught up on their age because they can go on and be evaluated and visit the surgeon and even determine if they're good surgical candidates.

So this patient was actually evaluated for a cochlear implant, if you go back one slide Terry, back three years ago and he was not ready to go at that time. He wasn't motivated, he was not sure he was ready for it. Three years later he came back for another evaluation. He's a perfect example of a hearing loss that the old version of myself prior to becoming a cochlear provider would've said, "Well, he's hearing well enough." I mean he's wearing hearing aids. He would say, "Well, I hear okay", but his wife would say he doesn't. He was struggling with normal conversations, struggled in church, restaurants, meetings, and it got to a point where he finally had enough and was ready to kind of seek the next steps.

So I used to view cochlear implants as a last resort. I no longer view them as a last resort. And I hope that when you see some of the outcomes that we present today, that you see the benefits they can provide to the patients that we serve. Okay, next

slide. So after testing him in the sound field to confirm that what he was getting from his hearing aids, if you look at his aided thresholds, you can see in both ears he really had limited access to speech information. AzBio Sentences were presented in quiet individually to each ear aided. He got 0% in the right ear and 51% in the left ear. And that was presented at normal conversational levels.

And even in quiet, he is not getting a lot of information. At this point, I'm suspicious or suspecting that his right ear would be the implant ear. So I did not do the right ear alone in noise if he can't even get any of the sentences correct in quiet. If we go to the next slide, I did do a test with a bilateral aided condition that gives us information that is typical of an everyday listening situation for him and it's good to use postoperatively to evaluate outcomes. He certainly met the criteria for implantation based on an aided sentence score of less than 60%. And given his motivation now, his family support, he seemed to have realistic expectations.

He was referred onto the surgeon for a medical evaluation and all that that entailed and he did decide to proceed with an implant and his right ear was implanted. We can go to the next slide. And I wanna take a moment and focus on the audiogram. So you'll see there his unaided thresholds, the A's are his aided thresholds in sound field with his hearing aid and the C's are his thresholds with the cochlear implant only in that right ear. I hope that it's not lost on anyone how much more access to speech information he has with that cochlear implant in those high frequencies. And it was astounding to me when I first started the process to see how much better people did, even when we put them back in the booth and did CNC Words and AzBio Sentences, even if those scores weren't high, if the patient was bimodal and had a hearing aid in the non-implant ear, the cochlear implant provided so much more access to speech information that they perform better even just talking one-on-one, even if you couldn't quantify it.

But if you take a look at his postoperative scores, this is three months postoperative, his AzBio Sentences in quiet went from 0% pre-op to 83% postoperatively and in noise, just the right ear alone, he was performing better than he did in the bilateral aided condition, preoperatively. CNC Words, he was getting 54% of words correct, which is a really great score for him. And it's not uncommon to see aided thresholds with an implant similar to what we see for this patient. It's also very common to see that the implant ear becomes the dominant ear and the better ear for our patients. So he is doing exceedingly well. He worked hard at it. There's a lot of oral rehab that's entailed postoperatively.

So it's important to make sure that the patients are motivated to do what they need to do to succeed. So that is our first case. We can go onto the next slide. This is the second case. This patient has bilateral hearing loss. We might go just right to the next one. Her aided thresholds. Oh, I see the slide is there, okay. So she definitely meets the 60:60 rule. She meets at bilaterally even though her thresholds in the left ear in the low frequencies are better than what the FDA indications are, but she's got significant hearing loss bilaterally. We can go on to the next. This woman is 73 years old. She has a history of Meniere's disease in the right ear.

And about a year prior to the evaluation, she had a dramatic drop in the right ear. She did not wear a hearing aid in the right ear and she stopped wearing the hearing aid in the left ear. She would only wear a hearing aid in the left ear to help her on the phone. It's also very important to note that she has a perforated left eardrum, which actually, even if her thresholds did meet criteria, she would not be a candidate for a cochlear implant in that ear unless she had the TM perf corrected surgically first. This is someone who loved to play piano, very musically inclined. Not only did she have difficulty hearing in restaurants, in the car, you could not have a conversation with her one-on-one, face-to-face.

She would write notes down. Very highly motivated, could not wait to get moving with a cochlear implant. We can go to the next slide. So we did AzBio Sentences in quiet. The right ear scored 10%, the left ear scored 39%, which qualified her based on Medicare indications of less than 60%. Terry had mentioned best stated condition and focusing on the implant ear. It's important to note that it's up to the clinic to decide what the best aided condition is. So it can be a bilateral condition, it could be the ear to be implanted. And I do agree that it's great to be able to move away from a bilateral condition and focus solely on the ear that needs to be implanted.

So we can go on again. So she was referred to the surgeon after this evaluation. Just of note, we did do some noise testing with AzBio and she only got 8%. Again, no concerns about her candidacy in terms of motivation, family support and willingness to commit to post-surgical rehab and so on. And so she was evaluated medically. She did get implanted in that right ear. I did not include the aided thresholds on this post-op audiogram. This is annual result a year later. But I did include her three month CNC scores and AzBio Sentences in quiet as well as some six month data for her. And she exceeded any expectation I had. Part of my concerns with her was that she had gone without auditory stimulation for many years and I didn't know how she'd react to hearing again, let alone whether she'd like the sound of the piano, you know, with music and so on.

So CNC words at three months were 7%, which jumped to 84% by six months. And her AzBio Sentences in quiet were 92% already at three months, which were 10% preoperatively. And so we added noise at six months and the right ear alone was at 69% in noise in the right ear. So again, another example of really great benefit from the cochlear implant. These are not atypical results of what we see for people who are motivated and good candidates for implantation. So she has been a pleasure. We can go on to the next one. So the next one is a patient with single-sided deafness. This is a

patient who we are currently in process with. She was evaluated the end of January for the cochlear implant candidacy.

If you look at her right ear, she has significant hearing loss. Her initial test results showed no response at the limits of the audiometer. She was under the care of an ENT who treated her with prednisone. All radiographic studies were normal so she was cleared there. And the audiogram you see shows a stable threshold that she has returned to. We can go to the next slide. This patient is a 64-year-old female. She is currently single and trying to date people. And one of the things that I wanted to mention about cochlear and the services that they provide because I think it is very helpful for patients to talk to others who've been implanted and to understand the process.

'Cause it's not something that people just come in and say, "Yep, I want a cochlear implant and I'm rearing to go." It's surgical, they wanna make sure that they do their research. Cochlear has patient engagement managers that are there to help guide patients through the process beyond the services that they get in your clinic. They're able to establish connections between patients and other cochlear implant volunteers who can talk to them and provide information about their experience relative to their implantation. It's kind of funny because this woman was paired up with a gentleman with single-sided deafness who also was single and dating. Not sure if it was a love connection yet, but stay tuned and maybe we'll have an update on February 20th.

Anyway, this poor woman is so debilitated by her hearing loss. She feels like she doesn't even have any awareness of her body in space. Spatially she's thrown off, she feels clumsy, she can't concentrate. But we did CNC Words with her and she scored 18% in that right ear. We are working to determine if insurance will cover the implant for her for single-sided deafness. Not all insurance plans will cover that, though we're seeing more and more will cover it. Another division that cochlear has is a division that

looks into insurance benefits and helps to seek insurance approval for coverage. And they help make a case for medical necessity for patients. They also help to fight denials if denials happen based on cochlear implantation.

So a wealth of resources for not only the patients, but us as clinicians. They help take a big load off from the insurance aspect. So we're working with her insurance right now to figure out if that is something they will cover though her CNC words don't meet technically the clinical indications based on FDA, she is referred to the surgeon anyway. There are many surgeons who self-report that they will do an off-label implantation for patients and it's not always just based on audiologic information. If we go to the next slide, you can see this patient we did some more testing with her. So her CNC words were 18%, AzBio in quiet on that right side was 24%.

We also did a test with her bilaterally, a hearing aid in the poor ear, obviously no hearing aid in the good ear at a zero dB signal to noise ratio and she got 13%. So that gives some view of how she's performing in a noisy environment. It's also very important to consider the role of questionnaires because they will provide a lot of insight beyond what is reflected on the audiogram. The questionnaires that she completed showed that she is greatly affected and debilitated by her hearing loss in many, many facets. She also has very debilitating tinnitus and her tinnitus handicap inventory score has her in a significantly handicapped category based on her responses. So though she has not gone through the implantation process, she is awaiting her appointment with a surgeon to talk to him about her surgical candidacy.

But I did counsel her on what we would expect to see and what we counsel patients on related to single-sided deafness and cochlear implantation. Some of the outcomes we expect to see in those cases are improved localization, improved spatial awareness, improved speech recognition, especially in background noise. There also is a large hope that she can experience tinnitus reduction in that implanted ear. She's got such

significant hearing loss that a hearing aid really did nothing to help her with that. We definitely hope to see improvements in quality of life and she found it quite helpful to meet with a recipient who had single-sided deafness. Funny enough, once we started talking she learned that she had a cousin who had a cochlear implant and friends of friends who are implanted.

So until she got to that point, she was unaware, but we have high hopes that this is something that she can pursue because she is very motivated to move on. So hopefully that will happen.

- Okay, so I'm gonna go ahead and wrap us up. We're right at time. Tracy, that was phenomenal. Thank you for taking us through those evaluations so we can understand what you did with these patients. And we really hope that it shows that a variety of patients can be evaluated for cochlear implant candidacy, including those with single-sided deafness. So we look forward to hearing how that lady does. We've taken you through the components, audiometric testing, speech recognition, functional evaluation, really looking to see if this is the right technology for this patient as Tracy recommended at the right time. And we see that intervention with cochlear implants typically result in great improvements in detection, speech recognition, as well as quality of life.

And we should note that many of our patients continue to wear a hearing aid in the contralateral ear and really receive great benefit bimodally. So we hope you enjoyed today. We hope you will join us on February 20th for a review of how the 60:60 guideline can help you determine if the time is right for you to refer some of your patients for a cochlear implant candidacy evaluation. So we appreciate your time and Tracy, it was a pleasure to present with you today.

- Thank you, likewise.