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**Standard of Care: International Consensus and
Candidacy Evaluation for Cochlear Implant Use in Adults:
An Audiological Perspective**
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- [Terry] Hi, everyone, welcome to today's session at this time Renee if you're ready to get started, I'll hand things over to you.

- [Renee] Great, welcome everyone, we're so thankful that you're all here joining us today, if you're in live or if you're joining us at a later date, welcome. Me and Dr. Zwolan, we're gonna be talking today about standard of care and the international consensus and candidacy evaluation for cochlear implant use in adults. And we're gonna be approaching this from an audiological perspective, and this is related to a brand new JAMA otolaryngology paper that just hit print today. And we're gonna be introducing you to all of... Everything about that paper. So the first thing we're gonna talk about is cochlear implant use in adults. There is a bit of a concern because really there's no international guidelines on who meets candidacy for a cochlear implant. In fact, it's not only is there no international guidelines, things vary across countries and sometimes even within countries, despite the fact that there are typically regulatory processes in place that will specify which indications are for which patient populations. For example, one clinic might do things a little bit differently than another, and it does add to some confusion and a little bit of an inconsistency. And also the other issue with this is that there's really poor utilization of cochlear implant technology. We know that there are hundreds of thousands of people, if not millions, worldwide, who could actually take advantage of this technology, but very few people are actually pursuing it. And there's a number of reasons for this, there's barriers with respect to public awareness. You know, I often will say, if you walk into, you know, go down to target and you just walked up to someone and asked them if they knew what a cochlear implant was, you know, I don't even know these days, about 10 years ago, I'd be willing to say almost no one would know what an implant is, today I think it's a little bit better, but it's still not where it should be given just the life altering nature of this technology. There's also a number of issues with respect to knowledge about cochlear implant criteria. And I'm not even talking just amongst the public, although that is of

course an issue. A lot of the people, even in the lay public who might know about implants, they don't always know who's a candidate, and I've talked to so many adults where they'll say, "You know, I had no idea I was a candidate, I thought this was just for infants." Or "I thought this was only for people who couldn't hear anything." And of course, there's also the concerns about the lack of knowledge about criteria with respect to referring providers. So, you know, unless you're actually working actively in a cochlear implant program or center, a lot of people aren't really sure, like, is this patient a candidate? Should I refer them on? And so that leads to some confusion, and that's also a barrier to access of this technology. And then of course we all know there's concerns about the lack of a defined care pathway. Who's going to be the primary referring provider for this. We all always tend to think about audiology and otolaryngology, but the reality is a lot of people, especially adults, aren't necessarily in the care of an audiologist or an otolaryngologist. And so maybe getting more knowledge into the hands of the, you know, family medicine providers, the geriatricians, internal medicine, other more general practitioners to help really bring this knowledge of awareness to them, bring the knowledge about cochlear implant criteria and getting those referrals in the right place.

And so you might be thinking, "Okay well, okay, we know that this is an issue, but why is this potentially a problem that there's this lack of uptake of the technology and lack of knowledge?" Well, the problem is that there's this global burden of hearing loss, really hearing loss is one of the leading causes of overall disability across the globe. In fact, if you can see the world health organization has estimated approximately 466 million adults and children, who are really 6% of the entire world's population has a disabling hearing loss. And this is actually projected to rise to 630 million and over just the next 10 years, and again, gonna rise to 900 million by 2050. So in other words, the incidents of disabling hearing loss is going to essentially double, over the next three decades. And so that's concerning, it should be very concerning to us that even today with all of the people who have, you know, 6% of the world population, having a

disabling hearing loss, and a very poor uptake of the technology. And we also know that hearing loss of course has just a substantial impact on our lives. I mean, it's not just the communication difficulties, it's not just our overall quality of life and wellbeing, there's so much to human communication and just, you know, contact with our fellow humans, which I think we kind of are seeing a little bit more now in 2020 than we ever have. In fact, we know disabling hearing loss is going to be leading to isolation if left untreated, too many people, for those of us who work with particularly adults, how many times have you heard someone say, "You know, I just, I basically don't wanna go out anymore. I don't wanna socialize with my friends. I don't wanna go to Thanksgiving dinner, 'cause I can't understand anything." And I think that we're all probably acutely aware of how important communication is, in the last five to six months. So even we were all aware of course that, you know, communication is a multisensory experience since we've been, you know, most most of our time in our clinical and our personal environments, when we leave our home. We really had to adapt to a life where communication impairment really is very obvious and can be significant problem, not just for individuals with hearing loss.

So why is this important? Well, there's a huge importance because we know there's an increasing risk of incident dementia amongst individuals around the world. I mean, realistically people are living longer, we have longer life expectancies, and what's happening is we're seeing greater risks of dementia that are happening. And so I'm sure many of you are familiar with the Lancet paper that came out in 2017, that was basically showing the results of the Commission on dementia prevention intervention and recommendations. And then that was updated in 2020. So just very recently, they came back out and updated their life course model of depression. And really what they found was, is that hearing loss is really one of the largest risk factors for dementia. And in fact, in their 2017 model, it was the largest risk factor. And when they redid their modeling and their analysis in 2020, it came out to be the second leading modifiable risk factor behind education in the global population. And so what they did was they

actually have identified 12 risk factors, that if identified and remediated or intervened in some way, could potentially delay dementia. So for example, education, hypertension, smoking, obesity, depression, physical inactivity, diabetes, excessive alcohol consumption, head injury and air pollution in addition to hearing loss. And hearing loss alone in their model, shows that if you can aid hearing that there's a potential for an 8% reduction in dementia, if the risk factor is completely eliminated. And so this is a big deal. I mean, obviously these data out there are our correlational nature right now. We don't have causality out there, but I don't know about you, but I definitely, if there's something I can do to prevent, you know, my patients, my family, myself from developing dementia and aiding my hearing loss is one of them I'm going to pursue that. So that brings us to cochlear implant use in adults. So we know that really cochlear implants have been available, you know, the single channel implant was approved in 1984 and then the multichannel implant in 1985. So we're talking over 30 years of availability in most countries.

And we also know that cochlear implants are clearly considered standard of care intervention for infants who have severe sensorineural hearing loss. And in children thankfully, the utilization of cochlear implants is very high. In fact, Sorkin and Buchman in 2016, they presented these data in otology and neurotology paper. Where they showed that it's a little bit dependent upon the country, but utilization of cochlear implants and in infants with severe to profound hearing loss is anywhere from 50% in the United States, up to as high as 95% in Australia. So meaning that we're really getting, you know, the children who need this technology are largely receiving it. Now in adults, it's a different situation. Many people don't even think about a cochlear implant in the continuum of hearing healthcare. They sort of think, "You know, this is only for something when my hearing aids provide me zero benefit," and many adults really are just simply not being referred. You know, they'll just say, "No one ever told me I was potentially a candidate for an implant." And really, if we're going to increase the uptake of this technology in the adult population, we have to define cochlear

implant use as standard of care for adults. And so what do we know about cochlear implants? Well, as a reference, you can see that adults will... Clearly, we're not in a place right now where we're debating whether or not cochlear implantation is beneficial, it is clear that cochlear implants in adults and children with severe to profound hearing loss, significantly improves speech perception abilities, educational and employment opportunities. And as well as quality of life, the data are clear. But the problem is we're seeing very little use or penetration of cochlear implants and people who could actually benefit from it. And from a global perspective, the numbers are somewhat varied, but it's anywhere from about four to 5% of individuals who actually meet a candidacy criteria are getting a cochlear implant. And those numbers haven't changed for at least 10 years. And so I wanna give you a reference.

So you know, there's a number of different statistics out there, and this particular statistic from also the world health organization, it's a little older than the previous one I had provided to you. So this is from 2018, and the total adults globally with disabling hearing loss at that time were 432 million. And at that time also the prevalence of severe to profound hearing impairment. So like disabling hearing impairment versus much greater severity. So 53 million at that particular point in time, now to put that into perspective, 53 million people is the entire population of South Korea or the country of Colombia or Kenya. So those entire countries that's how many people globally had severe to profound hearing impairment. Let's put it into perspective in the US, that would be like combining the populations of California, Pennsylvania, and Washington, DC. All of them combined, would have severe to profound hearing impairment. But only four to 5% of these people are actually getting cochlear implants, and this is a huge problem. So we know that there's a global burden of hearing loss, clearly, this is a problem, we don't have international or really any consistency on the guidelines for adult candidacy, there's a number of barriers to cochlear implant access. And of course we know as I've been focusing on that, there's very poor utilization of this technology. So what was the actions? Why are we all gathered here today to talk about

this? Well, there was a group of individuals who were otolaryngologists, audiologists, hearing scientists and industry reps, who all came together to form a Delphi panel, and our goal was to develop a series of consensus statements, regarding... we really started broad, looking at unilateral cochlear implant use in adults. And the reason many of you might be thinking, "Well, why not bilateral?" Keep in mind that there are a number of countries in different regions that bilateral implantation in adults is simply not gonna be covered from a medical care perspective. And, you know, realistically, even just starting with a single cochlear implant is a great first step to bringing someone much improved communication, quality of life and overall wellbeing. So this is... What we're gonna be focusing on for the next several slides. So the first step is as part of this, we want it to sort of come to a standard of care, right? Earlier I mentioned, you know, for infants, cochlear implantation is absolutely standard of care, not so much for adults. So what does standard of care mean?

It's actually, there's different definitions, depending upon which perspective you're coming from. So for example, from a medical perspective, it is really considered that's the process, a clinician should absolutely follow for a given patient with a certain particular illness or circumstance. And so it basically is describing the treatment based on considerable scientific evidence in collaboration and approval between a number of expert professionals in that particular field. And then from a legal perspective, if something is to find a standard of care, that's really that puts us as professionals, it kind of holds our feet to the fire that we are required to recommend... at a very minimum educate our patients. That look, "This is an indication for you that you would benefit from it's obviously they don't have to adhere to our recommendations, but we're really obligated to mention, you know, that cochlear implants are part of the hearing healthcare continuum. And actually you're, you know, you're getting to that point where you're a candidate, for this technology, and we're certainly not there from an audiological perspective, not even in 2020. So there's plenty of room for growth, not only from a global perspective, but also within the US as well." So why is this

important? You know what, it's really... It's not only important for us as clinicians and for our field, it's so important for patients because once a particular intervention is listed as the particular standard of care, this means that we're gonna get much better treatment and referral guidelines. So that pathway is gonna be much more defined, and it's gonna be much easier to bring people in from whether they're just seeing their primary care physician, or they're seeing an audiologist at a, you know, an otolaryngology office, at a academic medical center, or even someone in private practice. It's ultimately gonna provide better access to cochlear implant technology and aftercare for these patients. And of course, we know that when we can remediate severe to profound hearing loss, that we're gonna see not only improvements in communication, but overall quality of life participation and engagement in one's life. So what did we do? We got together as a group and we basically completed a systematic review with the goal of coming up with a number of consensus statements that would drive the delivery and development of a standard of care within the field from a global perspective. And so, as I mentioned earlier, we were really wanting to start with unilateral implants. So we could use this from an international purview.

And so a number of individuals we formed what's called a Delphi consensus process or a Delphi consensus panel. And this is a very well established consensus technique that really allows for you to get very important information from a number of experts in a particular field. And the way it works is that, you first start with the systematic review of the literature, and then you come up with a number of general sort of consistencies across those different publications. And then you go through several rounds of actually voting. So a number of statements are generated that are based on the systematic review, and you go through these rounds of voting and questions, and we're looking for, again, a consensus. So are we getting, you know, 75% consensus or higher amongst this large group of professionals interdisciplinary that are going to result in a series of consensus statements that will be relevant to a particular field and intervention. And so with these consensus statements, we are hoping that this will

drive clinical practice guidelines, which ultimately improve our knowledge, our awareness. It will take down the barriers to this cochlear implant technology, and develop both best practices as well as standard of care for adults to receive cochlear implants. All right, so I gave you this kind of a high level view of the Delphi process, I'm gonna just give you just a little bit more information, just so that you're aware how this works. So a group of... So Dr. Craig Beckman at Washington University, he was the chair of this process and he pulled together a number of experts, as I mentioned in hearing science, audiology, otolaryngology, and came up with a steering committee, as well as the panel. And oops, I'm sorry, hit that too quickly. And then as I mentioned, we did a systematic review of the literature, which then we came up with 25 consensus statements, and that was all based on what was the evidence that was presented in the literature. We then actually went through three separate rounds of voting on these consensus statements to refine things and to come up with... We had to come up with a consensus. So 75% or higher agreement on a particular statement.

And then the final goal of this process was to create this publication, which would be a consensus statement, a group of consensus statements, which would ultimately, as I mentioned, build best practices and ultimately identify standard of care. So there were, as I mentioned, a large population of panel members, coming from a number of different areas in otolaryngology and audiology. and Dr. Beckman was the chair and there were 30 Delphi panel members. And that was, you can just see from the map here, we really tried to get a very large global representation and 30 different or 13 different countries were represented within this panel. And of course, it's also extremely important to, you know, not only bring in what you would consider the experts, but we have to bring in individuals who have hearing loss and take their perspectives into account. And in order to really fulfill this, we also pulled together a Consumer and Professional Advocacy Committee, or the CAPAC. And the goal here was just not only to distribute knowledge amongst experts, but we really need to get, you know, all of the key stakeholders at the table so that we can really come together

and be working together as partners in the advocacy for these consensus statements should drive best practices in standard of care. And so you can see that we brought in individuals from, you know, the Hearing Loss Association of America, the International Federation of Hard of Hearing People and President of the German Association of the Hard Hearing, as well as a number of different individuals representing, you know, community stakeholders with hearing loss. And when we came together, they were able to comment on the consensus statements and we were able to refine things based on their input. Now, I did mention, we came up with 25 consensus statements, but those 25 statements, were actually within seven individual categories, and those seven categories are shown here. Right now, we're gonna focus on the first two categories, which really is sort of the one of the biggest impediments today, the lack of awareness, and what's the pathway. How can we get these patients in the pipeline to be evaluated for cochlear implant. And at this point...

- [Terry] Thank you Dr. Gifford for that great description of the Delphi consensus, I'm really hopeful that this is gonna help us spread the word and educate people, not only about the importance of cochlear implants, but about the benefits and all of the advantages that can bring to our patients. So my part of this will be to review some techniques that we've developed to help cochlear implants become the standard of care. So as Renee talked about the importance of standard of care, but in order for the implants to become the standard of care for patients with significant hearing loss, we really need to recognize who should be evaluated for an implant, and we can't do those evaluations if the referrals aren't there. So if current estimates are accurate, the penetration of implants in eligible adults is as low as 5%, which is really kind of eyeopening that tells us that many candidates are not making it through the door of the cochlear implant clinics, and they're not being evaluated. And in our clinic, we developed the 60/60 guideline because people I'd go out in the community and people would say, "So when should I refer someone?" And it was really hard to come up with a clear number. And at first we'd think, "I don't know, 50% is grim or maybe 60%." So

we really wanted to look at it, in a large group of individuals. And this was recently published this month in otology and neurotology. And so why is this recommendation needed? Well, it's really hard for audiologists to know when a patient should be referred. Candidacy for adults is based on audiometric test results, as well as the ability of the patient to recognize words and sentences when using appropriate amplification. So the testing that we do is very different than what most audiologists do, who are not involved in cochlear implant programs. So the non-implant audiologists most often perform comprehensive audiology, which includes thresholds and unaided speech recognition, but they don't perform sentence recognition testing, which is really what we're using in basing candidacy upon. So it's really difficult for referral sources to know who might be a candidate, when candidacy's based on a measure that they're not actually performing. And importantly, audiologists care about their patients. They don't wanna send them to an implant clinic that might be three, four hours away just to find out they're not a candidate. They really wanna make their trip worthwhile. And they wanna be certain that somebody is a good referral before they send them for a cochlear implant candidacy evaluation. So we're really helpful that now we have some data that they can base it on, and they can say, you know, this test indicates that your chances of being a cochlear implant candidate are actually fairly good. But remember, it's a referral guidelines, so it's not a given, and it's to guide referrals, not to guide the decision about the cochlear implant. And really we wanted to focus on routinely collected data. That's collected by the non-implant audiologists, who are our referral sources. That's who's sending these patients our way. And really in a nutshell, the 60/60 recommends that patients be referred for an implant evaluation. If they have a pure tone average in their better hearing ear, that's greater than or equal to 60 dB HL. And if they have an unaided word recognition score again, in their better hearing ear, that's less than or equal to 60%. So why these two measures again, because they're routine routinely collected. And because they're related to those things that we look at for the FDA indications, so let's look at that. Let's look at those FDA indications, and what do I mean by traditional candidate? So the FDA indications for

the more traditional candidates state, that they must have a bilateral moderate to profound sensorineural hearing loss in the low frequencies and a profound hearing loss, in the mid to high speech frequencies, and that they should also have a best aided sentence recognition score of less than or equal to 60%. So most clinics will repeat the audio metrics unless they've been performed recently. Then we might not repeat the audio metrics, and we'll start to focus on the aided testing. The aided sentence recognition test that's most often used is the AzBio test. And really those indications don't tell us about the presentation level or how we should present those sentences. So some sentence or some clinics you'll find we'll present those sentences in quiet. Some will base their decision on sentences presented in noise, and some will base it on sentences presented even more noise. But at most clinics, this is defined by the score that the patient obtains, when the sentences are presented in a signal to noise ratio of plus 10, which as you all know means that your signal, your sentences are 10 decibels louder than your background noise.

So this the 60/60 really gives you an indication of someone's good for a traditional candidate. So they're probably gonna be our poorer hearing people that come through our door. And as we talk about the 60/60, it's always important to remember that there are many nontraditional candidates who receive cochlear implants. So we might see a patient in our clinic who has poor speech recognition, they don't meet the audio metric criteria, but because those are FDA indications, they're not the law, it just really means we have to talk to their insurer and say, "You know what? Even though they don't meet those FDA indications, we feel they're a really good candidate." And oftentimes a large number of our implant patients have been implanted outside those indications. So the other group that we might often see might be those with asymmetric hearing losses, where one ear is profound or moderate to profound, but the good ear might prevent them from meeting indications. Because if you look up here at the indications, you see that here we go, that the best aided sentence recognition score must be less than or equal to 60. So, typically the better hearing ear is gonna contribute the most to that

score. But we might have a patient who has a better ear that's gonna keep them out of candidacy, even though they're poor ear is a great candidate for a cochlear implant. So in our children and our adults, we're in planning a lot of patients with asymmetric hearing losses. And then even more recently, we've seen the FDA approval of more nontraditional candidates. Those with single-sided deafness, so with normal hearing in one ear and deafness in the other ear, and those with asymmetric hearing losses. Again, one profound ear and a hearing loss in the other ear, as opposed to normal hearing, but just remember here, the 60/60 focuses on traditional candidates 'cause clearly if we're only doing 5% penetration, we're missing a lot of those traditional candidates, because I think it's hard to know who's a candidate. So to develop the 60/60, we looked at preoperative data of 529 patients who are seen in our clinic for a cochlear implant candidacy evaluation. And out of those 529, 250 were candidates, and 259 were not candidates when we looked at these traditional candidates. We looked at the unaided thresholds for each year, that pure tone average, and then we also looked at the best unaided monosyllabic word recognition score when the scores for the right and left ears were compared.

Now this was a little bit of different than the regular data collection we do, because we actually went through the audiograms that are frequently sent to us by the referral source. So if available, we use the score obtained at the referring clinic, and if it was unavailable, we would use the score that we obtained as part of their implant evaluation. But the caveat was when we started to look at this, we found that, boy, everybody's using different materials. Some people are using NU6 or CNC or CID-W22s. We also noticed that sometimes they're presented taped, sometimes they're live voice, and often they were at a variety of presentation levels because they're unaided. And, you know, typically based upon the MCL and different factors, different people use different factors and found a lot of times it wasn't indicated on here. But this was truly representative of what's being used out there. So we thought it was reasonable to look at these scores being obtained by our referral sources. And it's

important to note that of all the records that we reviewed, not a single one included aided sentence recognition testing. So we really saw firsthand that disconnect between what the referrals that sources are doing, and what we're doing as part of the implant eval. So first we wanted to look at those candidates, we had 250 candidates, and we wanted to say, where are the pure tone averages of most of our candidates fall. And so in this first graph here, what you see here is cumulative percentage data for our patients, so for example, this first bar you'll see that 100% of our patients had a pure tone average in their better hearing ear that fell between 30 and 120. And as we narrow that down, the number of people who fall into these different categories get smaller. But if we looked at between 60 and 120, we found that 95% of our candidates had a pure tone average, and the better hearing ear that fell between 90, oh I'm sorry, between 60 and 120 decibels. If we look at the proportion of patients with various pure tone averages over here in this other graph, so we see that very few of these candidates had a better ear pure tone average that fell between 30 and 40, very few between 40 and 50. But we see this nice jump, once we start to include those people with a pure tone average of 60.

Most of them have a pure tone average that falls into 70 or 80. But if we put this line here, we can see that we're going to grab most of our traditional candidates. And what about their unaided word recognition? Well, 92% had a better unaided word recognition score that was less than or equal to 60%. So again, here on the left, we've got the better ear unaided word recognition score, accumulative percentage. So we had 100% of them, had a score that fell between not zero and 90%, and as we go to the left, we're gonna see that it includes fewer percentages. But if we draw a line again at that 60, we're going to see that that's where that 92.3% of our patients fall. And again, our proportion of patients with various word recognition scores, very few has scores that that would fall sort of 91 to 100, or 91 to 90. But again, if we draw that line at 60, we see most of our patients are gonna fall to the left of this red line. What's interesting is that most patients had a score less than 20%. And what that tells me is

that a lot of these patients were probably candidates years ago when their scores were a little bit higher, and we do find that patients will do a little bit better if we catch them right when they become candidates, rather than having them be centrally deprived for years with poor hearing. So in summary, we saw that 95% of candidates demonstrated a better year pure tone average greater than or equal to 60 and 92% of candidates for whom a better unaided monosyllabic word score was available, demonstrated a word score less than or equal to 60%. So I think for referral sources is important like, "Okay, so what's my hit rate gonna be? What's my miss rate gonna be? Is this a good way for me to look at my patients to possibly send them on?" So the hit rate based on 415 patients that had data, both data points, meaning both pure tone average, and that unaided word recognition score, was that 340 out of 415, that it was effective for 82% of the patients, and the miss rate was 75 out of 450. So 18% of patients who met the 60/60 guideline, did not qualify for a cochlear implant, but it's important to know that if we're gonna air on one side, it's better to air on the side of over referral, because remember we're doing this pretty stringent with these traditional candidates who have worse hearing. And many of these patients return the following year and they eventually become candidates.

We oftentimes see people who come back annually and they keep coming, and until they're eventually a candidate. Many of our referrals were nontraditional candidates, but they still received an implant because they might have fallen into that category of asymmetric. And then many returned to their referring audiologists because they say, "I'm not a candidate." And we look at them and say, "Yeah, you're not a candidate, but you really should be optimizing your hearing better. And those hearing aids are seven years old, there's been a lot of developments made," and they often go back to their referring audiologist and they obtain new hearing aids. So one way to also look at the accuracy of this, or again, what are the chances a patient will be a candidate? They meet the 60/60, so there's two ways to look at this. One is a positive, predictive value, which we can see over here on the right. And basically for the PPV, we're looking

across this top line here of candidates who meet the 60/60. So those who met the 60/60, 212 are candidates, and 67 were not candidates, but if we look at 212 divided by the total number that gives us a PPV of 76%, which means that patient has a 76 probability of meeting traditional indications, if they also meet the 60/60 guidelines, we can also look at sensitivity. So how sensitive is this measure for determining if someone's a candidate or not? So for this one, we're gonna go in this column here. So we had out of the candidates 212 met the 60/60, and we really only had eight, who did not meet the 60/60, but we're still candidates. So we might've missed them if we had this strict requirement, but still it resulted in it being fairly sensitive and that 96%. So the proportion of people who are candidates who will meet the 60/60 was 96% for this dataset. On the reverse side, we're gonna wanna look at what are their chances of patient will not be a candidate if they don't meet the 60/60. So for this one, we're gonna start with the NPV, and we're gonna look at this line here, and we're gonna see that 128 non-candidates out of 136 gave us an NPV of 94.

So there's a 94% probability that a patient will not meet traditional indications if they don't meet the 60/60. And then additionally, with specificity down here, we're gonna look at this column. We have 128 non-candidates who did not meet the 60/60. So that gives us a specificity of about 66%. So again, we're okay erring on the side of caution with this, we'd rather have people come in who are not candidates, then turn away people who are candidates or who could be a non traditional candidates. So I wanted to just take you through a couple of case studies, and these are actual audiograms from some of our referral sources. You might look at this audiogram and go, "Wow, he doesn't have much hearing at all." And he really doesn't, I'd look at this audiogram and go, "Oh, I bet he's an implant candidate." And then we look at the speech recognition that I've got circled up there, and he's got 16% in the right ear and 52% in the left. So that left ear was pretty close 60. But when we did his cochlear implant candidacy eval which is where we're looking at aided responses, we see that his CNC scores are zero and 20%, his AzBio scores are terrible. They're 2%, 2% and 8% bilaterally. We didn't

even test him in noise, because he did so poorly in quiet. If we look at his results a year later, I worked in all honesty are pretty typical, a lot of the patients we see, we've taken that left ear from a CNC of 20%, and it's improved to 76%, which is really tremendous. His AzBio has gone from a preop of 2% to a postop of 96%. And postop, we're able to do testing and noise, and he's doing really well. He's understanding 60% of those words and sentences. We have another patient here, he's got a little bit more hearing than that last patient looks like a good candidate has a moderate to profound sensorineural hearing loss. So he's gonna meet those FDA indications, his speech recognition is a little bit better 'cause he's got better hearing, but you see over here, the left is 60%, so ooh, his better ear is 60, he's right there on the borderline, his right ear's 20%. But the reason I wanted to show him is here down to the audiologist note. And this was patient who self-referred, this was not referred from an audiologist, is they indicated they were updating his audiogram for new hearing aids.

So when I asked the patient about this, he said they really hadn't talked to him about cochlear implants, he actually had a friend who had one that really was the one that convinced him to come. So when we put him in the booth and did our testing with hearing aids, his CNC scores are low as well, 8% and 24%, his sentence scores, like the previous patient aren't really high enough that we needed to test him in noise. And he scored 24%, 24%, 28%, so his best aided was 28%, which is less than 60%, which made him qualify as a traditional candidate. We look at his one year post-implant scores, we see the same thing, he went from 8% to about 82% on CNC's, on his sentences he went from 24% to 98%, which is really tremendous. And what I like to show about this one is we do testing with both his right implant and his left hearing aid. And you can see that he does really well in noise, and he does better when he uses his implant plus his hearing aid, then he does when he uses the implant alone and many of our patients today are bi-modal, and that's what gives us the ability to look at those nontraditional patients who are asymmetric hearing loss. They can keep that good hearing with the hearing aid, we can optimize the poor hearing that they have with their

poor ear, but together we're gonna make them significantly better off than what we saw, he was receiving pre-implant. And last I wanted to show someone that did not meet the 60/60 clearly has a pure tone average in each year that meets the 60 part, but we see a speech recognition that exceeds 60% it's close. So it might be a good referral, and I think it is a good referral, especially since these were done using taped, which are gonna be a little bit harder. So we did get this referral from our audiology clinic. When we put him in the booth, we see that he actually does better with the aids than he did on aided, he's got scores of 80 and 56% on the CNC's, but wow, look at those AzBio scores those are really high he's scoring, 92%, 93% and 88%. When we tested him in noise, there wasn't even really that big of a drop he's still doing fairly well. And that score exceeded the traditional candidacy or traditional indications of 60%. So this patient actually, we did not recommend an implant for, and a lot of that was based on those AzBio scores that we obtained both in quiet and in noise. So I hope those demonstrated for you. Some of the patients that are pretty typical of what we see the 60/60 we think is really going to be a helpful guide, that can be used when trying to determine if a patient should be referred for a cochlear implant eval. We feel that doing so will capture many traditional candidates and may also provide access to implants for patients who do not meet the traditional indications, but are still good candidates for a cochlear implant. And we won't approve access until the referrals increase. So sending those patients to determine if they're a candidate is really the only way that we're going to improve access to implants, and then we'll get even closer to implants becoming the standard of care as Dr. Gifford has mentioned before. So now I'm gonna hand it back to Dr. Gifford, so she can take us home and tie all of this together for us.

- [Renee] Thank you, that was really great. I love to see how that just plays out with some case studies. So, as I mentioned earlier, we came up with these 25 consensus statements that were largely broken down into seven categories. So doctors will and spent the majority of the time on the first two, because that is sort of the crux of this entire presentation. You know, the fact that we are not getting people through the

system who need this technology, and we wanna increase those referrals, but while we're here, we also wanna just kind of give you an update on what the other categories entailed, and what just the general summary was for the different consensus statements. So the third category was really more aligned with the surgeons and basically dealt with the fact that cochlear implant surgery is absolutely safe, it's a routine procedure, our fetologist will say it's the easiest procedure that they do, adults of all ages show benefits. We know of course that older individuals may show less benefit, but it doesn't mean that they're not deriving significant benefit. We also, the additional consensus statements had to do with the fact that we also wanna consider acoustic hearing preservation and that that can improve outcomes for our patients. And that, you know, when you have acoustic hearing preservation with surgery, that patient can then combine electrical and acoustic stimulation or EAS in the same ear, as well as potentially across years.

The fourth category dealt with clinical effectiveness, and as I mentioned earlier, this is not something we have to debate anymore, we're not at a point where we have to determine the efficacy of cochlear implantation, 'cause it is quite clear that cochlear implant recipients of all ages with severe to profound hearing loss, derive significant benefit for speech understanding as well as quality of life and overall wellbeing. We also wanna point out that older age alone should not be a barrier to pursuing this technology. And of course, while we know that longer durations of deafness are generally associated with poor outcomes, doesn't necessarily mean they're not gonna get benefit from this technology. And so clearly there's more data that needs to be collected in larger populations of patients in a prospective manner to really look at, you know, a number of these patients, specific variables like age duration of deafness and a number of other potential, you know, etiologies and other variables that might impact outcomes. The fifth category dealt with the factors that might be associated with outcomes, And as Dr. Zwolan mentioned on that one potential case where when added hearing aid that he did so much better in the bi-modal condition, and of course that

was one of the consensus statements that adding a hearing aid to the cochlear plant, whether it be in the implanted ear, the non-implanted ear or both, it's gonna yield significant improvements over electric hearing alone. And as mentioned previously again, long durations of hearing loss, that might be something we wanna counsel our patients that, you know, maybe guarded expectations, but it does not rule out the fact that they can still get benefit from this technology. Also, we found in the literature that of course, patients can't just get activated, then go home and never come back. They do need regular postoperative programming and, you know, refinement of those parameters to really optimize their outcomes. And of course, additional research is needed in this area as well. The final two categories, the category six, there's a lot of information with respect to the relationship between hearing loss, depression, overall cognition, and the development of dementia. I did touch upon this slightly earlier. Of course, we wanna, again, reiterate that these studies are largely correlational in nature to date, but there are a number of longitudinal prospective studies that are ongoing right now. And, you know, while it may be correlational, again I said, I'm a believer I wanna you know, I wanna optimize my chances for not potentially obtaining dementia.

So I don't certainly tell my patients that, you know, you get these hearing aids or cochlear implant, and you won't develop dementia. But I would say, you know, there's evidence to suggest at least in the statistical modeling that while it might not cause dementia, that if we treat the hearing loss, and we can provide you with, you know, optimal audibility, there is the potential that the risk for dementia is gonna be significantly diminished. And of course, time will tell on those studies of causality, whether or not this is in fact the case. The seventh category dealt with cost implications. And in fact, as many of us know, cochlear implants are absolutely considered to be a cost effective intervention. They're economically favorable with respect to, they can increase one's medium yearly income. It increases employment rates, and it actually has positive effects on the healthcare or in the economy and health related quality of life for not only the patient, but for those around them. So in

summary, we know cochlear implants highly effective, and so terribly underutilized, many of you might be thinking, okay, these consensus statements, this isn't, you know, all brand new info and that's absolutely right. And in fact many of us, you know, especially at progressive clinics and medical centers, we know that these statements, we know that people can benefit. We know that, you know, acoustic and electric stimulation together provides benefit, but the reality is that's not everywhere and without additional action at not only the regional and the national and on the global level, we're not gonna break down those barriers to this technology, and so if you remember earlier, I mentioned that sort of the last step in this Delphi process was to publish the findings, which again are out today, but that's really not the last step.

The last step is really with us. We are all tasked with bringing this information to our colleagues, to our potential patients and not just to, you know, to our audiology friends and colleagues, and ENTs. I'm thinking about, you know, go up there, pound the pavement, go out there and do grand rounds at nurse practitioner academies or physicians assistants, primary care providers, we've gotta get out there and spread the word. We have to be also committed to outreach. I can say that this absolutely is beneficial. I've been here now in Nashville for almost 10 years and just actually going and meeting with people in the community, with these potential referral sources and also ensuring that they know that we're working together as partners. I find it extremely helpful to let them know that I'm never going to take a patient from them. You know, I might be their audiologist for providing with the implant, but when they need another hearing aid for the non-implanted ear, I'm absolutely gonna send them back to that referring provider. And that builds trust, and it builds that patient or that patient is a grateful to their referring audiologist and that audiologist is then going to send additional people. So it really is going to take a lot of effort from all of us, you know, I often tend to think, "Oh, that's the responsibility of the society. So, you know, AAA and ACCA and the ACIA, they need to do that." Well, guess what, who are those people? It's us, and so we have to get out there and spread the word and get this information

out there. And so at this point we wanted to talk about everything and really kind of engage in a dialogue with everyone here. I don't see if there's any questions at present, although Dr. Zwolan and I have some questions that we've pose, should we not get any questions, so Terry, do you wanna lead us in the next points?

- [Terry] Yeah, let's just start on those and feel free to enter your questions in the chat, and we'll keep our eye on it, and we'll be happy to answer those. And we'll put those over the thoughts that we've had, but Renee, I'd love to hear your opinion on this, what's the most common thing you see in regards to referrals for cochlear implant evaluations that you'd like to sort of share with our group either good or bad?

- [Renee] Yeah, so I think the thing that I've just been seeing consistently for the past two decades is that, people when they come in they are always so surprised, like, "I really had no idea that I would have even ever been a candidate for this technology." You know, in fact, someone that I saw two days ago for a workout, he was like, "You know, I just thought this was something for babies. You know, I just didn't know," and realistically with his audiogram and his level of difficulty, he probably would have been a candidate more like 10 to 15 years ago. How about you Terry?

- [Terry] Yeah, I agree completely, I'm always surprised when I have patients that are probably were a candidate five, 10 years ago and they say, "Well, my professional told me I'm not a candidate that they're only for people with absolutely no hearing." And would have thought that 30 years into this, we probably have a different story. And then there's some patients that will say that, "You know, my doctor said I'm not a candidate, and then also it seems as though professionals just seem to forget about an implant and they'd been long term hearing aid patients. And so they just keep putting them with hearing aids, and so I think that we have to do what you mentioned with the Delphi, and that's get out there and communicate. So people start thinking about recommending an implant. 'Cause I honestly feel like a lot of people just forget.

- [Renee] Completely, and one of the other things that it did actually come to mind that I was thinking about this morning is one thing is a lot of adults, and actually parents of children tend to be at least at the preoperative process. They're concerned about the external processor. And I do, you know, it's not necessarily just vanity. Some people are like, "Oh, I don't know if I want something, you know, on the outside of my head, you know, you said this was an implant, I thought it was totally under the skin." And I can say today that there has not been really one person that once it's activated and they see how much benefit they're getting, they just don't care about those external anymore. Do you happen, do you still see that as well?

- [Terry] Absolutely, and I love it, I love it because they see the value and everything else gets thrown out the window. They don't really care, they just wanna hear. And it's great that way. I do see some questions here, let's grab the first one, which says on candidacy, do your clinic support a plus five or plus 10 AzBio for candidacy? I have noticed a lot of debate in the community. So I'll start with that one, and then Renee, you can chime in. And I think in our clinic, plus 10 is sort of the bar, I agree with you that it's really a quite a bit of debate in the community, I will say I think we're probably moving towards the direction of words down the road because of this variability that exists in clinics. And I know a lot of clinics will use plus five for those asymmetries or for those more difficult situations. But for adults, we primarily use plus 10, but for children in our clinic, we will go down to the more difficult situation of plus five, how about you Renee?

- [Renee] Yeah, so we're kind of similar. We actually did get rid of plus 10. And the only reason is that the reality is the vast majority of people we see for referrals. It's not like we test them at plus five 'cause we have to get them to candidacy, their candidates. I mean, they're getting, you know, less than 20% sentences and quiet, but the reason we chose as a clinic to go to plus five, it really just has to do with ecological validity. If

you look in the, you know, out in the environment when you're in a restaurant type of environment or an airport, or, you know, other very large, well maybe not an airport in 2020, but you know, an airport prior to COVID, the average signal to noise ratio that you experience is closer to plus five. And so we want it to just kind of bring a little bit of that validity to the clinic, but, you know, plus 10, plus five, it really just it's a clinical decision. But I agree with you know, Terry that we're living as if we're moving to word recognition criteria, and I'm actually really happy about that. It takes some of the con you know, the contextual and the linguistic issues a little bit out of the context. And it will help also bring things more uniformly from a global perspective because that's what a lot of countries are using already.

- [Terry] Agree, agree, it takes out a lot of the older age factors of processing skills that might play in sentence testing or even in noise testing, so I agree. I think there'll be some advantages. We just get smarter, the longer we're involved in, in all of this work. We do have a question here and I'll just address this one really quick. Someone asks is the clinical data on PPV and NPV on referral available in the publication, and it is. So if that is in otology and neurotology, so if you access that, you'll be able to see all of the PPV and NPV data, and then we also have a question here. So what does your pre CI eval consist of? Monosyllabic word recognition, sentence recognition, quiet and a noise and anything else. Renee, would you like to start with that one?

- [Renee] Sure, yeah, so that's exactly what we do except ours is a plus five. We also administer some questionnaires, so we give the SSQ12 to all of our patients, as well as the cochlear implant quality of life, 10 questionnaire, so the SQL 10, and then we also, we have an internal questionnaire that's not necessarily validated quite yet, but it has to do with listening fatigue. And so we really find that those additional subjective questionnaires really help us because you might have someone who looks like maybe borderline, but they're reading that they're significantly struggling. And so I feel like it really kind of helps look at the whole person.

- [Terry] Absolutely, and I would agree with that. And I really feel as though the monosyllabic word recognition, really sometimes they might have 0% or 2% on the sentences and they might do a little bit better on the words. And that might help us define better, which is the better ear or the poor ear, which might influence our decision. If we're gonna go ahead with a unilateral implant. So I feel like the more information we can get on a patient, the better to base our decision of, are you going to be better off with an implant and which year should we start with. And certainly in the asymmetric cases, it's pretty straight forward, which ear, but some patients who are hesitant to go by lateral right out of the gate, it does help us determine which is a better ear, those questionnaires, tell us how they're actually using their hearing in their daily life, and I agree that the noise really gives us a more accurate picture of the difficulties that they're experiencing, because we know that it's a pretty noisy world. And there aren't many other many quiet situations where we're just listening. And we're getting close to the hour, so I just gonna take us through to one of our final slides. Renee mentioned the Delphi Consensus Paper Publication, which is today, it's very timely. So we hope that you will all look for this article and you will use it in your practice and you'll share it with others. It's a very valuable publication that hopefully we can all refer to a lot in a lot of work that went into that publication. And then we've added some resources to our next slide, which are additional resources that you can go to look for about adult candidacy. So the American Cochlear Implant Alliance, Cochlear Americas, there's great resources out there regarding cochlear implant candidacy in adults. So with that, I will sign off and say goodbye, Renee, any last thoughts?

- [Renee] No, that was a lot of fun talking with you today and talking with everybody here. And again, like I said, we've got some work to do, so we're excited to go out there and hopefully make some change.

- [Terry] Great, well, thanks Renee. And thanks everybody for joining us today, we appreciate it.