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Best Practices for Adult SSD CI Candidates and Recipients, in partnership with American Cochlear Implant Alliance

Presenter: Allison M. Biever, AuD, CCC-A

This is Donna. Go ahead. American Cochlear Implant alliance. And you are joining us today for cochlear implant best practices for adults and children with single sided deafness. This is the first in a two part series.

Next, and I want to just begin with a little bit on who we are, and you might wonder why there is another organization in hearing health. We are a membership organization that's focused entirely on cochlear implantation and access to care. And our members are audiologists and physicians and speech pathologists, educators, and others on teams, as well as consumers and parents and advocates and hearing aid specialists. We have a website that's very comprehensive, that's intended for those both in and outside of CI to support the whole continuum involved in hearing health. And we are highly collaborative with other organizations, probably organizations that all of you are members of, and we welcome your involvement if you're not currently involved in ACI alliance.

And we've given you some resources there on how to reach us on our website, Facebook, and Twitter so we could go on to the next slide. And our mission is to advance access to the gift of hearing provided by cochlear implantation through research, advocacy, and awareness. And we stay pretty tightly to those aspects of our mission. We address factors that contribute to the underutilization of cochlear implants, and those have to do with a range of factors, including people not being aware of the benefits or the candidacy aspects. And that's certainly one of the things that we're talking about today, understanding candidacy and outcomes in single sided deafness.

And we definitely want to improve that awareness. So on to the next slide. So why this topic is really critical now. Our perspectives about unilateral deafness have really changed, and in the 25 years or so that I've been involved in this field, we have gone from looking at cochlear implants as something that we provided to people with bilateral severe to profound hearing loss, to an expanded candidacy, both for those

who have bilateral deafness and those who have deafness only on one side. And that's because we've realized that the impacts on someone not having hearing on one side are significant.

And so we want to measure those impacts, which we have done in various studies and looked at how it affects someone's quality of life and their ability to participate. And we know that many hearing health professionals are unaware of when and whether to refer for a cochlear implant for somebody who has unilateral hearing loss. The other thing that's really changed is that insurance coverage now increasingly does address CI and SSD. And initially this was a really hard way to get coverage, but now we're finding increasingly various coverage. And we are actually working on getting coverage under Medicare with a study that's going on right now.

Now that will hopefully lead to a change in Medicare coverage to cover SSD. And we know a lot more about it than we did before, a lot of information on those outcomes for people across the age continuum. So we could go to the next slide. And this is a resource that I wanted to make you aware of. We have done two task force efforts that look at our guideline as an organization for the clinical assessment and management of cochlear implants.

And we've done one for adults, which we've given you an infographic for here, and you can find more information about it on our website. And the next one, next slide is a comparable clinical guideline that we've done for single sided deafness in children. And that's the topic that will be covered in the next of this two part series. Series. Okay, so we go to the next slide.

And with that, we're going to delve right into our talk for today with Allison Biever, who's an audiologist from the Rocky Mountain Ear Center. Allison has been in the field of cochlear implants since 1992. So our involvement is similar. 1992 is when I received

a cochlear implant, and that was when my keen interest in this really began. And Allison was one of those early, early providers who supported people like me at the time.

She sees both pediatric and adult patients and works on candidacy and provision of services. And she participates in cochlear implant research studies and has published numerous articles on cochlear implants. And she's also served as president and currently serves as the secretary for the Lisson foundation, which is a wonderful nonprofit organization in Denver. So with that, thank you so much, Allison, for being with us today. And I'm turning the floor over to you.

Thank you. Go ahead, Donna. Yeah, I was just going to say that people, please put your questions in the q and a section at the bottom, and we will answer those at the end. I'm sorry. Go ahead, Alison.

Thank you so much for your introduction, Donna. I really appreciate being here this morning with you. These are my disclosures and the learning outcomes I've listed on this slide that after this course, you will be able to list the candidacy requirements given by the FDA. For adults, there will be a pediatric part two, but for adults with single sided deafness, you'll be able to describe at least two speech perception tests that can be used to assess postoperative improvement, and you will be able to list additional measures that can be used to quantify improvement post activation. So who is a candidate?

I want to start by saying that 32 years ago, the candidate looked very, very different, and the FDA requirements were such that you had to be profoundly deaf in both ears. In fact, you couldn't even understand a single word with appropriately fit hearing aids. In the very beginning, that candidacy evolution has really morphed into something very, very different. Even ten years ago, when I would go into the waiting room to call a

patient back for a CI evaluation, I had a very strong sense for whether they were an implant candidate or not, because indications did not yet exist for single sided deafness. The patients that we were seeing ten years ago were no longer profoundly deaf in both ears, but certainly had hearing loss in both ears.

And while some clinics were offering this as an intervention option for patients off label, there were not FDA guidelines to indicate that it could be used in that population. So who is a candidate today for a cochlear implant? First, the candidate has to have severe to profound sensorineural hearing loss in one ear, and normal hearing to mild hearing loss in the contralateral ear. And I'm really going to talk about normal hearing in the contralateral ear. For the majority of this discussion, the word recognition score needs to be 5% or poorer in the ear to be implanted.

And per FDA guidelines, the person who's being considered for the implant must be five years of age or older. So these are FDA guidelines.

I want to talk a little bit. I'm going to go back to the previous slide. I'm going to talk a little bit about why this is so different. So anyone that is familiar with how a traditional candidate is assessed, we use sentence information, and many audiologists would assume that that would apply to this population, and it does not. So we do not look at a sentence score for someone with single sided deafness to determine if they are a candidate.

What you see on the screen is what we look at for candidacy.

I want to talk a little bit about the difference between FDA guidelines and manufacturer indications, because there are two different things that are often confused used by audiologists. So in 2019, Med El received approval from the Food and Drug Administration for indications of their particular device for anyone five years of age or

older to receive a cochlear implant. If the patient had profound hearing loss in the poor ear and normal hearing, to mild hearing loss in the better ear, and then in 2022, cochlear received FDA approval from the, from the Food and Drug Administration for indications for their product to be used with patients who have severe to profound hearing loss in the poor ear. So it expanded the indications a little bit to include severe to profound hearing loss, and their indications were for normal hearing in the better earnings, once again, age, five years of age and older. What typically happens for patients that come into a clinic who have single sided deafness is we often look at the least restrictive, the least restrictive labeling that the FDA has given us.

So what you'll notice on the screen is that there are only two companies, Med El and Cochlear, who have FDA approval for using their device in a population that would describe a single sided deaf individual. And yet, if a patient walked into a clinic, in all reality, most clinics are going to let a patient choose whatever device they want to use, even though advanced bionics does not technically have indications from the FDA to use their product for that population.

I could talk at greater length to you about how that's true. Even with aged implant for children, what tends to happen in clinics is when a patient walks in and they want to be evaluated, the clinic doesn't usually say, well, if you go with this particular device, these are the indications, and if you go with this particular device, these are the indications. Some clinics do follow that. And in fact, some insurance companies could deny someone if you chose a device that went against their labeling. But in general, most clinics would adopt in practice, taking the least restrictive definition of who is a candidate.

So you can see on this screen what the manufacturers actually got FDA approval for.

I want to point out on this slide as well, that Medicare does not currently cover CI surgeries for adults with single sided deafness. And that's a really important distinction when I'm talking throughout this talk about who's a candidate, I am not talking about Medicare patients. We have some single sided deaf patients, not very many, who either paid for a device out of pocket or who perhaps got a cochlear implant as a single sided deaf individual before they obtained Medicare coverage and are still covered under Medicare currently. But it's a very, very small population because Medicare does not currently cover CI surgeries for adults with single sided deafness. And Donna alerted you all to some studies that are being done, some task forces that have been initiated to look at this population in hopes of getting Medicare to cover it for this population.

So when we see a patient who comes into our clinic who has single sided deafness, there is a pretty significant amount of counseling that needs to be done. And I want to say that although we have been working with single sided deafness for longer than indications have been available, it's been done off label. And it has been a very interesting and eye opening experience for me in terms of need. And Donna very eloquently pointed out that this is a population that needs intervention. And quite early on, as we were starting to work with single sided deaf patients, my thought process was, I would prefer another audiologist work with single sided deafness because I want to work where people need me most, and that is with people who have bilateral hearing loss, significant bilateral hearing loss.

And I was very much humbled by the experiences I have had the opportunity to have with patients who have single sided deafness. When somebody, particularly somebody, loses their hearing very suddenly, there are a lot of things that are immediately taken from them. And I think that there is a lack of awareness that exists in the community about the impact of single sided deafness. I have worked with some patients who have told me that spouses, friends, colleagues have said to them, but you can still hear from one ear. Aren't you glad?

And isn't this something you can just adapt to? There is a lack of understanding about hearing loss in general, but what it means to hear from only one ear. So a lot of these patients that come into our clinic again, particularly the patients who have lost their hearing, suddenly they're very grieved and they will say they have a very difficult time localizing, that's oftentimes referred to as auditory spatial awareness. Suddenly everything they're hearing from their good ear. It is like there is no sound on that poor ear side.

So they have a very difficult time locating the sound source or having any auditory spatial awareness. They also experience a head shadow. So, for example, if they've lost all of the hearing in their right ear as a driver, they can't hear anyone that's talking to them on the right side. And it becomes somewhat of a safety issue, the need to turn their head to make sure they can hear what's being said and still attend to the traffic in front of them. It becomes an issue in terms of positioning people.

A lot of the patients I work with with single sided deafness have said I can no longer just walk down the street with my friend when we go for a walk, she forgets, but I'm constantly repositioning myself so that my good ear is over on the side where she's standing. If I'm in a meeting situation, I will have helpful friend sit on my deaf ear side and make sure that what's really important is on my good ear side. So they experience something they did not experience prior to losing that hearing. They also will comment that they have a tremendously difficult time in background noise. And when these patients come in, I talk about each of these, these difficulties that they're experiencing.

And, you know, very recently, I had a patient with single sided deafness, who's also a grief counselor, become very emotional during the counseling process. And she said to me, Alison, thank you for putting into words what I've been experiencing. And so the need, as Donna said, is very, very important in this population. So squelch is

something I've listed on this slide, and that means that patients are having an exorbitant amount of difficulty managing background noise, and they never had this problem before. Someone can be speaking right in front of them, right to their face.

You go to dinner with a friend, they're sitting right across the table from them. But because of background noise, especially background noise directed to their better ear, they are not following the conversation very effectively. It causes auditory fatigue, it causes stress. It is a situation that has really prevented some of our single sided deaf patients from wanting to go out into noisy environments. It has been really a life altering experience to lose hearing in one ear.

Many of these patients experience a significant degree of tinnitus. So that's always a part of our counseling is, are you experiencing ringing, roaring, buzzing, any kind of a head noise from the poor ear side? And the vast majority of patients with single sided deafness that we see will report that they're having a very difficult time with tinnitus. Another counseling issue that we like to address is duration of deafness. And while the literature is a little bit variable in terms of how much duration of deafness is too much, there are some studies that would indicate.

Jill first and colleagues have published several papers that would suggest that duration of deafness is not as much of a variable as you would expect, that it is possible to obtain really good results even with long term deafened adults who have single sided deafness. A lot of the studies that have been made available have capped candidacy and have said we don't want to take a patient in a study who has a duration of greater than ten years, indicating that there may be still some issue with duration of deafness. In general, the duration of deafness is not so much of a strong indicator for our clinic, except for whether the patient was congenitally deafened in that ear or whether it was at and acquired hearing loss. So if we were working with a congenitally deafened adult who had single sided deafness and came to us at age 20, or for that matter, age five or

seven. We would be far more reluctant to consider this technology for someone with congenital deafness.

And stay tuned for part two when we talk about the pediatric component to this, the pediatric series, because FDA states indications are for children five and older. So stay tuned for part two when we will be talking about candidacy with that population. But again, in general, if we're working with an adult who was born deaf, we would not recommend a cochlear implant. We would recommend a bone conduction implant for a patient like that.

What does the assessment look like when these patients come in? The vast majority of the time I spend is in the counseling portion of my appointment. There's far less time spent in the assessment because if you'll recall from a previous slide, the candidacy in terms of FDA indications is really pretty clear cut. So the vast majority of the time we're talking about their difficulties. What difficulties are they having?

What do they perceive their handicap to be? What is challenging for this patient? So now we've determined this patient is struggling, and quite frankly, they are likely not going to be having an easy time or they wouldn't have shown up in your clinic. So these are patients who you may be seeing, who are saying they're having a hard time and should be referred on for a cochlear implant evaluation. Or perhaps you are the audiologist who will be doing the cochlear implant assessment.

So it consists of a comprehensive audiogram, which includes air conduction and bone conduction, and speech perception. It also consists of CNC recorded words with the normal ear mask. So we aid that ear, if it's aidable at all, and we test with CNC recorded words and masking the poor ear. I put asterisks on this slide because those two assessments are what FDA requires, remember from a previous slide, severe to

profound hearing loss, if you look at the least restrictive guidelines. So that would require a comprehensive audiogram and a CNC word score of 5% or poorer.

But what else would be an appropriate assessment tool? Because it's not enough to show to me a patient that they're struggling understanding words in a deafened ear or in a severe to profoundly deafened ear. The patient is reporting to you that they're struggling in noise. So we like to administer some type of real world test to measure the difficulty this patient is encountering. And we administer, in our clinic, AZ bios with a zero decibels signal to noise ratio.

And there are at least three conditions that you could administer this test in. An AZ bio test that I'm about to describe would be a fixed signal to noise ratio test. It is not adaptive. It is a fixed test. So the speech and the noise are presented at the same decibel level, and there are basically three conditions you could present this test in.

If the patient has a profoundly deaf ear and they are not aided, perhaps they've tried a cross aid. And I will talk about this a little bit later in the presentation. But many insurance companies require a hearing aid trial. While it's not part of FDA indications, some insurance companies will deny a patient from getting an implant until they have participated in a one month hearing aid trial. And that would also include a.

A cross aid. I'm just going to respond to a quick question, because this is a timely question about discussing the difference between an implant and a bone conduction implant. And I'm going to just go ahead and answer this question live. I see it came up in the Q and A. We kind of lump implants into one category in our clinic, but most people, when they think of an implant and they come to our clinic, are really asking about a cochlear implant.

So for someone who was congenitally deafened, for example, and they're seeing me as an adult because they've passed a critical stage of brain development, and we're concerned about neuroplasticity, and we don't anticipate that they would be able to get significant benefits from a cochlear implant. We might recommend for that patient a bone conduction implant. That is what we call a signal routing technology. That means the patient would receive an implant on their poor ear that would essentially vibrate the bone and send the signal to their better ear so they wouldn't, in fact, be hearing from their deafened ear. The signal would be routed to their better ear.

When we think back to the difficulties patients have, localization, in other words, spatial awareness, we think about the head shadow. We think about performance and noise. We think about tinnitus. A bone conduction implant is going to eliminate a head shadow problem. So if I was congenitally deafened and my audiologist said, you shouldn't get a cochlear implant, we would recommend a bone conduction implant.

They would have a processor on their deafened ear, and when someone was sitting in the passenger side of their vehicle, they would be able to hear them, but they would be hearing them essentially through their better ear because they're still only hearing from one ear, they wouldn't be able to tell where sounds are coming from. They wouldn't be able to filter out background noise. That is something that requires binaural hearing. So those patients would not get relief from tinnitus. But that may be the best technology for that person.

So I'm going to hold off on describing that in greater detail. But if you have additional questions during the q and a, we can certainly talk more about the difference between a cochlear implant, which would help you hear from the deafened ear, versus a bone conduction implant, which is a signal routing technology, and it's going to send it to the better ear. Going back to the assessment, we want to test them in a real world

scenario. For some of these patients, they've tried a hearing aid and it didn't work. They've tried to cross aid and it didn't work.

So their everyday listening condition might be just with one normal hearing ear and one dead ear. So we're going to test them. We could test them in three conditions with speech coming from the front speaker. Oh, great. Thank you for your feedback and with about the bone conduction and then with noise coming from the front speaker.

And my experience has been that that is a relatively easy condition for patients with single sided deafness. If you test them with speech in front and noise in front, they do remarkably well. But if you separate out the speech and noise, you will see that people are struggling. And so we most typically make sure if we are short for time, that we test them with speech in front and noise being delivered to their better ear, and we will see that they really fall apart. The MSTB three, which I'll touch on in a few slides, suggests presenting it at zero decibels.

So speech is coming from the front and noise is coming to the better ear at zero decibels.

This would require three speakers in your booth. So we generally have one in front, one in back, but in our booth we have one on the side, and we can turn the patient, depending on whether their right ears, their better ear, or the left ears, their better ear, so that we are delivering noise to the poor ear. That is by far and away the hardest condition. So when you look at which one of these listening conditions does a single sided deaf patient have the greatest difficulty with? It's when speech is in front and noise is either diffuse or presented to their good ear.

And in the real world, as you can imagine, this happens all the time. They're talking to their friend in a restaurant and there's speech all around them, but maybe a noisy table

over closer to their better ear, and it really makes it difficult for them to follow what is being said. And thirdly, you can present speech in front and noise to their poor ear, which you might imagine would not be nearly as challenging as the second condition. So that's a fixed sentence task. And again, this is not required by insurance.

That's why I don't have a red asterisk there. But it is recommended by the MSTB three, and we were incorporating sentence testing for a very long time because it's a very realistic world like experience for these patients. I feel that an adaptive test is also very important. So in an adaptive test there are several of them. We use the BKB syn.

Another one is the quicksyn. And what happens in that scenario is the background noises is getting louder as they're getting the answers correct. So you start with a fairly low signal to noise ratio. I should say you start with the speech well above the noise, with a very favorable signal to noise ratio. And as they get each sentence correct, the background noise gets louder and louder and louder.

You can administer either the BKB syn or a quick sin in the same three conditions I just described. Speech in front, noise to the better ear. That is the most difficult condition, and that's the condition we tend to administer for both AZ BiOs and BKB sins.

Other assessment tools that you might want to look at since most of these patients really struggle with tinnitus, we make sure our patients complete a preoperative tinnitus questionnaire. We also make sure they complete an SSQ twelve survey. And I'll show you just quick examples of each of those. But in talking to other clinics, some clinics look at an auditory fatigue scale, some clinics look at an anxiety scale in terms of pre and post treatment option. A quality of life assessment is recommended as a possible survey or assessment tool.

Pre and post operative lead by the MSTB three. So, you know, you can look at different types of assessment tools. But I would highly recommend considering this as a cochlear implant team so that you know what your protocol will be when working with this population.

This is an example of the mini tinnitus self assessment scale that we administer to all of our patients, whether they're single sided, deaf or not, who report tinnitus. But certainly in the SSD population, it is very, very common for them to report tinnitus. And the SSQ twelve. For any of you that aren't familiar with it, it's really a beautiful assessment tool. That's very short and easy to administer.

It really came from the larger SSQ that consisted of 49 questions, and they basically measured three domains, the speech, spatial and quality domain, and the items were avoided. That attracted a single significant number of not applicable. So on the larger SSQ, there were quite a few questions that really weren't applicable for patients with hearing loss, and there were twelve questions that were found to be really, really important. And so those are the twelve that we administer. So an example of one of the questions might be you're talking with one person and there's a tv on in the same room.

Without turning the tv down, can you follow what the person you're talking to is saying? And in purple you can see what a normal hearing, how a normal hearing adult would respond to that question. And so we would have our single sided deaf patients take this survey preoperatively and then we would administer it postoperatively.

So I keep talking about the MSTB three and I want to just kind of put a plug in for another audiology online class that I want you to look for in the resources tab because I think it's spectacular. The MSTB three, basically it's an amazing tool that you want to refer to for testing bilateral traditional candidates, but certainly single sided deaf

candidates as well. The Institute for Cochlear Implant Training is responsible for the MSTB three. It's a test suite that's updated and streamlined for preoperative determination of candidacy and postoperative assessment of cochlear implant performance in adults. And I'm going to share with you the adult, preoperative and post operative candidacy and post operative assessments for single sided deaf candidates.

It contains important practice guidance for clinicians working with cochlear implant candidates and recipients. It's digitally downloadable, it has report templates. It's a fabulous resource for you. So if you go to the resources tab, you can find a little bit more about the class for the MSTB three.

These are the content experts that were responsible for putting this revised protocol together and the stakeholders that were involved, and we want to thank our stakeholders. So on this screen, what you'll see is the MSTB three SSD adult candidate preoperative flow sheet. And I'm hoping you can all see this on your screens fairly well. So what the MSDB three document is a guidance for your protocols and a prioritization given to CNC words because sentence testing really is testing some additional factors. I won't steal the funder for this class that you would hopefully take on the MSTB three.

But basically there is priority given to a word task. What you'll see here is if someone's coming in with single sided deafness, the MSDB three document is going to guide you to obtain a CNC score in the ear to be implanted in the best dated condition. For some patients, it may not be an eight able ear and that may be a 0%. But if a patient has any measurable hearing and they're in the severe to profound range, we would fit them with a hearing aid, we would mask their contralateral normal hearing ear, and we would obtain their best aided CNC recorded word score for that severe to profoundly hearing impaired ear. What the MSTB three SSD protocol does not define for you is what is your cutoff?

We know what FDA says, that that word score needs to be 5% or poorer. And if you are working with a candidate who has a score higher than 5%, it may be that you would need to work with that insurance company. And again, I'm not talking about Medicare, but you may need to work with that insurance company to try to get it overturned or appealed. You may need to request that it be done off label, but indications are that their score be 5% or poorer. So assuming they meet that candidacy in the best aided condition in that poor ear, we're going to test AZ Blos.

And now you're following along the left side of the screen with one full list. So you know that's a 53 word list, the first three words of practice, and then they're going to have 50 words to repeat back in the ear to be implanted in the best stated conditions. That may be with a hearing aid, that may be with the cross. We're going to use a zero decibels signal to noise ratio. The signal will be 65 decibels and the noise will be 65 decibels and the signal will be in front.

And as I said, the noise will be in the better ear because that's the most difficult condition. And then if you follow along on the bottom, I just love this flow sheet because it helps organize what you're going to do to further evaluate their hearing status. And for pre versus a post operative comparison, you're going to consider testing them in the everyday listening condition with the other conditions that I described previously. Speech in front, noise in front, speech in front, noise to the poor ear. In addition, you're going to administer some of the other assessment tools I described.

You are going to administer a quality of life, the QoL ten, the SSQ, twelve, and or a tinnitus inventory. Hearing inventory. If the person meets your clinic's criteria for an implant and the insurer's indications for coverage, then you're going to continue on with a medical evaluation. If you're working with a patient, like I saw a few weeks ago,

whose word score is poor, it's actually about 36% in the ear to be implanted. And he really wants an implant, but he hadn't tried a hearing aid.

We're going to recommend that. And it's quite surprising to me how much benefit he's noticing from just wearing a hearing aid in that poor ear. So, as a clinic, you may say, that's too much hearing. Their insurance may say, absolutely not. This patient cannot receive an implant, and you may recommend that they be retested in a year or sooner if there's a change in their hearing.

So it's a really nice flow sheet to help organize what your protocol, which tests you would administer and where you would give priority. And then there's a beautiful post operative flow sheet as well. So I won't belabor the point, but we're going to administer recorded CNC words in the best dated condition. So now we. This is with their cochlear implant, and we are going to be administering the words at 60 dba, just as we did preoperatively, while isolating their normal hearing ear.

And in our clinic, that is done by masking the normal hearing ear. And if the scores are poorer than to be expected, we're going to evaluate the programming we've done, and we might want to see this patient back a little more. On average, there are a number of clinical trials that would suggest the average patient performs at around 60% with their cochlear implant on a recorded monosyllabic word test three to six months post activation. So if I'm working with someone who's maybe, and I have a case study like this that's maybe performing poorly, we're going to reevaluate how they're programmed and maybe take a look at how much they're wearing it and other factors that may affect their success with the device. So this is another really nice flow sheet we're going to read, minister.

The AZ bios and the BKB sends the MSTB three is suggesting that we are using AZ bios, zero decibels and R speech in front noise to the better ear. So we're

administering that same test postoperatively, and we are administering some of the same assessment tools. The Cochlear ten, the SSQ twelve tinnitus survey. So it's a really nice flow sheet. And again on the MSDB three, you will see recommendations for when those tests would occur.

MSTB three would recommend three months postoperatively, twelve months. And annually, after some clinics may have a different protocol. It may be, it may be six months out, it may be twelve months yearly. It's going to depend a little bit on your clinic, but this is a really beautiful guideline to help you along the way as you're putting together protocols. Some insurance caveats.

So although, as Donna mentioned, we're seeing insurance coverage for this, it is not unusual to have our billing coordinator in our clinic have me review a policy to see if the policy would include cochlear implantation, not bone conduction implant, but cochlear implantation for someone with single sided deafness. And in reviewing some of those policies, many insurance companies are looking at a PTA score. They are defining severe to profound hearing loss. They are sticking to a 5% word recognition score. They are recommending a hearing aid trial prior to pursuing a cochlear implant.

So we really have to know what the policy is to be able to determine whether the patient can get an implant. And one of the things I've learned kind of the hard way is I don't want to instill hope and say, yes, there are indications for this, yes, you're a great candidate, but it is still possible they could get an insurance denial. So maybe more so than a traditional candidate. It's important to raise awareness to the patient that they might actually get denied and to be prepared that that could happen. So while we're on this topic, someone asked a question about looking at phoneme scores, and to the best of my ability, there are no insurance companies looking at phoneme scores.

They're looking at word scores. And 5% word score is the indication by FDA. Certainly you could make a case that while their word score is a little high, their phoneme score, you know, they're really struggling with it. But to the best of my ability, phoneme scores are usually higher than word scores. So it might actually work to your disadvantage in this case, to look at a phoneme score, it's usually easier to get a little bit of it right, but not the whole word.

And FDA is really looking at a word score at this point. The postoperative test, I'm not going to belabor this slide because I want to get to a few of. I have two case studies, but the post operative testing we are following along with MSTB three. We are doing the recorded CNC words in our clinic. We are isolating the better ear.

There's been discussion about how do we best do that. There are some studies our clinic has participated in where we have opted to mask the better ear preoperatively and post operatively. But there have been some clinics that have felt that direct streaming, once they have an implant, was a better way to test them in the sound booth. Yes. You can't calibrate when you are streaming directly through Bluetooth, through the mini mic.

You can't calibrate the decibel level of the signal that you are presenting to the ear. But if you are presenting it at their most comfortable listening level, it's a really good indication of how well they're hearing the words. Some clinics really prefer to do direct streaming. We are testing them in their everyday conditions. So speech and noise, and one of the things that's been amazing to see for me is how much better they get when noise is to the front and speeches to the front and noises to the better ear post implant.

What a difference it makes. And we are also doing an adaptive test. So we do the same thing with the BKB syn, and then we're readministering these surveys and seeing very significant improvements. Our clinic especially administers the SSQ twelve and the

Tinnitus survey, and that's where we're seeing very, very big, big improvements in performance. So I just want to share two quick case studies with you, and then we can open it up for questions and answers.

So this is a 28 year old female. She was diagnosed with mild hearing loss, actually at age 21. And then she had a sudden hearing loss at age 28, normal hearing in the other ear. She was scanned and the etiology was determined to be an EVA. She tried across before she even saw me and said it was not helpful at all.

She was extremely, extremely grieved because she said, you know, I just can't localize. I want that spatial awareness. I have young kids. It's hard for me to understand with all the noise. And as you can imagine, the cross is not mitigating any of those complaints.

Additionally, she suffered from tinnitus. She's a nurse. She is in noisy environments in her workplace. So you can imagine how difficult it is. This is her audiogram.

So in her right ear, you see normal hearing with 100% word recognition. And you also see she has poor hearing on the left side. Now, this is an audiogram that would indicate this is not entirely a severe to profound hearing loss. So she has a mild threshold at 250, and she is moderate to profound, not severe to profound for a significant number of frequencies. Her word recognition, however, is only 8% under headphones.

When we tested her with recorded c and c words, she did even poor under 5%, but she very well could have been denied. And her insurance company, we report this as it is. And although she. She does not have severe to profound hearing loss, her insurance company pre authorized it and she was able to get approval. So at her CNC mass word score was 8%.

So I apologize. So again, it's above that 5%. When you look at her performance three months post. Oh, I apologize. This is a patient who's in a study.

So she did not get it approved through insurance. She was denied. And the reason for sharing this slide with you is because I want you to see how important it is for this population to receive this intervention. So one of the things that I'm hoping ACI will, Acia will continue to work on is expanding those criteria. 5% is a disgustingly low percentage of words to get correct before you can get an implant.

And if you score above that, you could be denied. So she was not able to get insurance coverage through her. She was not able to get approved through her insurance, and she's a study patient. At three months, her CNC recorded word score is 60%, and at six months, it's 86%.

Yes, you do need to submit letters of medical necessity if you're implanting off label. And we tried that for this patient, but we were not able to get it approved. It stated in their policy what it is. They were adhering to FDA guidelines and we were not able to get it approved, even with a letter of medical necessity asking that it be done off label. Her BKB sin.

So let me explain these scores to you. The higher the number, the poorer the outcome. So, preoperatively, when speech was presented to the front and noise was presented to the better ear, the speech had to be eight and a half decibels louder than the noise in order for her to correctly understand the sentence. At her three month visit and actually her six month visit, they're not statistically different. The speech only had to be four and a half decibels louder than the noise in order for her to hear and understand what was being said.

So a three decibels improvement is considered statistically significant on this test. So if she had gone from 8.5 to five point, we would feel like she had a significant improvement in her listening ability. In this noisy scenario. But in fact, we're seeing even larger improvements than that. Her data logging, at this point, she's one year out, and her data logging, she wears her devices, her device, 15 hours a day.

One of the things, again, addressing what Donna said about the need in this population at her three month visit, when I walked her to the door, this is when I went, oh, my goodness, there's such a need. She was very emotional, very tearful, and she said to me, Allison, I just want to thank you. And she started to cry. And she said, this has been such a game changer for me, because, again, the layperson doesn't understand. Spouses sometimes don't understand.

You can still hear from one ear. Can't you just accept that you've lost hearing on one ear and move on? And I think hearing loss is so terribly misunderstood, we forget about what's been taken away from that individual. There are all of the abilities that I've described earlier on have been taken from her, so to be able to get that back is just huge. This second case, I'm just going to whip through so we have time, but really speaks to the impact of data logging.

If you're not going to use the device, you're not going to perform well. That's what this case will illustrate. This was a 49 year old male with idiopathic sudden hearing loss. And he had the hearing loss seven months before he saw me for the CIA valve he had already tried across with no benefit. He was very frustrated with his localization abilities and his performance in noise.

He works around noisy machinery. He has terrible tinnitus. In this year, also very, very depressed. Clearly meets candidacy, clearly meets FDA guidelines. Normal hearing.

If you call his right ear normal, he has mild high frequency hearing loss, even in his good ear. Profoundly deaf in his poor ear. No word recognition, not an aidable loss. 100% understanding in his good ear. So he was seen preoperatively, and you can see his CNC word score was zero.

At three months he's getting 34% understanding of words. At six months he's getting 32%. And then at twelve months, he gets 60%. So we see a steadily improving understanding of words. What appears to be it's getting better, although there's not much of a difference from three to six months.

You'll see on that on this screen. And in terms of how he performs in noise, when we administer the BKB sims, he needs the speech to be 11.5 decibels louder than the noise when speech is in front, and noises to his better ear. At three months it only needs to be eight and a half decibels better db louder. At six months you don't see a big improvement, but at twelve months you see a huge improvement. Why?

So his data logging. His data logging is. This is not correct. This is not 15 hours a day. I want to break it down for you.

Please excuse this as an error, I just missed it. His data logging is not 15 hours a day. So what we were noticing and we had been talking to him about it every step of the way. At three months he was only wearing his device 4.8 hours a day. And when we would prompt and say, what can we do to help you?

Is it a wearing issue? Is it retention? Is it the way it sounds? Is it. He just said, I forget to wear it because I have a normal hearing ear and I'm in noise.

And it really wasn't until a six month visit when we said we really don't feel like you're going to make great progress because you're just not wearing it as much. And I don't

know what was said exactly to motivate him, but when he came back in his twelve months, he had more than doubled his wearing time. And I really believe that's why we've seen this huge improvement in his CNC word scores and in his performance and noise. So it really speaks to the fact that patients need to be counseled. If you're not going to wear the technology, it really is not going to help you, even if you were wearing it for tinnitus relief.

And I do have one patient like that, she averages 5 hours a day. Her performance isn't going to be great. And lastly, I want to just put a pitch in to consider anatomy based fittings for both medial and cochlear. You can make adjustments when programming to improve sound quality so that the electrode, depending on where it's sitting, is better matched to where the cochlea would produce that particular signal. And that has really improved our patient's sound perception.

So I'm going to open it up because we have three minutes left for Q and A. I'm sorry, I should have given us more time. I know. There was one question to ask if I could briefly highlight the candidacy criteria for single sided deafness. And the candidacy criteria is severe to profound hearing loss with word scores of 5% or poor.

Any other questions? I've been trying to answer the Q's and A's that they as they've come. I've been looking at the Q and A section, but I just want to open it up to any other questions people may have while we're waiting for people to put questions in. Alison, I loved your commentary on 5% or less understanding in the SSD era as being disgustingly low. I'm sorry, it is disgustingly low.

It's really. It's reminiscent of when bilaterals first, when traditional, bilaterally profound deaf adults first came to our clinic in the early nineties and late eighties, and you couldn't even understand anything. 5% is not a functional school. Yeah, it just doesn't

make any sense at all. And I think some of that is just the way the FDA submission was done by the companies.

And hopefully in the future we will definitely try to get that changed because that's not good enough. I had one question about your patient that was not wearing his CI for very much time, and even when you got him up a little bit, he was only up to 8 hours a day. Do you find that sometimes people have difficulty acclimating to a CI if they have single sided deafness because they can get along without it and it's different. I feel like at activation, they acclimate really well because their good ear carries them. They don't complain as much as someone who's a traditional candidate, I feel like they acclimate, but one of the things as a clinic, and I'm sorry I didn't incorporate this into my slides, the therapy is so critical for these patients.

So they need to be streaming, doing audiobooks, basically. They need desperately to be doing rehab on that side. And that is critical to their success. And I think that when they start streaming and we introduce it at activation, that is when they are overwhelmed. And to exactly your point, Donna, they think, well, I don't really need that ear to hear, and they can become a little bit dismayed.

So at activation, we put up some passages that have audio and visual and have them follow when they're Bluetooth directly to their newly implanted ear. And it's amazing. They can understand some of the words, but without the script, they may be having a hard time. And that gets better and better and better with practice, but it can be overwhelming, and they can feel like they don't allow need to have the implant onto here, so it can be something they forget to put on. 8 hours is still low.

He's still one of our lower, one of our poor data logs, but he's made such a big improvement, and it's clearly impacted his performance that we definitely see it as a

win. And when we look at his data logging. He is in noise, significant noise, probably 20% of his day work. So that might have something to do with it too. Sure.

There was a question asked. I'm going to answer it about anatomy based fittings. Is that based off of a surgical note of insertion depth? Largely, yes, angular depth of insertion. Doctor Buchman's done quite a bit of work and has published work on trans tympanic ecogs in the orange and the electrical ecog and how they're using that data at Washu to look at anatomy based fittings.

There are metals, certainly when they look at their. Cochlear is looking at where that electrode is sitting in the cochlea in our clinic. Just making some adjustments to the frequency band of each of the electrodes can really improve the sound quality. And for both medal and cochlear, it's a really easy thing to adjust that can improve sound quality tremendously with advanced bionics. When I've called to ask them, because I have two transfer patients with advanced bionics who are SSD.

And that just tells you that it's possible to get a device from any of the manufacturers, regardless of what their device received approval for in terms of indications for their device. And I'm not able to make changes to the frequency allocation tables to see if I can improve sound quality. I hope that answered the question about what we're looking at to make those changes. But you can do it perceptually as well. Marina asked a question.

Criteria of severe to profound with 5% word scores without hearing aids or with amplification. Really, if it's a 0% and it's a profound ear, it's probably not going to change aided, but whenever they have aidable hearing, we fit a hearing aid and we present the words recorded with a hearing aid. So it really could be presented either way. If it's a dead ear and there's just nothing there, I don't expect that you would be able to get an. You would be able to fit a hearing aid.

Somebody posted. Over my career I've seen several patients who have had very poor word recognition scores. But pure tones might only be in moderate or severe range, similar to these folks. They don't do well with cross recommendations for this population. Again, to Donna's point, hopefully indications will expand because this is a group that's getting left behind.

You can certainly try off label use and try to submit letters of medical necessity to try to help the payer understand how important it is. You could try to make a case for safety, depending on what the patient's doing in their work environment or whether they have kids. But at the end of the day, the payer may not cover it. So one of our patients actually changed insurance and was able to get insurance approval even though they didn't fall quite in a severe to profound range.

I just see the questions. If you want to add one other parting comment to our audience, please go ahead. I think the only parting comment I would make is that it is a population in great need that we need to hear their voice, we need to understand their difficulty, and we need to make sure that this is being presented as a treatment option. We need to spread awareness to dispensing audiologists that it is a treatment option. I think that there is so much work to be done because it's still by some audiologists kind of, it's not a treatment option that's on their table.

They don't consider it. So we really need to improve the awareness that it's an option and we really need to be a voice for our patients who have single sided deafness.

Thank you so much doctor Beaver, for that very clear and valuable presentation today. And thanks to all of you who joined us. Join us next time for single sided deafness in children. This is Donna Cochlear from American Cochlear Implant alliance. And our thanks also to audiology online for so competently hosting this event.

Thank you.