Optimizing Outcomes in Hearing Technology: Hearing Aids and Implantable Devices, in partnership with American Cochlear Implant Alliance

Recorded March 29, 2023

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- Welcome everyone to "Optimizing Outcomes in Hearing Technology: Hearing Aids and Implantable Devices." This course is being given by Rene Gifford. And I'm Donna Sorkin from the American Cochlear Implant Alliance and we're so delighted that you would be with us today for this last in our series. Next slide please. This is a five part series on adult assessments in hearing healthcare, and we have covered adult assessments in general working across the continuum, the role of audiologists and dispensers working with hearing aid users, the quality of life instruments that can improve and personalize care, adult perceptions of hearing status and options, and then today's course, "Optimizing Outcomes in Hearing Technology." We can go onto the next slide. So you may wonder why there's another organization in hearing health.

American Cochlear Implant Alliance is a unique organization whose membership focuses on cochlear implants and access to care, and our members are from across the care continuum. We are highly collaborative with other organizations, including our friends at AudiologyOnline, and we have a website that's designed for those who are in and out of cochlear implants. We welcome your involvement at any level, and then we've given you here our website and our social contacts and we are quite active in terms of in social media. We can go on to the next slide. So our mission is to advance access to the gift of hearing provided by cochlear implants through research, advocacy, and awareness. And this course today is a combination of all three, but probably focused on research and awareness.

And we consistently address factors contributing to the underutilization of cochlear implants and really working to improve awareness regarding candidacy and outcomes. Next slide, please. So our course today on optimizing outcomes is being given by Dr. Rene Gifford, who holds the Fred Bess Chair in Audiology and is a professor in the Department of Hearing and Speech Sciences at the Vanderbilt University Medical Center. Dr. Gifford is also the director of the Cochlear Implant Research Laboratory, a very unique entity in in cochlear implants. And her research focuses on improving

auditory based outcomes and ensuring that we're using data-driven recommendations for hearing and speech language innovation for our patients of all ages. She is an NIH funded researcher and has been for the past 20 years.

She's published over 130 peer-reviewed articles, book chapters, and also now is is the author of a book that's in its second edition, "Cochlear Implant Patient Assessment: Evaluation of Candidacy, Performance, and Outcomes." She is uniquely qualified to provide this course today and we are most grateful to her for being with us. Thank you so much.

- Thank you, Donna. And thank you all for tuning in. It's just a pleasure to be here with you today. I am going to be focusing, of course, this is the adult session, but I am gonna, I kind of interspersed some pediatric information there as well because I know that sometimes there are individuals who do work across the lifespan. And of course my background has been in primarily in pediatric audiology, although I also do see patients across the lifespan, both in my clinical practice as well as in my laboratory. So thank you again for having me here today and here are my disclosures. And here are our learning outcomes. Okay, so I think we probably are all aware that hearing loss is quite prevalent.

In fact, right now the World Health Organization has estimated that over 1.5 billion individuals around the globe are affected by hearing loss. And apparently, approximately 430 million individuals worldwide are affected by what they call disabling hearing loss. So hearing loss that is requiring some degree of intervention in order for them to have more effective communication. To put this into better perspective, of the 438 million, that's 5% of the world's population. So this is a very highly prevalent chronic condition that, of course, can impact our ability to communicate, which is a fundamental aspect of being a human. And it it connects us with other individuals and other humans. And the thing that's also a little bit scary about this is that the World

Health Organization has also estimated that this incidence of hearing loss is going to essentially double by 2050 for various, you know, reasons: longevity, increased lifespan, use of more kind of personal sound amplifiers.

So using AirPods, headphones all the time. The world is a noisier place. There's more toxins, there's a lot of reasons for this. But what that means for us is that we, as audiologists, really need to be up to date on all of the available hearing technologies that are available for our population. That ranges anywhere from over the counter products all the way through implantables. And of course we are gonna be covering all of those today with of course a little bit more focus on cochlear implants, because, of course, that is my area of expertise. All right, so just to bring you kind of full speed and give you a bit of a historical perspective. Audiometric criteria for cochlear implantation in adults have evolved quite a bit since cochlear implants were first FDA approved in 1984 for single channel devices and 1985 for the multi-channel cochlear implant.

In 1985 basically adults were required to have bilateral profound sensorineural hearing loss and essentially no benefit at all from appropriately fitted hearing aids. And then in 1995, a decade later, they loosened the criteria somewhat to include bilateral severe to profound. And then we've seen some kind of incremental expansion over the decades. And so about another decade later, there's a bit of a trend there, the expansion was once again in to include those who have bilateral moderate sloping to profound sensorineural hearing loss. In 2014, we saw the first introduction of a hybrid or electric and acoustic stimulation indication, which allowed individuals with precipitously sloping hearing losses to pursue cochlear implantation. In 2019, we saw the first FDA labeled indication for cochlear implantation in adults and children five years of older who had single-sided deafness as well as highly asymmetric hearing loss.

And I'm gonna go into a little bit more detail in that in a moment. Now, how does that fare for children? So children, of course, we've seen similar kind of incremental

expansion of these indications, although not quite as expansive as we've seen on the adult side. So on the pediatric side, initially when cochlear implants were approved by the FDA in 1990, we saw that children were required to be 24 months of age with bilateral profound loss. And really, again, similar to the audiometric indications for adults, children really weren't able to show really any benefit whatsoever from appropriately fitted hearing aids. And then eight years later, this was the age was reduced to 18 months of age and older. Two years later it was lowered again to 12 months of age and older.

And then there was an addition of a slightly different age criterion. So for children who were under two years of age, it was bilateral profound. For children who were two years of age and older, there was an expansion to children who had severe to profound bilateral sensorineural hearing loss. And then of course in 2019, there was the SSD indication that included individuals five years of age and older. And then finally, in 2020, we saw a big expansion to go from 12 months down to nine months of age with bilateral profound and again, still bilateral severe to profound for children two years of age and older. So if we want summary here, what you can see is that conventional cochlear implantation actually does include individuals with moderate to profound hearing loss, as shown here.

And I'm gonna have my laser pointer. As shown here on the left, you can see that this is actually a large proportion of individuals we see even in a hearing aid clinic who actually are meeting audiometric indications for cochlear implantation. Here we have the cochlear hybrid for the L24, and then immediately to the right is the MED-EL EAS indications for audiometric thresholds. And you can see again also there is a large proportion of our adult population that we see in our hearing aid clinics that are as probably cochlear implant candidates for an EAS or hybrid system. And then over here on the right, we see the indications that are shared by both cochlear and MED-EL,

indicating that the poor ear needs to be profound and then the better ear is essentially normal limits.

They also have an asymmetric hearing loss indication that's approved with that 2019 indication. And what that allows is you can see thresholds on the better ear up to about a moderate to severe loss, and then in the poor ear, severe to profound. For children, of course, the criteria are a bit more restrictive, both on the audiometric threshold side as well as on the speech perception, which we'll get to in a moment. For children, of course, you can see it's profound bilateral sensorineural hearing loss for under two years of age and bilateral severe to profound for two years and older. And they share the same SSD criterion as adults. Alright, aided speech recognition. Of course we know the audiogram is a nice tool, but it's just one estimate of audition and it doesn't necessarily capture functional communication abilities.

And so we really need to look at aided speech recognition performance with well fit, appropriately fitted hearing aids. And so for adults on advanced bionics with labels less than or up to 50% sentence recognition in the best aided condition. They also, their labeling still does reference postlingual onset of deafness, which we know is not necessarily evidence-based at this point, but we'll get to that in a moment. Cochlear, up to 50% sentence recognition in the ear to be implanted, up to 60% in the best aided condition. MED-EL, up to 40% sentence recognition in the best aided condition. And that is the same indication. Oh, this needs to be changed. This should be up to 60% sentence recognition in the best aided condition.

Let's see if I can change it right here on the spot. There we go. 16% sentence recognition in the best aided condition for Medicare, which was a big expansion that we recently saw last year. For children, lack of auditory progress for the youngest children who of course can't do speech recognition assessments. And how does this guide it? Usually on the basis of parental questionnaires, like the IT-MAIS, MAIS, Early

Speech Perception tasks or more modern questionnaires such as the LittlEARS Auditory Skills checklist, et cetera. For older children, the indications are a little bit more restrictive than they are for adults. So less than 12% open-set words for AB, or up to 30% sentences. Up to 30% sentence or words rather for cochlear, and less than 20% words for MED-EL.

Now moving forward, there we go. Okay, so I did mention a moment ago that some of the labeled indications are still quite restrictive, but there is considerable evidence in the literature that expanding those indications, so individuals with slightly less severe losses than are indicated by the current candidacy criteria, as well as those who have slightly better aided speech recognition scores than are listed in the labeled indications. And thankfully there actually is a mechanism by which we can recommend an FDA approved drug, biologic, or biomedical device, in this case medical device, for individuals who do not necessarily meet all of the labeled indications as specified on the manufacturer's package insert. In fact, the FDA specifically says that good medical practice and the best interest of the patient require that physicians and providers use drugs, biologics, and devices according to their best knowledge and judgment.

So based on what we know in the peer-reviewed literature that shows the evidence, as we can see here in these, this is just a sampling of studies that have demonstrated this, we are able to recommend cochlear implantation and in fact get FDA, I'm sorry, get insurance approval for that surgical intervention for our patients. It's important for us to recognize this because, of course, audiology is a doctoral level profession and we know that our patients rely on our professional clinical judgment and our knowledge of the data that's out there in the peer-reviewed literature. And that's what makes us a clinician provider as compared to a technician who simply does a screening test and it's either pass or fail.

We're required, we are expected to use the knowledge that we have to provide the best recommendations for our patients. All right, what about bone anchored implants? So there are a lot of different names and acronyms that are used for bone anchored implants. I tend to use bone anchored implants or BAI, but there's also bone conduction devices, bone anchored hearing systems, bone anchored hearing devices, and of course the original bone anchored hearing aid, which has been shortened to Baha. All right, so we're not gonna focus a ton on this, but I do want you to be aware of what those indications are. Currently, today, there are at least two different kinds of bone anchored implants. We have passive systems and active systems.

So on the passive side we have percutaneous as well as transcutaneous. So a percutaneous, it just provides direct sound transmission through a implanted device as well as an abutment that has, it's percutaneous, so it's open to the outside environment and allows you to couple that external processor with that implanted system. Now percutaneous systems are highly effective, they can provide tremendous amounts of gain, but there's a high incidence of soft tissue complications, because of course you have a foreign body that's essentially placed on the outside and it's a direct conduit to the inside or the the skull of that individual. So for that reason, we've seen introduction of these transcutaneous systems in recent years. So transcutaneous systems, as shown here, these are also passive devices that use a magnet.

And so you're not penetrating the skin, it is trans across the skin. And so the only issue with transcutaneous is it's more palatable in terms of, you know, cleanliness, hygiene, less breakdown of the skin, however, we do see a little bit of attenuation loss because you have that transcutaneous loss of that information. So typically we expect to see slightly less gain with the transcutaneous passive system as compared to a percutaneous. Now on the other side, there are active systems. And so these, all three of these as shown here are transcutaneous. So again, there's no abutment or

percutaneous pedestal. And so we've got the Osia 2, the Bonebridge, and the Vibrant Soundbridge. What makes this a active system is that there's an implanted actuator.

So this is actually an active mechanical system that allows you to overcome some of that transmission loss due to the crossing that skin barrier. All right, so what are the indications here? So for sensorineural hearing loss indications, there are indications for both percutaneous and transcutaneous passive systems. We're focusing on passive right here. And so what you can say here are the labeled indications for sensorineural indications, specifically for bone conduction in the poor ear. These are SSD as well as air conduction thresholds in the better ear that are normal. Now of course, these SSD indications for these passive systems have been available for over 20 years, prior to the FDA clearance of cochlear implantation for SSD. So as I indicated, this is completely overlapping with the SSD indications for cochlear implantation.

And in a moment I'll show you some data to maybe help you make decisions for your patients who might fit these indications. Now, on the conductive and mixed side, I'm not gonna spend much time here, only to provide this as a reference for you. You can see that both the percutaneous and transcutaneous passive systems do have labeled indications for those who have conductive and mixed losses. And the ranges are shown here on these audiograms. For the active systems, specifically with sensorineural hearing loss indications. So you can see on the left we've got the Osia system, 12 years of age and older. This is approved for individuals with SSD, and on the Vibrant Soundbridge you can see that they have the slightly expanded, so they have indications that are approved for slightly more severe hearing losses.

Keeping in mind, of course, that these both overlap with labeled cochlear implant criteria for SSD, as shown here on the left, and for the EAS and hybrid indications, and even in some cases for the conventional, because you can see that individuals who have moderate sloping to profound hearing loss, their bone conduction thresholds

could be in this range. So we have lot of overlap, a lot of blurred boundaries between these indications and these different interventions. Now with respect to the active systems that for conductive and mixed losses, you can see here are the bone conduction threshold ranges, for the Osia 2 and the Bonebridge, these are 12 years of age and older. And for the Vibrant Soundbridge, this is 18 years of age and older.

All right, moving on to hearing aids. Of course, hearing aids really does constitute the largest incidence of individuals across the lifespan who are using hearing technology. And the reason is that really the indications for hearing aids span the entire range of audiometric configurations from mild hearing losses really up to profound losses as shown by all of these audiograms here. And we've all seen individuals with all of those audiograms who are hearing aid users, though many of whom are likely also cochlear implant candidates, getting our information from a number of guidance documents, clinical practice guidance documents, standards, and so forth. There are a number of those out there that give us guidance in terms of recommendations for amplification for our patients, ranging from infants through adulthood.

And here are just a few examples of those here. Now, with respect to bilateral sensorineural hearing loss, there is this guidance document that was published in 2020, and I do wanna point your attention here. This provides this comprehensive information about how we can help treat our patients, adults, who have bilateral severe to profound sensorineural hearing loss. I will indicate, and I will reiterate several times throughout this presentation, that realistically you are never going to get better outcomes with anything besides a cochlear implant once you have seen severe to profound hearing loss. There is absolutely no evidence in the peer-reviewed literature that hearing aids or any other intervention is gonna provide superior outcomes as compared to cochlear implants.

But, of course, we know not everyone is going to pursue a cochlear implant. There may be insurance restrictions, there may be medical restrictions or reasons, and there are just some people who might not be ready. And so in those cases, there's a lot of guidance in this particular document. Here's another document, but this is on the pediatric side. So this is from Elizabeth Fitzpatrick's and colleagues in Canada, and they provide you with a review of the guidelines and recommendations for fitting amplification in children. All right, so looking at these audiograms again that kind of constitute the broad range of individuals for whom hearing aids are indicated, what you can see is that really, these are the exact same indications for bilateral sensorineural hearing loss, with the exception of those two audiograms on the left.

So individuals of course with mild hearing losses or even mild to moderate, of course are not meeting labeled indications for cochlear implantation. And again, these are not necessarily cochlear implant candidates. Having said that, we all know we've seen individuals, adults, children, who may have, for example, auditory neuropathy or other types of etiologies that can result in a less severe hearing loss, but very, very poor fidelity. So meaning that even if we provide them with the well fit, appropriately fitted hearing aids, they're just not getting that information that they need for high levels of speech understanding and communication. But for the most part, what we can see is that there is a lot of overlap in these indications.

And so how can we verify and then validate the fittings for hearing aids, bone anchored implants and cochlear implants? Well, this is a very important question. It's something that all audiologists are aware of and something that I believe most audiologists are actively doing. But of course there's different ways to verify and validate these fittings across the different interventions. So of course for hearing aids, we all know really are measures, probe microphone measures are absolutely the gold standard, considered to be the standard of care. It's, there's just no negotiation on this. There's evidence, just a, you know, ad nauseam at how important providing these prescriptive fitting

formulas and then verifying the output in the ear canal, how important that is to have an individual achieve their highest outcomes.

Now for cochlear implants, of course we can't put a, we can't put a probe tube in the inner ear. And even if we could, it wouldn't be useful because we're looking at electrical stimulation. So what we have of course is cochlear implant aided thresholds, which is also often referred to as functional gain. Which is absolutely not appropriate for at least for verifying hearing aid fittings. Now some audiologists may want to do those and show those for a counseling tool, but that is not considered, functional gain is not considered best practices for hearing aid fittings. Now for bone anchored implants, same thing. We can't necessarily put a a probe tube or something in, you know, in the skull.

And so what we're looking at, of course, is to fit these appropriately, we need unmasked bone conduction thresholds. We measure aided thresholds in the sound field following the fitting. So again, functional gain. And we can also do earlier measures using a skull simulator. Now this is for percutaneous systems only because, of course, you can couple the external processor to the skull simulator and at least get an estimate of the output that that individual is getting. And then we can kind of tweak that programming somewhat to really to provide maximum audibility for that individual. But of course that's limited to percutaneous systems and often it's not necessarily a direct estimate of what that specific individual is receiving.

Now one thing you'll note is that all of these verification procedures, as shown here, are threshold based measurements, right? So we've got CI-aided, we've got unmasked bone conduction, and the real ear measures even are based on unaided audiometric thresholds and then providing gain and output that exceeds those thresholds. So I'm gonna just reiterate it just quickly as far as cochlear implants and bone anchored implants go, and why we would use functional gain measures and really what we're

aiming for. So of course what's our target with cochlear implants and bone anchored implants? We don't have real ear measures, as shown here. So really what we have, again, functional gain. And so I wanna show you here, this is a simplification of the Aided Speech Intelligibility Index.

So the Speech Intelligibility Index, it was the result of really decades of work that originally started at Bell Labs in the 1940s that was really designed at maximizing transmission of audio signals through electronic sources. So through telephones, through other types of electronics transmission systems, for example, such as in the defense system. And what they were able to do through a series of, you know, speech perception, psychoacoustic, physical output measurements is determine the frequency waiting functions for each of the individual frequencies encompassed within a speech stimulus. And so what Killion and Mueller in 2010 did was they transformed that into something that's a little bit more useful for us in a clinical environment. So what they did is they transformed the Aided Speech Intelligibility Index into a count the dot method.

And so what you can see is that these are all individual dots that represent these individual frequency importance functions for everyday speech. I do wanna point out that you can see that this is, there's a range. 'Cause of course we know the typical dynamic range of speech at any given moment is about 30 dB broad. So you have your average long-term, average speech spectrum, the RMs, and then typically we see plus 12 in terms of the speech peaks and then minus 18 for the speech valleys. So we see this in, you know, this range of 30 dB. Now this is a average speech at 60 dB SPL, which has been documented in a number of studies starting in 1977 with the Pearson's paper, that was a paper funded by the Environmental Protection Agency where they went into number of different listening environments.

So department stores, restaurants, train stations, you know, airports. And they measured noise levels and they measured how individuals spoke in the presence of various types of background noises, as well as asking individuals, can you speak any quiet, at a quiet level? Can you speak in an average conversational level? Can you speak in a loud, you know, speak in a loud or shouted conversational level? And what they found is over really hundreds of individuals, average conversational casual speech was about 60 dB SPL. So that's, this has been transformed to an HL based audiogram. And so what we can see is here are the speech peaks, and then of course the speech valleys would be here up near the top of the audiogram.

Now if we can imagine that we have our cochlear implant patient or a bone anchored implant patient who has aided thresholds in this range. Now this is not too bad, and in many cases this is gonna be way better than what they would have had they not had the amplification through the bone anchored system or through the cochlear implant. However, what's happening is this individual is missing all of that information in that shaded region. So a lot of information which is contained in consonants, affricates, fricatives, which make speech crisp and clear and really provide information that's important for us to glean the meaning of a speech. So of course there is a number, there are a number of papers that have of course looked at this, starting, of course, with Margot Skinner and her colleagues in the 1990s.

And there's just a lot of research that has shown that, particularly for cochlear implant patients, if we can get aided detection thresholds in the range of 20 to 25 dB HL across the speech spectrum, as shown here, we're going to see maximum outcomes in terms of speech understanding at various different levels. Of course, we know not everybody always speaks at an average conversational level. And so in order to maximize that audibility, this is the range that we want to see. This has been documented in the literature. Now some people might say, well why stop there? Why don't we make the thresholds even better? And we have to sort of fight against that because the reason is

that the, if we make the thresholds even better than as shown here, then we're introducing noise that isn't necessarily gonna be useful for speech understanding and can actually mask the target stimuli.

We're also then increasing the likelihood that that individual is going to have audibility of the circuit noise of that particular system. So really, you know, Margot Skinner, Lisa Davidson, colleagues, Jill Fuerst, a number of individuals have shown 20 to 25 dB HL across the board really does give us our maximum outcomes in terms of speech understanding. All right, how do we validate? So you're thinking, okay, verification, sure. So verification is largely based on threshold based measures. So what is the unaided audiogram and how do we fit those prescriptive fitting formula? And then of course, aided thresholds, right? For CIs and bone anchored implants. Validation comes more about how are they then using that information after we fitted these systems?

How are they using that information for functional communication abilities? So this is really important, because this is now looking at super threshold measures. And so what we do there is speech recognition testing in both quiet and noise. And we can look at things such as aided versus unaided for individuals with hearing aids and bone anchored implants. And then, of course, for cochlear implants, we can look at aided post-op, so following cochlear implantation as well as their hearing aided. So with hearing aids preoperatively, so we can kind of gauge that level of benefit. Now there's, we don't stop at just aided speech recognition testing because that's only one portion of that functional communication. We also know that individuals, we want to see how they perceive their ability to communicate and how they might be struggling, how they might perceive their hearing related quality of life and so forth.

And so we want to include, of course, Patient Reported Outcome Measures, often referred as PROMs, to gauge constructs such as satisfaction with the intervention, how is the general overall communication difficulty, quality of life, which is increasingly

important, particularly amongst insurance providers. People wanna know, have we improved that individual's quality of life? Tapping into other things such as, you know, how fatigue, listening related fatigue or how much effort does one have to put forth in order to communicate effectively on a day-to-day basis. And then of course there are some, the patient reported outcome measures, that really do focus on individualized such as goal setting, such as the cozy, where we can ask an individual, you know, what are your goals with this hearing aid fitting?

And then, you know, track and measure their progress following the hearing aid fittings. Okay, let's first focus on speech recognition testing. So there are a number of guidance documents out there that have outlined the recommended test batteries as well as, you know, recommended kind of configurations. So for example, the Minimum Speech Test Battery that the most recent one was in 2011. And this is actually in the process of being revised now, as well. And then the British Society of Audiology also has a guidance document as well. Both of these are for adult listeners. Now the Minimum Speech Test Battery is, it includes things such as monosyllabic word recognition with the CNC word recognition task, AzBio sentences in quiet and noise, as well as the BKB-SIN.

So again, that is a pseudo adoptive speech and noise task. For the British Society of Audiology, they are recommending the QuickSIN, HINT, BKB-SIN and CUNY sentences. Now the MSTB is largely aimed at cochlear implants recipients. However, we can also use these tools in individuals with hearing aids. And then the BSA document as outlined here, is really more focused on hearing aids. There's also the Pediatric Minimum Speech Test Battery or the PMSTB. This was a large group of over 50 professionals across a number of, you know, clinicians, clinician scientists, industry representatives, who all kind of volunteered, got together, and kind of came up with this guidance. It was aimed at all children using all hearing technologies. And so they've recommended various types of measures, including closed set tasks for our

youngest children who might not be able to participate in an open set, you know, speech recognition task, as well as a number of open set types of measures ranging from, you know, multisyllabic words, monosyllabic words, sentences in quiet and then in noise.

And then ultimately transitioning them to adult materials when they are at that developmental stage. Patient reported outcome measures. So this is a really important thing as well. Again, as I said, this is, it's tapping into a different construct or series of constructs than we are gonna get with aided speech recognition measures. Now with respect to the MSTB that was published in 2011, this did not include any subjective questionnaires, but as I indicated, this is under revision and these will be included. So stay tuned. But some very common ones that are utilized, particularly in cochlear implant clinics, are the Cochlear Implant Quality of Life questionnaire. So this was developed by Ted McRackan and Judy Dubno and colleagues at Medical University of South Carolina.

There's two different versions, the CIQOL-10, which is just 10 items, and then the original, the CIQOL-35, which has, it really taps into more domains and more questions per domain. But the CIQOL-10 is a really very good measure. It's quick and it's useful for clinical purposes. The Speech Spatial and Qualities questionnaire or the SSQ, there's the, the standard SSQ, the 35 item questionnaire, as well as the SSQ12, which is condensed to a 12 item questionnaire, again, which is more feasible and usable for clinical purposes. And then to really kind of tap into auditory related fatigue, there are a number of scales. The one we're using at Vanderbilt, of course, is the Vanderbilt Fatigue Scale, which we actually have one for adults and children now.

On the pediatric side there are in the PMSTB, both were listed, the LittlEARS as well as the Auditory Skills Checklist. These are very common parental questionnaires that are used today for children, really of all hearing technology, you know, hearing aids, bone

anchored implants, and cochlear implants. With respect to the American Academy of Audiology, in their pediatric amplification document, they provide recommendations and reference a number of these patient reported outcome measures, most of which are, you know, parental based questionnaires. And so here are just a few of those here. Okay, so what are some of the factors? We've gone over the indications, we've gone over, you know, the validation and the verification of these systems, but what are some of the other factors that might actually influence outcomes?

So of course we know that bilateral fittings are generally considered to be standard of care, and this is across all interventions. So the Audiology Practice Standards Organization or APSO has recently come out with a standard that has basically stated that the fitting of bilateral hearing aids is the recommended protocol if the patient is a candidate for hearing aids in both years, as well as the American Academy of Audiology on both the adult side and the pediatric side. And I think if you've been in this field for, you know, really any period of time, you know that bilateral intervention is superior to unilateral in pretty much every arena provided that they meet candidacy for that intervention in both ears, of course.

And, of course, it's not just for the purposes of fitting bilateral, there is evidence to show, you know, better outcomes, better subjective outcomes, better objective outcomes, better quality of life, et cetera. With respect to cochlear implants, bilateral cochlear implants are actually considered the standard of care intervention for adults and children who have bilateral severe profound sensorineural hearing loss. This was first introduced in 2008 by the British Cochlear Implant Group as well as the William House Cochlear Implant Study Group. So both across the UK and the US in 2008, it was indicated that the literature was clear even then that bilateral cochlear implant were going to yield highly superior outcomes as compared to a single implant. And then the Canadian Society of Otolaryngology followed in 2010.

Okay, bone anchored implants. Interestingly, the labeled indications, if you look at the package insert, they do specify that bilateral bone anchored fitting systems are actually recommended for those individuals who meet criteria. However, it's not necessarily something that is really gained popularity. Now these three papers down here, I do want to point you to these, these are showing you evidence for the fitting of bilateral bone anchored hearing systems. But again, for some reason this just hasn't necessarily caught on in audiology. And a lot of insurance providers are actually, they provide restrictions and say no, you can, you know, they'll approve a single bone anchored implant. So we wanted to look at some research on this project. And so Hilary Davis and I did a relatively small project over the last couple of years.

We recruited 11 adults and children who had conductive and mixed losses. And we wanted to basically look at the impact of a bilateral bone anchored implant as compared to a unilateral bone anchored implant on really very high, highly complex speech understanding tasks as well as spatial hearing tasks such as a localization type of experiment. Now you might be saying, "Okay, why bilateral?" Because you know, we were all sort of taught, at least in our original introduction to audiometry course and hearing science that the inter-aural attenuation for bone conduction is essentially zero. Well, guess what? That's not exactly accurate and in fact it varies from patient to patient. There are things such as head size, density of the skull, a number of factors at play.

And actually we do see substantial inter-aural attenuation, especially in the high frequencies, which of course is very important for speech understanding as well as localization in spatial hearing. So that's one of the reasons we wanted to look at that. So I'm gonna show you just a, some, these are kind of like hot off the presses data. And so what you're looking at here, this is percent correct and this is for AzBio sentences that were presented in diffuse noise. So the sentences were at zero and then the noise was at 45 through 315 degrees in 45 degree increments. And so the unilateral

fitting is in black and the bilateral bone anchored implant fitting was in gold. And you can see that all but this one individual here showed either equivocal or improved performance when adding that second implant.

And it's really interesting too because this was speech at zero, which we know is not always the case. And so, and this was found to be statistically significant. This is a spatial hearing task. So we call this minimal audible angle. So it's very similar to a horizontal plain, so sound localization task. But instead of hearing a single sound and having to indicate where that sound came from, you'll hear two sounds. So, shh, shh, and the individual's task is to determine did the second sound originate to the right or to the left of the first sound? And so in this case, a lower score indicates better resolution or better spatial resolution. And so this was a broadband stimulus.

And so what you can see is there was a high degree of variability, but most individuals with a few exceptions did actually show again, either equivocal or better outcomes in the bilateral condition. I do wanna indicate that the two individuals here, as shown here, who showed, you know, pretty substantial decrement in performance with that second bone anchored implant, they actually only had a single implant and we fitted the second one via a headband or soft band. And so it's not necessarily the ideal, the ideal fitting and assessment, but of course we're limited to the number of individuals out there who had bilateral bone anchored implants and then of course who were willing to participate in this study that actually started the summer of 2020.

So our, we had really bad luck in terms of the timing of this. Okay, so we know bilateral, two ears, are better than one and that's, you know, we were designed to have two ears. There's tremendous bilateral benefits in a number of sensory systems. It's binaural redundancy, it's important. Now another thing that can impact the outcomes of all of these interventions is the severity of the hearing loss. And this is more specifically with hearing aids and bone anchored implants than it is for cochlear

implants. But we know that we start to see diminishing benefits from just conventional amplification as well as with bone anchored vibratory stimulation once thresholds start to get to be about 65-70 dB HL.

Why this range? Well we know that once you get to a hearing loss where thresholds start to exceed 65-70 dB HL, we're starting to see substantially greater inner hair cell involvement. So destruction or dysfunction of the stereocilia. And then in many cases complete loss of inner hair cells. Inner hair cells are primary sensory transducers. So 95% of our afferent auditory fiber synapse with inner hair cells. So if those are not functioning or they're gone entirely, we cannot get that signal faithfully through the cochlea to those primary auditory neurons. Just can't do it. You could get the most expensive, the best hearing aid out there. It's not going to be possible because we see greater prevalence of cochlear dead regions, of course, which is an area where there's essentially complete absence of these inner hair cells.

We see super threshold distortion. So we know that at higher levels, higher presentation levels, we know that the auditory filters broaden. All right, and this is even in normal hearing listeners. And then we know as you go higher and higher and higher, which is required with these more severe hearing losses, we're going to see some super threshold distortion effects. And so this is, again, this is something we know is a phenomenon even in individuals with typical hearing. You present things sufficiently high enough, performance deteriorates. Another issue is that the more severe the hearing loss, the greater the compression ratio that's needed in order to take the very large dynamic range of speech and repackage it into their much reduced dynamic range.

And there's considerable evidence that with higher compression ratios, prior input based compression ratios, that outcomes are not quite as good. So I wanna show you here, this is on the left hand side. This is I recreated a figure by Brian Moore and

colleagues just basically looking at the width and the shape of the auditory filter for even an individual with normal hearing at various different input levels. So you can see that as you go from 20 to 40 to 60 all the way up to 80 dB SPL, those filters continue to broaden, which is going to be letting in more and more information, including masking and background noise into those filters, making it more and more difficult to perceive the target stimulus.

And then over here on the right hand side, this is a figure from Pam Souza and colleagues looking at vowel recognition on the y-axis plotted as a function of frequency selectivity. So basically the width of that auditory filter. And they've plotted this in terms of ERB or equivalent rectangular bandwidth. So you take an auditory filter kind of as shown here and then we essentially transform that into what would be the equivalent bandwidth if we turned it into a rectangle, essentially. So what's this range? And so as you can see here on the right that as the ERB widens, which is broader filter, vowel recognition deteriorates, and that was statistically significant. All right, what else is impacting audibility?

Audibility is critical. I think we all know this. It's basically kind of the basis of verification of hearing aids, cochlear implants, and bone anchored implants. And as you are seeing here, this is a, on the y-axis, this is bilateral QuickSIN SNR loss plotted as a function of the better ear PTA on the left hand side and then the better ear high frequency PTA on the right. And so you can see, of course, is that as hearing loss severity increases, the SNR loss also increases, meaning speech and noise performance is poor, as shown here. So this is a well known phenomenon, and, of course, even though they're looking at unaided Pure-tone average, this is gonna impact the ability of us to provide audibility for that individual with conventional hearing aids.

Other instances of audibility, this is in children. So here on on the left, we've got the Peabody picture vocabulary test. So an estimate, a norm referenced assessment of

vocabulary plotted as the function of the better ear as aided, unaided SII, that is. And you can see that as the unaided SII is larger, so meaning they have greater auditory access, we also see better or higher vocabulary scores. And we see something similar here on the right from this Bruce Tomblin and colleagues, you're looking at a mean language score. So this is a standard score, just like here, meaning everything is normed to a hundred and then plus minus one standard deviation is 15 points. And what you can see is that's plotted as a function of the better ear Pure-tone average.

So we've got less than 45, 45 to 60, and then greater than 60. And you can see that these bars, particularly these black bars are decreasing. So poor language with greater severity of hearing loss. All right, what about frequency lowering technology? Well there is, the evidence in the literature is all over the place on frequency lowering technology. So we can see frequency compression, we can see both proportional frequency compression as well as non-linear frequency compression, in addition to frequency transposition, where we're just taking, you know, higher frequency information and just moving it to a lower frequency region where it's audible. Well there are a number of studies that have shown that it can provide significant benefit, mostly in terms of like for example, recognition of plurals, which of course that S sound and the Z sound in some cases is very high frequency.

Speech and phoneme perception as well as high frequency audibility, which makes sense, cause we're making a larger proportion of the speech spectrum audible. But there for every study that shows benefit, there's at least one study that shows where there's no benefit, and in some cases, actually show a decrement, particularly for speech understanding tasks that really force us to use spectral information, such as vowel recognition. And so things are all over the place. I do recommend if you want a little bit more information here, here are two systematic reviews by McCreery and Akinseye, and then Pam Souza and colleagues had this great, this is part of their conclusion for their study looking at frequency lowering technology and basically the

conclusion is frequency lowering, it can be viewed in terms of, it's sort of a trade off between improving audibility for high frequency stimuli versus increased levels of distortion.

So it's a trade off and it's gonna gonna vary by the individual. It's gonna vary by like how much are we compressing, how much are we transposing? So there's a lot of things at play here. But generally, frequency lowering technology is not going to be sufficient to render an individual, not a cochlear implant candidate. So meaning if they meet cochlear implant candidacy, frequency lowering technology is not gonna change that. And here is a figure by McCreery and colleagues which is just showing the change in word recognition with non-linear frequency compression as compared to conventional processing or CP. So a positive score means they did better with frequency lowering technology as compared to just standard amplification and then plotted as a function in the difference in audibility.

So how much gain in audibility was achieved by using that frequency lowering technology? And what you can see is for the most part, we're not seeing a tremendous increase in the SII that we get with frequency transposition and large degree of variability, with some people showing a decrement, some showing really no improvement, and some showing tremendous improvement. And then a small cluster of individuals here, both adults and children, showing that you know, if we can make greater changes in SII, that they actually can get some benefit there. Alright, data logging, we're getting close to the end here. Data logging. So daily use of your systems. So we know that on the pediatric side there's a significant correlation between what is often referred to as auditory dosage by McCreery and Beth Walker and others who've kind of defined that, basically an equation for determining auditory doses, which is based on how many hours they wear their hearing aid each day, their better ear speech intelligibility index, as well as referencing it to a 24 hour period.

Lisa Parks and colleagues have termed this hearing hour percentage for cochlear implants. But it's basically the same thing. You're looking at their wear time, but in this case, referencing it to the typical awake time for children with typical hearing of the same chronological age. But really what we're looking at here is just showing that children who wear their device longer, you know, for longer periods of time every day, they are showing better outcomes on vocabulary, on the left, language, just general overall language scores, the Tomblin in the middle, and then expressive language on the right. We see the same thing for adults and children using cochlear implants as well. So here is just a figure from Holder and colleagues, which is showing a very strong correlation between speech perception outcomes and daily CI use for both CNC and sentences.

And this is, I made this figure, since it was not an open access figure. So this is not exactly the figure from the Wiseman paper, but looking at basically speech and noise and quiet plotted as a function of the daily CI use for children. So statistically significant correlation. So, and thankfully data logging is available in all systems. We have it available in hearing aids, bone anchored implants, as well as cochlear implants. And that might be one of your quiz questions. Alright, how then, we see overlapping criteria, how are we gonna make these decisions? Well, it's complicated, so I'm gonna just take it single-sided, then we'll go mild hearing loss, moderate, severe, and severe to profound.

Okay, so single-sided deafness. You might be thinking, you know, we're spending a lot of time talking about this, but the reason we are is that it's pretty highly prevalent. In fact, we are seeing, you can see that on the adult side, anywhere from 12 to 27 individuals per 100,000 are going to have this. And really the literature kind of is all over the place, but it's a pretty prevalent condition. And on the pediatric side, one in a thousand essentially are born with unilateral hearing loss. So that's like, that's a large proportion of the patient population that we're going to see. And so what can we do for

SSD? There's lots of things we can do. You know, when I went through school, it was sort of like you do nothing or you provide them with remote microphone, an FM system.

But now we know there's lots of options. I am gonna focus on bone anchored implant and cochlear implant for obvious reasons, and I'm gonna contrast those. Well first of all, cochlear implant patients with SSD or highly asymmetric hearing losses are constituting a large proportion of our patient population. In fact, in this paper we published just last year, we saw that nearly a third of the patients, the adults who were coming into our clinic for a cochlear implant met the SSD or asymmetric hearing loss indications. So this is a large proportion and it's growing. We're seeing more and more of these patients every single week. How do we decide between a bone anchored implant and a cochlear implant?

What comes down to unilateral auditory stimulation versus bilateral auditory stimulation. Even an active transcutaneous bone anchored implant system is going to be transferring that information across the the skull and then stimulating a single cochlea. So even though you're getting information from both sides, you're still working with a single unilateral auditory pathway, which we know can result in poor localization, spatial hearing abilities, significant crossmodal neuroplastic changes in the brain, as well as aural preference syndrome, or this asymmetrically driven neuroplasticity because of the asymmetry in auditory input across the ears. So while it can provide some benefit, subjective benefit, and some benefit for speech understanding, particularly when speech is coming, you know, presented to the poor ear, we're still working with the single ear.

So for the most part, cochlear implants are going to be the superior intervention because it provides you with true bilateral auditory pathway stimulation. Gives that listener access to high frequency ILDs, internal level differences cues, which we know

yields superior localization skills, superior speech recognition and complex noise, significant reports in terms of subjective reports for patients and how they feel that they're communicating, as well as tinnitus suppression. Really cochlear implants are tremendous tinnitus suppressors. And it's been, even though I'm showing just two papers here, this has been documented over and over. So really, at Vanderbilt, we're going to recommend a cochlear implant basically for every individual who comes through the door who has single-sided deafness. Knowing however, that that's not necessarily going to be the option that everyone chooses, but we're going to tell them that information from the literature, it's unilateral versus bilateral stimulation.

And if you wanna know a little bit more about this, I do wanna turn you to these guidance documents from the American Cochlear Implant Alliance that were published last year. So this Dillon article for adults, this Park article for children. And quickly in the Dillon paper, they do provide you some information about how you can assess these individuals in terms of the listening condition and the loudspeaker configuration. So for listening condition, how do we isolate that? You know, the implanted ear, when you have a normal hearing ear. You can go direct audio input, which these days is largely Bluetooth. You can do what they call the plug and muff. And so you're basically putting a ear plug in the ear and then putting a, you know, a sound circumaural muff over, and then you still have the cochlear implant, as shown here.

Or you can provide masking in the non-implanted ear. Now Emily Buss and colleagues showed no difference in terms of outcomes when there was masking versus no masking but in Park et al., for at least a group of children, they did actually show that when you provided contralateral masking, scores actually went down, but there was no difference between scores for direct audio input as well as the plug and muff method. So those are really the two methods that we prefer at Vanderbilt, to either go direct audio input, and if that's not possible for whatever reason, we're gonna use the plug and muff method. And then of course now Dillon and all of those individuals that are

included on that ACIA document do indicate that it is critical that we use a spatial hearing configuration for assessing SSD, because that's the whole reason they got an implant in the first place.

They wanted to improve their spatial hearing abilities. They want it to have bilateral auditory stimulation. So it's not enough to just use a single loud speaker and look at speech and quiet or a noise. We do need to have spatially separated speech and noise conditions. Alright, we're coming to the end. What do we do about bilateral sensorineural hearing loss? How do we make these, you know, data-driven recommendations for our patient population? Okay, mild to moderate sensorineural hearing loss. For adults, really the indicated interventions are prescription based hearing aids or even over-the-counter products for the more milder losses. And so this is a paper by Melanie Ferguson and colleagues where they specify that hearing aids are effective at improving hearing specific health related quality of life, as well as general communication abilities in adults who have mild to moderate hearing loss.

And there's considerable evidence there as well. This is another paper by Sereda and colleagues basically showing the same thing. Individuals who have mild to moderate sensorineural hearing loss are going to gain benefit from amplification. Now on the pediatric side, I know we're, this is not focused on children, but remember that over-the-counter products are not currently, are not indicated for use in children. And that is extremely important for us to re remember. Of course, I suspect we're going to see some children who are using these systems as we go forward. But keeping in mind that our recommendations for our patients, mild to moderate sensorineural hearing loss, should be considered for children who have this degree of hearing loss.

Because we are seeing improvements in academics, speech understanding, generalized auditory fatigue, et cetera. Moderate to severe sensorineural hearing loss. What do we do? Because we know that there are indications essentially across all of

these interventions. So on here on the left, I'm gonna show you just a quick figure from Leigh and colleagues. So in Australia, they are looking at children who had moderate hearing loss here, severe hearing loss here, and profound hearing loss. All of these, this is open set word recognition scores for children using hearing aids. So bilateral hearing aids with these three different severities of hearing loss. Over here on the right, this is a group of 78 children with bilateral severe to profound sensorineural hearing loss who are using cochlear implants.

And what they found is that there was no significant difference between the children wearing bilateral hearing aids who had moderate hearing loss, and the children with severe to profound hearing loss using hearing aid, I'm sorry, using cochlear implants. But both of these groups significantly outperformed the children with more severe hearing losses who were just using hearing aids. So, and this is, that it's quite clear that cochlear implants are going to be the superior, are gonna yield superior outcomes for children and adults, frankly, who have, you know, moderate sloping to profound sensorineural hearing loss. And this is a figure that you've already seen showing the QuickSIN as a function of the better ear PTA and high frequency PTA in a group of 107 adult hearing aid users.

So once you get to a more severe loss, you know, we know that implants are going to be the better option. Severe to profound hearing loss. So on the adult side, there are at least two guidance documents that have been published in just the last few years. So Buchman and colleagues published a consensus statement document, which incorporated 30 different clinician scientists and scientists across 13 different countries and four continents who got together and basically came up with a group of consensus statements based on the peer-reviewed literature. And it was determined that without a doubt, the evidence is clear that adults who have severe to profound sensorineural hearing loss are going to achieve statistically significant better outcomes with a cochlear implant as compared to even appropriately fitted hearing aids.

There's just no question about that. Of course, we know this isn't necessarily gonna be accessible to everyone from a global perspective, but this is the thing we wanted to get, this global consensus document and guidance document out into the literature. And then Laura Turton and colleagues came out with something similar in 2020. And again, the statement was that for severe to profound, the best intervention for achieving the highest outcomes is going to be cochlear implantation. Of course, we also know there are gonna be some people who for many reasons, may not want to pursue that intervention, in which case bilateral hearing aids are going to be the best option. But again, cochlear implants, absolutely. It's the standard of care for adults and children with bilateral sensorineural hearing loss.

This is almost my last slide. And so what we've got here is, this is a figure from Christine Yoshinaga-Itano in 2010 looking at a group of children who had, all had bilateral were using hearing aids and those who are using cochlear implants. And what we're looking at here is this is the TACL. So this is a language score on the y-axis. And then over here on the right is the expressive one word picture vocabulary test. And the the black reference line, so the bolded line represents the age equivalence line. So meaning where we would expect a child with typical hearing to score on that particular task as a function of their age. The dash or the gray line represents the modeled trajectory of their outcomes based on their performance over time.

So what we can see is for the hearing aid children, we're not gonna necessarily see those lines intersect, meaning that those children are gonna demonstrate substantial persistent delays in vocabulary and language over time. Whereas for the cochlear implants, these were much greater, I'm sorry, much more symmetrical, much greater congruence between the slopes of those lines. And in fact, as you can see over here, at least for expressive vocabulary, those lines, they matched. So the children actually did catch up over time. So how do we refer, and I know we have, we're almost done,

we're out of time, but this is just the last, who do we refer for a cochlear implant? So Terry Zwolan and colleagues came out with this great indication in 2020, and basically they're referring it to the 60/60 criterion.

If you have a patient who has an audiometric threshold in or PTA of 60 dB HL or greater, and unaided word recognition of 60% or poorer, refer that patient for a cochlear implant evaluation. Has a very high hit rate, 82% hit rate in terms of looking at all of their patients and a relatively low missed rate. And it's okay if we refer someone who isn't quite a candidate yet, that's okay, at least we have a baseline for them. And then we can track that performance over time. Ultimately, we do expect the likely progress to a period of candidacy, but do not worry about those referrals. We want these referrals, we want to to see these patients, and we wanna partner with you in the care of these patients.

Children, who do we refer? So basically if you have a child who has severe, you know, greater than a moderate hearing loss, we are going to expect that they're gonna achieve better outcomes with a cochlear implant. So again, children who have a Pure-tone average of like 65 dB HL or greater, at least refer them for an eval. They might not meet criteria quite at that point, but again, we can track things closely over time should that child enter into cochlear implant candidacy. So in summary, we know hearing loss, it's the third most common chronic condition that we see in the US, according to the CDC. And the fourth leading cause of global disability by the World Health Organization.

There's so many different technologies available and many of them have overlapping indications, which can be really confusing. Of course we know in order to get our patients their best outcomes, we must follow best practice standards. We have to verify the fittings, ruler measures, functional gain. Functional gain for CI and bone anchored. And we have to validate the fitting, which is just as important as the

verification. Aided speech rec for CI and bone anchored, and in terms, I'm sorry, aided speech recognition as well as patient reported outcome measures for everybody ranging from hearing aids through cochlear implants. And then finally, while I've provided you with some data-driven considerations for recommendation of intervention, we do have to take into account that every patient is an individual who has an individual set of needs and demands and symptoms related to their own hearing loss.

And so even though someone may not look like the typical profile, we really need to have that conversation with an individual and start that conversation. They may not be ready today, but they may be ready in a few months or a few years. And so we're starting that. And so thank you so much for having me. I know that I, I try not to go over it. I didn't go over in my practice, but of course here we are. So I do think we're gonna go over a little bit for Q and A. I'll turn it over to you, Donna.

- Yeah, we have just one question that shown up so far, but people, you can go ahead and put in a question or two for Dr. Gifford and thank you for that extraordinary journey, data driven across 10 and sometimes 20 years of research on a range of hearing technologies. And I personally love the part at the end where you got right to it and helped us to see which technology is right for which category of patient. So your usual amazing talk, Rene, thank you so much. Thank you everyone for joining us.