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The Future of Clinical Care (Part 1):
An Evidence Based Approach
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- [Mary Beth] Hello everyone. Thank you for joining us today, whether you're live or recorded, listening to the recording later, we really appreciate you being here, and taking the time to attend. The Future of Clinical Care is a three part virtual workshop, and this is the first one today. So we're excited to get this started with Barb Buck. The purpose of this three part workshop is to address the common challenges in cochlear implant care that clinicians have been reporting for a while, and we wanted to pull that conversation together to identify the root cause of some of these primary challenges and present different ways that clinicians have found solutions and explore what we at Cochlear can do to partner and support with these efforts. We like this to be interactive, but that can be challenging with such a large audience, so please do enter questions or comments into the chat and we'll do our best to integrate those throughout the presentation today, and we do have some poll questions throughout to kind of make that a little bit more interactive as well. I am very delighted to introduce Barb Buck, the Clinical Project Manager at Cochlear who has been leading discussions around the country about evidence based practice and the impact on clinical care. So Barb, thank you very much.

- [Barb] Well thank you everyone for joining us here today. Yes, I am a Clinical Project Manager with Cochlear. I've been with Cochlear for 19 years now, and I'm based in Pittsburgh, Pennsylvania. So that's where I'm coming to you from today. You know, there's been dramatic changes to cochlear implants and the way we deliver care over the past 30 years. Including, you know, the technology itself. When we look at the electrodes or the sound processors, but also changes to indications and outcome. As well as the inclusions of tools, and services, and products to assist clinicians in providing care throughout the patient's hearing journey. And what I'd like to do today is just take a look at how clinical care has changed over time, and how we can use data, and what we've learned over the years to help this evolution into the future. Now, I have to first, make sure that we read out the learning outcomes for this course. So after

this course, learners will be able to identify barriers to treatment for hearing loss. After this course, learners will be able to explain evidence based practice as applied to cochlear implant care, and after this course, learners will be able to describe the difference between expected versus observed compliance to follow up appointments. Now, let's just take a look then at clinical care over time. When I started in the industry in 1990, I was in a academic center. We had a very few number of patients. Surgery took a long time. Usually about anywhere from four to five hours. Typically the patients stayed often, not just overnight, but maybe for a couple days. We were implanting people with profound hearing loss. The activation typically took two days. We were measuring every single electrode. We were using DOS software. The patients had a body worn processor. We didn't really talk about telephone use at that point in time, or accessories, or anything like that because, again, we were just trying to get awareness of sound, environmental sounds, looking at pattern perception, and things of that nature.

Fast forward to 2006. I had then now been working with Cochlear. I had left the clinic and went to work for Cochlear. We were starting to implant more people. Candidacy had expanded so now we're implanting severely, as well as profoundly hearing impaired people. The surgical technique changed. Now we're down to about two hours of surgery time. Typically we were still doing two day activations, but usually it was maybe two or three hours per, that time that we spent with the patient. We were using a programming pod. We had a behind the ear processor. We're now using more of a streamlined approach to programming, as well as NRT, and then that was also when we introduced smart sound, right? So, the processing, the signal processing, and at that point, the first thing was whisper. Here we are now in 2020, and we have expanded indications. Now we're implanting people with much more residual hearing. We've just gotten expanded indication down to nine months for children. We're using technology like Bluetooth, smart apps, remote check, remote programming. Now we have an off the ear processor, and also as a result of all the technology we use in our

daily lives. We have things like Hear Always, We can download maps right from the cloud, Cochlear Link, ready to wear. There are so many things when you think about how technology has changed, and I sit back and I look at this, and it's amazing, right? All the changes that have been made over the years, and the ability to provide this type of new and innovative care is really because of the technology, right? The technology has evolved. We have the internet as I mentioned, the wireless connectivity, mobile phones, the cloud. So now we also have access to a lot of data through technology that we didn't have before, to help us create these tools and services and innovative products, and really to try and base it on evidence, right? Data in combination with what we've learned over the years to really help drive some of the challenges that you all are facing in the clinics. Things like trying to help improve clinic efficiency. Trying to reduce that clinic burden, in terms of non-billable time. While at the same time, working to improve patient outcome and hearing satisfaction over the lifetime of that patient's hearing journey.

But, truly when we look at access to data, and what we can learn from that, it can really help us understand where we still may have gaps, where we're meeting the mark in terms of the way we deliver care, and maybe where we still need to work to improve, right? Particularly that patient hearing experience and outcomes, and again, of course as well as to try and provide you with tools and resources to help you deliver care in different ways throughout that patient's hearing journey, and it is really right, because for all of us, it's all about that patient hearing experience and that outcome. It's really at the center of all that we do. Now we know that there's a growing need for hearing healthcare. We see the World Health Organization has identified hearing loss as a top priority. We know that as the incidents of hearing loss increases, and we learn more about how it can impact a person's quality of life, it becomes even more critical to try and educate other hearing health professionals on the benefits of this type of technology, and help more than the 5% of the people who actually get an implant. There's so many more people that can actually benefit from this technology. Now, we

talk about again, access and awareness and helping more people, but with an ever changing healthcare landscape, you know, treating hearing health has become more complex, right, it's become at times, burdensome, and can require significant support and professional expertise. So it's almost you know, a double edged sword in a way. We have all these wonderful pieces of technology, but again, that also adds that layer of complexity, and on top of this, many professionals are being asked to see this growing number of patients in less time, while still trying to maintain the same clinical headcount without adding headcount, and now on top of this, we have a pandemic. That creates another layer of complexity. Particularly when treating what is a large portion of our cochlear implant population, right? They're over the age of 65. Many of these individuals have compromised, they're compromised medically. So again, now we have another layer, and so this creates undue burden on the healthcare facilities today.

Now, even before this, even pre-COVID, we had some challenges. So, as we've been, as I've been working on this project over the past couple of years, we've really tried to collect data. Whether it be through surveys or observations. A lot of different ways that we've done this, and one of the things we did is had Fuel Medical go out and do some observations in nine different clinics. Now these were university, private practice, hospital, a variety of clinics, and what they found, it was estimated about 30 to 50% of the time, was non-billable for audiologists, and again, this is focusing on cochlear implants, and at that time, there was an average of about four to six cochlear implant appointments a day, and again, these sites were focusing on cochlear implants. There was limited collection of outcome data, and part of that had to do with just limited access to the booth, right? We want to collect data of course. We want to collect that outcome data, but unfortunately, it was inconsistent, whether the patient didn't feel like going in, or again, most of the time, it was about booth access, and that created a problem. Now we have schedules now with COVID. So that schedule has probably totally been redefined for some people, and now clinicians are being asked to kind of

prioritize care. So, what are those key items that we really need to consider whenever we're evaluating or collecting or trying to help this patient through their patient journey? And this can be really a challenging question and challenging to answer because we see a lot of inconsistency in the way we deliver that care. In terms of the protocols, the tasks, maybe when we see the patients, how we program the patients. There's a lot of inconsistency, and part of that, of course is just we all learn in a different way. We kind of put perhaps our clinical experience and how we were taught and influenced by our mentors. Now, Camille Dunn out of the University of Iowa did a survey looking at just clinical practice. Now she was specifically looking at best practice for CI patients with residual hearing, and, Camille had presented this at ACIA back in 2018, and what you can see is there's a lot of variability, even when we just look at candidacy, right, the tests that we use. Is it CNC, is it sentence, is it a noise, is it plus five, is it plus 10, do we use patient reported outcomes? And again, we have guidelines that we follow, we have our indications, we may be doing a test to help counsel a patient, but there's a lot of variability is the point, and, we also, even if we looked at other aspects. Whether it be programming. Whether it be bimodal versus bilateral. We see those differences.

So with all these insights, all the things that I've just already talked about, the growing complexity, the challenges that we're facing within the healthcare, within what we'll call the new normal, it really does shed light on there being a greater need to have a consistent delivery model in place, but also, to have a way that we can continuously improve. That we can evolve and expand based on the need of the clinic, but also based on the need of the patient. When you look in other places in the medical community, when they've looked to try and implement guidelines or a standard way of practice, they typically see that it can help with the efficiency of the professional, and what it can do then is actually free up that clinician time so that they can spend again, the time on the patients that probably may need more of their assistance. Those complex patients. Maybe patients that are more difficult that need that expertise, and I

think most people when we ask whether it be here in the U.S. or across the globe, when we've asked this in focus groups and surveys, most estimate that complex group to be about 20 or 30%. So our mission statement really drives us to solve these issues, some of these challenges, and things that I've just talked about, and we really do take this to heart, and particularly with our current challenges, within the hearing health community, we've really dedicated a significant amount of resources to innovating, and transforming, and empowering, and that's really what I'm here to talk about today. How can we power, how can we partner, to move forward to try and address some of these challenges together? And again, part of this then is really trying to continue to partner with professionals to develop, and maybe refine the guidelines that we have, and the goal of this is really to help with clinic efficiency, to reduce that clinic burden. Particularly with that non-billable time, and then continue to work to improve patient hearing outcomes and satisfaction, and I would argue that that satisfaction isn't just hearing satisfaction, it is also service satisfaction.

So, that these patients still feel like look, I'm getting the best care possible. So no matter what tool or service, or guideline we come out with, we should be thinking about how does it impact these first three things? That's what we need to be able to answer, and then the other thing is, do we have the data to show that in fact it does at least improve, or if it's not going to compromise outcome, it's at least consistent, does it improve in these other areas? So, we have guidelines. We do most certainly, there are guidelines that exist. The most recent was from AAA back in the fall actually, and it's interesting though when we ask clinicians, and again, this has been through a couple different ways, through surveys, through focus group, ethnographic study, a lot of different ways, but we used an outside agency, Frost and Sullivan, and when we asked this question in 2017, 2018, clinicians said you know I know there are protocols, I know there are guidelines out there, but I might not agree with what those are, and also I have a certain approach based on how I've learned from my mentor and the years of my experience, and what we're saying is, is there a way that we could just

look at what are those key minimum milestones that all of us can agree that there are certain things that we do need to do? That we do need to address. That we do perhaps need to collect data to help us know whether this patient is on the right trajectory. Can we agree upon some of those things and what those may be and work together then to use the data, use our clinical experience, use some of the guidelines we already have to address these clinical challenges. Again, without sacrificing or even, actually, potentially, improving outcomes, to have more consistent outcomes, and again, to have that patient satisfaction, that service satisfaction across all of the various clinics that serve these patients, and that's really what we're hoping for, right. So, healthcare professionals across a variety of modalities really have addressed trying to get consistency in challenges. They've addressed this by applying an evidence based approach to practice, and that's really no different in what we've done with it in the audiology community.

By sharing a combination of our clinical experience, by using data, and looking at patient values and expectations to help guide- to kinda guide that clinical decision making, and potentially even reshape certain aspects of the adult cochlear implant, that delivery model. What we see though is perhaps sometimes it's not as easy to have access to that data or to have those patient, to make it easier for you to have this information that you potentially can use. So that's where we have taken the evidence based practice and expand this idea to obtain more data around analysis, around the model, so it's not just about programming tools, but also other aspects of the delivery model. Like, as an example, having a treatment plan. What does the patient want out of this device? What are their goals? And then, how can we kind of use other tools and services to help them make sure that they actually meet those goals? Looking at just performance. We know we have enough data to know where people should be in terms of that trajectory. Are they on the right path in terms of the three month or six month, or even after that? How much do TNC levels change? We have that data as well. So these are some of the things that we could look at to have more of a

structured delivery of information, and then based on the patient type, we can determine what other tools or resources might be most appropriate for them. Whether it be, you know, look, you're gonna need to come in to the clinic, or, it could be there's some things they could do from a self care standpoint. There are things potentially that could be done remotely, but again, understanding what pieces might be most appropriate for which patient segment and we're along their hearing journey. So, one of the key pieces is about data, and that's really gonna help us understand what should be modified, what potentially shouldn't change, cause we do a lot of good things. We've learned a lot of stuff over the past 30 years. And then, where's the gap? Where do we need to collect more data or where do we need to have more analysis? And to take a quote from Steve Jobs, "Deciding what not to do is as important "as deciding what to do." And we've been faced with that most recently with our current situation and the pandemic, right, trying to make decisions and triaging and prioritizing, but now we have this data. Again, through lots of different means through technology, whether it be through Cochlear Link, whether it be through some of the databases we have, it's not just study data, it's also real world data that's collected out there in the clinic. It could be actual publications.

There's a lot of different places that we can pull from, and again, always kinda looking back at what we've learned over the past 30 years, again, with the drive to help clinic efficiency, reduce that clinic burden, and again, try and work to potentially improve patient outcome and that's hearing satisfaction over the lifetime of that patient journey. Now it starts with data, and as I mentioned, a lot of different places, and I'm gonna talk about some of those here in the next few minutes. Just give you examples of where we've collected some of this data, and then getting insights, in terms of how it can affect or improve the products, the tools, and the services that we're creating. And then again, where might we use these? Where would they be most effective? Who will they be most effective for? And then validating that that model in fact supports some of those key items that we talked about in terms of never sacrificing patient outcome

while still trying to support clinic efficiency, and the big important part here is this continuous improvement. We need to always be updating and looking at the data to see how things are changing, particularly when we see such a changing world, and a changing medical landscape. That becomes even more important. We think of course not only about the clinical challenge, but again, also, we need to think obviously, and we all do of course, about the patient needs. You know, and particularly now, in the new normal. And again as I mentioned, many of these cochlear implant patients fall into that high risk category, so, that's even more magnified now in the middle of a pandemic. But then, also even post pandemic, what will that look like? Is it that perhaps, again, the way we're delivering care is changing? And again, if we're gonna make changes, let's make sure we're making them for the right reasons, and we're doing it and supporting it with data. So let's take a look at this. Let's just look at some of the things that we've done over the years, and maybe why we do them. So, let's as an example look at our visit schedule.

So we had a workshop back in March before this all hit, with 16 audiologists, and these audiologists were from academic, hospital, private practice ENT, as well as private practice audiologist, so the Cochlear Provider Network. We kinda had a nice span, and we just asked what's your typical visit schedule for an adult cochlear implant patient? And what you can see is it really hasn't changed too much, I mean some people still do a two day activation, but most are pretty much doing initial activation, a one to two week, and one, a three, a six, and a 12 month, and, I asked the question, why do we do it this way, and where did it come from? So I would like to ask the audience here the same question. So, within the chat, if you could just put where did this come from or why do we do it this way? Don't be shy. Any thoughts? I have no idea, good question, yeah. Maybe based on hearing adjustments. That's how you were taught. It's how it's always been done. Yep. And that's really, previous way- Great, yeah. That's exactly, all of these things, is exactly what was said by the audiologists in that room, right, and the question is do patients comply with this? Like, we have a visit schedule.

We tell them to come back. Do they do it? And then, is this what we need now? In terms of programming, now obviously people need to come back for lots of different reasons, but let's just talk about from a programming standpoint. Given all the changes, and again, with who we're implanting, performance, technology, is this what we should still have? This actually came from, it's study protocol. This is the protocol if you look at all of these, this is what was used when we started back in 1990, and then it was adjusted slightly of course, based on what we're doing now. And the question is, well does it need to change again, and if it is, what are we gonna base that on? So, we have another project, it's called the retrospective study, and this was start about two years ago. There are 14 sites that are involved in this, and we all said, look, it'd be great to have a shared database, right? So, Dr. Jed Grisel, who started with the Hermes database, helped up with this project, and so, we entered, the various sites entered data, it's de-identified, right now we have close to 9,000 individual patient records, but when we first started this, the study manager, when we were, what, 2000 patients into it, looked at it and said, you know, we're looking at speech perception data. We're missing data points.

And the question is, well why? Everyone was following the same schedule, that same schedule I showed you. Typically, one, three, six, nine, 12 months. Well why are we missing data? And so, he looked at, this is what we would expect to see in terms of at least just one speech perception score. Whether it be CNC, AzBio, whatever it was, right, one speech perception score, given where they are in their journey, right, and this blue line is was what was observed. So you can see it drops off pretty significantly. Now look, there could be a lot of different reasons for that, right? It could be patient's tired, I didn't have booth access, there's lots of lots of reasons for it, but it really I think took everybody by surprise, and a couple of the sites, two of them actually, said let's look a little closer. Are patients even complying with coming back to the clinic? Forget about speech perception. Are they coming back for any reason? So two sites, a private ENT and an academic university, took it a step further, and they actually looked at their

EMR system. So did they come back for any reason audiologically? Like troubleshooting, programming, counseling, in those time based one, three, the schedule. So, what you can see is that the compliance is actually really good the first year. 70% and that's awesome, but what you see is, it kind of falls off after that two year mark, where you have about 60% of the people that aren't coming back. Now again, could be a lot of reasons, right? Could be last followup. I'm doing really well, I don't need to. I transferred to another site. I'm doing really poorly, I don't want to see you. There could be lots of reasons for this. Now, there's another, there are two other sites that are actually going to look at this and try and answer the question of why. To actually go in and pull data to see why aren't people coming back? And one of the questions could be then do we want to push people to have that schedule? Do we really want to get our administrative staff on the phone, calling these people, going hey, you need to come back?

Cause that makes a difference. That's gonna make a difference in your outcome. That's gonna make a difference in your hearing journey. Or is it that it doesn't? Or is that perhaps it's based really on performance and they're not coming back because they feel like they're doing okay? So, the question is should our schedule, and when we see patients, be based on a certain point in time? Or should it be based on the performance of the patient, and where they are in their need at whatever point in time? So, we looked at some data. Again, retrospective database, this is fast forward a year. So, we looked at CNC performance over time. Now this is 805 people. Now look, different etiologies, different duration, I mean this is just real world clinical data where 14 different sites are putting in data. So I think it might actually give us a little bit better indication. Now I should say within that is some of our study data as well. Actually all of our study data. So, when we look at this, I mean, it's pretty interesting when you look at, let's just look at the median. Which is the line. So hopefully you can see that. So huge jump at one month. They're about 40% against CNC. Another big jump, a good 10% when we get to that three month. About seven or 8% then when we get to that six

month, But then it kinda levels off. There's not much change. It's minimal actually. At 12 months it's 58, and at 24 months, it's 59%. So by six months, typically that's where that patient's gonna be performing. So for those patients who are satisfied, and they're following that typical path or trajectory. Again, they're satisfied, they're performing as we would expect, maybe they don't need to come back as often. Every six months, or that yearly check. Maybe there's a way that we can monitor their performance in a different way, and that's where a tool like remote check, that can be used through the Bluetooth technology, that might be a good option for a person like that. Cause they're not coming back to the clinic now, but there's a way that we can still touch base with them. We can still monitor and make sure that they're on that right trajectory. So something to think about. When we look at the data, it just really causes us I think to pause for a second and to ask some of these questions that maybe we haven't asked in a really long time.

We just do what we do because that's the way we learned and that's the way it's been done for quite some time, and yes, we've made lots and lots of advances, but maybe it's time to just take a pause and just ask some questions. Like, what are those key milestone visits? And what should we be assessing? What's the minimum? We may not have time to do everything, but if there's one or two things that it's really critical that we do so that we know this patient's on the right pathway, what would those be? And then, what information are we using to answer those questions? So, as we kinda go through this, and I take you through how we've approached this, and again, this wasn't just in a vacuum. There's been a lot of professionals involved along the way. Just think about this. Just take a minute and think about what might those be. So, when we think about the patient journey, when we think about the patient journey, it's not just the patient. It's also the clinicians helping them. They're helping them through this journey, and we would probably say there's some key milestones along those first few months. That they're going to have audibility in that first month. They're gonna accept their device. They're gonna wear it. Eventually then, one to three probably we're

looking at a mapped optimization. We can see just based on the data where TNC levels, minimal changes, we can see where performance, we can look at pre-post changes, we have some of that information, and then we get into, now they're out in the world. Maybe they're having more difficulty in the real world sitting at dinner or they want to be able to hear their grandchild on the phone. What are some of the tools that they could be using to help that experience? And then trying to do anything to maximize that performance in the real world, and then continuing to support them through things like upgrades, and through other tools or technology that becomes available. So we have a group of people that are along this pathway that follow that, and it's typically that timeframe that I talked about, but we also know that there's another group that potentially could vary, and they might need something a little bit different.

So, when we think about you all as clinicians and what you do to support the patient through these various milestones along the journey, what assessments do you need to do? How often do you need to do that to make sure they're on that right path? That they're meeting those milestones. And again, when we look through the data, and we engage clinical experts, not just here in the U.S., but even again I go back to that focus group that was done by that outside agency, Frost and Sullivan, back in 2017 and '18, and we asked the question how many patients do you think are on your typical pathway and how many are veering off over here that need something different? And the majority of clinicians would say, and I would like to see what you say as a group, so what percentage of your patients do you think are more complex and need something different? What percentage of your adult patients? Just quickly in the chat. Just put that in there. Is it 10, is it 20, is it 50? What percentage of your patients are more complex that require a different level of support? Okay, great. Thank you. So, whether we're asking this question in the United States or whether it asking it in Brazil, or somewhere else in the world, it's typically between 20 and 30%. That we just know that these are patients that need something different. and when I'm asking you to think

about today, is just the bigger group. The 80%. And for the 80%, is the patient on the right pathway? When and what do we assess? And then, what might be that minimum assessment that we would propose? And then if they're not there, that's when they go off into the other 20% bucket and we do something very, very different. So, now, as I mention this, you say that it's about 20, anywhere from 20 to 30%, that you have this more complex. Think about how that impacts your clinic then. In terms of, with all these challenges, this means that you're seeing people that really need your expertise. This 20 to 30% that are very complex, that need to be seen in the clinic, and then you have this other group of patients that you want to make sure are marching along on the expected course, right, and this is where some of those tools and services, and products, and maybe other things that can be used, not necessarily in the clinic, but perhaps can be done through self care or for remote care might be very helpful for this other group.

The group that you want to make sure, I just want to make that they're still continuing on this right path. Things like remote check, ready to wear, video support through the Recipient Solutions. There's a number of 'em, right? But again, we know that there's this other group, but again, that's where the data can help us decide what tools and services and products can be used with this particular patient segment, and what might need to be addressed in other ways. Now I thought I saw, I'm gonna take a minute because I thought I saw a hand go up. So I don't Mary Beth if you can help me with that? Did I just imagine that or did a hand go up?

- [Mary Beth] Did you want to undo, I'm not sure if you can unmute on this system or if you want to type in a question or a comment?

- [Barb] Sorry, an error. Okay, no problem Regina. So let's just- We've talked a little bit about the patient schedule, we've talked about the challenges, and kind of the two groups, and we've agreed now that we're gonna really try and focus here on the 80%.

So, let's look at one of the key measurements and assessments that clinicians complete and that's Ts and Cs, right, and that's pretty much done throughout the hearing journey. But, how much do these really change over time? And then, how often do they need to be measured? So what's the current data telling us? We measure Ts and Cs, every electrode, all the time, and again, there is a lot more change potentially when we were doing this back in 1990, or even in 2006, but with the current electrodes, and again, the patient population that we're seeing, how has this changed? So I'm gonna go to the literature now and look. There was an article and I'd encourage you to take a look at this. Looking at changes in Ts and Cs over time and per year, and looked at it over an eight to 10 year period. Pretty good sample size, 128. Now these are adult patients. What's interesting is the median change was less than 3%, and 75% showed less than 6% change. So for a MAP with an average dynamic range of 33 current levels, this would translate to less than two current level change per year. Now, there was a group though, there was a group, a percentage of patients showed a significant trend in their Ts and Cs, and for this group, it was they showed approximately equal proportions of increasing versus decreasing trends in those Ts and Cs, and again, that's that 20%, but when we talk about the larger group, seems like it's minimal change.

Now, that was three years ago, that they put this article out. So we said, you know, we'd really like to look at our data, the 532 study. So this is, we had 60 subjects, and we looked at their CDX files. Now we were just looking at overall change in Ts and Cs. We know that there can be more change in a certain part of the array than others. We know that. But this is more in general how do Ts and Cs change over time? And what we were most interested in looking at is this one to two weeks, right, so is there that there's a lot of change during that first week or two, or does it maybe kind of level off? So, when you look at this, the dynamic range is in red, the T level is in blue, and the C level is in green. Now, what surprised me is the standard deviation and how tight these were, but when you look at this, at initial activation, again, this is an average, for these

60, there's not a lot of change in T level. There is more change in C level. So, we always change Ts and Cs and does a two or three current level make a change in their performance? It's not to say it would not make a change in their sound quality, but, potentially, would it make a change in their performance? The other thing that I think is interesting, we had instances with this situation with COVID, where people were activated, but then they couldn't come back to the clinic. So, when you think about that, we are in a position with looking at the data to know how much on average Ts and Cs changed. So potentially we could say, look, we know T levels are gonna change let's say about 15 units and we know that C levels are gonna change on average 15 to 20. We could do that through progressive MAPs within the processor so that while they're not able to come into the clinic, they could progress through and actually acclimate to the sound, right, and then if we have people that are further along, and their Ts and Cs are more stable, but there are sound quality issues, now we have master volume, bass, and treble, that they can make those slight changes and that will help them with sound quality. Again, it just shows what's the need of the patient? Not everyone of course I think would be comfortable going into their smart app and making a change with master volume, bass, and treble, but there are a set of patients that could or should. And so this is again, looking at the data, and understanding particularly with where we are and what we'll call the new normal, not knowing perhaps what we'll face over the coming months, there are things that we can do, again, using the data to help us manage patients, and this is just one example. Now, we've looked at Ts and Cs. We've looked at the schedule. Let's talk a little bit about performance, but I'd love to get some insight from all of you before we go there. So I believe there is a poll question. So let's go ahead and we have two poll questions that I would like to complete now, and then we'll move on.

- [Mary Beth] Okay, is everyone able to see the poll? So we want to know what is commonly done in your clinical practice. Thank you for voting. I'll leave it up for another three seconds.

- [Barb] Yes, thank you.

- [Mary Beth] Okay, great, do you want me to put the other poll up Barb?

- [Barb] Yeah, so it looks like majority are doing pretty much sentences. It doesn't look like anyone here, and how many people, so not very many people have responded. Looks like 10, 12, okay only a very small portion of the 40-some that are on the phone. Okay, yeah let's go ahead and do the other one next.

- [Mary Beth] So what do you consider a clinically significant change in performance? So if you're using a 25 word monosyllabic word test, comparing to a previous date, what makes that a significant change?

- [Barb] Okay. Okay, so about half of the people are responding so I think we're pretty good. So 15, 20%. Okay, great. Thank you. Okay, so, let's talk about speech perception. So, we know there is a variety of speech perception measurements in the MSTB. And my question to you all, and you kinda, again, you kind of alluded to this in the poll, but looking at, if there's one key measurement, cause again, we know there's not a lot of booth time, we know that it's not easy to get speech outcome data, but if there were one measurement that we could look at to look at is this patient tracking along? Are they meeting as we would expect? Again, that pre post improvement. What would that be? And then what would be clinically significant? And so that's why I've asked some of those questions. Now, we know that we do mainly AzBio in sentence. I'm sorry, AzBio sentences in quiet, and then some people do it in noise. So we do that for insurance purposes. It's part of the labeling. You may do it in noise to help counsel the patient. If we look at one test though that really looks at cochlear function, that probably actually would be monosyllabic words. When we look at the sentences and we start getting into then that other level of processing, again, particular when you look

at how again cochlear function and then what we're doing with those higher levels of processing, and most certainly when you get into noise, that's when you see a lot of variability. A lot of variability, and that's where sometimes what we'll see is we'll have testing done preoperatively in quiet, but then postoperatively, or preoperatively I should say in noise it'll be done, and then postoperatively they don't do it in noise cause the patient's not performing as well. So we'll do it in quiet, but does that really give us a measurement of how this patient pre to post, how are they performing and are they on the right pathway? So that's where in getting a group of clinicians together and asking this question, that's where CNC came up. That that might be a good test or milestone. If we had to do one thing, and the other thing is about significance though. So that's why we ask the question. And actually, I think most of you said somewhere between 15 and 20%.

So, we decided to let's take a look at, we said CNC words, let's look at the data. Let's look at the 532 data because it's most current, and we looked at again, the study, so we compared the pre-opt score and then three months, and six months, and got the difference, or delta, and then calculated how many patients had a delta of 20% or more, 30% or more, or 40%, and what we see is 80% of the patients had at least 20% improvement, and it looks like for many of you, that's what you would consider to be clinically significant. If we looked at a binomial, 50 word CNC word list, it would be somewhere, binomial would be somewhere between 15 and 18%. So we're on track there. When we look at six months, 80%, almost 80% at a 30% improvement. So we also looked at this, at that same database, that larger retrospective database, and what I like to call, cause this is study, this is very controlled, but we also looked at the larger, and took out the study data, and looked at just real world and saw a very similar finding. So we could say that at three months, a milestone on CNC quick check would be do they have a 20% improvement from pre to post? And then at six months, do they have at least a 30? And that just gives us an idea, are they on the right path? And if they're not, then we need to ask some questions. So, are they using their device?

What about rehab? What about their etiology? What about comorbidities? And then, it's like, okay, we need to do, let's take a look at programming. Let's really look at those Ts and Cs, and even potentially, is there something else that we should be doing? And then, is this patient a complex patient? That they need something different. They're gonna be needing in-clinic support more than potentially some of these other tools that we may have available. Now, again, in an evidence based model though, it's not just necessarily about data. It's also about what the patient wants or needs. So do we get everything in terms of what that outcome is for the patient just using CNC or a sentence score? What about the daily hearing experience? What about their hearing satisfaction? And that's where, that's the other part of this, we know that we have patients that, look, they're poor performers. There's a percentage of patients that are a poor performer for a variety of reasons, but you know what? They're satisfied. Because you know what? Now I'm able to hear in a small group conversation or I'm able to hear my grandchild, and we also know there's another group of patients that are topping out, and they're 90% in noise, and they're not satisfied. Well that's a counseling issue.

That's a different conversation and that may be with a different professional perhaps. But it's just looking at again, a combination of these various measurements, and it's not just about a speech perception in a booth, cause that doesn't resonate with a patient, right? It's also about their day to day. Is it as simple as asking some of those questions before implant candidacy? How satisfied are you using your hearing aids with the TV? How satisfied are you in terms of ability to listen and appreciate music? And then we do the same thing and we check these same five questions at three or six months and look at the satisfaction of the patient, or we do, we use things like the COSI which is great because it's very specific and goal oriented to that patient. So again, I think it's changing the conversation. It's not just one, it's not just one thing, it's a combination, but what are those critical things that we need to look at? What are those critical things? And that's really what we're trying to answer. And so when we ask is the patient on the right pathway based on these key milestones and when and

what to assess? First thing is we talked about we need to make sure that they acclimate to sound. That they have basic device use, that they're wearing the thing. The next one is audibility. We could just do Ling Sounds to make sure they have audibility. We could put them into the booth, but we want to make sure that their ability- That's one of the first things that an implant delivers, right? Is audibility. So let's make sure that it's at least 25 dB or better. And then, what do they want out of this device? What's important to them? What will success mean? And that's where COSI, which is an awesome tool that can be used, and then, again, we should continue to have that audibility. We know Ts and Cs kind of level off. If we have that good audibility, what about their performance? Because we should be seeing at least a 20% improvement, and if we're not, something's up and we need to dive a little bit deeper. We can then go back and look at our COSI. What other accessories or things do we need to provide along the patient journey to make sure that they're meeting their goals? And then of course, we get to they should have, there should be stability. We shouldn't see any changes in performance.

As many of you indicated, 15, 20%, if we're seeing a change of 15% poor, something's up there. We need to think about that. What's going on with this patient? Has something changed with their medication? Has something changed in their lives? Is there something else going on that we need to take a closer look at? And again, the patient reported. Whether it be COSI, the SSQ-12 is really not a satisfaction. It's really a hearing disability, but it can provide you with information. Or is it as simple as those five questions that I just mentioned? So I really encourage you to look at your data. Take a look at this, but, for the majority of people, look, they're on this trajectory. We can check to make sure they're on the right path. Those other 20 or 30, they're gonna need something different. They're gonna need something very different, and they're gonna need that expertise level of support. So, you're gonna begin to see some materials that maybe will help you make it a little bit easier to continue to use that evidence based practice, and again, this is just the foundation or starting point.

We're saying this is the minimum. If you don't have the time or you're trying to, try and triage patient, this might be something that you want to take a closer look at, cause again, it is based on data. It is based also on clinical experience. So, we're gonna continue to partner with you and to reevaluate how care is delivered to that adult CI patient. We're then going to look at this and learn from it, and see how we can apply it to pediatrics, and we're also gonna look at how we can incorporate additional in-clinic self and remote care tools and services so we can provide the best possible outcomes and experience for your patients. So I really, really thank you for your time. It looks like we have one minute left. I don't know if anyone has a question. If not, again, we can put my contact information. Again, love to see what your data looks like, and again, I encourage you to take a look and use your data to help answer some of these questions. So with that, I'll end and I'll turn it back over to Mary Beth and Melissa.

- [Mary Beth] Thanks Barb, that was outstanding. I love hearing you talk. You're so smart and I love how you pull all this together and make it so clinically applicable to everybody. I don't have anything else to add, but we do have two more work hours in this workshop coming up over the next few weeks, so hopefully we'll see some of you at those sessions as well.

- [Barb] All right, well thanks everyone. Have a wonderful day.