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Continuous Clinical Improvement and Remote Programming in Cochlear Implant Clinics

Presenter: Rene Gifford, PhD, CCC-A

Okay. Well, we want to thank you all for being here today. My name is Allison Dixon and I am a clinical specialist in the Mid Atlantic region. We also have Lori Hambrick here from Education and Training who is going to be assisting with polls and any attendee questions. I have the pleasure of introducing our guest speaker to you.

Rene Gifford holds the Fred H. Best Chair in Audiology, is a tenured professor at Hearing and Speech Sciences, and is the director of Implantable Hearing Enhancement and Amplification Research Laboratory at Vanderbilt University in the School of Medicine. Her research has been funded by the NIH for over 20 years and focuses on auditory perception for individuals with cochlear implants and hearing aids, including basic auditory function, audiovisual processing, spatial hearing, as well as speech, language and literacy. She has over 160 peer reviewed publications and is the author of several book chapters and two books aimed at professional management of CI candidates and recipients. Thank you Rene, for being here and I'll let you take it away.

Thank you, Allison. Hi everybody. It's my pleasure to be here with you today. I am Rene Gifford. And of course, while I'm the one whose name is on this presentation, I want to make sure that I give credit to my co authors as we put this together as a group several years ago, both as a project and then ultimately we've given a similar presentation at American Academy of Otolaryngology.

So I want to definitely provide some kudos to our otolaryngology colleagues, Dr. David Haynes, Dr. Erin Moberly, and our audiology hearing scientist colleague colleagues, Dr. Jordan Holder and Dr. Katie Burke.

So thank you to everybody there and thank you for joining us today. It's great. All right, so we know that there's really one consistent thing in life and that is going to be change. We also know that change is not always easy and in fact often not welcome. Right.

We see that in various aspects of our life, both professional and personal. And so what we can see is that change is happening rapidly, but because we're in the middle of it, we might not need to. We might need to step back for a moment and really take it in. So for example, if you look at the original Fortune 500 companies, which were defined in 1955, 88% of them as of 2016 were gone. So most of them were gone.

And so because a lot of those companies, such as Kodak, others, they the market completely changed such that what they were offering was no longer relevant to the current consumer. And so one thing we know we need to do is that if we want things to be better in the future, for whatever aspect of life we're talking, we have to be ready for change, at least in some way. And of course, the W. Edwards Deming, it's not necessary to change because survival is not mandatory. So I would hope that we hopefully are viewing things.

As an optimist, I can't say that I always do. But looking at these as opportunities for us to improve things versus a difficulty or an obstacle to overcome. All right, so one of our biggest difficulties in the world of cochlear implants, of course, my area of expertise is that the utilization of cochlear implants globally and also in the Western world and US is quite abysmal. So, for example, we know that as of late 2019, the National Institutes of Health, the National Institute of Deafness and Other Communication Disorders estimated that about 118,000 adults had been placed, had had cis and about 65,000 children. Now, if you look at the proportion of the population in this country, so this is just related to the United States.

If you look at the portion of the population that could actually benefit from this technology, what we know is from the literature on the adult side, there are a number of statistics that are out there, but depending on the criteria that were used for that particular paper, it could be anywhere from 2% up to about just under 13% of adult candidates for a cochlear implant who actually have at least one. So

most individuals, almost all who are candidates for cochlear implant actually don't have one. Thankfully, things are a little better on the pediatric side. In the US the utilization of cochlear implantation in children that are born with bilateral severe to profound sensorineural hearing loss has been estimated at between about 50 to 59% utilization. So certainly higher than what we see on the adult side and certainly higher than what we see globally.

But if you compare our data to other nations, such as Australia, the UK Sweden and others, we're highly underutilizing cochlear implants even in children. Whereas, for example, in Sweden and in Australia, it's like 95 to 98% of children born with bilateral severe to profound hearing loss have at least one cochlear implant. So we have to ask ourselves, what is the problem? Right? I mean, there's clearly there are issues that we need to overcome.

And of course, one of the bigger issues is there are a number of barriers to cochlear implantation, some of which are within our hands, some of which are outside of Our hands, some are more in the clinician side, others are more on the patient side. But here are some big ones. And so, of course, we know awareness is probably been identified as one of the largest, if not the most influential barrier to cochlear implantation. So not only does the public not necessarily know who a cochlear implant candidate is, many people in the public don't even necessarily know what a cochlear implant is or if they know, they might think, oh, well, no, that's only for children, and that's only for children born with profound deafness. And so there's a lot of confusion and misunderstanding even amongst professionals.

So you can have professional, you know, good audiologists, good otolaryngologists, but if they're not working in this space, they may not necessarily know the current criteria that would require them, you know, or that would allow them to refer on appropriately. So again, it's just, it's an education, ongoing awareness that we really have to nurture and continuously uphold. There are also so many different

interventions that are possible. We have, you know, hearing aids, cochlear implants, there are acoustic, you know, middle ear implants, there are bone conduction devices, depending on the severity of the loss. And a lot of these indications have at least some degree of overlap, which of course adds to further confusion.

Another big one, of course, is the lack of defined care pathways. So, for example, if you are a patient and you're not within the audiology of the hearing healthcare community, who do you go to first? You notice you have hearing loss, you notice you're struggling more lately in terms of communication. Do you go to your primary care provider first? Do you go to an audiologist?

Do you see an otolaryngologist? Where do you start? And there really is no definitive answer to that question. Insurance, of course, is one of the barriers. Although, interestingly, from a global perspective, we might expect the insurance issue to be more problematic in the US Than it actually is.

In fact, it's very rare these days that we have an individual who has insurance restrictions or who does not have insurance for whom we could get a cochlear implant. So, for example, even if we have a child, let's say, who does not have health insurance, is not eligible for or Medicaid or whatever the healthcare program is in that particular region, I can promise you, if they come to us, we are going to find a way to get them an implant if that's what the family wants. We have charitable funds, we have foundations, we have a number of things at our disposal. We also have state funds for certain cases like this as well.

Another huge one is access to cochlear implant clinics.

We know that cochlear implant programs, particularly the large ones, tend to be located in large metropolitan areas. However, you know, about 20% of the US population lives in what we would call a rural area. And you might think, okay, 20% of the population, that's not very much. Well, 20% of 335 million, which is roughly the population of the US today, would be about 67 million individuals. So we're talking nearly 70 million US residents live well beyond the metropolitan area.

So with respect to cochlear implant growth, I want to show you just a little bit of information about our program here at Vanderbilt. And so basically, when I got here at Vanderbilt in 2011, as shown here, we were implanting roughly. Oh, sorry about that. I think we've got some issues there. Okay.

So first of all, we do want to make sure we understand that the average cochlear implant program, the size of the average cochlear implant program in the United States is about 25 devices a year. So when we're talking about the programs that have hundreds of devices that are being implanted, that those are, you know, those are the rare exceptions, they're not the norm. So, and given that we know that we're going to be seeing more growth, right, because we know that as expanded indications continue to expand. So we had hybrid EAs bilateral when we used to only have unilateral, and now we are looking at single sided deafness. There's a lot of different indications that are going to continue to expand our population, our candidate population.

And there are literally millions of individuals who have moderate sloping to profound sense for neural hearing loss who could benefit from cochlear implantation, whether it be an EAS or hybrid system or a standard cochlear implant with the goal of hearing preservation. So if we think about this with the average program being 25, I'm going to give you just a story about what our program looked like here. So as I indicated when I got here in 2011, we implanted about 150 that year, which is a large program, but this is a very large medical center and we are located in a relatively large state. And, and we're centrally located. So most of the state does tend to converge upon the Nashville area and Vanderbilt for cochlear implants.

So when I got here, of course, we definitely wanted to grow the program. And so we saw that it took about eight years for us to see an initial doubling of our cochlear implant program. So we got up to just over 300 in 2019. So it was really exciting to see how we were able to double that program over the course of eight years. Interestingly, if you look at a different eight year period within this trajectory, so

starting for example, at 2013 and then moving up to 2023, you can see that again, we're looking at about an 8 to 10 year duration that it took to see a doubling of that, of that program.

So if we use these projections, so we've had a healthy growth. Of course we had a little bit of a stumbling block with the pandemic, as most programs did. But if we look at that regression and we just kind of make the assumption that we're going to continue at this level of growth, we won't see another doubling of our cochlear implant program here at Vanderbilt until roughly 2055. So our next projected doubling is going to be many years, 30 years in the future. So that would be if we passively continue to do things the way we're doing them today.

And that's the key because we're going to have to change, we have to do something different if we're going to want to see change in our profession and in our candidate population. So I wanted to show just a little bit of detail about this particular paper. So this paper was authored by my co authors and they looked at the number of cochlear implants at these large major metropolitan area clinics and really kind of wanting to define where are their patients? Like what's their catchment area? Where are they getting individuals from?

And so thankfully they did find that, you know, 91% of the patients that they see do in fact come from about a 200 mile radius around the center. But if you look over here, you can see there's very large ranges of catchment. And even though we have these circular regions, you can see there are kind of these outliers over here. And there are individual individuals who just don't necessarily know, you know, where should they go and how to get there. So a lot of things that we want to think about is what can we do?

What's our ability to make change. So for example, are we providing satellite cochlear implant programming, surgical offerings at our satellite, maybe ambulatory surgical centers? Do we offer telehealth, remote programming options and additionally optimizing our clinical care delivery process?

And I'm going to be focusing most of our Time today on optimization of our clinical care model and then additionally talking about telehealth and integration of remote programming options for further growth.

Okay, so at Vanderbilt a few years ago, my colleague Dr.

David Haynes went and got a master's degree in public health. And I did not get a master's in public health, but I feel like I got a partial master's in public health from helping him with this project, which I'm so grateful for because I learned so much. So as part of this project it was defining what's the patient experience like for those individuals who are either referred here for cochlear implant eval or they self referred wanting to come in and saying, you know, I'm struggling with my hearing, I'm really noticing I need something, I'm coming in for your professional opinion. So we're talking about, you know, surgeon appointments, audiology appointments, device selection, imaging, preoperative anesthesia appointments, of course, the surgery and then all of the device mapping and you know, follow up programming that comes with a cochlear implant surgery and activation. And so what we found is that in that first year, from the time they come pre op to the time that they're one year post activation, we're looking at 12 or more appointments for that individual.

That's a lot of time. And in fact if you think about that, that can be anywhere from 6 to 12 days that are completely missed from work. Right? So this is an issue especially for individuals who aren't paid or don't have time off or it could be missed school for children, which can be really problematic for those that are coming from a distance. We're talking hotel stays in many cases as well as extended travel time, up to 60 to 120 hours of travel.

Particularly if you think about individuals that are coming from the upper corner, for example of our state. Here we are in Nashville in the middle of the state, middle, upper center. We have a relatively large population of patients who are living in the Bristol area up here in the upper basically northeast corner of the state. And as you can see it's a, you know, assuming there's no traffic in i40, which is a

huge assumption, right? It's a five hour one way trip.

And so asking someone to drive over 4,000 miles in that first year, all these hours of travel, all these hotel stays, missed work, missed school and money, it costs a lot of money, not just even healthcare, right? There's the hotel, there's the lost potential revenue from your missed income and then there's gas, right? So I'M going to assume, you know, 35 miles per gallon, and if we look at about roughly 350 a gallon, which is roughly what we're seeing here now, that's \$400 in just gas. So this is really, if you think about this is completely, not only unacceptable, it's completely unsustainable. And I have to, I have to always think how many patients never even make that initial appointment once they learn that this is the process.

Because I'll be honest with you, I don't know that I would, I would be as willing to participate in this particular type of intervention recommendation if my provider said, you know, I'm going to need to see you 12 or more times over the next year, I'd really have to think twice about that. And I bet many of you sitting there are thinking exactly the same thing. Now, as, also as part of this project, Dr. David Haynes, we, he developed this process map which involved our entire team. And so if you're not familiar with a process map, it's basically defining every single step in the process of whatever you're looking at.

And to define where are the weight points, maybe where's the bottleneck, and how much time each one of those points take. So if you remember back like from high school or maybe even middle school, remember you probably had some in your English class where it was want you to write directions on how to make a peanut butter and jelly sandwich or something similar to that. And, you know, you realize how detailed that has to be. You can't just say, you know, take some peanut butter, put it on the bread. You know, otherwise you take the jar of peanut butter, put on the bread.

There are things, right, the instructions and details associated with this process. So this is, this was our process map when we initially started this process, which was like 2015, 2016. And so what you can

see is that from the time of that initial referral, whether the referral comes in electronically through a fax or a phone call, there were 19 patient contact points. From the time of that first referral through the first 12 months following activation, 19 contact points. And along that point, but that process, nine wait periods.

So a wait period, What's a wait period? So, for example, you're calling in, you call in, you want to make an appointment, you might have to wait on hold for a while, you might have to leave a message and they get back to you. And then once you make an appointment, a of course there's going to be, you know, you're going to receive some information from the medical center, whether it be through their patient portal, whether it be through secure email, usually you're going to have intake packet and other things that you need to complete before they can schedule you for your appointment. Interestingly, we found that we lose about 5% of referrals just from this particular, this part here. So we lose them on, they don't return the intake packet.

For those that do, of course, then we further go on to get them their preoperative evals and moving through this process. But this, going through this, this is a highly convoluted process for a relatively straightforward intervention. So if we were to quantify this process into actually how long does this take? On average for us at that time, about eight years ago, roughly this whole process was about 22 weeks. So a little over half of a gestation of a human infant.

Right. So this is a long time, 22 weeks and two days to be exact. So we really, we recognized pretty early on that this is not ideal. And it's something that we really need to actively and intentionally change. So as part of this process and with the help of our colleagues here at Vanderbilt, we came up with what we called the same day patient consultation and surgery.

And so we started this just to kind of almost a proof of concept. So we started with Medicare patients because of course, all of the you who work in this space, you know that Medicare does not provide prior

authorization for any procedures. You simply have to meet the criteria. You can complete the procedure, but you have to just document that the individual met Medicare's criteria for that particular intervention. So what that means is we did not need prior authorization for cochlear implantation.

So in our process, for example, if we went back here and we got the information from the patients, we could have our audiologist triage that look at those patients. Because of those patients, nearly all of them are reasonable referrals. And what I mean by that is we're not getting referrals for, you know, mild to moderate hearing loss or individuals with, you know, normal hearing through 3K, most patients who are being referred to our program are absolutely cochlear implant candidates. I mean, we're talking about bilateral severe to profound sensorineural hearing loss. So that even that added piece of information makes this 22 week period even worse.

Because these are individuals who meet criteria and likely met criteria a decade ago or even more. In this particular project, we created this same day surgery just to see how condensed and how focused we could make this process. We actually found that we can be successful. We can very easily and effectively, with high sensitivity and specificity, identify one of our kind of what I'd call a slam dunk cochlear implant candidate and provide the pre op eval and surgery on the same day. Now I know many of you are probably thinking, oh my goodness, we're not ready for that.

And I completely can understand where you come from. So let's take a few steps back and let's talk about other ways that we can drive change and then we'll work our way back to the same day description of our, of our process. All right, so just like with many other aspects of, you know, behavioral science, there is an entire science related to behavior change. And while there are many models, this is one of the most prominent models of behavior change called the stages of change model. And so we know that there are five stages of change going from pre contemplation all the way through maintenance.

Now of course pre contemplation is you really don't necessarily have any attention to make a change, but you're like potentially thinking about, okay, yeah, I think we likely are going to need to do something. And then in the contemplation phase is when you start to go, okay, we want to make a change. What is our, you know, what are some of the things that we might be able to change? So you're just kind of identifying, you know, your options at that point. And then there's the preparation phase.

And so that actually is going to combine your intention to change, which is your contemplation, as well as having, developing a plan. So this is where you say, okay, we know we want to do this, this is how we're going to do it. At least this is going to be our first phase. And then of course we have the action where we, where we modify the behavior actually in real time. And then of course this can require multiple layers of refinement, right over time, maybe the first process or the first prep didn't necessarily work or didn't work as effectively as we might expect.

But honestly, I can tell you from experience that the maintenance phase is active and must receive our attention, our nurturing regularly. Because if we sort of become complacent, this can very easily revert back to the old ways. And I've seen it even in our own center here. So moving forward. So I'm going to describe how we initially were able to streamline our post operative cochlear implant follow up process at Vanderbilt.

And in doing this, this was right around the time that we were starting to look at the process map and really identifying we have a problem and guess what? We are the problem. So we're going to, we're going to work towards a solution. And so we wanted to move forward, but we wanted to move forward in a data driven manner. We didn't want to just come up with like this is what we think, you know, expert opinion.

We want it to look at our own program's data and make informed decisions about how we could streamline their follow up care. So I do want to give you just a little bit of history here. And so historically

we've spent a lot of time with our cochlear implant patients. So in fact if you look at Advanced Bionics original clinical trial protocol when it was known as the Clarion system for adults, it was recommended that they have anywhere from a 12 to 16 hour activation that is actually right over several days and then they had follow up regularly at 3, 6 and 12 months. So you know, pretty extensive amount of time as part of that clinical protocol.

And the other companies had similar. And so for example, with the N24 clinical trial protocol which was in the later 90s, that FDA clinical trial called for seven to eight follow up visits in the first year following activation which also included a two day activation. So back to back activation days including two weeks, one month, three months, six months, nine months and 12 months. And then if we look at the Med El Combi 40/clinical trial also in the late 1990s, they were calling for five visits in the first year following surgery. So activation, one week, one month, three months, six months, 12 months.

So we have a long history of spending hours and days with our cochlear implant patients and we've for, I don't know, I want to say unfortunately, but we've maintained that practice through today. So in 2019 there was a AAA clinical practice guideline committee and these individuals did their due diligence and they reviewed the literature and so they used the information that was available to them at that moment in time to come up with a recommendation about really how we would be completing our follow up for these patients. And so what they found from the literature was basically similar to what we just discussed, that there was evidence in the literature for six visits the first year as shown here, and that was for adults and then for children, seven visits in the first year. Okay, so this is not terribly unlike what we saw all the way back in 1991 or 33 years ago. Okay.

And we are not alone in this. So I'm not, you know, I don't want to just point the finger at us and say, oh, look at us in the US we're doing things so wrong and taking so much time. This is a global phenomenon. So this particular study from 2014, this was a study that included seven cochlear implant

centers from 17 different countries and in five different continents. And sorry about that.

And what they found was that this particular clinical care model, they were asking these individuals how many visits they had between activation they call switch on and 12 months for their patients. Okay? So I want you to see that if we look at this, about half of the sample said they spent anywhere from seven or eight or more visits in that first year. So this is completely aligned with what our AAA clinical practice guidelines were in 2019, as well as what we've been doing again dating back to 1991. So once again, I have to state that this is completely unsustainable.

If we want to grow our program and we are spending this much time with our existing patients, we simply just. We're going to run out of personnel. We're going to run out of space. And if we think back here to all of these visits back in these days, so 1991, 97, we were still in the early phases of FDA clinical trials with cochlear implants, and we were still actually defining the efficacy of these devices, right? So we're defining, are they effective, and if so, what's the extent of the effectiveness?

We can reasonably say today we are no longer debating whether or not cochlear implants are effective. They're highly effective. So with that in mind, we're no longer assessing safety and efficacy. So why are we still applying that same clinical model? And so it makes me think a lot about something similar that has occurred in my life at a very unique time in my early adulthood or early childhood, possibly.

So what you can see is that. Remember these guys? So we had Blockbuster Video. It was like every Friday night, right? You go on a date, you go to Blockbuster.

That was the fun thing. You get your popcorn. And we do things very differently today, don't we? We have Netflix. We have all these different streaming services.

Interestingly, a little bit of history. In the year 2000, Netflix approached Blockbuster, and they. They actually wanted to be acquired by them. They said, look, we're. We're willing to sell to you for \$50 million.

And the story is that the. The CEO of Blockbuster basically laughed them out of the room. Like, are you kidding me? Get. Like, get out of here.

We. We're not Interested startup. Well, today I think you know how the story ends. Today Netflix is valued at like \$340 billion billion and they could have been purchased for 50 million 24 years ago. And in fact, Netflix is currently ranked 117 on the Fortune 500 list.

So whereas Blockbuster unfortunately is not on the Fortune 500 list. And in fact there's really just one Blockbuster available still. And so if you're, if you're not familiar with this, I, I recommend you look at this documentary. It's about the last Blockbuster that is in Bend, Oregon and another little kind of cautionary tale. That last Blockbuster is now actually operating as an Airbnb.

So if you want a little bit of history and a little bit of a cautionary tale in action, you can, for a small fee, stay at the last Blockbuster. You can sleep on a pull out sofa, watch all the video cassettes you want, and you have unlimited snacks. So that's really what's left of that business model. And today, completely different world. We have all of these streaming services, we have all these abilities to see really whatever we want on demand.

We would have never even assumed that to be possible in the year 2000. Well, we see sort of the same thing with clinical care delivery, right? We are as audiologists still operating a blockbuster clinical care delivery model. We're still doing the same thing we were doing 24 years ago, even 33 years ago. So we have to recognize that we're part of the bottleneck, if not the primary bottleneck, in increasing our access to cochlear implants and increasing our patient population.

So I'm going to tell you what we did. So this is what we were doing when I first arrived here and we were still seeing adults, six to seven visits. We were seeing children for seven to eight visits in the first year, which again was not unreasonable at the time. And then I can tell you that from 2016 on, we saw a significant reduction in our postoperative follow up schedule for adults and slightly less of a reduction in our peds cases. But we still have reduced and we're continuing to monitor those data regularly.

But I'm going to give you just a highlight as to why we had to make this change. So in 2015, we lost three cochlear implant audiologists and two of our surgeons. That was a huge blow to our system. And by the first of May in 2016, I remember being at the American, the American Cochlear Implant alliance in Toronto and being getting an email from our coordinator saying we are over nine months out for a new cochlear implant evaluation. Clearly this was a problem, so we had to make a change.

So what we did was we met as a group and we have a very large exhaustive clinical database for our cochlear implant patients. So we looked at all of our data for patients who are 18 years and older because of course we always start with adults, right? Because we want to start with the least vulnerable population. And we know that from our clinical protocol we have, we require all of our patients to have, you know, low level stimulation levels giving us aided detection in the range of 20 to 30 dBHL. So that's been well known since the late 1990s from Margo Skinner and colleagues that this range yields the best outcomes in terms of speech understanding.

We also have for years been doing esrts at the one month post op appointment. And so basically the goal of that is to shape the upper stimulation level profile. If you want more information on this, we go into this a lot more detail in other audiology online as well as at our ICIT advanced audiology course. Then we also at Vanderbilt we've had what's called autopilot, so not unlike what otoplan would be for Medow, we've had Otopilot for about 12 years. It's our own internal CT imaging data in our database analysis.

And what's really great about this is that we've known for that period of time, for example@ activation two extra cochlear electrodes, or you know, this one is perhaps maybe over inserted or this one, you'll know right away what the potential issue is. And so that's very valuable information to us as an audiologist. Right. We know, okay, if there's two extracochlear electrodes, we can start from day one and deactivate, you know, increase that trajectory to optimization. And so then what we did was with all three of those things already in place, we looked at our database to see all of our adults for whom we had visit follow up appointments at one, three and six months so that we could see how that played out.

We were able to identify 171 adults, 178 years that met these criteria. So, so what we found was plotting CNC percent correct as a function of the time point here. And this is the ear that was implanted. And so of course you can see that going from pre op to one month we see this big increase, which of course is the efficacy of cochlear implants. Right?

And we see that huge bump, large increase in that first month of device use, well, we also see another bump from one to three months. But what we did not see was statistically significant benefit or significant improvement or further improvement from 3 to 6 to 12. We made the assumption of course, that we've met all of these criteria Right from day one the patient's wearing the device. Why do we keep seeing them when we largely optimize their cochlear implant programming at the one month appointment? So based on these data, we made the decision to eliminate the three month appointment.

That was an arbitrary decision. Honestly. We could have easily also gotten rid of the six month if that was what we wanted to do. And in fact other centers, I'm aware, have actually chosen that. You know, they do the pre op, one month.

Three, six. I'm sorry, pre op, one month. Three month and then going on to annual. So with this streamlined protocol alone, we just went, we cut out that three month appointment. We went from 161 devices in 2015 to basically 301 in four years later.

And now we're well over 330 devices. We're, we're on track. I mean we could easily hit 400, 500 next year if we continue at this pace. The problem is we can't continue at this space with our current personnel and our hospital space that we have. So what you can also do, again, you can with your team make a decision.

I actually highly recommend you look at your own clinic's data. Don't take my word for it. And you make the decision with what you all feel most comfortable with, with your team as far as eliminating a mandatory appointment. Now I do want to make sure I highlight that any one of our clinicians can absolutely see any one of these patients whenever they feel it is necessary to do so. We definitely want our professional autonomy, our professional clinical judgment in those cases.

It's just that this is not going to be required for every single adult coming through our program, especially those who meet such great, who make such great progress in that first month. Now if you're like me, you might be thinking, okay, well that was, you know, those are mean data. I want to look at individual data. And so did we. So what we have here is this is another figure from this Berg et al paper where this study is described.

So we have cochlear and our CNC WordRec at three months and it's plotted as a function of CNC at one month for the CI year on the top and then the best data condition on the bottom which would be bimodal for most of these individuals or bilateral CI for those few individuals. And so what we have is that the 95% confidence interval for test retest variability is located in this little dashed lines here. So if your data point falls within those dashed lines, that would represent essentially equivocal performance, meaning no different from the one month appointment. No different, no worse, no better, at least from a

statistical standpoint. Now if the data points fall above that line, such as these in blue here, that actually represents an individually significant improvement in their own performance beyond what we would expect from just standard test retests variability.

Which is exciting, right? It's showing that from the one month to the three month appointment those individuals actually made a dramatic improvement that was significant. Thankfully we didn't see anybody that actually got worse. So anybody whose performance went below that line for the cochlear implant side. Now in the best aided condition, we did actually see two individuals here that showed a decrement and I will indicate however, those two individuals lost more hearing in the non implanted ear.

So then when you looked at the best dated condition, that impacted their ability to achieve similar performance to what they had previously. But it's a very small proportion. And so in fact even if we move this out to six months in this second column here, you can see that we're not missing patients. So our biggest concern is are we going to be missing a large or even a sizable proportion of our patients who could actually really be doing worse, who need our expertise? It doesn't appear to be the case.

And in fact, if you are obtaining ESRTs post operatively, especially at the one month appointment, I do want to let you know this is a particular figure that my colleague Dr. Holder presented at ACIA, I think it was last year. And if you look at where things move at the esrts, where the actual upper stim levels are set at the one month appointment which is indicated by the one, and then again at the six month appointment which is indicated by the six. You can see it's essentially a uniform increase if anything. So it's not as if we're going to be doing individual electrode manipulations all the time.

If we get that profile, we can make global adjustments over time, which we can do easily with volume for advanced bionics. Right. Because in fact with volume on advanced bionics it is moving those upper stimulation levels. So we're in good shape there. So with that information in mind, that's how we start it.

We started by the streamlining our program on the basis of our patient data. And then we decided to really focus on our same day program and see, you know, really it was a proof of concept to start. Can we actually do this? So what we started with, and this was prior to 2020, we started with telehealth. And so we did that initial appointment via, you know, a HIPAA protected encrypted service.

Of course we didn't have all available to us what we have today because it was prior to the pandemic. But it worked very, it worked very well. We had captioning, we had multiple individuals, you can see this is Dr. Haynes, he has a whole audience of individuals there and it was quite, quite effective. And I do have to give lots of credit to Vanderbilt.

They provided support to this project and paid for our program to get six video educational videos made. So these are professionally done videos with our own team and our own patients. And we as part of this six video production, we came up with what we found was the most important pieces of information for patient education in the preoperative period. We also know from the science of teaching and learning that individuals attention span is pretty short. So even if we spend, let's say two hours with an individual and providing them all of this information, we know they're not going to be able to retain all of that information.

And additionally preoperatively we're talking about an individual who has significant hearing loss. And so there it can be that, you know, communication breakdown as well. So we have starting with what is a cochlear implant? And I want to highlight that every one of these videos the goal was between three and five minutes. But like three was our goal.

So we got five minutes on this one. And this is with one of our patients is a cochlear implant right? For me just over three minutes. And then we have the patient education. How do I choose the right cochlear implant?

And really the bottom line is this is a screenshot from the video. There are no wrong choices because independent studies of clinicians and programs that work with all three and that have, you know, the expertise in all three, there's no evidence that one device is going to yield highly statistically significant benefit over one of the other. And so we want to make sure that people understand whatever the choice is that they make, it's going to be the right choice for them and that we're going to provide them with evidence based programming to get them where they need to be. Finally, chapter four. It was the cochlear implant surgery.

So just a little bit More information. This is our longest video and it's completely animated. So, you know, nobody really wants to necessarily watch a real surgery. And so we just wanted to really kind of demystify the process and show that this is outpatient surgery, this is not brain surgery, despite the fact that that's often touted in that way. Then we have cochlear implant activation and mapping with my colleague Jordan Holder there.

Then finally we then have our implementation strategy. How do we do this? One of our former residents, Dr. Nasiri, he's now at the University of Colorado. As part of one of her projects, she looked at the amount of information that had been retained from patients who had been given this information through the video education series that we created.

Or were they given it in person directly from an audiologist? So basically the same exact information was presented in both of these situations. And then they assessed their level of understanding and they did not find any difference. So statistically speaking, the amount of information was retained similarly. And so that tells us that by condensing that education to those series of videos of short videos, we're able to get the same information conveyed to our patient as if we spent an hour and a half or two hours with them.

Here is a video. For the sake of time, I'm not going to show that this is one of our first, if not the first, same day, cochlear implant patient. This is on YouTube. She describes her experience. It was highly effective.

Now, with that in mind, I want to describe what we did with this information. So we took this information and ultimately Vanderbilt created a bundled service. And so a bundled service is of course, just a. They have a negotiation with insurance companies such they have a single payment that includes all of the services associated with a single episode of care. And an episode of care is basically, if you consider all the services that are included to treat a particular condition or associate with a particular procedure, that is, that would be all the services associated with this particular bundle.

So for example, we have, you know, my maternity bundles, we have orthopedic bundles, weight loss bundles, and what we, of course, my very favorite one is my hearing health bundle, and that's the cochlear implant bundle that we have here at Vanderbilt. And so with that, for two or three insurance companies in the area, should one of their insurers meet criteria for cochlear implant, they're going to pay a single fee that's going to cover them from the preoperative period through the first three months of post op, post op activation, so forth. And so and it's actually quite a cost savings, not only for the insurance provider but, but also for the patient. So basically with these types of bundled services, you can really drill down very easily into identifying what is the value of this and are we delivering this as efficiently and effectively as possible. And as we move toward a value based insurance system, which we are increasingly doing, we're going to see more and more of these types of value based models.

And so right now we have three systems that have subscribed to this. So obviously if you're a Vanderbilt employee, you can get the My Hearing Health Bundle, the National Metro Schools and Gaylord Entertainment. And in increasing. So with this, let's stop for a moment and just kind of think for you and your program, what are your goals? Every one of us is likely going to have different goals.

So for us at this point we've already streamlined, now we want to do, do further streamlining further efficiency and effectiveness. But maybe you're at the point where you're like, okay, you know, we, we kind of feel like we're seeing our patients too often and especially when, how many times, you know, if you optimize, what are you going to do when they come back? And if they're at the same performance level, that's a wasted, that's a wasted visit for the patient and it's a wasted cost to our health care economic system. So think about what's your goal and by defining what your goals are for your program, this is going to help you to implement your ability to deliver care differently. And it's going to be different for every single process and every single group.

So remember where we were in 2011, we were still doing things as if it was 1991, which was a great year. But we don't want to necessarily keep doing things like that today. And then from 2016 present, we've dropped things down to three to four visits for our adult patients and four to five visits for our children. Now I want to tell you, we've actually done it again. So Dr.

Holder, my colleague looked at our data again. Right. We haven't done this since 2016, reviewed our data again and for adults we identified that we're now going to be having just like part of a required follow up two visits in the first year. These are going to be the required, we're going to schedule these at the time of surgery. So it's going to be activation and the 1 month, 3 month and or 6 month will be at clinician discretion.

So if you have a patient, for example who needs a little extra help if they might have additional disabilities, additional needs. This is exactly the kind of patient we're going to want to reserve our schedule for so that we can spend our time with the patients who really need our expertise, the patients who are going to be doing extremely well with these devices from the get go. We don't need to see them three, four, five, even six times in that year. We do then of course recommend the one, the one year appointment so that of course we can look at the other ear in those cases. We can check the

hearing aid if they're using a bimodal configuration, we can check for candidacy in the other ear and then from that point forward it sort of follow up as needed because we're increasingly getting access to remote services and remote care, which we're going to talk about in a moment.

So if you think about a program that let's say you're doing about 260 adult implants a year, which was roughly what we were doing a few years ago, this by cutting two audiology visits in just the first year, you're cutting 520 visits per year on your program. That is 1040 hours for those of you who have two hour appointments, 780 hours for those of you who have 90 minute appointments, and of course 520 hours for those of you with one hour appointments. Imagine what you can do with that extra time.

You're going to be able to see more individuals, increase your program size, provide more and careful care to those more complex patients. Patients.

It's really an excellent opportunity. Now our protocol for children is under construction. Obviously we take much greater care and are operating much more cautiously for pediatrics because we certainly don't want to do anything that would cause any harm to their trajectory and development. I'll tell you to stay tuned on that and we'll be back in touch later. So really the future of audiologic clinical care, particularly for our cochlear implant patients and like the 80% of cochlear implant patients who are like standard, typical, no anatomical anomalies, no additional concerns, no facial nerve stem, we really can start utilizing remote services and really leaning on these services to continue to provide high levels of care but with not tax, you know, not taxing our healthcare economic system and also no more burdens on the patient, not making them take 12 days off from work or spending 400 on gas alone just to come to your appointments.

So with that, of course we all know this is, this is sponsored by Advanced Bionics and Advanced Bionics is currently the only of the companies that has a complete remote programming profile. Now we have lots, we know that we have opportunities to use remote support with our other devices. But in

terms of remote programming, I mean we can do essentially anything that Target CI can do. We can do that in the remote programming visit. And in fact, I want to describe the very first remote programming visit I did.

Once we got target v1.5, that version, I was really nervous. I mean I've, you know, doing this for a million years, you change your process. It does, you know, it would bring up some anxiety and start it with a patient who I've known well, you know, well, existing bilateral AB user. Now this is a patient who loves to talk. And I was like, I don't know how this is going to work, you know, on remote.

His appointment was at 1:00. We logged in a little early and by 1:07 we were done. And I, I'm being serious, like it was a seven minute appointment. We addressed his issue. He was in his own home.

He was able to listen to different sounds that he had had problems with. We make those adjustments, bam. He's happy, we're happy. Seven minutes onto the next one. So really, really exciting.

So we have this ability, I mean like I said, if you can do it in Target, you can do it with remote programming. In advanced bionics, we can measure ECAPs, we can create entirely new maps, we can make adjustments to global profiles, individual electrodes. We can actually also even continue to program bimodally. The only thing we can't do, of course, is we won't have a verifit system or any type of real ear measures in that ear. Although I suspect something like that will likely be available in the future.

I look forward to that. There are so many benefits to this. I want to make sure people understand I'm not promoting this simply to grow our programs. While I very much want to do that simply to provide this technology to those who really could use it and benefit from it, There is tremendous benefit to the patients for this. They have access to their hearing healthcare providers.

Even if they're One of the 67 million individuals who are living in the rural areas, they can schedule their appointments around their own busy life. People are working more, people are working, people are working longer. We, we want to make sure we can also use those real time, real life adjustments. Right? They can be in their naturalistic environment where they have the most difficulty and we can make the, the changes right there.

And as I said, you can do anything in this, in the software. So really you're getting the same level of professional service at a distance and you know, the patient can choose where they want to receive their own health care. It really puts, it's, it's a powerful process for the individual. Obviously. I think it's, you know, the, the benefits to us as professionals is huge.

We can provide service really from any location, of course, provided that we have, we're licensed in that particular area. So for example, right now I'm licensed in three states. We might ultimately have to find that we're going to be licensed in several states, particularly if we have a lot of, of, you know, if we're pulling in from a number of different states in our surrounding region, we have flexibility and scheduling appointments. So you know, we're going to reduce the effect of the no show rate, right, or, or how many times, you know, you see, you start your day and your 8 o'clock shows up at 9 and that's just, you know, your whole day is going to be completely off the, you know, off the rails. So it's really going to be allowing us to have greater control of our schedule, greater autonomy, more efficient.

We can provide greater solutions for our patients, you know, even if they're a more complex patient, but they, they live at a distance, we can help them. It might not be the most ideal situation, but we're going to be able to provide that help to that individual. And like I said again, we're real time, real life, naturalistic setting. We can make those adjustments.

The industry, there are huge, huge benefits. This is sustainable. This is going to be cost, cost savings for healthcare economy from the insurance, from the patients, out of pocket for the hospitals. We are

really, this is going to be a good thing for our field and our healthcare. We can also start to really differentiating care, making room and leaving space for those patients who really do need more of our professional attention.

And then of course it's really going to allow us to provide access to a larger population of individuals. And that really is going to essentially democratize our ability to make this available to a larger population of people. So I do want to let you know if you, if you don't know a ton about remote programming and the reimbursement process. Advanced Bionics has a number of resources available for you all shown here. I'm still learning.

I can't say that I'm an expert at all in this space. So I'm learning right along there with you. So to summarize, we know there's poor utilization of these devices. We also know that our current clinical protocols in audiology for follow up are onerous. 12 or more clinic visits from the pre op point to the post op point.

If we optimize our clinical protocols, we really can start to think about we're going to be eliminating those non needed visits, those visits that are simply not evidence based. We can start including more remote programming and remote support options. This is going to open us up. It's going to give us greater opportunities to spend time for those really complex patients. Like I said, this benefits not just us in our industry and our ability to reach more individuals.

It benefits the patients, it benefits our economy. We're not going to be billing for procedures that are no longer needed. And for evidence based cochlear implant programming, this is going to be a superior auditory outcomes, right? If we are going to be using these evidence based processes, we are going to expect outcomes should continue to increase. Even if it's just incrementally.

We are going to free up our schedule. I really hope that with this we're going to see that each program can significantly increase their program size and then we just continue to work at it so that we can get more and more individuals access to this technology and allowing us of course to operate at the top of our license. Now if you want more information on this and you are really interested more, I highly recommend that you consider enrolling in the Cochlear Implant Team Efficiency course for the Institute for Cochlear Implant Training. It is exceptional course. It goes through the science associated with all of this and it's led by Dr.

Sarah Zidlowski at Cleveland Clinic Clinic, who has a lot of initials after her name. Very, very smart lady. She's a business person, she's an audiologist, she's a scientist. I can't, I cannot recommend this enough. And so with that information, I want to also let you know about the Advanced my next Virtual Workshop series.

I think perhaps Lori or Alison, did you want to provide a little bit more information on that or do you want to go to questions and comments at this point? Well, since we're at the top of the hour, I'll just quickly say this is a series that is a five part series that we completed in September and October and it is available on demand in audiology online. So if you're interested, there will be a flyer added to the chat and you can learn more there. And then if you'll click to that survey slide, I would also say that while we're addressing the questions that have come in. If you would please, please complete the short survey.

If you're requesting the ceu, obviously, you know, audiology online asks for some information from you, but we here at Advanced Bionics would also like some additional feedback. It is just two short questions, so if you could please complete that, we would appreciate it. And then Dr. Gifford, if you still have a few minutes, we have a couple of questions that have come in. Do you have time to address those?

Absolutely. Fantastic. All right, so Jolie asks, are there any recommendations for the over 80, 80 year old patient population? They are challenged with using virtual visits, tech hearing, visual issues and slower to progress with hearing due to dimension cognitive issues, et cetera. Great question.

Yeah. So the, in fact we talked about this as a team. We, for our clinicians who work primarily in the adult population, they even indicated that they thought that this might even free up their schedules to really kind of focus on that, that over 80 population. Now of course there are some individuals over 80 who are like better on their technology than I am. Right.

And so they're going to be fine. But there are more, you know, that that's going to be more of a technology hesitant group. And so, but thankfully that's going to be changing with time. Right. Because more and more individuals and more generations are familiar with that technology.

So what we're doing here is that largely for those patients that are tend to be a little older, we might have some cognitive concerns, really struggling, you know, maybe with the more remote communication. We're going to reserve those in person visits for them, but we still want to encourage them to utilize the remote programming when possible. Maybe bringing in, you know, spouse, partner, child, friend to help assist them with the technology. Great, thank you. And this is a question from Nicole.

Are you utilizing remote programming as a supplement to the activation series or are you incorporating it in between specific appointments? Excellent question. So right now it is not. We did this on purpose. We did not define how it would be utilized.

We're allowing each individual, each professional to discuss that individually with their patients. As I mentioned in a recent presentation, I offer it to everybody, you know, beyond that one month appointment. And it's so funny because I thought that the patients who live super far away were going

to be the ones that jumped on it. It seems like everybody's jumping on it. And in fact, almost more people who live in the area, like I, a lot of the people I've seen remotely like live two miles down the road, but they're busy and they're at work.

And it's like, if I don't have to drive into downtown Nashville and then find a spot to park in that crazy medical center with all the construction, it's a. It's a win for them. Right? And so I. I don't blame them at all.

And so I was actually really pleasantly surprised to see that it's like, it's not just for those that live far away. Thank you for that. And I appreciate that you pointed it out, pointed out that it is something that potentially can be for everyone. And I loved your example of the patient that you did your first remote programming session with, because I think a lot of people are a little hesitant for those patients who are really chatty and who are the ones who really want to be engaged and feeling like maybe that patient could feel slighted or like it could negatively impact the relationship. But I've heard numerous times that the patient, in their own environment, they're also not as interested in spending their day chatting with the audiologist for two hours.

They want to get the job done. They want to say, hello, you can build a relationships, you know, meet their pets. But yet there's still a little more focus on let's do what we need to do and move on with our day. So thank you for everything, Dr. Gifford.

This is a fantastic information and so valuable in our field where there are so many people who need to get services and so many clinics who are really, really full these days. And I just want to say again, thank you for your attendance. For those of you who attended, please again complete the survey you see on the screen. And everyone have a great rest of your day. Thank you.