New Models of Cochlear Implant Care: Today and in the Future

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- [Melissa] Welcome to today's course. New Models of Cochlear Implant Care: Today and in the Future. Presented by Amy Donaldson and David Catlett from Cochlear Americas. It has been said that innovation is seeing what everybody has seen and thinking what nobody has thought. This month on AudiologyOnline, we're celebrating innovation in the hearing industry with our third industry innovation summit. Thank you for joining us today and we hope to see you in other summit classes. We would like to thank our title sponsor CareCredit and Cochlear Americas and all the other companies joining us this year. It is my personal pleasure to now turn the microphone over to our presenters, Amy and David.

- Hello everyone and welcome to our presentation today. We are really thrilled to be part of AudiologyOnline's Industry Innovation Summit. It's very exciting. My name is Amy Donaldson. I'm an audiologist with Cochlear. In my current role, I work with the connected care team helping to support and implement new technologies like Remote Care into the marketplace. Dave, do you wanna go ahead and introduce yourself?

- Sure. My name is Dave Catlett. I'm the senior manager of Clinical Technical Services at Cochlear.

- Great. So Dave and I are gonna take you through a little bit about the trends that we're seeing in cochlear implants, especially as it relates to our care model. We're gonna talk about how we care for those with cochlear implants and then sort of describe to you how things might be changing a little bit now and how things might change over time and into the future, really with a goal of leading to more patient-centered care. Today our focus is to share some of the research that underpins this care, right? We shouldn't be changing just for the sake of change, we wanna make sure that there is some research to support it and so we'll focus on that in our presentation today.

I do wanna mention that our discussion will focus mostly on the adult care model, although there is definitely some learnings that we're gonna take away when we talk about pediatrics as well. But a lot of what we'll focus on today is focusing on the adult clinical care model for cochlear implants. So let's dive in. As you all know, hearing loss is a chronic condition and it's something that must be managed by a patient for their entire lives. New advances in care are really supporting this more patient centered care model, and what this means is it allows the patient to manage their care themselves and have more autonomy in their care, which as you can imagine is important when you're talking about a chronic condition like hearing loss.

What we know based on research and literature is that patients who are involved in their care have much better outcomes and are better likely to manage their condition over time. One place that you can go for some research on this is a group called the Ida Institute. They have a lot of really great research and they champion patient-centered care in audiology in general, not just for cochlear implants. And they stress that patient-centered care should be guided by evidence and it can result in more efficiency in appointments, better adherence to treatment acomodations by patients, and an increase in patient satisfaction. So it's one of those things that's good for patients and it's good for you as well and good for the clinic.

I want you to take a moment and think about how this actually works in practice. So when you're seeing patients for care, either for hearing aids or cochlear implants or whatever you work with, is it really the patient need and and what the patient needs that dictates that care? Like things like the number and length of visits. Or is it just that you've had a set protocol for many years and this is what your scheduling system does? And so when you have a cochlear implant patient, they're just seen for this number of visits and that's it. And then think about how as our technology has improved and changed over the past several years, how might that actually support

you to be able to offer that kind of patient-centered care and kind of put the patient in charge of their care and their care planning?

In the cochlear implant industry specifically, we have a lot of converging trends that are leading us to consider how this care model might change. We definitely want to provide more patient-centered care, but we also have more and more patients who are seeking that care. In 2015, it was estimated that about 12% of the patients who could benefit from a cochlear implant audideologically actually got one. Now, that doesn't mean that 87, 88% of patients just decided they didn't want an implant. What that probably means is it comes down to access to care and knowledge about candidacy, being able to find an implant center, understanding they're a candidate and and getting into the center. We've increased the number of patients getting implants pretty significantly since 2015, right?

We've seen a lot of growth in the number of patients who've got an implant, but in actual fact, our penetration, the number of patients that we're treating out of all of those who could benefit is going down. And the reason for that is because of several things. We have an increase in awareness about cochlear implants. Things like the 60/60 criteria, which we'll talk about in just a second, are helping people to know better who to send for an implant evaluation. We have an aging population, right? That baby boom generation and we know that age is associated with hearing loss. And so that aging population means that there are more patients who could potentially benefit. And we have expanding indications, right?

Things like the expansion of cochlear implant candidacy to treat patients with single-sided deafness and the expansion of Medicare criteria to match the FDA guidelines last year. All of this means that the potential pool of patients has increased. So even though we're implanting more patients than ever before, were now only treating about 2% of the patients who get benefits. So in some ways we're kind of

going backwards. I mentioned the 60/60 criteria. As a quick review, what is that? A recent paper by Terry's Zwolan and her colleagues discussed how challenging it was for an audiologist who doesn't do cochlear implants on a regular basis to know who to send because the tests we use are different, there's a lot of reasons why it's challenging.

But we know that a lot of the implant recipients feel they waited too long to get an implant and we know that audiologists really wanna do right by their patients. They wanna send the right patients for care at the right time. So they looked at the data and they tried to find a good rule of thumb, an easy rule of thumb that could be used in referring a patient for CI. And what they found was that a 60/60 rule worked out really well. And what this means is that the patient has a pure tone average that is greater than or equal to 60 dB at 500 hertz, 1000 hertz and 2000 hertz, pure tone average and a single word understanding in the better ear of 60% or less.

When you apply this criteria, a full 96% of patients are candidates under our traditional candidacy criteria. So it's a really good rule of thumb that you can use, allows you to use that traditional test result that you might get in just a diagnostic audiogram to determine whether somebody might be a good referral for a cochlear implant. It means you're significantly likely not to over refer patients, but also that you're gonna catch patients who need treatment. And I also think it helps you a lot with counseling when you're more certain that a patient is a candidate. If you're a referrer, it allows you to speak less in maybes and a little bit more about what a cochlear implant can really do for them over a hearing aid.

And the good news is that when a patient does finally receive a cochlear implant, advances in surgical techniques and technology mean that the vast majority of patients are really happy with their outcome. In a recent large scale clinical trial of the CI 532 device, 95% of patients were satisfied with their outcome compared to 9% with their

hearing aids alone prior to surgery. I'd also like to note on this chart that 71% of patients are satisfied with their ability to talk on the phone. 68% are satisfied with their ability to listen to and appreciate music. So if you're someone that's been in the industry for a long time like I have, that's really different than it used to be. And it's really something when you think about how you counsel a patient who might be considering an implant, what they might be able to achieve with that implant versus maybe what they could in the past.

So we have more patients who are potential candidates and we have a growing challenge to support them to get the best care possible. So let's take a look at what our current care model looks like and how it supports patients and what happens after you make that referral. All of us have kind of a go-to person when we have challenging questions and Dave has always been that person for me. So I'm excited to ask Dave and know more about your thoughts on the current care model. We have more patients that need access, but our model doesn't seem to be keeping pace. What evidence do we have about how our care model is working for patients?

- Well, those are some very kind words, Amy, but I think you know we tend to have more discussions than Q and As, so- That's right.

- I do appreciate it. Right? So look, as you well know, the current clinical model reflects decades of cochlear implant practice, right? It's largely based on the clinical trials that were completed 30 years ago that dictated follow-up appointments reflecting a time-based kind of interval paradigm, right? Seeing the patient at one months, at three months, at six months rather than a need-based paradigm, like what follow-up does this patient actually need based on their performance? You can understand that because the studies to get implants approved and to expand indications over the decades needed a lot of data. So those data points were critical to building the

evidence we needed to go along. That being said, this model is very ripe for change and certainly the pandemic highlighted this need for change.

There's no standardized approach to post-op cochlear implant care. Most centers still base their protocol on the clinical trial model with a few tweaks of modifications over time that they've made. But when we look at critically, we find that adherence to this traditional pathway is pretty poor, even in centers that work hard to retain their patients. One study found that only 35% of patients attended their two year post activation visit. And finally we have challenges in the realm of billing and reimbursement. Arisa' study found that just over half of audiologists who worked in cochlear implant programs were unfamiliar with the most current billing guidelines, which do change pretty regularly. Their billing practices can be very inconsistent, which can lead to lost revenue and the reduced health of the cochlear implant programs themselves.

Patients are pretty unanimous as well, that the burden of follow-up care can be pretty significant. So in this image, you are seeing the steps that a typical patient has to go through to qualify for, receive, and use their cochlear implant, right? It's pretty crazy to see it spelled out like this. This is a simplified version of what can be an extremely long and pretty arduous journey for all involved. This information was taken from a recent article by Dr. Ashley Nassiri from Mayo Clinic and her colleagues, but in a recent clinical survey that Cochlear completed earlier this year, we confirmed that this is still true. The average CI patient can take up to 10 visits preoperatively and be required to go to as many as eight or more follow-up visits within the first year after surgery, right?

So that's potentially 18 visits that require missing work, arranging for childcare, travel, parking, insurance coverage, just time in general. So it's no wonder this burden can be a deterrent to patients who might be thinking about getting an implant. It's a pretty high barrier to injury, I think we could all agree. Another thing we know is that there are non-cochlear implant centers in every city, right? In reality, there is a relative scarcity of

cochlear implant centers with most of them being in larger urban areas. In another study by Dr. Nassiri and her colleagues, they looked at whether patients in more rural areas were still able to access care. And what they found in the seven large centers they studied was that about 91% of patients came from less than 200 miles away and 71% came from less than 100 miles away.

When there's not a cochlear implant center in every state and city, this means that there are a large number of patients and potential candidates who may not have the ready access to cochlear implant care. A recent survey that we conducted revealed that the typical patient traveled an average of 104 miles to get to the closest center. As centers grow, they need to address this geographic barrier, right? So potentially with satellite clinics, the use of Remote Care and other telehealth options and other tools. Another thing to look at is how well patients are able to adhere to the care schedule prescribed to them under the current model, right? As mentioned, it is still a time-based paradigm where patients come into the clinic at certain time intervals rather than truly based on what the patient needs.

Even clinics have confirmed that patients might not need the level of support that is being required, but sometimes what's precedent is just what continues. Right? In this study analysis that is shown here, two clinics found that their follow-up rates by patients were not nearly what they prescribed or expected. They dug into their EMR systems to determine if the testing just hadn't been done and maybe the patient was seen in the office for some other thing, or if they were never even seen back for any reason, be that audiology appointment, appointment with the physician, et cetera. What they found was that even at one year post activation, only 60 to 70% of the patients came back. And after two years, only about 35 to 50% came in for care.

So while clinically monitoring performance is a critical part of care for that recipient, they aren't coming in as often as we might think or endorse. And so it makes us

question, why is that? One thing we can look at is how these patients might be performing with their CI, right? Often patients are told it will take months or even years before they fully realize the benefit of their implant, but it's truthfully not what the data shows. There were several large multi-center studies we see over and over that map levels stabilize and performance stabilizes in just the first three months of implant use. Now this doesn't mean that patients don't continue to need care or that they don't continue to improve or need adjustments, but the intensive treatment and care that is needed in the first few months of implant use often doesn't need to continue throughout a patient's lifetime for most patients.

So why aren't those patients coming back? Well, the data suggests they don't really need to, they're performing well and the time and travel burden of seeking care is significant. So maybe there's a better way that we can provide this care.

- Yeah, that's amazing, Dave. You've given us some really good sort of food for thought. It definitely seems like there might be ways to change how we provide care both to increase access to cochlear implants and make that care more patient centered and focused on what they need. Cochlear's really been privileged to work alongside several of our industry partners and leaders and organizations to begin thinking about this challenge. And I would say that that's really taken off over the past five years and of course since the pandemic. And what I'd like to share with you is sort of a new vision of a clinical model that can support that more patient-centered care. The goal with this new model is to maximize performance and really put the focus on the patient need where it belongs.

And what happens is if we do that, we find we can give more efficient care and potentially open up care to more patients. So the new evidence-based patient-centered care delivery model uses hearing goals, satisfaction and outcomes to influence clinical decision making. The goal is that we provide clinics with a model that

they can follow that will maximize performance while still being efficient with those visits. This model is for general clinical practice, right? It's not a research protocol. Those patients would go down a different track. At present, this model is just focused on adults. So though as I mentioned, some of the principles may be applied to our pediatric care and that's an area that we're definitely exploring.

The model is based on evidence, which is very important. As Dave mentioned, we've had all this follow up care and we tell patients, it might take you six months or a year to really realize the benefit of your implant, but our studies just really didn't show that. Our studies show that patients really are doing very well within a month after switch on. And so it's important that we ground what we do and what we talk to with patients in the research and the literature. And the care needs to be able to be delivered through a variety of different modalities. So using that whole connected care platform from what we do in the clinic to what we can do with Remote Care and self-management of the patient, we wanna make sure that all of those things remain connected and allow you to stay connected to your patients even when they're not coming in for an hour long visit.

Right? The final thing I would mention about this model is that audiologists, we love to think about the exceptions, right? We love to think about those really challenging cases and I'm sure there's lots of folks out there going, wait a minute, what about that guy that just doesn't... That can't use his smartphone and that really needs lots of extra support and care. That's not what we're talking about, right? The idea is that if you focus on kind of what the care model should look like for the majority of patients who do quite well, quite quickly, we can reduce the amount of time we spend with those patients who are doing really well and instead spend our time with that guy who really needs you and have more time in the clinic to be able to take care of some of those more challenging patient situations.

So this is really focused on kind of those 80% of patients. All right, so we've led up to it. What does this new model actually look like? It probably won't look like rocket science to most of you who work with implants, but the idea here is to try to get patients up and running with their device quickly. We wanna use evidence-based tools and we wanna guide that by what the patient themselves is needing. So in this model we might use tools like objective measures during surgery to help guide that activation to get a good map on that patient as quickly as possible. Our goal at activation is a map that is audible and has an appropriate dynamic range.

And in this case it might mean that it sounds a bit loud to the patient to start, right? So we may be a little bit less slow about ramping up that sound, but we go ahead and try to get that patient acclimated to sound as quickly as we can. At a recent workshop at New York University, one of the audiologists there said, "We're really robbing time from patients if we don't provide them with their best map as quickly as possible." It was really an eye-opening moment where I think a lot of folks in the audience thought, you know what? That's a really good way to put that. After that first two week period, we begin an optimization phase, we're ensuring the patient can hear the sound and we optimize the map only based on the patient report and how they're performing, not just because we think we should.

What we find out is that maps are actually quite stable and they don't need a lot of tweaking or changing. Once we get to that stable map, the patient report should be the only thing that determines whether or not the map needs to be adjusted or changed. And after that first three month period, the patient will enter this maintain phase. Once they've acclimated to their device, we just do everything possible to let them monitor and care for the device on their own with minimal intervention from the clinic. They don't have to come into the clinic. And we can use tools like Remote Care to really help us do this. So supporting this new model is gonna require not just change in the clinic, but it requires us to think about the technology that the patients use.

We have to have that technology available to allow us to do this. And over the past several years, Cochlear has developed some revolutionary new technologies that support recipients self-management of their device. Our Smart Apps allow not just for kind of your typical remote control volume and sensitivity changes, but things like data logging, user-based map controls, like master volume-based and travel set at hearing goals and access to the data logging themselves and access to Remote Care within that app. We now have things like recipient solutions managers and these folks are people that help patients get acclimated to their device and take some of the things that audiologists don't get billed for. Pairing to an Apple phone and figuring out your Apple ID and moving that into a different kind of care model rather than having to take valuable clinic time to do that kind of thing.

Helping them kind of set up and get started on their journey. CoPilots, a new app that's available for new recipients to provide that early rehabilitation and tips and tricks and tools like Cochlear Family and myCochlear give them access to device information and troubleshooting rehabilitation and support. So the idea here is to extend the reach of the clinic. Patients should not be left on their own completely, but they should remain sort of connected to the clinic and connected to Cochlear even when they're managing their own device, even if they're not coming in for appointments. And we can use things like Cochlear Link where we can program and replace sound processors very quickly without the need for clinic involvement.

And we have things like Remote Care. So we've mentioned Remote Care a couple of times, but for those of you who are not aware, our Remote Care solutions for Nucleus patients include two different tools. One of them is Remote Check, which is an evaluation tool, consists of several different checks. Things like checking data logging, device impedances, speech perception, audiogram, questionnaire. The audiologist can assign these different checks, the patient completes them and sends them back to the

audiologist for review. The audiologist reviews it and then can decide if there's further follow up needed or what's necessary. So it really gives you a way to monitor your patients without them having to come in. Then Remote Assist is a tool that allows you real time connection through the Smart App.

So you can connect to the patient's device, you can make some mapping changes, you can make global map adjustments, you can change processor settings. All of this can be done remotely and very efficiently. We have a growing number of clinics enrolled in Remote Care. It's growing weekly and it's very exciting to see how clinics are starting to use this tool. This tool has only only been available now for about a year and a half, two years and it's been absolutely fantastic to see how different clinics and tools have started... Or different clinics have started using these tools to support their patients. So I'd encourage you to get in touch with your Cochlear representative if it's something that you might like to try.

So Dave, we're seeing patients less and we're trying to get them acclimated to sound very quickly. And this sounds like it might be a little bit risky, right? 'Cause you and I both remember when we used to have activations that had to last an entire day and we would tell patients we had to have them back every two weeks for the first six months and it was really a lot of care. How do we go from that to this? Have any clinics actually tried this with their patients? And if so, I mean how did things go? How did they do?

- They have, right? So efficiency in the absence of performance is not something that we're looking to do, right? So the first question was can we base our fittings more on objective tests and measures evidence rather than depending solely on patient report, which is important but maybe has been elevated importance beyond where it really needs to be. There was an interesting study several years ago that gave us a confidence that we could use data in our fitting software and objective information about performance to guide the fitting. This study used a reduced visit schedule and a

consistent process and approach to patient fitting. All the clinics in this study followed the same basic model and collected data at similar points in time.

Things like CNC word scores, auditability, et cetera. The data showed comparable performance outcomes for this method as compared to a group of experienced clinicians. And this data really kind of helped lay the groundwork for an evidence-based clinical care model. While that study showed that the patient can benefit and get a good map using more objective tools and with a reduced visit schedule, we wondered if there was a benefit for the clinic as well, right? Is there something in it for both parties. In this study that you see here, three clinics followed a new evidence-based clinical model that was based on what was learned in that previous study. Each of these clinics completed a baseline survey to establish their current state to understand how many visits and how much time was spent with newly implanted patients, during that first year of CI use after surgery.

The new model was then implemented and the results were frankly pretty striking for the clinics. On average, they saved three hours of time per patient in the first year of implant use, right? Which is no small feet. As an interesting side note, the number of hours spent with patients in that first optimization period is in line with what was reported in the literature for hearing aid patients, right? So reducing the burden of care for implant patients to something comparable with the delivery that they're used to with their hearing aid follow ups is great. It's increased familiarity for them, right? So this was definitely a reduced burden on the clinic and the patient. Of course, the other question was to confirm that the patients with a reduced clinic schedule using the specified protocol had equivalent or even better performance compared to those patients who were seen more often with a more traditional programming approach.

And what you see here is that they did, right? The data you're looking at for the patients enrolled in the CI 532 benchmark study is on the left. And that's from 2019

compared to the reduced visit on the left here, I should say. I got that backwards. The CI 532 benchmark study is on the right. The patients involved in this new reduced visit model are on the left. And what you can see is the performance is really comparable, right? The short answer is yes, clinics who explore this type of model have seen similar performance from their patients and in patient surveys they're very satisfied with their care. I think that what this showed is that more visits doesn't always equal better outcomes or better care.

The other question is how patients might react to receiving some of their care remotely. Right? We've kind of told them that you need to see us a lot so we can get you where you need to be. Remote Care was only just getting started when this study began. This data you see here is from a controlled market release of Remote Assist and demonstrates that patients are really quite satisfied with it as an option. A very large majority of patients felt that Remote Care saved them time and or money and would want it to be a part of their future care with a third of them saying they wanted only Remote Care from now on. So I guess be careful what we wish for, right, Amy?

- Yeah, right. They don't even wanna come into the clinic. I think it's interesting 'cause I think sometimes we go back to what we've always done, but inpatient is a new patient, they don't know what we've always done-

- That's right.

- So when you tell them they can get some of their visits... They're gonna have this many visits and some of them can be done remotely, they're like, great, fabulous. Sounds good. Exactly.

- So it's really exciting and it's encouraging to see some of these pioneer clinics and what they've done to really support this model. We talked at the beginning about how

many patients need implant care and how few patients we were able to treat. And something that we hear time and time again from clinicians and especially referring clinicians, is how often they have a patient who's a great candidate for an implant but they just aren't interested in pursuing it because of that barrier. And sometimes it'll be kind of surgery, they don't want surgery, but it's also just everything. All those visits that Dave showed you at the beginning, that's a large burden and sometimes patients are just like, I'm just not sure I can fit this into my life.

With new models of care and with new technology, our goal is to provide a complete suite of care solutions with something that will support patients' needs and get them be able to access care quickly and efficiently. And we hopefully can do that and support them wherever they are, whether they're in the clinic, whether they get their care remotely, whether they're managing their care themselves or with the data and the information that we receive from surgery. And what I'd like to do, just to wrap up here, is to share a story that we heard from a clinic who started implementing this new model. They had a 72 year old who was a very active guy and he had been a candidate for implant for many years.

He lived quite far away from the clinic, so one of those people that would've had to travel in and he always said no. So he's referring audiologist had been begging him for years talking about what you can do with the hearing aids, but it was just too much. He looked at how far it would take him to get into the clinic and he's just like, this is not gonna work. Especially in the wintertime. He never thought he'd be able to manage all those visits. And then a few years ago his local audiologist during the pandemic knew that the audiologist at the implant center was doing more remotely and was seeing patients on a kind of reduced schedule.

And so finally he said, "Okay, maybe this is something I can get to work." He was given the option of participating in this new model and in their new approach he had two

in-person follow-up visits in the city, right? So he had his activation and then he had one follow-up and the rest of his visits were all done remotely. He's performing better than he ever expected with his implant and he's really thrilled with his progress. So this case is such a good reminder, I think, for all of us about all those patients who might never receive care if the care model isn't really truly focused on their needs and what they need. And we're excited to see more cases like his in the future.

So it's really exciting to see what the future might bring. I can't thank you guys enough for joining us today. I'd like to leave you with some parting thoughts and conclusions. So first, we all have a goal of improving access to care. We want patients to get the right care at the right time. So be sure to remember the 60/60 rule if you don't work with cochlear implants on a regular basis, if you want more information about this, our Cochlear representatives would be more than happy to share. We've got things like little magnets and reminder tools and that kind of thing that we can share for you. The second thing I wanna make sure that everybody remembers is that the vast majority of patients are very happy with their implant and they wish they had gotten it sooner, but just like Jim, in many cases, it's the burden of care that can hold them back.

So it's on all of us to really consider how we can provide more efficient and patient-centered care. And then finally, it's the advances in technology that allow us to do this. Cochlear is committed to not just improving those patient outcomes, but also improving access to care and ensuring patients and clinicians have technology that can support them to do what we know that we need to do to help patients. We invite you to follow us on this journey and find out more by checking out some of our other learning opportunities. You can subscribe to pronews@cochlear.com to keep up to date on new technology and clinical tips. If last year was any indication, these new clinical models will be the hot topic at our conferences in the spring.

Things like AAA and ACIA. We'd love to see you there, encourage you to attend our manufacturer's symposia and check out our booth. If you want more information specifically about Remote Care, we do have some new AudiologyOnline courses about Remote Care for Nucleus as well as for Baha. So we'd encourage you to check those out on AudiologyOnline. And then finally, we actually have a new series that's coming in the spring called "Inspired by a Lifetime of Hearing Performance" where we have some leaders in the industry who are gonna share the latest research on performance and how to maximize performance in implant patients. The best way, the easiest way to follow that is if you follow us on LinkedIn, we'll go ahead and those links will be shared and those webinars will be shared on LinkedIn. So thank you all so much for your time and have a wonderful rest of your week.

- Thank you.