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The Evolution of Pediatric Candidacy for Cochlear  
Implants: A New Indication  
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- [Natasha] Hello, everyone. My name is Natasha McDougald, and I am the pediatric product manager here in Cochlear Americas. At Cochlear, we understand it takes a village to raise a child with hearing loss. We foster a partnership with you along a child's hearing journey, providing you with a wealth of resources to enrich their hearing progress, opening up a world of possibilities. In this vein, I am delighted to welcome you to The Evolution of Pediatric Candidacy for Cochlear Implants: A New Indication, presented by Dr. Melissa Tribble, manager of the Pediatric Audiology Department at Stanford Children's Health in the San Francisco Bay area. Dr. Melissa Tribble received her Bachelors of Science and her Doctorate of Audiology degree from Kent State University and joined the Pediatric Audiology Team at Stanford Children's Health in 2007. She is a licensed dispensing audiologist and has been an active clinical educator for audiology students, had served on the board of directors for the California Academy of Audiology, and has been lead audiologist for the Cleft and Craniofacial Team at Stanford Children's Health. Taking pride in providing family centered care, Dr. Tribble's expertise in serving the pediatric population is centered around hearing aid, assistive listening devices, and cochlear implant. She provides a full range of services to cochlear implant candidates and recipients, including the programming of all FDA-approved manufacturers of cochlear implant. On a personal note, as a fellow Silicon Valley geek, Melissa is a go-to resource for the Marvel Cinematic Universe, always amazes me with her movie recommendations, and makes me laugh with the warmth and finely developed sense of humor, especially around her obedient human training with her dog. Thank you so much, Dr. Tribble, for doing this presentation, and I want you all to please welcome Dr. Melissa Tribble.

- [Melissa] Thank you so much, Natasha, I really appreciate your introduction. Hello, everyone. Thank you very much for your interest in this course. I'm excited for the opportunity to share information regarding the new indications, as well as share my team's experience with early implantation. I hope that you find this information not just

informative, but relevant to your interest and experiences. Very quickly, I would just like to review the plan for this course. Following this introduction, I plan to review the history of pediatric cochlear implant candidacy, industry data supporting cochlear implantation for infants nine months of age and older, our experience at Stanford Children's Health with implantation of children under 12 months, current technology for pediatric cochlear implant recipients, and, finally, if time permits, I will take some time to answer any remaining questions that you have. I'll be honest and share that this is my first time presenting virtually. So in planning this, I realized that it will be helpful for me to take some time to ask questions of you as well. Throughout this presentation, I plan to ask some poll questions that will allow me to get to know a little more about those enrolled in this course and your experiences. I hope that you will take the time to engage in some of these questions.

.So to start off my poll question, I'm interested to learn who is in our live audience today. So I should now see the opportunity to answer this question. I see a few more coming in. Okay. I think I'm gonna stop there. And it looks like we have mostly audiologists as expected, but we do have a speech pathologist in the group and someone else in another profession. So that is great. Thank you for answering my first question. And for my second question, I am just interested in, sorry my slide went a little ahead of me. And who is in our, sorry, there we go. What is your experience with cochlear implants? All right. And there is a wealth of experience here. We have some people with about one to three years, a good number of people who have 13 or more years of experience. All right. Well, I probably should have some of you jump in and help me with this course. But thank you for answering that question, it's good to know what the years of experience is of the people who we have in our course today. And then let me see if I have this . I'm just gonna skip this slide. Okay. Based on your poll responses, it seems like we have quite a bit of variety in the professionals here today, as well as the amount of experience of working with cochlear implant recipients. It is the goal of this session that you will walk away with the ability to describe the history of

pediatric cochlear implant candidacy, describe the data that supports earlier implantation in children with bilateral severe to profound sensorineural hearing loss, list Cochlear's new indications for pediatric cochlear implantation according to the FDA, and list features in modern cochlear implant systems which contribute to success in pediatric recipients. Again, I do hope you find this session to be engaging and informative. We will start off today with discussing the history of pediatric cochlear implant candidacy. So cochlear implants were initially approved for adults with bilateral profound hearing loss in 1985. In 1986, early leaders in the area of cochlear implantation held a pediatric conference which sought to further understand how technology could be effectively used in children. This, ultimately, laid the foundation for the factors that would be considered when recommending cochlear implantation in children, and it set the framework for the FDA approving cochlear implantation for children in 1990. The original guidelines set the minimum age for cochlear implantation to be 24 months. In 1985, the NIH released a consensus statement acknowledging that for most, so I'm gonna emphasize most, who receive a cochlear implant, the technology improves their communication abilities and leads to positive psychological and social benefits. This then leads to the year 2000 when the FDA approved lowering the minimum age of cochlear implant in children to 12 months. For almost 20 years, there has been minimal movement with regards to updating and changing the age criteria for children.

So that is why there is a black, a black bar there. That's me being dramatic. This is my opportunity to be dramatic 'cause I'm not typically dramatic, but I'm gonna be dramatic here 'cause it makes sense. I do wanna acknowledge that cochlear implantation for single-sided deafness was approved down to five years of age in 2019. But specific to children with bilateral hearing loss, there hasn't been movement in changing the FDA criteria since 2000. And here we are in 2020, and it has been quite the year to remember. But one bright spot this year is the update of the indication for cochlear implantation in children. But before discussing this indication, I wanted to

quickly discuss this timeline from another perspective, specifically, how does this timeline of changes to the FDA criteria compare to the experience of patients and their providers? And, also, what was happening in the meantime? This visual is a breakdown of the changes in the FDA criteria in relation to the evolution of early identification and early intervention. As most of you already know, historically, specifically prior to the initiation of universal newborn hearing screenings, unless known significant risk factors were present, children, typically, were not identified with hearing loss until around two to three years of age. It wasn't until the early 90s that newborn hearing screenings became available, and it wasn't until the late 90s that we had true universal newborn hearing screenings in all states. The early 2000s saw the implementation of the goal to screen by one month, diagnose by three months, and provide intervention by six months. And in 2017, all states in the United States had an early hearing detection and intervention program.

For me, as I try to paint this picture, what's evident is that although the needle didn't move much with regards to the change in FDA criteria, there was significant movement in early identification and implementing early intervention. I'm curious about your experience during this time and have one specific poll question I would like to ask. Although not approved by the FDA, do any of you have experience working with children who were implanted prior to 12 months of age? This is not just for my mapping perspective, I'm wondering if you've referred anyone for early implantation, if you've provided therapy to someone who was implanted prior to 12 months of age, or any other experience. All right, I was actually anticipating this exact spread, so I'm proud of myself. All right, so we have, oh, wait it's changing a little bit. But not much. All right, awesome. Okay, so it looks like about 60% of you have experience with working with a child who was implanted prior to 12 months of age. We're all a little bit of rule breakers in this group, that's good to see I'm in good company. Again, to give kudos to the work that has been done over the years, let me get back to my slides here, I want to take the time to acknowledge what has been happening in the

meantime. Specifically, there has been more awareness of earlier identification and early intervention outside of our immediate circles of audiology and speech pathology. For example, I find that we have many more pediatricians who are making referrals to our clinic when there's even any hint of concern of hearing or speech and language delay, so I know in our area we have quite a few physicians who are very eager to have hearing assessed. I also find that some parents are more eager to start the process than to want to put things off. I would say it's fairly often that I have a parent tell me that, "This is a critical time for my child, "and I want to make sure we are as proactive as possible." I do recognize that there are still a lot of parents out there who do not share that same sentiment, but in my years of experience, I've definitely noticed that parents are more proactive now than they were in the past. As noted by the responses in the poll question, infants under 12 months were being implanted at various practices and implant centers.

So, specifically, about 60% of you say that you have experience working with children who were implanted prior to 12 months of age. And there have been changes in implant electrode arrays and surgical approaches as well as advancements in external components of implant systems. Implants have gotten thinner, MRI compatibility has been improved upon, as well as surgical approaches. I am so impressed by how quickly most infants and children bounce back after their surgery. Lastly, there has been research studying the impact of these advances on cochlear implant recipients overall as well as those under 12 months of age. And I plan to review this with you now. We now have research that has confirmed that, first, that cochlear implantation is a safe procedure, that the electrode array remains stable, that auditory deprivation has negative impacts on development, and that earlier implantation prevents irreversible gaps in development. And, finally, we've learned that early access to sound and early intervention are the dynamic duo. We truly do need both for our patient to be successful. This new indication is specific to Cochlear Americas. I would now like to share the industry data that supports the lowering of age criteria for cochlear

implantation in children. This study was sponsored by Cochlear Americas and involved five sites who participated in the data collection. The sites that participated, as you could see here, were the CI team at NYU, the CI team at SickKids, the CI team at UNC, the CI team at Hearts for Hearing, and our CI team and Pediatric Audiology Team here at Stanford Children's Health. The purpose of the study was to gather safety information on children implanted prior to 12 months of age by performing a retrospective chart review. The study looked at the demographics of the patients, the surgical variables, anesthesia variables, and postoperative complications. There were a total of 136 patients under 12 months who were implanted at the five sites between 2012 and 2017. As you can see, majority of these patients were implanted prior to seven months of age. 61% of the patients were implanted between nine and 11 months of age. And only a very small fraction, about 2%, were done less than six months of age. Majority of the patients received bilateral simultaneous cochlear implants.

It was about 78%. And regarding the common comorbidities, they included developmental delay, genetic syndromes, congenital malformations, CMV, meningitis, and seizures. Regarding the surgical variables, they looked at the weight of patients, estimated blood loss, the duration of anesthesia, and the recovery time for all patients. So this was regardless of the unilateral and bilateral cases. And as you can see here, we have a nice comparison of what was found between the unilateral cases and the bilateral cases. I think one thing that's good to point out is the duration of anesthesia. Although a bilateral case does take longer, it's definitely not twice as long. And the recovery time is not significant either. There's not a significant difference in that recovery time either. Another thing I'd like to point out is the estimated blood loss. And although there is a large range between the unilateral cases and the bilateral cases, on average, the blood loss is not significantly different. So I think what this information does demonstrate is how efficient a bilateral simultaneous surgery is and in situations where your work-up does dictate that bilateral simultaneous may be the way to go.

Specific to reportable events, for those who may not know, reportable events are any issues that are encountered during the study. These can include additional diagnosis like a diagnosis of Usher syndrome. It can include unrelated illness such as cold symptoms. It can also include issues at the surgical site like swelling or infection at the surgical site. In this study, it was found that 39 out of 136, or about 29%, of the subjects experienced a reportable event. Eight events were related to temperature regulation during or immediately after surgery was recorded. Out of the events that were reported, five events met the medical device reporting criteria due to their relationship to the device procedure and the requirement of surgical or antibiotic intervention. Examples of such events are device issues that require explantation or medical issues such as wound infections that require hospitalization and/or intervention and permanent disability such as facial nerve paralysis due to the implant surgery.

In this study, there were no device malfunction reported, however, the five cases included a patient with a cerebrospinal fluid gusher, one with swelling at the site, one with treatment for infection at the site, one with a seroma that required intervention, and one with a seroma for which the device was explanted and reimplanted. The 3.7% MDR rate was similar to the manufacturer's database of 2.5% of those implanted prior to 12 months and 3.1% implanted between 12 and 24 months. The slightly higher rate in the study is not surprising due to the mandatory reporting imperative within a clinical trial versus the voluntary commercial reporting practice. Overall, the rates are similar, and substantial difference was not seen in the surgical or postoperative complications profile for these children that were under 12 months. Temperature regulation intraoperatively and postoperatively led to the recommendation that a pediatric anesthesiologist should be present during surgery for infants implanted under 12 months of age. Here, we are looking at the events involving the device and procedure. The big take-home here is noting the rate of reportable complaints is not any more significant for children implanted under 12 months than it is for children implanted

between 12 and 24 months. On the table, I just wanna highlight the last two columns, and specifically looking at the reportable complaints rate, it was 2.1% for the infants nine to 11 months, that kinda total average there. And that is not too dissimilar from what was predicted for patients that were in the 12 to 24-month age range. And then the overall complaints too is not too significant either. Across the United States and Canada, cochlear implantation under 12 months of age was routinely performed in a variety of clinics although the practice was not approved by the FDA in that age group. Average surgical parameters and reportable safety events with implantation in this population represented here as collected by five North American clinics. The study found that a substantial difference is not seen within the demographics, surgical complications, nor with the postoperative complications. Finally, the communication outcomes demonstrated in the literature show an undeniable benefit of early implantation for those children who qualify based on their degree of hearing loss. As we move on to the next sections of this course, I find myself once again oh so curious about your experience and would like to ask a few more poll questions.

Namely, in your experience, do you feel that the process for a pediatric candidate to be implanted early is smooth? Okay, looks like we have some stability in our answers here. As you can see, oh, we got a couple more coming in. All right, not quite 50-50, but definitely a divide there. All right. So we got about 40%, 41% say it's very smooth. So for you guys, let's exchange information so you could tell me how that works for you 'cause I wanna hear your stories. And then we have close to 60% that are saying that it's not quite as smooth. And so for my next poll question, I'd like to ask, how long do you feel it takes a pediatric patient to complete the process? And this is just like from time of referral, maybe identification to the time of surgery. All right. It looks like I'm in good company. All right. There's an impressive group of you out there, about 8% who can get this knocked out in about one to three months. Again, let's exchange information somehow, someway, so we could chat. And it looks like, and you'll find out this in a little bit with our group, we kind of are in the same realm of that four to six

months. So about 60% of you are about four to six months and then some of you feel that it's taking greater, around nine to 12 months. Okay. And I'm gonna move on to my next poll question, which is, what are common challenges patients and referring providers face to complete the process in a timely way? So you are okay here, you can choose as many options as you want. You can choose all of them, you can choose none of them. I'm gonna give this one some time to give you guys enough opportunity to check, to check the options. I'm gonna screenshot this for myself. Okay. This is a really good question. It's good to see what everyone's experience here is. I believe you guys can see all the polling and that you could see this, but just to share, it looks like a majority feel that one of the challenges is expectation in the social issues of the family. And then another good amount of you find that the timely referrals and scheduling is a big challenge. And then kinda following up to that are the long wait times for appointments, the delay the diagnosis, and lost to follow-up. Lost to follow-up is definitely one that keeps us up at night for those kids. And it looks like we have someone who has never faced that problem, or that not aware of who a good candidate is.

So I'm hopeful that today, again, that information I'll be sharing next will be able to address some of thong things and also possibly let you know you're not alone. Again looking at the experience that everyone has here and then also looking at your responses to these questions, there is a lot of variety. And I recognize that some of what I'm presenting here today is preaching to the choir. But I do want to take some time to share our experience here at Stanford Children's Health working with this population and to just let you know either that you're not alone, and maybe on the other side, I can share information for how we try to navigate moving our clinical practice with the times. So, specifically, I plan to share our process for working up hearing loss and how we strive to expedite the process; our patient data, and I plan to share some case examples; and then I also plan to share how our team works to navigate care and rehabilitation postactivation. First, I just wanna give a shout-out to

my awesome team here at Stanford Children's Health. I'm gonna highlight our audiologists who are amazing. We are a very young and diverse group. And I am just so honored that I have the opportunity to lead such a fantastic, passionate group of young professionals. And also that I have the ability to learn from Jan Larky as well who just amazes me with her knowledge of cochlear implants too. Our team is unique in that we all are kind of Jack of all trades. Most of us doing diagnostic ABRs, fitting hearing aids, and also doing cochlear implant mapping. I believe that that also helps with some of our access and our ability to help patients navigate the system. I do also wanna give a very enthusiastic shout-out to speech pathologist, Kayla. I do not want her to ever leave us.

She is fantastic and is just a wealth of knowledge and is just a great collaborator for us. And then our otologists are just a very strong group of surgeons who are passionate about how we can continue to provide excellent care for these patients. Our process for working up a potential candidate is fairly standard with regards to our audiologic evaluations, our otologic evaluations, and speech evaluation. Our audiologic assessment is pretty standard. Regarding our audiologic work-up, ASSR is a standard for our practice. When we have a click response, that is no response and ANSD has been ruled out. So we do like to have that diagnostic assessment. We do incorporate a behavioral hearing evaluation, and that would be aided and unaided. And then we also want to make sure that we have appropriately fit amplification. We do have a pretty robust loaner hearing aid bank as well. So for some of these patients that we know are on that , we are able to fit early and then also provide families with hearing aids to use in the meantime. Regarding our otologic work-up, this, typically, includes lab work. Routinely, our surgeons will test for Connexin 26 . In the past, they used the test for Connexin 30, but I find that they don't do that as much. And then imaging is standard with the CT scan and MRI. With our surgeons, sometimes they make the decision about CT scan and MRI based on our results. So if we're finding measurable hearing, if we're getting any type of threshold, then they may lean towards doing a CT scan over

the MRI. However, if it's no response or the ASSR response is no response at the limit of the equipment, they may be more likely to pursue doing an MRI instead. But our audiologic work-up does help our surgeons with what they opt to do for the imaging. We also have a speech and language evaluation and we make referrals for developmental assessment. And the goal of this is to establish a baseline to monitor outcomes and growth, and also to identify anything that can have a role in adjusting expectations. We make referrals to our developmental clinic, especially when there are other comorbidities present that can have an impact on what realistic expectations may look like for a patient and their family. Noticeably absent on here is the social work and psychosocial assessments.

To be honest, this is a sore area for our group. And we are working to have designated support for our team. But in meantime, we make referrals to our social work department on a case-by-case basis for families that are showing clear red signs of needing additional support. So lowering the age required, it means that we also need to have a structure in place to allow for these children to go through the process as quickly and smoothly as possible. So here is just a quick review of, one, how we aim to do that, and, two, how referring providers can help with this. First, one my goals for my team is to keep everyone in the loop regarding cochlear implant candidacy and what's needed for an evaluation. Actually, right now we're working on adjusting our protocol so that everyone is clear about what's needed and so that we all can have a hand in the work-up for the audiologic component. I believe that it's important that we each have the knowledge to recognize a potential candidate. And this allows for all of us to be an advocate for educating a family regarding their options as this is key to getting patients and families on the right path. Second, it is imperative to have as much information as possible at the time of referral. So receiving full reports which include the waveforms, when warranted, can be helpful for us to determine if we feel the result should be repeated so that we can schedule the appointment correctly. Historically, we always repeated test results, but in some cases when the results come in and we're

able to review them in their entirety, and they look complete and we don't have significant concern, we may not repeat the ABR, we always repeat the behavioral. So having that information and as much information as possible allows for us to be able to make a decision about what that initial appointment should look like so that we can get everything set up correctly. Basically, the more information we have at intake, the better we could set up the visits in a timely way. Third, Telehealth visits as a form of intake. This is newly been incorporated by our team, but we are finding value and success with this. We offering Telehealth intake visits for potential cochlear implant candidates. This type of visit does not take the place of having the patient come in person for a diagnostic assessment, but it does help us get the ball rolling regarding history taking, expectation setting for the in-person appointment, and also for the physicians to start placing lab orders and orders for imaging. I'm sure that there are a ton of questions regarding billing for this, and thrust me, we're trying to figure that out as well.

But at least for the otologists, this can help with them putting the orders in for the radiology evaluation and for the lab work, and it can save a lot of time. In a large medical center like ours, sometimes it can take two months for a person to get imaging, which, as you can imagine, will have an impact on a timely movement through the process. Lastly, we are very fortunate to have our audiology services in the same location as our otologists. And we are even more fortunate to have a speech pathologist who is designated to our service and is in our same site. This allows for us to be able to coordinate visits for the same day when possible. is our medical record system and we have a set-up to allow for paneled appointments. What this does is it forces the scheduler to schedule all three visit types on the same day. And if that cannot occur on the same day, then they are forced to schedule them all within a specific timeframe and actually in a specific order. And if that still cannot happen, then the scheduler is prompted to contact us directly. So they contact our department directly, at which our CI coordinator will work to find ways to have the patient seen in a

timely manner. Our CI team here at Stanford Children's Health is relatively young compared to most out there. This slide details some of the demographics of the children we have implanted who are under 12 months of age. Over the years, we have done a total of 23 cochlear implantations on children under 12 months of age. 21 of those patients received simultaneous bilateral cochlear implants. 57% of the children, and I found this to be really interesting myself, but 57% of the children implanted under 12 months of age have tested positive for Connexin 26 mutation. 69.5 of these patients are currently using, listing a spoken language as their primary communication mode. I do wanna note that we do have patients that we implanted here, but they like moved away, so I don't have any updated status on them. That's about 17% of the patients that we have. And then, lastly, and this kinda goes back to the experience that others have with how long it takes to get through the process, it takes our patients about six months to receive surgery after the original referral to our clinic. So please keep in mind, some of this may be related to the time at which the child was initially referred to our clinic for evaluation.

For example, kiddos that came in at an older age were usually assessed and implanted within two to three months. Whereas, someone who was referred very early, like at a month or two of age, typically wasn't implanted until around seven or eight months. Post activation, we work closely with our speech pathologist and take advantage of performing co-treatment sessions. These sessions are used for different reasons, such as families traveling from a great distance, assistance optimizing a map once the map is relatively stable, allowing for patient and parent coaching, and making sure we are sending a clear message to families about the importance of rehabilitation with their child's use of this technology. So on these days, we will team up with a speech pathologist. We, actually, schedule so that we're both blocked together, and then we work through the appointment together. We also strive to have good collaboration with early interventionists and local deaf and hard of hearing programs. Due to HIPAA, a core component to good communication is having the release of information on file.

This is key to timely communication and receiving reports. We also refer to area programs such as BabyTalk. BabyTalk is a program that is run between the Weingarten Children's Center and Stanford School of Medicine. And they provide teletherapy for children between zero to three years of age. Listen To Me! is a summer camp for area children who are either cochlear implant recipients or will be soon receiving a cochlear implant. that's provided to families to help them navigate the rehabilitation that will be required for their child. Although we are focused on good auditory access and language development, we also find it important to stay in tuned with the child's overall development. When developmental concerns become present, we work to initiate this discussion with the parent and possibly their medical home to have the child seen for developmental assessment. Lastly, Telehealth visits in collaboration with the CI manufacturer's patient supports team can be very helpful. With regards to Telehealth, COVID-19 has forced us to figure out how to continue to stay connected with our patients, and Telehealth has allowed for that. We are now using Telehealth visits for the purposes of counseling and for checking in with newly activated recipients.

Our speech pathologist, who I just cannot praise enough, has been beyond amazing and has been providing teletherapy for many of the patients she was previously seeing in person. This has gone a long way, especially since many of these patients have not been able to receive this service from school. Lastly, the three cochlear implant companies all have patient support teams that are there to support the patient and the professionals. I've had patients frequently reach out to them for support and when they have questions. So now I would like to share a few case examples of patients we've seen in our clinic who were implanted under 12 months of age. I call this one the case with the multiple opinions. This patient was born to a normal pregnancy and delivery. She failed her newborn hearing screening and received an outpatient newborn hearing screening at five weeks of age. She, ultimately, had three ABRs. She had two at one location and one in another location all within about two to three months of age, and all with various interpretations. Specifically, her first ABR suggested a mild to moderate

sensorineural hearing loss. Her second ABR suggested a mild to moderately severe sensorineural hearing loss. And her third ABR that was done in another location noted a present wave one and absent wave five. So they were concerned about retrocochlear involvement. This resulted in her coming to our clinic for a third opinion, which ultimately was her fourth ABR. During that visit, we diagnosed a bilateral severe to profound sensorineural hearing loss. She, actually, underwent another ABR with ASSR at seven months. We did that under sedation. And it was just a way to just confirm everything. But, again, confirmed her severe to profound sensorineural hearing loss. This patient was fit with hearing aids after obtaining medical clearance. The family was counseled regarding all communication options. The family was connected to local auditory oral program in addition to early intervention program. Her medical work-up noted a negative CT scan and she was positive for Connexin 26. Per our protocol, she received a speech evaluation and developmental assessment. The developmental assessment was normal, speech evaluation noted delayed expressive and receptive language, but not too significantly delayed.

We did her behavioral hearing evaluations aided and unaided. And, ultimately, this patient was implanted at 10 months of age bilaterally. And post cochlear implantation, so she received early intervention and was also enrolled in her local auditory oral deaf and hard of hearing school, and she started there at infancy. She received intensive therapy focused on listening and spoken language. The family participated in the local Listen to Me! camp. And they are very invested and dedicated to their oral rehabilitation plan. So as you could see here, she gets great benefit, she performs really well on her AzBio and CHC works look great. Today, she is a six-year-old in a mainstream classroom with continued speech therapy. I put deaf and hard of hearing support, but she, actually, has an educational audiologist. For my second case, this one is the importance of timely referral and benefit of developmental assessments. This patient was born to an uncomplicated pregnancy and delivery. He failed his newborn hearing screening and he underwent a diagnostic ABR at an outside facility at two

months of age. Referral to our clinic was received when the patient was five months of age, but we didn't receive the records until he was six months of age. The patient was ultimately seen in our clinic from this outside referral for the first time when he was eight months of age. This is just the ABR results from the outside facility and their report there. He underwent his cochlear implant evaluation at eight months of age with a speech evaluation which noted a delayed language development. He also underwent a developmental assessment at nine months of age which noted delays across all domains. So that was not just in his expressive and receptive language. And earlier learning skills were noted to be delayed. Genetic testing was negative and his CT scan was normal, there was no concerns there. And he underwent bilateral cochlear implant surgery at 11 months of age. What I suspect is that when we identified that he likely was gonna go that route that what we did while we waited for some of the other things to be approved was that we secured a surgery date. And that will come up for the next case as well, but we kinda secured a surgery date while we're still working things up. I know this differs for, here in California, California Children's Services, we kinda need to show everything before we have approval. But, in general, that is sometimes what we do especially to expedite things for these young kids. Post-cochlear implantation, there were concerns regarding aggressive behavior and limited social interaction. And this resulted in a referral for follow-up developmental assessment.

And, ultimately, at three years of age, he was diagnosed with autism. Today, although he fatigues quickly, it seems like with his test results here that he is getting good benefit from his cochlear implants. He is receiving ABA therapy. Instead of being in a deaf and hard of hearing program, he is in a special day class and he's receiving speech therapy twice a week. He's a full-time user of his cochlear implant. If it falls off, he will put it back on, and he does seem to have attachment to his cochlear implant. And for my third case, this is the ideal case. This is when everything goes as expected. This patient was born, again, to an uncomplicated pregnancy and delivery. She failed her newborn hearing screening and was seen for an outpatient screen at four weeks.

She was seen in our clinic for a diagnostic ABR and ASSR at two months of age, which confirmed the presence of bilateral severe to profound sensorineural hearing loss. For this patient, I was doing her ABR, and in counseling the family, saw how anxious they were about getting the ball rolling, so I ran down the hall to ask our ENT if he would be kind enough to see her and the family on the same day so that we can get medical clearance and start the work-up. And he said yes. This patient was fit with hearing aids pretty fast. I think like within a couple of weeks we had ear molds in and we got hearing aids on her. She was fit at two months of age. Similar to the first family, they were counseled regarding communication options. They expressed wanting to focus on listening and spoken language, so we made the connections for that. This patient is Connexin 26 positive. She underwent a speech evaluation and developmental assessment as well. We did our behavioral hearing test before surgery. This patient was implanted off-label at seven months of age. Now she's receiving early intervention, she is enrolled in the local auditory oral deaf and hard of hearing school. She receives intensive speech therapy.

The family also has participated in Listen To Me! Again, they are very dedicated to her oral rehab plan. Now this patient is 23 months. She's speaking in two to three-word phrases. She knocked my socks off several months ago when she's emerging for CPA. She, actually, was doing CPA. We did a combo CPA-VRA for her appointment, but she can do CPA and is patient and listens, and it was just, I just was in awe. It was a shock to see. All right, so we are in the homestretch, and now I plan on discussing current technology and considerations for the pediatric population. Specifically in this section, I will discuss Cochlear American's indications for pediatric CI candidacy, current technology considerations for the pediatric population. Examples in this section will be specific to Cochlear Americas. But the overall idea is that this information can be considered regardless of the CI manufacturer. Lastly, I would like to share other considerations that may be helpful with working with the pediatric population. And this is gonna be specific to COVID-19. This slide is just a reminder of what the indications

have been. Cochlear implantation has been approved for children 12 to 24 months of age who have bilateral profound sensorineural hearing loss and demonstrate limited benefit from appropriate binaural hearing aids. And then the criteria changes to severe to profound once children are 24 months of age. And they still need to show the limited benefits from binaural hearing aid trial with word recognition score when that can be obtained less than or equal to 30%. The new indications now state that children nine months of age to 24 months of age need to present with bilateral profound sensorineural hearing deafness and still demonstrate the limited benefit from appropriate binaural hearing aids. Children who are two years of age and older may demonstrate the severe to profound hearing loss bilaterally. Again, I do wanna make sure that I note that in order to reduce the risk of anesthetic related adverse events, a pediatric anesthesiologist should be present during the surgery for any infants implanted under 12 months of age.

So I've been talking for quite a while and I just miss hearing all of your opinions. So for my last poll question, I'm going to ask what is your favorite feature, and this is specific to the pediatric population, of the modern cochlear implant processor? Okay.

Datalogging has a big fan. All right. It looks like datalogging is one of the favorites of the features, as is the flexible wearing options, and processor size. I would say that, yeah, I do love datalogging. That is a very, very helpful feature to have and I'm happy that we have that in all of our CI processors amongst the many factors. I am surprised that no one mentioned the find my processor. Okay. All right, so I'm gonna just quickly kinda go through this. It sounds like, again, from your experiences, this may not be new information for you, but some considerations for the pediatric population are gonna include the small processor size. The processor size has changed significantly. And also the battery. You have the option, specifically with the N7, you do have the option of the compact battery and the standard battery size. With our team, we tend to do more of the standard battery size, and I'll go into that in a little bit. But with regards to the wearing options, you do have several including the tamper proof earhook, the

snug fit, the hug fit, the ear mold, the koala clip, and the retention clip. I may be in the minority here, go back to , I may be in the minority here, but I have quite a few patients that just swear by ear molds. I have patients that have used all the gamut of these options, but for whatever reason I have a lot of patients that like ear molds. I think that's where the cute colors come in. And then the LED lights. So just keep in mind, LED lights are there. This can be helpful for communicating to parents about the status of the processor in a specific moment. And then also the tamper proofing options. Again, kind of alluding to the battery, our team tends to rely a lot on the standard battery even for our little ones. It's just nice to know that we have a battery that'll last a little bit longer. And because of the small size of the processor and battery packs in general, we don't feel that that's compromising, that size compromise is something that's truly felt by the patient or has an impact on their ability to wear their processor. Another big consideration is having the IP rating, which is related to the dust and moisture that can get into a processor.

The fact that the processor has the, specifically the N7, has the water resistant feature even with no Aqua kit on it, but then being able to have the Aqua kit option as well for full immersion in water. And then also I'm gonna throw out wireless connectivity. Again, this may not come up for our super tiny ones that are the subject of today's talk, but processors and implants are going to be lifelong and it's something that these children will have to be able to interact with as they get older. So consideration of having that wireless connectivity is a reality for a lot of us. I think even as we get to the stage with COVID-19 and therapy and meetings and things being more online, the ability to have our processors and hearing aids that connectivity really helps with people being able to still stay engaged and have the audibility that they need to be successful. We also have the Roger system, and specifically the designated Roger 20 receiver. And in those cases where the Roger 20 isn't the desired receiver, then using a MyLink and activating the T-coil is also an option. And then as was a fan favorite, datalogging. So because it's a fan favorite, I don't think I need to tell you more about datalogging, but it is a

great feature to have. When you're trying to work on goals and you may have someone who's underperforming possibly in your opinion, it's nice to be able to have a sit down with the family and give expectations and let them know. It also helps with identifying what types of situations that they are in, as well as just can give you some feedback about any issues that the patient may be having. And then specific to the N7, you have the Nucleus Smart App. That is kinda taking the place of the remote assistant. It will allow for patients and parents to be able to check the battery life and the full function of the processor. You also have the speech input tracker so that you can set goals for families. So if you are trying to ramp up that time in speech, that could be a good tool to be able to do that. And then also the finding your processor. That is another feature that's there in the N7 and that you can access with the Nucleus Smart App. Another consideration, and I thought that this would be something that may be worth sharing given our times with COVID-19, but one thing that came up in our clinic was, in March when we had to cancel elective surgeries, cochlear implant surgeries were on that list. And one of the surgeons asked, excuse me, one of the surgeons asked, "What is a reasonable amount of time "to postpone a surgery for a specific patient?" It got me thinking about how we could be equitable in making that type of decision as we work on reschedules, and then ultimately how we would navigate the patients that we were still seeing in clinic for CI evaluations during this time to give realistic expectations.

In our clinic, and this may be similar to other places out there too, we developed an urgency scale. This can be a tool that's used to assist with rescheduling surgeries, in this case secondary to COVID-19. Also setting realistic expectations for surgery dates for those patients who started the process during the stay-at-home orders. Honestly, I felt like it helped for us to be as equitable as possible for the needs of each individual case. So if you were to implement something like this, basically, your team can choose the criteria that you feel is appropriate based on your patient population and the resources you have available. Our group decided to use four criteria. We used etiology,

aided residual hearing, the age of the patient, and then what their language was, like are they someone who has spoken language or is already talking, do we have significant language concerns or are they a child who has no language? To us, all of these cases are urgent. Then we decided to figure out a way to rate them. We rate them as like super urgent, moderately urgent, or like routine urgent. In the end, for each patient we would go through that criteria, give them urgent, kinda a point for which type of urgent that particular criteria fell into. And then we would have a score of urgency that helped to form our decision. And then what each provider does is they use this tool to justify their recommendations when we discuss at the team meeting. And this is also information that we had to take to our operating rooms as well because even if we made a decision, then we also had to be able to give a case to the people in the operating room to make a decision for why we should proceed with surgery. So this was very helpful. We, actually, had a patient who did have meningitis and was scheduled for surgery like the very first week of our stay-at-home orders. And so this was something that was able to help us make sure that that patient still was able to receive their surgery. So in conclusion, the key goal of early identification and early intervention is early access to the technology that will aid in meeting the language and communication goals of the family.

As shown today, research supports the safety and benefits of implantation as early as nine months. Success takes a village, and that village includes patients, families, audiologists, speech pathologists, deaf educators, surgeons, and the infrastructures that support the needs of children who are deaf and hard of hearing. And, lastly, CI technology has many pediatric solutions that promote easy wear and empower recipients and their caregivers. I think I went a little bit over my time, but I am more than happy to answer a few questions. I'm gonna go back. I have a question here. One of the questions that was asked here, change the slide. One of the questions that was asked was, does our speech pathologist focus on assessment and then refer out for treatment? She's being very considerate, this person's being very considerate of our

speech pathologist, of having audiologists, and being the one speech pathologist. Yes, to answer your question, she will do the assessment, and then how we up is that she makes a determination about who can be referred out. If we have people who are already getting resources or have therapists in their area, then we definitely want families to be able to go to their home location. In California, the traffic is horrible, there are people who drive hours and hours. And so, realistically, we don't want all those families having to travel in for routine therapy or increase the likelihood that they would have to cancel or reschedule. So when possible, we refer out for treatment. And then what we do is we combine some of our, we do the co-treatment. We may identify someone who would benefit from having her be present for an appointment. So that's kinda how we balanced the two. And I see another question. Our average volume of patients getting implanted annually. Off the top of my head, I have to look back, but I think last year we did about 60 implants. Not specific to this age population, but we did about 60 implants and we've been growing slowly every year with our implant surgeries. I have another question. One question was, why do we choose to do ABR and ASSR at the same visit? I'm trying to think of how I wanna answer this question. We, actually, have enough time. I'll be braggadocious and state that, and state that our ABR slots are three hours.

And I fight really hard to keep it that way. We probably have more wiggle room and time for our ABR which is why we're able to do both at the same time. It is important for us to, when we are able to have a diagnosis, to also have the time to be able to counsel a family and get the ball rolling. I had a patient who was a CI candidate one time, they had been seen some place else, and they really appreciated that I was able to do the ABR, I did ASSR, I took ear mold impressions, we counseled, we did all of this. We do at the same time because we have the time to do it at the same time. And, again, if that helps with being able to let our surgeons know as much information as possible for their ordering of the imaging, then that's why we would choose to do that. And then I see, what does your clinic consider good aided benefit? We're, actually,

looking at, I'm seeing versus a CI candidate. Okay, what are you . We're looking at several things. One of the things that we're looking at is their speech and language evaluation. We would take someone, maybe an example would be... an example would be someone who possibly has maybe their hearing aid, with their aids on, they're getting aided benefit in the detection of pure tones in like around 40, 45. Maybe even 35. But if their word recognition is really poor, then that is somebody that we may have that discussion about CI candidacy for. And then we're also looking at what that patient wants too. That may be a part of that discussion. It's definitely harder for younger kids who don't have the language. And so sometimes it really does help to have the speech and language evaluation and have someone who can do a formal assessment about what their skills are, especially if they do not have the spoken language to be able to demonstrate that in doing a list or even if they don't have the language, to be able to do a whip-py. How long of a hearing aid trial do you have and what measure do you use to determine benefit?

We will do a trial for as long as we need. We try to get families to do a trial for at least a month or two. We do want patients to have experience with using amplification, not just to provide some auditory stimulation, but also to get families an opportunity to work with the technology and see what it would be like to actually have to handle using equipment. It sounds bad, but it's kind of like giving a test. It's kinda like testing the patient to see their readiness for managing equipment because a cochlear implant is going to be equipment that they have to manage. If you have a family that is struggling with keeping it on, the hearing aid on, they're gonna have that same struggle with the CI. As far as what we use to determine benefit, so we use questionnaires. We implement the Little Ears, we implement the in some instances, but we do lean more towards the Little Ears as our measurement. And then we are also starting to utilize the PEACH as far as being able to determine benefit, and then also discuss realistic expectations with families. A question I see here is, how much earlier are infants' fast track for implantation if they have meningitis compared to other infants? Wooh, all

right! For that question, I would say we probably get those patients in within about a month. It takes about a month for those. Yeah, it's about a month. Some of that, to be honest, we ran into a little bit of an issue with our state-funded insurance. We, actually, had a patient where the patient was referred to us, but it took a longer amount of time for the authorization to come in place so that we could do the evaluation. It took several months to get them scheduled because we are waiting for the authorization. And then having to provide all of the things that were detailed for the payer for them to approve the surgery. That was a case where sadly it took a longer amount of time, and it did have a horrible effect for that patient in that he did completely ossify, and it was a much more complicated surgery. However, that has since changed. We have a really good collaborative effort with our medical director for our state insurance, and so that has been streamlined significantly. So, in general, I would say about a month when we combine getting the patient in, getting them tested, and getting their imaging done. That is our version of urgent, so we get these patients in as soon as possible and we move mountains to make them get seen quickly. Someone asked for me to go over again the four criteria for the urgency scale. Yeah. So the criteria that we selected was the etiology. Basically, it was a way to kind of highlight meningitis, saying that meningitis trumps everything else. We may look and say, "Okay, "this is a kid that's meningitic, so we definitely need to "proceed regardless of the other factors." We'll list like EVA. We had a patient recently who has Usher syndrome. That was something that we kinda considered.

Because of his vision impairment, that was upcoming, we kinda put that on the more urgent scale. We consider that etiology the aided residual hearing. We have some kids who with their hearing aids on are getting absolutely no benefit from hearing aid. The hearing aid truly is doing nothing versus someone else who is getting aided thresholds in the like 40 db range or 35, 40, 50. And so we may consider that. The age of the patient. We still get referrals of kids who don't come to us until they're about two or three years of age, or later. And so we wanna consider that and their language.

Language is the other criteria that we chose to use for this scale. So with language, again, we're looking at, do they have an established language system, do they have the support that they need, and will delaying this have any more of a significant impact on their ability to have access to a language model. Again, another thing I will consider with etiology and language, we recently had a patient who have progressing hearing loss. In that case, her aided results were fairly good. But she's also had a history of more auditory awareness over time. And as a result, she has more language. So to us, that may not have been as urgent as someone else who was profound with no access and no language. And then can you elaborate on the BabyTalk program? Yes.

BabyTalk is a program that is here in California, so it is specific to the state. It is run through the Weingarten Children's Center. The Weingarten Children's Center is an auditory oral program that we have here. They focus on listening and spoken language for children. They use their therapists. Their therapists will provide the therapy, and then through the program, families are provided iPads. The program, actually, provides secured iPads to each family that takes part in this program. And then they have a scheduled time for their therapy session. They also have bilingual. Spanish is a popular language here, so they also have bilingual speech therapists who can provide therapy to the family. And I'm trying to think. They offer the service on kind of a sliding scale, so there are some families who are able to receive the service at no charge, and then there are some who that, it's billed through their insurance, that they provide that service. And, yeah, many families do take advantage of it. Initially when the program started, there were some limitations as far as how far away from the site they had to be. It was originally made to help families who lived further out.

But since then, the program has been opened up to allow for more families to be able to take advantage of that service. Another question was asking, do you complete ASSR instead of tone-burst ABR or in addition to? It's an addition to, if time permits. But it is an addition to. I think some of that is gonna be something we're gonna put more on our protocol. I think that as I've done more ASSR and have seen the newer

systems that are out there and how accurate they are, I feel more comfortable letting go of my tone-burst. They're like my security blanket, tone-burst ABR. So I'm feeling more secured in letting that go and I'm feeling more secured in getting a click and then going straight to ASSR. But every so often, especially if something doesn't seem right or something seems off, I will refer back to the tone-burst ABR. But, currently, right now, we do all. We do the full tone-burst ABR, click tone-burst, and then the ASSR. Oh, wow, this is a really good question. Ooh, you guys are testing me. How early can a child be diagnosed with ANSD, and then what are the chances of recovery and how long can this child wait for CI surgery? I'm gonna take a deep breath on that one. Okay. I think after this question, I may answer one more question and then I can get back to you with additional questions that you have. We'll be recording these questions, but I'll try to answer this question here. With ANSD, if that baby is getting to us in a timely way, then we are diagnosing it as soon as possible. As far as the chances of recovery, in my experience, I have only seen one patient, and it wasn't even my patient, I've only seen one patient who had a reversal of their auditory neuropathy.

So I have not had the pleasure of having anyone have a specific recovery. The question regarding how long this child can wait for CI surgery depends. Sometimes when we're getting a child diagnosed with ANSD, it, actually, may not be that it's a true, kind of your more textbook presentation of ANSD. It may, actually, be that they have a deficient nerve. And so it may be more anatomical, and that this child cannot proceed with cochlear implantation or cochlear implantation is an option but with the likelihood that it'll be a poor outcome. So with these kids with ANSD, and when we diagnose them, then those children are gonna get an MRI from our otolaryngologist. And then we always get behavioral testing on these kids. And then we monitor with behavioral testing. So at no point with a kid with ANSD would I just go off of the ABR and then let that be it. I tend to monitor these kids, and I do recommend monitoring these kids very closely because the presentations can be so different. For some of my patients, I have couple of patients who have ANSD who just perform like sensorineural hearing loss

kids, and they do great. And so for that reason, although we thought about CI surgery, we ended up not going that route. But for more of those patients, more often than not, we are implanting them. And I would say the earliest that we've done implantation is one year on a patient with diagnosed ANSD. And we opted not to wait to see if there was any reversal at around 18 months to two years of age. I would say we have been more aggressive, but I think that some of that has been informed by the fact that we haven't seen that many children have a reversal. I have a question here, and I think I might let this one be my last one. I do apologize, but I thank you guys for all of your questions, and we will get back to you with the questions that have been asked. Someone asked that, we mentioned the epic schedules within a timeframe and in a specific order, what order are the patients seen and in what timeframe? We, typically, do the order audiology 'cause we are the best. But everything is kinda dictated off of our results. So audiology is first and prioritized, ENT is secondary, and then the speech is tertiary. Just because we may have a patient that's been referred to us from another clinic, and they, actually, may not be a good candidate. And so the ball may stop with audiology or audiology and ENT. As someone alluded to before, they noticed that we have one speech pathologist for our many audiologists. As a result, I want to make sure that we protect her time and make sure that the people that are seeing her are the people who really do need to see her.

And so we'll start off with audiology and try to do audiology ENT. That way, before we enter in the speech pathologist, if per the review of the case it looks like that would be the smartest thing to do. As far as the timeframe, we try to get everything done with those appointments within four to six weeks that they have that window to get everyone scheduled in. But we really, really do, I would say it's more often than not, there were knocking most of those out within the same day. For families that come from far away, definitely, we try to do it all in the same day. Again, with the audiology portion of the evaluation, it's so critical for everyone else that we are the ones that start. Our speech pathologist does look at our aided testing and does look at our results. And so that

helps her too, as far as counting the family. I find that having a speech pathologist, there's just a way that they explain things, that even though I think I'm really good at presenting things in a way that's understandable, our speech pathologist, and this was the same for the last speech pathologist we had, there's just a way that they explain it that just makes parents go, "Oh, that's all you mean?" The more that we can give her to be able to help with that explanation, the better. So I went over on time, and I do apologize, but I do thank you all for taking the time to listen. I do appreciate everyone's engagement during this session. I am excited to be able to continue to communicate with some of you regarding some of the questions that you do have. I hope that you found this helpful, especially as you continue to serve the children and families who rely on your care and this use of technology. Once again, thank you very much.