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Utility of the New CI Quality of Life Instruments to
Personalize and Improve CI Care, in partnership with
American Cochlear Implant Alliance

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- Welcome everyone to our series on providing cochlear implantation across the care continuum for adults. Our course today is on "Utility of the new CI Quality of Life Instruments to Personalize and Improve CI Care" with Dr. Teddy McRackan. I'm Donna Sorkin from the American Cochlear Implant Alliance, and we're just thrilled to be giving this series with AudiologyOnline. You go to the next slide. So this is part of a five-part series. We've done those first two already. I'm working across the continuum and the roles of audiologists and dispensers, and we are today on that third one on the quality of life instruments. And there's two more to follow, one on adult perceptions and a last one on optimizing outcomes and hearing technology.

So let's go on to the next slide. And you might just wonder why we have another organization in the field of hearing health. We have actually been around now for about 10 years, a little more than that. We're unique in that our members are across the care continuum. We are also highly collaborative with other organizations in the field. And we have a website that's designed for both those of you who would be on this course today, and for the patient community and for hearing care professionals as well as clinicians who are from outside of hearing care. So we've given you our website and we're on social, so you can find us there as well. So let's go onto the next one.

And this is our mission to advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness. And we really do work on all of those three areas in terms of looking at those factors that contribute to the under utilization of cochlear implants. One of those being that people just don't really understand the way that cochlear implants contribute to someone's life beyond listening. And that's what Dr. McRackan's going to be talking about today. And we try to improve awareness of candidacy and outcomes. So let's go to the next slide. And this is the course that we're having today. It's being given by Dr. Teddy McRackan and he has both an MD degree and an MSCR degree.

He's a fellowship trained neurologist with a long research career focused on better understanding of communication, health, social, economic benefits of cochlear implantation in adults with hearing loss. So very much looking at beyond what we typically think about it, which is listening. And this is a really important part of what we should be talking about in terms of CI. His work is supported by a wide range of research institutions like the National Institute on Deafness and other communication disorders, the National Center for Advancing Translational Science, and the American Cochlear Implant Alliance, and a private foundation, the Doris Duke Foundation. And in May of this last year, he received the Triologic Society's Harold Motor Award for outstanding clinical research for his work, which is unique and wonderful and in lots of different ways. He's published over 100 manuscripts and book chapters, and we are just delighted to have Dr. McRackan with us today.

- All right, thank you very much, Donna for that wonderful introduction and AudiologyOnline for allowing me to speak today on this topic that is very important and close to me. So disclosure wise, this research is, you know, as Donna mentioned, has been supported by the American Cochlear Implant Alliance and the NIH/NIDCD, and I'm on the medical advisory board for Envoy Medical. And I was a former educational consultant with Stryker Corporation. So kind of the objectives for this course are be able to describe the background of the CIQOL or the cochlear implant quality of life instrument development, how these instruments can be used during cochlear implant evaluations, and how they can enhance post-cochlear implant monitoring and actually direct patient care.

So as many of us know, cochlear implants are incredible devices. They're the standard of care for patients with severe to profound or moderate to profound hearing loss. Who don't benefit from traditional hearing aids. And they're incredible, you know, life altering devices. And you know, since their approval in 1984, there's been right around a million cochlear implants performed worldwide, but 125% increase in the number of cochlear

implants performed per year in the past 10 years. And incredible technological advances with regards to how we kind of, you know, program these, the processors, the internal and external components of it. But what really hasn't changed is kind of the metrics we use to measure our outcomes, right? So how do we determine patient candidacy?

How do we measure patient outcomes and how do we kind of direct patient care? So while the actual numbers kind of have changed and the actual candidacy, the measures and the metrics we're using to accomplish these really have not changed. So these are data from a meta-analysis we did. And then really the current standard right now is speech recognition testing. Okay? And this can be, you know, a few things, words in quiet, sentences in quiet, percentage of sentences like, you know, that you get right in noise. And we know looking at the data that if you look at the average patient, we see kind of these, you know, improvements whether you're looking at words, sentences in noise.

Yeah, it's in noise. We see the kind of the pre to post implantation. We see these big, big improvements, right? But this is for the average patient. And, but we can see this huge, huge variability both in kind of patients who are, whether they're not, they're candidates and how those patients actually do. So it's pretty tough to kind of use these data to make decisions about patients, especially when we were talking about kind of just knowing for the average patient and not individualizing patient outcomes. When we look at actual individual patient outcomes, here's kind of what we see in this data from our center, and it's consistent with data from other centers. We see kinda, here's the pre-operative score on the x axis.

On the y axis is the post-operative score. And this is word recognition scores, but same pattern you see for kind of no matter what the speech recognition testing is, we see about 85% of patients improve their speech recognition ability compared to their

pre-operative aided condition. About 15% are in this kind of air zone where they're kind of no better, no worse than they did with their hearing aid. And very few patients actually do much worse with their cochlear implant than they did with their hearing aid. But the question comes, what does this actually mean with regard to how these patients do in the real world, right? What do these word and speech recognition scores mean when that person then goes up to the real world and interacts with it?

How does that really impact their communication ability? And how can you really use these data to counsel potential cochlear implant users? Yes, you can use these percentages that I threw out here, but how does this really, how can you use these data to have a discussion with an individual of how they might do with a cochlear implant? But the reality is speech recognition testing, you know, done in a very controlled setting really does not equal how patients do in the real world. We know this from this data from our center. If you look on the X axis for these is CNC, the word recognition ability, sentence recognition ability, noise. On the Y axis, you see the patient's self-reported communication scores.

And we see if you look at this, the very, very low levels of correlation. So yes, you know, there is a correlation, but it's a very low level of correlation. And, you could see that this is kind of across no matter what speech recognition testing you use. Now, while this is data from our center, if you kind of look at throughout the whole literature, we know that speech recognition ability only accounts for between four to 16% of the variance in patients' self-reported communication ability, right? So, and this is even lower if we do the kind of fancy statistical models of kind of putting other patient factors into it. Speech recognition ability only describes a very, very low level of how patients do in real world settings.

So we know that it really doesn't do, it is not really an accurate assessment of how patients do in the real world. Moreover, by focusing, you know, solely on speech

recognition outcomes, we ignore all the other impacts that cochlear implants have on patients' lives. And these include social engagement, changes in emotional state and kind of the mental effort associated with listening. All of these things kind of do change with cochlear implantation, but they're not measured using our standard metrics. So the question, and this is a quote adapted from Mitch Resnick who's a PhD education researcher at MIT. And the question arises, it's kind of adapted it from what he says, but are we valuing what we measure rather than measuring what patients actually value?

So are we focusing on what we're measuring rather than what actually matters to the patients? So, you know, the question arises if you're under, you know, doing a cochlear implant evaluation, what data and how can we actually have discussions with patients that, you know, do a better job of explaining what potential outcomes are with cochlear implantation? And this is where kind of our work comes into play. So either patient reported outcome measures, right? So not PROMs like you think of from high school. And these are instruments that capture patient's perspective about the overall health or a treatment. These are direct assessments of how disease or an intervention impacts patients functional abilities in real world settings. And that's the most important thing, right?

This is the movement from the audio booth into the real world, how they're actually doing. And PROMs are often equated with quality of life, but the reality is like, you know, most PROMs don't actually measure quality of life. That's kind of a little bit of an abstract concept. Most kind of look at real world functional abilities. Also, PROMs are extremely important because, you know, we talked about, you know, independent assessment of the patient's condition. It removes any bias, you know, kind of from the clinician. It can efficiently measure multiple constructs, as you'll see with our instrument. And from a regulatory standpoint, extremely important 'cause these are now required anytime a new device is seeking an FDA indication and it's also part of

the centers for Medicare, Medicaid services meaningful measured framework, which may ultimately be tied with kind of reimbursement and whether or not they're going to cover a certain procedure or medication.

So PROMs are kind of coming to the forefront, but, you know, PROMs aren't used that often when looking at cochlear implant outcome. And the question is, why? Why hasn't this been the case, right? You get a random number right on a zero to a hundred scale for a PROM, but what does that actually mean? So we know that there are difficult to interpret, right? What does a score of a 40 mean compared to a score of a 60 on a scale? And how can you actually use these scores to direct the care that a patient receives? And that's kinda the focus of our research. So, you know, this, I think we've kind of done a good job of overcoming this hurdle and I'll talk about how you kind of, the clinicians here who are listening today can use these instruments in their kind of everyday use.

So the CIQOL, the cochlear implant quality of life instruments, where are the first instruments used in hearing loss or cochlear implantation that have been developed using rigorous development standards. These include those developed by the FDA by Promis, which is now called Health Measures. And the COSMIN group, which is more European centered, but we kind use these rigorous development standards to create our instruments. I put this here cause I always forget to actually mention. So this is our research website here in the bottom left corner. The QR code will actually bring you to the research website where you can find more information about our instruments. You can download them for free. So that is there, and it'll be throughout most of the slides.

But the really important part of the development is the mix methods research design, right? So this is a mix of the qualitative part of research mixed with the quantitative analyses and that really gives value to our instruments. So this began kind of using cochlear implant focus groups. These were a series of focus groups where we

discussed what was important to measuring outcomes where cochlear implant users with actual cochlear implant users, which is unfortunately not always done. We then developed a series of items from those focus groups and did cognitive interviews to make sure that the items that we developed included our instruments, kind of cover what was important to patients and they were clear. So this really established the face and content validity of our instruments, but most importantly ensured that all subsequent work was being reported within a meaningful, patient-centered framework.

Then after that, they moved onto the quantitative portion of the analysis. And these are the psychometric analysis. So these are first confirmatory factor analysis to ensure that we're measuring a unit dimensional construct. So we're measuring kind of one domain per our domains. We're measuring one thing only. And then item response theory, which I'll discuss, kind of helped us understand the measurement properties of our items. These are very robust psychometric analyses. Required a large number of cochlear implant users from three to 71 from 30 centers. And we developed this cochlear implant quality of life consortium to help recruit patients for these studies and we're very, very appreciative of their involvement. So the process begins with kind of going from your item pool.

So those are the kind of what we developed from the focus groups. And we vetted in the cognitive interviews 101 items and seven different domains that we thought that the items would fit into. And then you do psychometric testing to get your ultimate item bank. So the psychometric testing. This is a picture of my son. So psychometric testing and item response theory in particular, selling these very abstract thing. But these are used all of the time for educational testing. They actually have their, that's where they originate from. So while they're using healthcare now, they really originated in education. This is a little brochure my son came home with kind of discussing the map testing that they were doing.

And it was actually, it was a wonderful description of item response theory and how it's used. So traditionally classical test theory has been used to develop these instruments. And IRT has some advantages. In particular classical test theory looks at test level psychometrics. So it's kinda like you think of your traditional math test in high school and it doesn't really tell you, you know, you know that a score of a 70, it's worse than a score of 100, but there's no real understanding of what that difference means. So scores are ordinal. So you can order someone doing better, someone doing worse, but there's actually no real inherent meaning in what that difference in score is. And, that differs from item response theory.

So item response theory, but I'll go over it just very briefly. You actually look at someone's, an individual patient's theta or ability level, and you look at the difficulty of each item that you have in your instrument or in your item bank. And then you actually, it's the interaction between those two things, which really helps you understand how difficult each item is with regard to the ability level of the population and make sure that you're actually measuring the full ability spectrum of your population of interest. Alright, so that's very brief. But basically doing that, we're able to move from our item pool to our item bank, which got went down to 81 items and six different domains.

And you can see one domain was lost and 20 items were lost cause they did not have adequate measurement properties. So then we have our item bank and that's essentially a menu, right? We can select the best items from that item bank to be included in our instrument. So using kind of the psychometric analyses, we selected the items that were best at discriminating patients from a different ability levels but that also covered the full ability continuum. And then finally, just briefly, we did a validation study, recruited an independent population of 334 patients, compared it to the NCIQ and the HUI-3. And we found that our instrument had much better psychometric properties was more comprehensive than the previously developed instruments.

Paper goes into a lot of detail. One of the other really interesting findings from it was how poorly reliable the HUI-3, the healthy utility index three was in the cochlear implant population, mainly because it uses the word hearing aid in five of the six items. And that gets pretty confusing for a cochlear implant user, right? Of not really knowing whether or not to consider their cochlear implant a hearing aid or not. Makes sense if you're looking at a broad population, there's far more hearing aid users than cochlear implant users, but doesn't really make sense to use in the cochlear implant population. And we did find in fact that it was very poorly reliable. So this is what kind of the 35 item instrument.

So this are kind of our, I call it our workhorse, the CIQOL 35 profile. It includes 35 items and response choices are never, you know, go arrange from whether you're able to endorse this from never, rarely, sometimes, often, and always. And these items are broken down into six different domains. So the communication, emotional, entertainment, environment, listening effort and social. And as you can see the entertainment environment and listening effort, the hint, a star hint there for another. These are really, those are highlighted in yellow because this shows the importance of engaging with the actual patient population that you're interested in. 'cause these are domains that really have not been covered in previous patient reporter outcome measures for this patient population.

But we're, you know, discussed to be of a high importance during our focus groups. So we have right around 500 user agreements for people to download and use our cochlear implant quality of life instruments. Once again they're free. You can download from our website. It has done undergone cross-cultural adaptation into Hebrew, German, French, Mandarin and Arabic. And there's four additional languages that are in process. So just real quick, we also developed a 10 item global instrument. I have some regrets about developing this cause the 35 item instrument really provides so much more data than the 10 item instrument. But this is just kind of a quick

assessment. Includes 10 items that were pulled from the 35 profile instrument. So you can use it alone as its own instrument to get a global assessment.

You don't get any domain information or you can calculate it actually from the 35 item instrument. All right. So that's kind of a little bit, I consider that the more of the boring part of the talk of kind of how we got here, but it's really important to understand and how we apply these instruments of kind of where we came from. So development's complete and kind of now what? Well, we still have several hurdles in place before we kinda get to widespread clinical implementation of the CIQOL instruments. And first is kind of what we talked about before. How do you interpret a score? What does the scores actually mean? And so really the rigorous mixed methods of research design that we used helped us overcome this problem.

So first of all, from a qualitative right? We know that our outcomes are reported within a meaningful patient-centered framework. And from a quantitative standpoint, we know that we have scores that are interval in nature. So when you combine these, right, we know they have scores that have inherent meaning. So scores are associated with a particular response pattern that's from the higher item hierarchy that you'll see in a second. And also the changes in scores actually have real meaning to them. And, and we'll show what that means. And to help, this is another hint here, to help kind of with this interpretation problem. We developed the CIQOL functional staging system. So what are functional staging systems?

Well, these are ways to enhance the interpretability of PROM scores. They provide detailed description of patient report abilities using clinical vignettes, but they actually maintain that psychometric derived hierarchy of the quantitative scores. And this has been used in many different health settings, not just unique to kind of what we're doing here. It's been used before. We're just kind of adapting this to cochlear implant users. All right. So we used the communication domain as an example here. So kind of using

the responses from 705 adult cochlear plant users from those 30 centers, all of them had at least 12 months experience. We used our item response theory analyses to kind of determine how many stages each domain should have and what abilities are actually show associated with different domain scores.

So once again, so this is our easiest item here for the communication domain. And you can see how the response patterns change based on what that outcome score is. So, you know, if a patient has a, you know, score of five, they're gonna answer never to the easiest item in the communication domain. And you see, these red arrows kind of are the IRT derived threshold for when someone is most likely to respond from, you know, never to rarely, to sometimes often to always. So you can see here for the easiest item, because it's easy if you're always able to endorse that item, you can still be associated with a wide range, okay? Of high scores. Now, contrast that now here, all the, these are just brief item stems of the items in the communication domain.

This is the easiest item and this is the most difficult item. And you can see how these response patterns really change based on how difficult it is. And you see that item hierarchy, right? So compare the easiest item to the most difficult item, right? Able to follow out conversations with five people in a restaurant without asking people to repeat themselves. That's the full item. But you can see if you can say, because it's such a difficult item, if you say you're never able to endorse that, well, you can still have a fairly high outcome score because that's such a difficult item. But in contrast, say you're always able to do that, you can see that, know you're gonna have one of the highest scores.

So kind of looking at what these outcome scores are associated with these abilities, you can get an idea for each score, what those actual abilities are and how patients are most likely to respond to those individual items. So then it's the staging system. We used IT analyses and expert opinion to identify these cut scores for where these stages

can be. Then you can see the five stages kind of along the zero to 100 continuum of the communication domain. And you can see that there's very different response patterns within each of these stages. But we also, and we can use those response pattern to actually develop clinical vignettes, but we can also look at our normative data. So we have normative data, right?

705 cochlear implant users. We can look at the distribution patterns of patients, right? And which stages they're actually in of those experienced cochlear implant users and develop an idea. And really the first understanding of what the real world abilities and the distribution of those abilities are among adult cochlear implant users. So we can develop really cool graphics like this. So here's the CIQOL functional staging system for the communication domain. We see that, you know, only 0.4% of patients are in stage one, unable to have a conversation in any listening environment. Around 13% are in stage two, can sometimes have a conversation in quiet environments, need people to repeat themselves to understand conversation in quiet environments, 64%. Stage three, sometimes able to have a conversation in a small group and quiet, have difficulty understanding even with lip reading and noisy environments.

20% are on stage four, able to have a conversation in small groups and quiet. Can sometimes have a conversation in noisy environments without lipreading. And then very few patients are in stage five, which is kind of like a normal, you know, normal listener, able to have a conversation in all listening environments with essentially no lipreading. So we can do this actually for every domain. Here, we can see, you know, this is a CIQOL for the, I'm sorry, this is actually for the entertainment domain. That's an error there. You can see in very few people, oh, I'm sorry, 17% are unable to enjoy music. Unable to recognize melody music, around 59%. Hearing loss prevents them from listening to TV or radio or may prevent them.

And music that does not always sound clear and natural. 23% are able to enjoy music. Music usually sounds clear and natural. And hearing loss does not prevent them from listening to TV or radio. And just as a reminder, you know, for every domain, we have a functional staging system, right? So we can actually develop a real understanding for all these different domains of how patients actually do kind of in real world settings. And we can have conversations with patients about this. So this is a novel application. Another hint here of IRT based psychometrics to provide real world understanding of the functional abilities of adult cochlear implant users. And you know, the increased abilities that are associated with each stage, or, you know, logical and maybe obvious, but it's the first time we've ever had the evidence to understand the abilities that define, you know, a low versus a high performing cochlear implant, a cochlear implant user, right?

And, moving beyond that speech recognition ability into the real world. So we kind of have a much better understanding. So I feel like we've done a good job of overcoming that first hurdle of kind of interpreting scores, you know, using the CIQL staging system, have a real clear understanding of what scores mean. But now another hurdle was kind of how do we actually use that and improve how we counsel patients prior to cochlear implantation. So our current standard, right, is to use speech recognition testing in the audio booth. And on top of that, we can have kind of these expectation discussions with patients. So, you know, based on the work of Sandy Parentis and others, you know, have shown that kind of how, you know, what audiologists and cochlear implant clinicians think, or how they, the patient's expectations, one of the most important things they use in deciding whether or not someone should move forward with a cochlear implant.

But we really don't have a way of kind of measuring what patient's expectations are, right? We can have these general conversations of what the patient thinks they're gonna do, and then we can kind of use our own personal experience with CI users and

say whether or not that is realistic or not. But what I think's realistic versus one audiologist versus a neurotologist, and even within centers and among centers, those might be very, very different conversations about what's realistic and what's not realistic. So this is kind of a bit of a black box of how we do this expectation piece. So kind of to improve upon this, we developed the CIQOL expectation instrument, right? And this kind of uses the CIQOL framework and we validated this instrument that actually can measure patient's expectations.

And this actually corresponds to the CIQOL 35 profile, which means that we can actually look at patient's expectations using this instrument and compare them to normative data that we collected, that we shared previously to determine how realistic patient expectations are. This is the first time we've been able to do that. So we see here the goals of this instrument were to enhance clinicians' understanding of patient's expectations and improve patient's understanding of what likely outcomes are. So here we see our reverse survival curve. This is a cumulative percentage, and here's a CIQOL score. This is for the communication domain going from zero to 100. So for here, if you look here, a score of 10, you know at least a hundred, you know, right around a hundred percent of cochlear implant users have a score of 10 or higher.

As you move higher on here, like a score of 60, for example, only 20% of cochlear implant patients have CIQL scores of 60 or higher. So, and then these are the different stages on top of that graph. So what does this look like? So right, you can have a patient, let's say their CIQL score, expectation score is a 70 where you can have a conversation with them, right? And you can say, well that's great, you know, but you have to understand that only 10% of cochlear implant users have that ability level or higher. So that's a bit of a stretch. Compare that to someone who, you know, scored around 53, their expectation score was 53. You can have a conversation with them and say, hey, that's that.

You know, that's good. You know, around around 40% of cochlear implant patients have that score or higher. So you can have kind of these move away from kind of predicting how someone's gonna do, but just use the real world data and use the evidence that we have to have these very discreet conversations with patients and how their expectations are measure 'em and how they compare to our normative data. And just a reminder, you know, you can do all of this and not just use these scores, but you can say, you know, you can use the staging system to use these clinical vignettes to get a real idea of what these ability levels are. So moving away from a score 53, but saying, oh no, that's stage three, right?

And this is what stage three means. And so you can have this kind of meaningful conversation with patients about what realistic outcome expectations are. Why are expectations so important? In addition to kind of the previous work that city apprentice did. Well, we know looking at the data from our center, that expectations often exceed what are likely outcomes. So here are the kind of the data from our development. So the communication, the global, communication demand, and the global measure. You know, if you look at the average expectation score for our cohort, you know, is over 60, which only about 19% of patients ever get that level of communication ability with their cochlear implant. You know, similar for the global measure scores right around 60 and only 22% of patients ever get that level or higher, right?

So we know that patients have higher expectations than are likely, but the good news is expectations appear to be modifiable. So again, for the communication domain, here we have 27 patients. These are scores how they changed from before their cochlear implant evaluation to after their cochlear implant evaluation. Okay? So this is the change score and we can see that there's about eight patients who had kind of increases that their expectations actually increased after the evaluation. You know, but the other, there are quite a larger number that actually had to decrease their expectations or did decrease their expectations after the cochlear implant evaluation,

after talking to surgeons and the audiologists about potential outcomes. So the good news is that this is a very, very modifiable thing.

Now, how many patients meet or exceed their personal pre-cochlear implant expectations? I'd like to reveal that. But outta respect for kind of upcoming meetings, we'll hold off on that. The ACIA will talk about this exact topic and we'll also talk about how patients expectations, pre-operative expectations affect their decision or regret and how happy are they that they proceeded or didn't proceed with the cochlear implant. So stay tuned. We have a lot of really exciting research from this expectation side of things. So how does this actually, what does this actually look like, right? For pre-CI counseling? Well, first remember we have patients pre-CI baseline, CIQOL scores. So not expectation scores, but we, you know, use the CIQOL instrument to measure their baseline abilities.

So we can use the same reverse survival curve and actually, you know, plot where their abilities are and what percentage of patients have that level, that ability level or higher. And once again, just a reminder, we can do this for all the domains, not just the communication domain. So we can actually plot actual patient scores. And I'll go through what this looks like. On top of that we can use the CIQOL expectation to use these data to have hard conversations with patients about what realistic outcomes are. And we can do all of that, right? We can do all of this using our functional staging system and using the language included in that to use real world examples of what these ability levels are.

So I'll take you through what this, the real patient, this is a patient from our clinic. This is kind of how you go from, you know, the interpreting of what do these little check boxes and all these things actually mean. Okay? So this is both the expectation and the CIQOL 35 profile. So if we look at that patient, right? Their score on their CIQOL instrument was right around 32. 32. A score of 32 means if you go from on the graph,

32, up to here, boom. You can tell this patient that 95% of cochlear implant users perform at that level or higher. So there's a good chance you know that you're gonna improve with your cochlear implant. On top of that you can use their expectations, right?

That person's expectation was right around 68 and that's kind of, you know, it's right around only 10% of cochlear implant users perform at that level. So this might be a patient you say, look, that's great and that's man, that's a really highly a laudable goal, right? To try to get to. And you may have to use your, you know, cochlear implant for, you know, a lot of hours a day, more than 10 hours a day. You know, you may have to use kind of auditory training, which we've shown kind of can improve quick. You can do a lot to maybe get to that point. But let's just be realistic when talking about how many actual patients get to that level.

And then once again, you can have that conversation with using this staging system. So kind of we've shown kind of how to use the CIQOL instruments to improve and enhance our pre-CI counseling. Okay? And then now how can we actually use this to monitor patients after their cochlear implant? Okay, so we're talking about pre. Now this is kind of post. So I mean first is, you know, to really be able to determine whether or not an improvement is clinically significant or beyond the measurement error. You kind of need to understand what that meaningful score improvement is. So this is a paper that's kind of just was recently submitted and we've calculated these conditional minimal detectable change values as a psychometrically derived property for CIQOL scores to really get a better idea of whether or not a patient's change over time is meaningful, is important, for individual patients.

So this is kind of work that that's coming out. I get this question a lot of kind of the interpreting the change score. So that is something that is coming and it should be available soon. So, but you know, kind of looking at how do we kind of monitor post

activation progress. So this is the, again, once again the communication domain and the staging system. And you can see, let's say this patient kind of was kind of right in this area at pre before their implant and you can see how they're kind of at three months, six months, 12 months, how they're scored nicely improved along the line, right? We wish this were everybody who kind of improved in this very reliable pattern.

And it's great to say, wow, this person's improving. But you, when you see this patient, right? And you see this score of 38. You can actually look kind of on these graphs and see where this patient is struggling, right? And where do they need help and what situations are they struggling the most with, right? And then we can kind of start to use this progression and the staging system to direct kinda where we're giving care, right? And really kind of hone in on what difficulties each individual patient is having, okay? And kind of give them exercise to do that are at the appropriate ability level. And this is very much in line with the kind of traditional rehabilitation model that we've kind of unfortunately moved away from a little bit in cochlear implantation.

This is something that's kind of commonly done in physical therapy or you know, recovery after orthopedic surgery. Kind of really goal-based exercises where you're really challenging patients at that point where they're having the most difficulty to get them to move beyond, right? Because if you have someone you know who's at stage three, it really wouldn't make a whole lot of sense to give them exercises, you know, that kind of work on the highest end of the staging system. You really want to give them something that's appropriate for their ability level. This is even more powerful if you kinda look at patient kind of progress. So important again to remember when you look at and interpret these scores, these are two patients, right?

And from pre to three months you see these two patients improvement patterns. And if you look at just the change score, it's like, it's great, right? These patients improve the same amount. They look like they're getting better. However, based on where their

baseline ability level was, you can see that what this actually means is very different for these different individuals and where they end up at three months, again, looking at the response patterns for our CIQOL staging system, you can see that where these different patients' ability levels are, are very different. But what happens if this patient, you know, doesn't get any better by six months? So they've kind of shown a little bit of improvement, but then they're overall pretty stagnant, right?

When it comes to a further improvement. Well kind of, once again using the CIQOL staging system, you can actually kind of look at what these patients ability levels are and where they're struggling. And this gets the principle of precision medicine. So not just giving the same care for all patients, but actually looking at the individual patient, looking at their score and giving them exercises, auditory training that challenges them at their particular difficulty where they're having the most difficulty. So the implementation of these, of the CIQOL profile and functional statement system, have the potential to enhance our understanding of what barriers individual patients are facing. And they can personalize rehabilitation strategies based on individual user ability thresholds, right?

And looking at this, and I kind of talked about prescribing therapy, maybe it's time we just need to develop new interventions, right? And we need a better understanding of where our patients are struggling and develop more listening exercises, auditory training that kind of are at of these individual differences. Cause we've been focused so much on speech recognition ability, you know, maybe we need to look at kind of what individual real world settings patients are having the most difficulty. And just another reminder that, you know, we have this ability to do this for all, for five additional domains. So we can actually look at where patients are struggling in all of the different domains. And maybe, you know, we need to broaden our umbrella and develop non-communication related interventions as well.

'Cause we do see people that show dramatic improvements in communication but still really struggle in social settings. So, you know, maybe we need to develop some psychological, psychiatric therapy, right? To kind of help patients, right? None of these patients, if they have had years and years of hearing loss, they've really become quite reclusive and we, you know, to be able to get them to kind of reenter the real world, maybe we need new interventions. And, that's what kind of some of our work is revealed. So we kind of talked about all the barriers we've overcome, but, you know, and we're hopefully getting closer and closer to widespread clinical implementation. We get, you know, emails all the time of new clinics using these on a routine basis and questions they have.

I'm gonna look at kind of how this has gone over time though. You know, we started with the actual instrument development, right? Using the staging system I've built, I feel like we're developing a fundamental rethinking of kind of how we measure and how we look at cochlear implant related outcomes. We've kind of shown how the CIQOL can be applied clinically and how we're doing it at MUSC to actually improve patient care in real time. But the, you know, what's next? And that's the exciting part of what kind of people, I mean people in this audience are gonna do with the instrument, ideas they're gonna have of applying it. One of our biggest new ideas is this CIQOL digital platform, which should be available soon.

This is a platform that we have developed to kind of overcome a lot of these barriers that we identified, right? So one of the biggest barriers kind of in our qualitative interviews with centers and patients as efficient data entry, right? It takes a long time to complete these instruments. Really doesn't when you compare it to speech recognition score. But, and, you know, it takes time right away from your clinic visit for patients to actually fill these out. When are they gonna do it? You know, we're trying to, we're overcome some of these barriers with our digital platform. Automated interpretation,

like I mentioned, we have the, we've calculated the minimal detectable change scores for our instrument, but they're not, you know, always easy to use in real time.

And, you know, having audiologists or clinicians kind of on their board of what's a meaningful change and what's not really kind of, we want, we should be able to in automatically interpret that change score. More importantly, kind of looking at, you know, I talked about the pre-CI counseling. How can we kind of automate that, right? How can we have an automated thing that patients can even use at home? And then an interactive format, you know, so kind of, so not just kind of talking about these things, but you know, stuff that patients can go home, play with at home and kind of get an idea of how to improve it. So we'll be revealing this in the very near future.

So acknowledgements, you know, none of this is possible and it's taken over 900 unique research participants to get to this point of our research. So eternally grateful for research participants, for giving us their time, their thoughts about this. We have a wonderful research team. Judy Dubno, Craig Velozo, Britney Hand, Craig Velozo and Brittany Hand are both Psychometricians who work with our team and our wonderful adult cochlear implant team at MUSC as has been involved throughout the whole process. And once again our CIQOL development consortium who were really instrumental in allowing us to kind of recruit the large number of patients we needed for this research. And of course, grateful to the NIDCD for their funding of this research and continued support and the American Cochlear Implant Alliance, who provided some of the earliest funding we had for this work and really was integral in getting it off the ground and getting it to where it is today.

So with that, wanna thank you for everyone for listening. This is my email, so please feel free to reach out if there's any questions, I'm happy to chat, have chat here and answer any questions that might come up. And this is the QR code, once again for our research website. We should have all of the papers uploaded in the very, very near

future. The vast majority of them are already on our website, but you know, in the very near future the most recent ones are gonna be up there. So thank you very much for listening.

- Thank you. Thank you, Dr. McRackan. That was a fantastic talk. And you are so adept at covering those elements that we often forget about when we're thinking about providing cochlear implants to people and the benefits that go way beyond just the spoken language outcomes that we often are looking to measure and document. I wanna encourage people to put questions into the Q and A and go ahead and do that. And in the meantime, I wanted to ask some questions. I wondered, Dr. McRackan, do you find that patients are surprised, satisfied, disappointed with those measurements that you're quantifying? I mean, how does the average adult patient feel about what you're looking at here?

- Yeah, no, that's really interesting because, so we've done some qualitative research with some patients kind of in the pre and post-operative period of kind of what are they like, what are they not like, kind of when it comes to looking at how outcomes are measured. And I mean, it's no question that the staging system rises to the top every time. It's essentially all patients really, really like to have those kind of clinical vignettes of kind of, they say it kind of accurately describes how they're currently doing and it kinda gets an idea of what's possible for them. So, but they're a subset that I likes secondarily to have the speech recognition as well, that likes to hear that, likes to know they kind of, people describe it like a math test.

But even more, there's even more patients who are like, yeah, that doesn't describe how I'm doing, right? You know, I know it says I'm doing 70%, you know, sentence rec, speech recognition or word recognition ability in the audio booth. That's great. That's an improvement from my baseline condition. But here's, I'm struggling here, here and here. And that's what the functional stage system helps kind of get across to clinicians,

right? It's those areas where the patients are still struggling 'cause I mean, it happens all the time to us. We see somebody and you look at their, you know, speech score and it's like, wow, they should be doing amazing. But then you realize like, that's a different ability, right?

That's a completely different construct that you're measuring is how that patient's applying. It's like, you know, okay you have, you've graduated from architecture school, right? And now you need to apply that into the real world and be a good architect. And then, so it's almost like a, it's like a check, right? It's, it's like kind of a, being able to understand speech in the audio booth is like what I want all my patients to do as good as possible in the audio booth. It's important thing to measure, but that doesn't describe how they do in the real world. So I think they like that. I think the expectation piece has been very interesting to use and implement clinically.

It really helps you kind of have very direct conversations with patients and overall, I mean they've really, really enjoyed those conversations when they're actually kind of directed towards a particular, you know, not just like, oh yeah, maybe your expectations are a little bit high, but like not, they're not just high, this is where they're high, right? You know, you think you're gonna be able to understand five people in a crowded restaurant and never have to ask someone to repeat themselves, but that's, you know, only a very few people are always able to do that, right? So you can have these kind of, and so I think people come away with this a really much clearer understanding of what to expect after their cochlear implant.

- You know, that's a really important element to get at. And I think if we have that we can also then apply some approaches that will help people overcome those challenges. I as a cochlear implant user who has had a CI for 30 years, I was an early adopter, you know, I could say that a crowded restaurant with five people is really challenging, but you can't overcome that if you use an assistive device. And I think a

lot of people don't necessarily, they're not necessarily proactive about that element. But I think having the data can provide an entree to talking about the solutions that get you past the typical booth discussion. So there's two questions here that I'm gonna pick up on. We have one person who's asked if there's a version in Spanish.

- Oh man, you know, that is, we need that so bad. So whoever asked that, if you wanna contact me and you wanna take on the. So what we've done with our instrument is really been very strict about. I mean the idea of kind of translating it is not enough anymore, right? It's cross-cultural adaptation is really the proper term. And, we've been looking for a partner to kind of, you know, adapt it into Spanish. So we have, you know, I've had three groups that have contacted me about doing it in Turkish, but yet no one has contacted me to really do it in Spanish yet. So I don't know why that is, you know, so it's really fascinating.

But you know, it's a bit of a process and International Journal of Audiology published guidelines for how to do this properly and kind of gave some tips for how to do this in kind of Audiological research. And so we're really following those guidelines. We wanna do it right. We've found fascinating things in the process. I mean words that just have very different meaning if you just directly translate them in French or Arabic was one of the big issues was, you know, the melody and music. It's just, it's very different music. And so that wasn't an appropriate term to use in the Arabic version. So it's been amazing what we find each time and, so no, the answer's no, but please, please, please email me. It's just my last line to me to see if you're interested 'cause we have been actively seeking partners for a Spanish version.

- Yeah, that's great. Someone has added in that EDEL has a great program for Spanish speaking CI candidates. So there may be some related materials, not exactly what Dr. McRackan has been working on, but some related materials for that aftercare aspect of it that are available particularly from the companies. And I agree EDEL has some

fantastic resources. So here's a another question that came in from Stacy and she says, "Do you have the patient answer the same CIQOL for both how they did with their hearing aids and then a second time for how they've are expecting to perform with the CI during the pre-evaluation process?"

- Yeah, so, they're actually separate instruments. So, one is just that we have them fill out the CIQOL 35 profile, right? And, the wording of that and the validation that was in a particular way where someone could answer it before they get a cochlear implant. So like the, how they're doing with their hearing aids or if they're not a hearing aid user, how they're doing in their kind of routine kind of listening modality. So they fill that out and there's actually a, it's a completely separate validated instrument is the expectation instrument. So the wording of it's different, you know, it's been, we've validated it, we've done a whole separate, you know, process to kind of make sure it's a valid instrument as well.

So yes, so we haven't felt both the wording of 'em is kind of basically like, I will be able to, right? Instead of I am able to and things like that. They're kind of future tense and the scoring and everything is the same. So you can directly compare, like I talked about how that patient expects to do, kind of compare that to the normative data to really get a good idea of, of how, what their expectations are and how realistic they are.

- Yeah, that's great. You know, as you've been talking about this, it made me think that we probably need to be aiming these tools beyond audiologists to speech language pathologists who may be working with patients, maybe not so much adult patients because I think we've really given adults the short shrift on the auditory rehab side. You need to do a better job of that. But I think what you've, the work that you've done would provides some really meaningful tools to engage SLPs to get involved in this process. So we need to do this course again with a slightly different tilt for this speech pathology audience as well. So.

- It's probably the audience that I get the most emails from. I mean, there's such incredible interest from speech and language pathologists from using this and it's kind of for that exact thing. It's how to direct, you know, the how to direct therapy, right? And, kind of using the staging system in particular that kind of help with auditory rehab rehabilitation. So it's great. It's a kind of direction that I had never thought of at the beginning of the process that that would be a part of it, but kind of something clicked a little bit along the way and made us realize that, and it was really kind of it's importance of kind of collaboration with people outside your own world because, you know, it is a, one of our main collaborators, Craig Velozo is a occupational therapist and how he approaches rehabilitation is much more from a classical rehabilitation model than what we do.

And for them it's just is kind of logical. And, when I said that this is not what we do, he was shocked, right? And, you can do it with this, right? You can't do it with, you know, a speech recognition testing, right? 'Cause a score of 30, you know, or a score of 40 compared to 60. I don't know what that means, right? And how you direct therapy for that. All you can kinda say is, well if a patient's not progressing like you want them to, well that stinks. Let's give them some monetary rehab, right? But where are they struggling? What situation are they struggling in? I mean, it is just hard to direct it based on speech recognition, but you kind of using the CIQOL in the stadium system, you can kinda see exactly where patients are having difficulty, so.

- Yeah, I find that aspect of your work to be very exciting and something that gives us a lead in to our whole area that we need to be working on as a community. So I'm really grateful to you for highlighting that and bringing us all into the picture. But we have time for another question or two if people wanna put those into the box.

- And while we're waiting, I mean, I think the other part of it is are kind of all the other domains that we've kind of ignored for cochlear implant users when it comes to kind of providing rehabilitation. Right? You know, I think, you know, you can think of listening effort and communication kind of being related, but kind of, you know, enjoyment of entertainment, right? Enjoyment of social engagement, emotional state. I mean, when we start to kinda look at these patterns over time, we really see that it's just not like one changes and the next changes. You know what I mean? You see these very interesting patterns of people who improve in some, and that's the importance of kind of all the psychometric analysis and the, you know, dimensional constructs, yada, yada, yada.

But the important thing is that, you know, we actually see these incredible response patterns. So just because you improve in communication doesn't mean you're gonna demonstrate improvement in every different domain. So we see a lot of very interesting response patterns, kind of when we start to follow this longitudinally.

- Right. Any other comments or questions from our attending audience today? If not, I think we can end it today with grateful thanks from all of us too, Dr. McRackan, for your very unique and important work on extending the cochlear implant field in ways that is very much lacking. So thank you very much for representing and for everything that you're doing, Dr. McRackan.

- Oh, thank you for having me. It was a pleasure.