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## **Evidence-Based Adult Cochlear Implant Counseling Using the CIQOL Instruments, in partnership with American Auditory Society**

**Presenter: Teddy McRackan, MD, MSCR**

At this time I'd like to introduce our guest speaker, Dr. Teddy McRackan. This course is in partnership with the American Auditory Society. Each year audiology Online holds two courses in partnership with AAS and we thank them for inviting Dr. McRackan as our guest speaker today.

Dr. Rackin comes to us from the Medical University of South Carolina where he is the professor in otolaryngology, head and neck surgery. He is also fellowship trained neurotologist with a research career focused advancing on comprehensive understanding of the functional benefits of cochlear implantation in adults and developing interventions to enhance pre CI patient counseling and post CI outcomes. Dr. McCracken's research program has been supported by the National Institute on Deafness and Other Communication Disorders as well as the national center for Advancing Translational Sciences as well as ACIA and the Doris Duke Foundation.

Dr. McRackan has received the Trilogical Society's Harold Mosher Award for outstanding Clinical Research and the American Auditory Society's early career research award.

Dr. McRackan also maintains an active clinical practice and serves as the medical director of the MUSC Cochlear Implant Program and director of the MUSC School Based Center. Welcome Dr. McRackan and at this time I'll hand the mic over to you.

Yes, thank you so much for hosting and allowing me to present on our research and also to the American Auditory Society for kind of co sponsoring this, this talk. So today we're going to talk about evidence based counseling. I'm sorry, evidence based adult cochlear implant counseling using the cochlear implant quad life instruments. And moving on real quick, let's see. There we go.

These are disclosures that I have. And we're always very thankful for our funding sources primarily for this project of the NIH and the American Cochlear Implant Alliance. So very appreciative of their support and continued support of our work. And here are the learning outcomes for this talk and then

we will move on. So the talk today is kind of personalized evidence based adult cochlear implant care using the CIQL instruments.

So really when we develop these, the Cochlear implant quality of life instruments, our goal wasn't just to create another patient reported outcome measure that could help improve, you know, measure outcomes in a retrospective fashion. We really wanted to do more and our goals were really threefold. One, to improve pre CI counseling, to improve the way that we monitor patients after they get a cochlear implant, and also to personalize auditory training. Now for the purposes of this Talk. We will really focus primarily on the pre CI counseling just for time's sake.

But these are all goals and things we continue to work on in the long term. So when it comes to a cochlear implant evaluation, there's really three parts. First, there's the auditory measurement. How's that person doing from a speech recognition standpoint with their hearing aids in place? What are their pure tone levels measuring with standard audiograms?

And that's kind of the first step to determine whether or not they are a cochlear implant candidate. Then the medical evaluation, it's making sure the patient there's no contraindications to getting a cochlear implant. And then third, and really the more complex one is the counseling, right? Determining whether or not a patient should get a cochlear implant. So not are they a candidate or not?

But is it in their best interest to go forward and get a cochlear implant? And this is really a bit of a mystery, right? And this is, this is an area that's gotten a little bit more and more difficult to determine over time. Work by Cindy Prentice and others have kind of focused on the idea that patients having realistic expectations and understanding potential outcomes or what clinicians value most when determining whether or not they recommend someone proceed with a cochlear implant. And this has gotten more difficult for several reasons, but primarily is the fact that the indications for cochlear implantation have changed dramatically over time.

So in cochlear implants, we're first FDA approved, you know, patients had essentially no hearing, right? No, no. Very minimal, you know, severe to profound loss on audiogram and you know, had to have zero percent word understanding with their hearing aids. So there really was. It's kind of made sense, right?

When patients come in like this, it's kind of a no brainer. There's no really other option available to them. Sticking with their hearing aid is not going to provide that much benefit. It makes sense to kind of go ahead and proceed with a cochlear implant. So that kind of counseling kind of is a little bit different.

Now here, here's where we are now, right? Patients can get cochlear implants now with much, much greater residual hearing. And you know, you can see on this audiogram the green area where patients hearing can be and still be eligible for a cochlear implant. Not only that, you know, they can now the new CMS guidelines. They can hear and understand up to 60% words and say or word sentences, I should say with their hearing aid in place.

So that's a very, very different patient population and has made this idea of kind of counseling much more difficult to determine whether or not it's in the patient's best interest to proceed with a cochlear implant. And so this is kind of a joke that we're kind of in the scale right now. Sometimes it's a 50, 50 in deciding whether a patient is better to proceed with a cochlear implant or to continue with their hearing aid. And really, the two main parts of the patient counseling are one, patients really want to know how they will perform compared to their current abilities with their cochlear implant. And clinicians, you know, as I said before, work by Senator Prentice demonstrated that, you know, patients, the most important thing that clinicians care about during this counseling process is whether or not patients have realistic outcome expectations, so whether how they think they're going to perform is how they're actually going cochlear implant.

So first we'll kind of talk about how patient's perspective of how they will perform the cochlear implant. So our standard outcome measures that we've used for years is speech recognition. Speech recognition ability. Right. So how that person is doing now compared to how they think they'll do after with their cochlear implant.

And I propose that we're kind of failing at answering this question using our standard outcome measures. And that's because one, about a third of patients who are going to proceed with cochlear implants report significant reservations about wanting to proceed with a cochlear implant. And in addition, about 20, depending on the papers, 20 to 36% of patients who are cochlear implant candidates opt not to proceed with a cochlear implant. And these are patients who it's actually recommended that they proceed with a cochlear implant by the clinicians. About 20 to 36% end up not proceeding with the cochlear implant.

And the primary reason for that is that patients have a lack of understanding. This is work that we've done have a lack of understanding of what their outcomes are going to be with a cochlear implant compared to where they are currently. That lack of understanding in 85% of patients is a reason that patients do not proceed with their cochlear implants implant. And so we have years and years of data. It's a meta analysis we did of looking at, you know, word and sentence recognition ability before cochlear implant and after, and looking at the data we can see, yeah, look, on average patients, you know, perform, you know, low with words and sentences before they get the cochlear implant that with their hearing aid in place and then they perform better afterwards.

Right. And so that's great, that looks like an improvement. But work by us and others have demonstrated that, you know, how someone does in the audio booth has very, very low levels of correlation to their real world communication functional abilities. So how someone does an audio booth really does not correspond to their self reported community self reported communication abilities. And if

you look at the data work by us and others have demonstrated that speech recognition ability only accounts for somewhere between 4 to 16% of the variance of patients self reported communication ability.

So really, really very low levels of correlation. And when you do multi variable regression models that are more complex that, you know, that correlation falls even lower and sometimes does not correlate even at all, you know, at any degree. Not only does it not report an accurate assessment of patients communication ability, it ignores things that patients care about such as changes in social engagement, changes in patient's emotional state and listening effort that can change with cochlear implantation. That was the main impetus for us developing the cochlear implant quality of life instruments. These were developed using the most rigorous standards that have been developed to date.

And there's no previous patient reported outcome measure that's been validated in a cochlear implant users that meets these current standards. And rather than bore you all and kind of talk about the years of development that went into it, we'll talk briefly, kind of just an overview of kind of how we design this and why that's important. So we use a mixed methods of research design to develop and validate these instruments, which is a mix of qualitative research and quantitative. From a qualitative perspective, we use cochlear implant user focus groups and cognitive interviews to ensure what we were measuring mattered to cochlear implant patients. Right.

So all the outcomes that we would report from our instruments are within a meaningful patient centered framework. And then from a quantitative standpoint, we used advanced psychometric analyses, confirmatory factor analyses, rash and item response theory to actually ensure that the scores that we're providing are interval in nature. So what does that mean? It means that a score that's ordinal shows that a score of 50 compared to a score of 40. There's a difference there and we know that one is better than the other.

However, scores that are interval in nature means there's actual meaning in that difference. In score. So going from a 40 to a 50 means there's an actual demonstrable change in abilities that happen between those score levels. And we'll talk more about that in a second. But The Cochlear Implant 35 instrument is our main workhorse.

And this is what it looks like, very straightforward, 35 items. And patients respond from never, rarely, sometimes, often always for their abilities to endorse or out endorse these different items. And there's six domains. Communication, emotional, entertainment, environment, listening, effort, and social. And what's important is kind of the engagement of the cochlear implant users themselves is really important because some of these domains have been used in prior patient reported outcome measures.

But ones like entertainment environment and listening effort really had not been covered at previous patient reported outcome measures. So that shows the importance of actually engaging patients in the research. These were finalized and validated in 2019. To date, we have over 1300 user agreements of independent researchers and clinicians using these instruments. It's undergone cross cultural adaptation to nine different languages.

And four different additional languages are in process. It's part of the National French Registry and it's actually included in the new minimal speech test battery version 3 that recently came out. So, you know, just because we have. So we're proud of the work we've done, but just because we have these instruments available really doesn't answer the question right. So the patient wants to know, how will I perform with a cochlear implant?

And just having a new instrument really doesn't help that. But the use of this mixed methods research design helps us get to the answer those questions. So by using this mixed method design, the domain scores have inherent meaning. So there's a domain score. We know that that score is associated with a particular response pattern that's reliable, that we ensured reliable in our test retest reliability.

And also the changes in scores have actual meaning. So that allows us to move a little bit step further than most patient reported outcome measures and develop what's called functional staging system. So what are functional staging systems? These are ways of kind of grouping scores to enhance the interpretability of PROM scores. So they provide detailed descriptions of the abilities of patients using clinical vignettes.

But it maintains that psychometrically derived item responsibility hierarchy of the quantitative scores. And this is nothing new that we created, this has been used in other healthcare settings. So at this point I'm going to walk through kind of what this looks like for the communication domain and then kind of get to, and then show how this kind of starts to answer the question that we wanted to answer with our, our instruments. And so to develop this functional staging system, we used responses from 705 adult cochlear implant users from 30 centers. These were experienced cochlear implant users, you know, all post lingual.

These were teachers who had 12 months or more of cochlear implant experience. We used item response theory to determine first how many stages each domain should have. That's a measurable thing. And also to identify the abilities that are associated with a domain score. So here we see the.

This is the easiest item for the communication domain. And using item response theory, we know, for example, if a patient scores a score of 50, okay, on the outcome score, we know that they are almost always going to answer that they're often able to endorse this item, have it, and this is just a very brief item stem, have a conversation quiet without asking the other person to repeat themselves. And we can know and reliably understand where patients will respond to that individual item based on where they score from 0 to 100. And then here again, never, rarely, sometimes, often, always response patterns. And IRT is used to kind of identify where those cutoff scores are.

Sorry, on the screen where those cutoff scores, those red arrows are hierarchies used to identify where those cutoff scores are. But we can do this with every item for every domain. So this is a little bit overwhelming. But here, all the items for the communication domain listed at the very top is the most difficult item and the very bottom is the easiest item. Right.

The lowest ability level. And you can see how the response patterns change based on how difficult the items are and where individual score from 0 to 100. So you can compare someone, you know who's at the very, very bottom here. So if you score five, they're going to say never to all the items. But contrast that with someone who's at the very, very high end.

Right? Someone who's at the high end is going to answer. They're always, if you score of 90, they're always going to, able to endorse all the items except the very most difficult. When, you know, following a conversation with five people in a restaurant when you're not able to see that person speaking. So you can see that there's this natural hierarchy ability that happens with increase in the outcome score.

We could then use IRT analyses and patient and clinician engagement to identify the cutoff scores that separate where the individual stages occurred for the functional staging system. We then looked at the response patterns that are within Each of those domains, I'm sorry, between those stages, to start to develop clinical vignettes that describe the experiences of the cochlear implant users who are in that particular stage. As a reminder, we had data from 705 experienced cochlear implant users. We can then start to understand how many patients are within each stage. Then we can make interesting graphics like this that finally get to the answering the question of what the patients want to know is how will I perform with my cochlear implant?

If you look at this, the functional on the communication domain example, you can see that only 0.4% of patients are on stage one, which is the lowest level, unable to have a conversation in any listening environment. About 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% are in stage three, sometimes able to have a conversation. A small group in quiet has difficulty understanding even in reading and lip reading in noisy environments.

20% are in stage four, able to have a conversation in small groups and quiet, can sometimes have a conversation in noisy environments without lip reading. And then very few patients end up in stage five. 1.4% able to have a conversation in all listening environments with essentially no lip reading. We can provide patients this information and have discussions based on the actual evidence based data how they might do in the real world with their cochlear implant. Just as a reminder, we have this ability to do it with all of our domains.

So all other domains only had three stages in them and we have the percentage breakdowns for all of those. And our QR code is on a lot of the slides here. And you can look at that and you can identify. All of this is available both in the literature and for our manual, which I'll talk about at the end. But you can have these conversations using the best available evidence for how a person might perform with their cochlear implant.

But now we're using this for pre CI counseling. So this graph here on the right, and this is a reverse cumulative survival curve. So here the cumulative percentage of patients on the Y axis on the X axis is the CIQOL score from 0 to 100. Okay, so as you go across here, you can see that 100% of cochlear implant experienced cochlear implant users. And this is from our normative data of 705 patients score at this very low level.

But as the score goes up, you can see that the cumulative percentage of patients who perform at that level goes down here, the stages overlying the CIQOL score, we can take an individual patient and we can look at their baseline CIQOL score and say, look, a patient who comes in with a score of 33, we can tell them that 95% of cochlear implant users have your ability level or higher. So there's a fairly high

likelihood that you're going to perform better with a cochlear implant than you're performing now. Okay, now compare that to someone who comes in to see us with the score right around 67. Right. If someone comes in with a score of 67, well, only 10% of cochlear implant users have that ability level or higher.

So we're not telling a person not to go forward with a cochlear implant, but we're providing them that information that, you know, it's unlikely that they're going to perform actually higher at a higher ability level than where they are now. And again, you can have this conversation using the CIQOL staging system. So rather than using scores and talking about numbers, a score 67, you can actually say stage one, stage two, stage three, stage four, and you can have the conversations and using the kind of evidence based clinical vignettes. Okay. But you know, the question arises, can we give more precise patient counseling using the staging system?

So to look at this, we performed A study of 101 adult cochlear implant users. These were traditional bilateral hearing loss patients, traditional indications. And we looked at where these patients were before they got their cochlear implant. So their pre CI functional stage. And this is for the communication domain.

You can see there are a few patients in stage one, 69 patients were in stage two and 20 patients were in stage three. And looked at kind of, where did these patients end up after their cochlear implant? Okay, so what stage do they end up in? 12 months afterwards? The first data will show are kind of that 3 to 12 month change in the communication domain.

And here we're talking about improvement being relative to our previously defined conditional minimal detectable change. Green is patients who improved. You know, yellow are patients who had no change within that kind of measurement error, and red were patients who were worsened. So looking at patients who started off in pre CI communication stage one, 100% of those patients improved from their

baseline abilities. Compare that to patients who started off in stage two.

You can see that most patients, 68% improved compared to their baseline at 12 months, but 28% demonstrated no change. And, you know, only one patient actually performed worse with their cochlear implant than they did before the with the cochlear implant than they did with their hearing aid. Then compare that to patients who are in stage three. Only 35% of patients demonstrated an improvement after cochlear implantation in the communication domain. But 60% demonstrated no change and 5% demonstrated actual worsened scores.

Okay, so this gets an idea of kind of how we can maybe use these staging systems to counsel patients before they get a cochlear implant. If you look at the average data over time and what this looks like, here's pre CI and then at 1, 3, 6 and 12 months, and on the y axis of the CIQL score, you can see that these patients were separated and bend them based on their pre CI. PEGI scores are in green. You can see that these patients obviously started low because before their cochlear implant they were in stage one. And you can see they improved over time and kind of plateaued around three months.

Now look at how that compares to patients who are in stage two. So by definition, they started off higher because they were in pre CI, you know, pre CI communication stage two. But you can still see that, you know, quite a bit of improvement on average for that patient population. But then contrast that with patients who are in stage three. So those patients once again started higher.

But you can see while they may have improved, that improvement is very, very small, especially when you compare that to patients who started off in stage two and stage one. We actually look at the hazard ratio for these patients. So we compare what is the risk of patients who started off in pre CI stage three, the risk of them not demonstrating any improvement? Well, patients who started off in stage three were twice as likely to not improve compared to patients who started off in stage one or stage two. If we define success as improving by one stage or more, that risk goes up to 7.6.

Patients who are in stage three before they get a cochlear implant have a much higher risk of not improving by one stage or more after they get a cochlear implant. What's interesting is, despite the fact that these patients have incredibly different trajectories with regard to their abilities over time. If you look at the standard outcome measure, their CNC word scores, they perform almost exactly the same patients who are in stage. Here they are binned. Once again, bin based on their pre CI communication stage.

So green is stage one, blue is still stage two, yellow is stage three. We look at their CNC word scores, we can see, yes, all these patients are demonstrating improvement despite the fact that they're having these very, very different functional ability changes or lack of functional ability changes over time. So if we use our standard outcome measures, we're not going to identify these differences in performance of these patients. Same score, you know, same stories happened with AZ bio, right? So looking again at patients bin based on their pre CI communication stage score, you can see that these patients have essentially the same experience in the audio booth.

Meanwhile, they have very, very different experiences in the real world. So when we get back to that central question we had, how will I perform with a cochlear implant? So the ciql instruments provide evidence based, real world clinical vignettes of user abilities that allow patients to understand the real world examples of how they might perform with a cochlear implant, and they allow comparisons with normative data. Now that we've kind of established a normative data set, we can compare where patients are now compared to where they might be with the cochlear implant. There's really a future huge role in modeling potential outcome with patients like we recently demonstrated.

But really importantly, qualitative research we've done with cochlear implant users before and after their cochlear implant. 75% of potential cochlear implant users prefer to have outcomes discussed using the CIQOL functional staging system when compared to either just discussing outcomes with speech

recognition scores alone or when just looking at CIQOL scores where they are. Patients really, really do enjoy having those clinical vignettes discussed with them and where they are now compared to where they might be with their cochlear implant. So kind of onto the next question that we had was, do patients have realistic outcome expectations? Currently, when we perform this counseling with patients, we rely on these kind of general conversations with patients about how they expect to perform, right?

We have, you know, we give them, ask them questions, we discuss, well, how do you think you'll be able to do X or Y? And so we have these generalized non measurable conversations with patients about how they, we think they're going to expect to perform. And then we compare that to our own personal kind of experiences with cochlear implant usage, right? And we kind of think whether or not that patient's outcome, you know, that expected outcome is realistic or not. And that's likely very different, you know, among, you know, different centers, different individuals within each center.

We have our own personal bias of how we think cochlear implant users perform. So we really don't have a good way of kind of measuring how patients expect to perform. And we have no really evidence to determine whether or not that expectation is realistic or not. And that's why we developed the cochlear implant quality of life expectations instrument. So this uses is based on the same CIQOL framework we validated in a large sample of cochlear implant candidates and actually measures patients expectations prior to surgery.

And because it's based on that CIQL framework, it corresponds directly to the CIQOL profile. So every item in the expectation instrument directly corresponds to an item in the Ciqol35 profile. That way we can actually use the normative data, which we are showing here again, but previously demonstrated. We can use that to determine whether or not patients expectations are realistic or not. So we can.

So CIQL expectation scores directly correspond to profile domain scores. So those could be compared and I'll show you what that looks like. So once again, instead of having these generalized conversations

and use our own personal bias to determine whether or not they're realistic, we can now measure patients expectations before surgery. Okay. And then we can compare those expectations to normative data.

And this is what we do at our center. Here's an example of a patient who comes in. Once again, this is the cumulative percentage on the Y axis and the CIQL expectation score or CIQL profile, either one on the. I'm sorry, no. This is the profile score, the normative data for the communication demand on the x axis.

So here you can see a patient comes in, they have an expectation score of 70. Right. And you can then use that to counsel the patient and say, you know, that's a really, really high expectations. We recommend you kind of go for that. But you have to understand that only 10% of cochlear implant users perform at that level or higher.

Okay. So you may need to reset your expectations to determine whether or not you want to pursue the cochlear implant. In contrast that the patient who comes in with a score around 54, you could say, yeah, that's a fairly realistic expectation. Right. 40% of cochlear implant users perform at that level or higher.

So that there's. When you're talking about the likelihood of outcome, that's in their kind of more realistic range. And then just once again, as a reminder, you can have these conversations with patients based on using these clinical vignettes. So rather than describing a score of 54, you can describe what a score of 54 means and how realistic and talk about the percentage of the patient. Patients who are in Those different stages.

So you can use a staging system also to kind of help guide these expectation conversations. So then the next question that arrives is now that we can actually measure patients pre CI expectations, how do

they perform relative to their expectations? Do cochlear implant users meet their expectations, not meet or exceed their expectations, which is how they think they are going to perform? So to look at this, look at this. We enrolled 60 adult cochlear implant users and we measured their expectations before they got their cochlear implant.

And then we measured how they actually did with the Ciqol 35 profile at 12 months. We then compared patients with whether or not they met their did not meet their expectations, they met their expectations, or they exceeded their expectations. And this was all within measurement, kind of looking at measurement error, error. So overall, looking at the outcomes, patients expectations were much higher than how they actually performed. Okay, so here each domain is listed on the X axis, listed in order of the highest percentage of patients who did not meet their expectations.

So looking for example, and the Y axis, percentage of patients. So for example, looking at the communication domain, 50% of patients did not meet their expectations for that domain, 43% of patients met their expectations and only 7% of patients exceeded their expectations. You know, very, very similar patterns are seen here for the communication, listening effort environment and global domains. Patients seem to have a little bit better, more realistic expectations when it came to the entertainment, social and emotional domains. Right?

You can see 34, 29 and 25% of patients only did not meet their expectations and larger percentage met their expectations for those domains. However, it's still not a great story, right? If you kind of look at those numbers, you know, you know, having, you know, somewhere between 25, you know, one and four to, you know, one in three patients not meeting their expectations, it's still not great. It's better than the other domains, but it's still really not great. How far off were patients when it came to meeting their expectations?

They were quite a bit far. If you look at the X axis here, data for the communication environment listening effort in global domains. And the darker blue is where these patients were before their surgery. The lighter blue is where they were at 12 months. Then the orange is where those patients were or how they thought they were going to perform with the cochlear implants or the ciqol expectation score for that particular domain, that was of course measured before surgery, but it's next to the 12 months, just to compare.

And so really large effect size differences were seen for the communication Listening effort and global domains when it came to comparing their 12 months outcome, a 12 month outcome to their expectations and a medium effect size for the environment domain. So these patients, you know, it really was not that close to where patients thought they're conform or they actually perform. So quite a big, big gap exists there. So why does this matter? Why does it really matter whether or not patients meet their expectations?

What are the implications of this? So to look at this we performed an Additional study of US of 38 cochlear implant users enrolled. Once again, bilateral hearing loss, traditional indications for cochlear implantation. And these were non, these are all post lingually defined adults. Once again we measured patients expectations before surgery and compared that to how they actually performed at 12 months after surgery.

But in addition we measured patients decisional regret. This is using the decisional regret scale and this is a widely used instrument that can be adapted for any medical intervention. And it asks patients whether, using a series of questions, whether or not they regret proceeding with your medical intervention. For this case we use cochlear implantation and outcomes range from no regret, mild regret, moderate or severe regret when you score it. We also looked at saddle scores, satisfaction with amplification of daily living.

This is an instrument and this we use the cochlear implant validated version of this, looking at the patient's overall satisfaction with their decision to kind of go forward with a cochlear implant. So looking at our outcomes, we were a bit surprised when we looked at it. So we dichotomized patients into two cohorts. One looking at 27 of the 38 only had either no decisional regret or very mild decisional regret. And 11 patients had moderate or higher degrees of decisional regret.

So while this might seem quite high, a recent study that came out by Sandy Apprentice, which is a multi institutional study, had essentially the exact same levels of decisional regret of cochlear implant patients. So really, really quite high. Some of the 20 to 30% of patients who undergo cochlear implantation have substantial amount of decisional regret with that decision. So shockingly high number for us and certainly warrants more investigation. But kind of looking at kind of what's driving, what differentiates these patients who had decision regret compared to patients who did not have decision or regret.

So here we're going to look at scores for the global communication environment. This Y axis, a little bit in this Y axis is a little bit tricky here, right? So if you're at zero, that means you had better alignment between your Expected outcomes and how you actually performed. Okay, so there's less of a difference between your expectation and how you actually performed. If you look at the top versus 35, this is worse alignment.

So there was greater differences between how patients thought they were going to perform and how they actually performed. So let's look at differences between these patients. So looking at all the other communication, sorry, global communication and environment domains, patients who did not have decision of regret had much better alignment between their expectation and their actual outcome compared to patients who had decision to regret. And these were all very large effect sizes. Looking at all of the data taken together, this appears to be for our understanding right now, the major driver of

patients who have decision regret.

They're basically not performing as well as they thought they were going to perform. And more data to come out on this. Interestingly enough, when we look at patient speech recognition score and kind of, you know, looking at the standard outcome measure that we've used for years, there's no statistical significant difference in patient's word recognition ability or their sentence recognition ability between patients who did and did not have decisional regret. So it's pretty fascinating, right, that our standard outcome measure that we've used for many, many years shows no difference in patients who have moderate or higher decision regret compared to patients who have no decisional regret. And you can see how that contrasts so greatly when it comes to not meeting their expectations.

So we continue to look for focus solely on word recognition and sentence recognition ability. We're going to really not be able to identify these patients who are regretting their decision for pursuit of the cochlear implant. Just for time's sake, we're not showing the saddle scores, but very, very similar patterns that we saw for the saddle scores. Patients who had higher satisfaction were more likely to meet their expectations compared to those who had lower satisfaction. But importantly, are patient expectations modifiable?

We talk about the importance here of patients having realistic expectations, but can we actually modify expectations? This is a paper that was just recently published in Ear and Hearing where we actually looked at this question. So we measured patients expectations before they came in to get their evaluation and then we measured it again at the time of their surgery. So if you're lower here, these are patients who lowered their expectations. If you're above zero, these are people who increase their expectations here.

Blue are the group of the patients who had lower expectations. Orange are patients who had higher expectations. And as you can see, counseling is having overall the effect we'd like it to have. Right?

Patients who come in with Very, very high.

Sorry. Very, very high expectations. Their expectations are decreasing from the time they came in for counseling to the time of surgery. And patients who came in with very, very low expectations, their expectations are increasing. You see, there's a few outliers here, but overall counseling seems to be having the effect.

And most importantly, we are able to modify patients expectations. So when it comes back to this question, do patients have realistic outcomes? Does the patient have realistic outcomes? Regarding cochlear implant outcome, expectation, outcome. The bad news is that many patients have unrealistic expectations prior to their cochlear implant.

Also, what I consider patients have unacceptably high levels of decisional regret after they get their cochlear implant. I think more needs to be done. The good news is I feel like we're entering a new era of these new instruments. We now have the ability to measure patients expectations prior to surgery and so we can actually understand where their expectation levels lie. And we have the data available to provide evidence based counseling.

So we have normative data on how patients are doing. We compare measured patients expectations before surgery and determine how realistic those expectations are. And also good news is that those expectations are modifiable. Okay. So I feel like we've come a long way of answering these questions that we want to answer and we wanted to answer with the cochlear implant quality of life instruments, but there's a lot to take in here, right?

And how do you do this on the fly? How do you do this when you're actually seeing a patient in your clinic who is filling out these instruments? How do you rapidly interpret all of these things? So to help with kind of all both of these, we've developed the cochlear implant digital platform. Okay.

So this is a app and web based portal that helps accomplish this. So one allows for efficient data entry. Patients complete the instruments at home, they can review data at home. So it doesn't take time from your clinical encounter. Not only that, you know, they, it should be all done before they come into clinic.

So it's available for the clinician to review prior to their, prior to their cochlear implant. It is automatically interpreted so you don't have to kind of look at and think about and look at different tables to determine kind of where this patient's expectations, whether or not they're realistic or not, where they kind of fit onto that reverse cumulative survival curve. All that interpretation is done for you. And also the interactive format, which I'll show kind of what it looks like in a second. But this is where patients and clinicians can interact with the digital platform and to kind of understand where their expectations, where, you know, their baseline abilities are and kind of look at how that compares to overall larger samples.

So this is kind of what it actually looks like. You know, this is an example. A patient clicks on their pre CI evaluation, they can then click on their baseline abilities. They can click and see kind of all the different domains that are there. And the patients, after they've completed it through the app, they can look at where their baseline pre CI score is here, their preci score is here, and see that they're in stage two.

They can go down to the bottom and the clinical vignettes are available. The patients, they can understand what stage two means. And you can actually look here to see what percentage of patients scored at that ability level or higher. Okay, so here you can see that, you know, for example, this patient scored a 32. And this automatically interprets that 95% of cochlear implant users score at that level or higher.

And the from looking at the clinician's view, the clinician's portal of this, this is what it looks like. So again, you have a patient who know their expectation score, for example, was a 45. It's automatically

interpreted for clinicians. So you can say 63 of cooklet percent of cochlear implant users perform at this ability level or higher. And once again, the staging system is available through the digital portal.

So you can look at that. And once again, looking at baseline ability levels, once again, scores are automatically, it's automatically scored and interpreted for clinicians, so you can say 90 for this patient, 32, 95% of cochlear implant users scored at that ability level or higher. And then once again, the staging system is available. And not only that, we can actually just talk very, very briefly. The it automatically interprets change and it can monitor patients over time.

So kind of looking at these little check marks at the top here, these compare patients scores at one month to their pre CI score, determines whether or not this patient improved compared to their baseline abilities. Once again, that is done kind of using the conditional minimal detectable change score. So you don't have to look at tables and determine whether or not it's improved or not improved. Then also if you click on the all tab, you can see patient scored over time. These arrows mean the patient had a measurable improvement from the prior time.

So this patient kind of improved initially, but then they kind of went down a little bit. And that's why they have that X there. And it's no different than that prior time point. But you can see how it automatically interprets whether or not they improved from that prior time point compared to where they are now. So all that's automatically interpreted.

We've also working on developing Decide. This is a multi level intervention to improve cochlear implant expectation kind of in cochlear implant counseling overall. So decisional support for cochlear implantation by discussing patient experiences. Decide. This is six different components for this and just briefly kind of go over, you know, and these are based on kind of qualitative interviews we've done with patients and clinicians to date to identify these components using, you know, intervention mapping techniques.

So comparison to patient's baseline abilities compared to potential cochlear implant outcomes, comparing the expectations to normative data, timeline for improvement. What are the limitations? What's the surgical process like? What are the surgical risks? This is all then, you know, using interactive graphical representations to kind of look at this, using video testimonials and risk outlines.

And again, the selection of these were based on what patients wanted, what they wanted to know. And then once again, this is kind of interacts with our digital platform. Right. So this is integrated within the digital platform and often be done as a unified front. And again the clinicians portal and these all lead to standardized discussions with clinicians.

Okay, so last thing, I'd like to very much thank our team, our research team first and foremost. You know, this takes a lot of patience to accomplish so very, very always, always grateful. Over 900 unique research participants have participated in this research to date to accomplish these goals. A wonderful research team and our incredible adult cochlear implant team here at MUSC that deals with me and all my crazy ideas and also very appreciative of the cochlear implant Quality of life research Consortium. This is a group that we put together to accumulate the normative data and to validate, to develop and validate our, the CIQL instruments.

And so finally, you know, questions. Happy to answer questions now, but always you can reach me on my email [McCrackenusc.edu](mailto:McCrackenusc.edu). you can use the QR code here to go to our website. All the instruments are free to download and as is our user manual so that it's available, you can click on our website and automatically download it. This is a user manual that kind of takes you through the how to use the quality of life to CIQL instruments, what they are, how to interpret the scores, the functional staging system, the expectations it kind of walks users through all of those things.

So it's a very, very. A helpful guide that we developed in the first version of. It's freely available online. So kind of at that point, at this point, I'd like to thank you all for tuning in and thank the American Auditory Society for allowing me, along with the audiology, online and continue ed for allowing me to present on our research. So thank you very much.

Thank you so much, Dr. McGrackin. We'll go ahead and open up the floor for any questions or comments that we might have from today's presentation. There's plenty of time, so feel free to type at any time for our guest speaker.

And I think I'm supposed to go to this slide right now. Yeah. Thank you, Dr. McCracken. This is just a reminder.

Once the course has concluded here, you can just stay on and complete the multiple choice exam, should you wish to take this course. For CE credit.

Dr. McRackan, could you maybe go back to the slide where they speak on where do most adult cochlear implants users typically perform? And that was stage. I think you said stage three. Right.

Could you elaborate on that for us a little bit? Yeah, you know, part of.

Yeah. So stage three is kind of. This is from the communication domain. So most cochlear implant users end up kind of functioning in that stage three. So 64% of users.

And, you know, this is kind of right in that middle ground of, you know, having, you know, consistently having difficulty, substantial difficulty in noise, even when they're lip reading. Right. So you kind of look at the clinical vignettes and kind of look at what those differences are. And this is kind of work we're doing to kind of help personalize auditory training. Right.

So if you look at that stage, you know, 3, 64% of users have difficulty and those particular environments. And you can see it's kind of a nice normative distribution when it comes to, you know, 13% of stage two, you know, 20% in stage four, and then fewer kind of. This is extremes. Right. And fortunately, very few in that, in that lowest domain.

But if you kind of look at going back to the staging system here, this is what speech language pathologists who do auditory training or maybe kind of automated can kind of start to use the staging system to kind of direct their treatments. And if you kind of look at where these patients are. Right. So a patient who's in stage two has very different ability levels compared to patient who's stage three. So, you know, a therapist might want to direct their use these data, which are available online, to kind of direct their therapy at.

What are those transition points? Right. How does some get from, you know, never to rarely? From rarely to sometimes? And what are those kind of abilities that are associated with the items that are going to get them there?

So rather than kind of applying, you know, the same auditory training to, you know, every patient that comes in, you can actually look at where patients are now and see where they want to get and what are those abilities they're going to need to get there. So this is kind of a work we continue to do, and it's not the easiest work to kind of quantify, but it's a logical. A logical model to use. Right. So someone who comes in, who starts off in stage one, and maybe by three months, they're still in stage one.

Well, that's very different than somebody who kind of by three months, they're in stage three. You know, those people are functioning at very different ability levels, and the therapy and training they need to get to that next level is very different. So. Yeah, and Dr. McCracken, you mentioned that patients in stage one are the most likely to improve beyond their free CI abilities.

Is that right? Could you. Could you take us back to that slide? Yeah, absolutely. So, yeah, I mean, if you kind of look at overall, I mean, it's logical, right, that patients who are in stage one, you know, all of them improve, you know, compared to their baseline ability levels, and that that gets, you know, as you get closer to how the average cochlear implant user performs, that number is going to get smaller and smaller.

So, you know, looking at these data, they're a little bit striking. It's almost like a reverse of the no change to improve and the, you know, improve the no change. Right. It's almost like you swap those when you go from stage two to stage three. And again, if you look at kind of these curves over time, you can just see that, yeah, patients, there's going to be a average that's going to be similar.

We know from all cochlear implant users from our data that there's a normal distribution of patients performing at a particular. That's most aren't going to end up in stage three. That's something to consider when you're counseling patients. And if you have someone who's in stage three and is pretty happy with how they're doing with the. With their hearing aid, it might be someone you say, look, it may not be the time for you to kind of proceed with your.

Your your with the cochlear implant. Right. Let's see how you're doing. Let's see if you fall into stage two, well then that might be the time to kind of consider going forward with the cochlear implant. So this is, you know, research we have ongoing to kind of look at that and to, you know, look at this in a multi current multi institutional study going on looking at this exact question, right.

Of can we use patients preoperative communication domain to not predict but kind of help counsel how they might perform long term. So a lot more research to come in this area.

Thank you, Dr. McRacker and I don't see any other questions in the queue. We'd like to thank you for your time and your expertise and also to the American Auditory Society for, you know, inviting you to this partnership. If you all have not taken any of the other AAS partnership courses, they're all on our course library. And we're just so delighted to have Dr.

McGrathen back this time around with AAS. We'll go ahead and close up the classroom. We thank you so much for your time. Have a great day everyone. Thank you very much.