Candidacy Evaluation for Expanding Indications for Cochlear Implantation
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- [Zwolan] Hi, my name is Terry Zwolan and I'm director of the Cochlear Implant Program at the University of Michigan and I'm really so excited to talk to you today about this study that we did with the CMS population titled An Evaluation of Revised Indications For Cochlear Implant Candidacy for the Adult CMS Population. I'd like to begin by acknowledging my co-author and co-PI on this project, Dr. Craig Buchman. Dr. Buchman and I have worked for several years on this project and we're really happy to provide these results with you today. We also acknowledge Dr. Kallogjeri for her statistical expertise and we also acknowledge Dr. Jill firszt and the late John Niparko because they both contributed greatly to the development and initiation of this study. This study was supported in part by the American Cochlear Implant Alliance as well as by the centers for Medicaid and Medicare Services so you can see it was truly a group effort and we would finally like to thank the participating centers for their devotion of time and energy to this study, without that we would not have been able to really finish this study and bring it home.

So, as you all know, CMS indications for a cochlear implant have been in existence for a very long time since 2005 and they require beneficiaries to demonstrate a bilateral moderate to profound sensorineural hearing loss and to score less than or equal to 40% correct in the best aided listening condition on tape recorded tests of open-set sentence recognition in order to qualify for a cochlear implant. These indications are more stringent than the FDA approved indications that many of us deal with with our non CMS beneficiaries, meaning that some Medicare patients are less likely to receive a cochlear implant because of their insurance. So, in the Medicare NCD or National Coverage Determinations, they also state and we've been able to do this for the past several years, that the evidence is sufficient to conclude that an implant is reasonable and necessary for individuals with hearing test scores of greater than 40 but less than 60% on sentences but only when the providers participating in and patients are enrolled in either an FDA approved category B IDE clinical trial, a trial under the CMS clinical trial policy, or a prospective controlled comparative trial approved by CMS. So, this provides background information by how we were able to do this study and this is

an approved study by the Center for Medicare and Medicaid Services. So, we all know that outcomes are improving and indications are expanding, we've seen so many changes in cochlear implant candidacy over the last several years, the FDA has now approved hybrid and EAS devices such as those approvals that both cochlear and MedEl have received and more recently, the MedEL device has been approved for single sided deafness as well as for patients with asymmetric hearing loss and both of those groups pertain to individuals five years of age and older. So, all these changes bring about important changes in candidacy and really, the time is right for Medicare indications to change as well. So, this study really started in May of 2011 when Medicare held what was called a Medcac meeting, where we reviewed the clinical evidence for cochlear implant procedures and part of the purpose of that meeting was to review clinical outcomes associated with unilateral implants with sentence tests scores in those two ranges between 40 to 50% and 51 to 60%.

Unfortunately, at the end of that study, it was concluded there wasn't enough data to support a change at that time to the indications so in July 2013, the American Cochlear Implant Alliance submitted a proposal to CMS to investigate expansion of the NCD to those two groups of beneficiaries and in July 2013, the CED study was approved and that's our national clinical trials number and information about this study can be found on clinicaltrials.gov. So, we started this CED study in 2013 but in September 2015, we changed our protocol because the initial study was started using HINt sentences so CMS approved a change in our study protocol to use AzBio sentences instead of outdated HINT sentences for candidacy determination as well as outcome measurement. Should be noted that we did enroll two subjects using HINT sentences and those two subjects have been placed into the 40 to 50% group. In September of 2018, we provided an interim review to CMS and then last August, we provided a final review where we had 12 month data that we'll be showing to you today and I'm happy to report that in this past March, we submitted a manuscript summarizing study findings and we're hoping that we can move forward with these changes to the NCD. I'd like to begin by acknowledging our participating centers, they're listed here. The

study initially started with 10 centers but our accrual of subjects was somewhat slow so we decided to spread those centers out even greater across the United States in order to give CMS beneficiaries better access to the Study and we increased it to 19 different centers. So, the purpose of this study on the proposed coverage with evidence development or CED study evaluates the use of cochlear implants and Medicare beneficiaries with preoperative open-set sentence recognition scores in quiet that fall between 40 and 60% correct and similar to previous NCDs, we are looking at that score falling in the best aided listening condition. So, our a priori hypothesis was that intervention with a cochlear implant would improve the AzBio bio-sentence score in the best aided condition by 25 percentage points or more and in the implanted ear alone by 30% or more.

Now, traditionally, Medicare has looked at that best aided condition so we included that but we also felt it was important to look at the implanted ear alone so we included both of those hypotheses. We looked at test scores obtained pre-operatively and then we compared it to scores obtained both six and 12 months post-activation, our primary test included the AzBio sentences in quiet presented at 60 dB A and pre-operatively, we tested that in the right ear aided, the left ear aided as well as both ears aided together. CNC words were presented at 60 dB A also in those three listening conditions and we actually added a telephone test where CUNY sentences were administered monitored live voice to the ear to be implanted pre-operatively as well as to the implant ear alone post implant, we utilized self assessment questionnaires and we're gonna go through each of those on the next slide. We felt that it was important to specifically look at hearing aid benefit or changes in hearing outcomes and the APHAB or the abbreviated profile of hearing aid benefit was helpful for that because this test or this questionnaire helps quantify the disability associated with a hearing loss. We also included the Short Form-36 or the SF-36 which is helpful to derive a preference based Health Utility Index through the use of utility transforms. It has really been used in several studies to differentiate the health benefits produced by a variety of treatments so in our case, the cochlear implant. We also used or looked at the Health Utility Index

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or the HUI which provides a comprehensive description of the health status of subjects in clinical studies. Importantly, we wanted to look at hearing aid use because, we know that if we're going to look at best aided conditions pre-implant that we're going to have input from that contralateral non implanted ear so we felt it was important to determine a way to include that hearing aid in the contralateral ear if it was used in our outcomes. So, all of our measures, of course, were administered in an implant alone condition post implant but if patients reported they used a contralateral hearing aid more than four hours each day, then all of the measures were also administered in the bimodal condition of the implant plus the hearing aid on the contralateral ear. One exception to that was our telephone test, we felt it was difficult to administer that bimodally so the telephone test was only administered in the implant alone condition and the best score, we would compare the score obtained when the implant alone was used, as well as an implant plus hearing aid in the contralateral ear, we compared those scores and whichever score was greatest was used in the calculation of best aided that you'll see in our result slides.

A total of 32 adult patients received cochlear implants between September 17th 2014 and July 10th 2018 were enrolled at eight participating centers. Those centers are listed on the far right side of this slide and you can see we had really nice distribution across the United States. Our total subjects sample included 31 patients who completed the study. Actually, that number went down to 29 at 12 months, we see that one subject was lost to follow up and one subject passed away prior to his 12 month time frame. We did break our study down into two groups, again, remember we have one group who scored between 40 and 50% or less than 50% and there were 12 subjects in that group and then we had 19 subjects whose baseline AzBio score fell between 51 and 60%. There were no significant differences in distribution of baseline characteristics between the two study groups so as we provide you with the results, you'll see those groups broken down into two groups but a lot of times because of that lack of significant difference between groups, we report them as one cohesive group of subjects. The baseline characteristics of the group as a whole, you can see here, we

had more male than female subjects at 74% of our participants were male, we had a few more right ears than left ears, their average age at activation, or their median age was 73.5 years and the only other thing I'll point out here is the length of deafness in their implanted ear is about 10 years. I would say we were pretty happy with these characteristics because, we feel as though they do reflect most of the Medicare beneficiaries that we're seeing in our clinics today who show up as potential candidates for a cochlear implant. The primary outcome measure was the change in AzBio sentence score from baseline to 12 months post implant and that was defined by taking their score at 12 months and subtracting their baseline score and remember, we had a one sided hypothesis that in their best aided condition, that that difference would be greater than 25% and in their implant alone, that that difference would exceed 30%, it would be equal to or greater than 30%. A Shapiro-Wilk's test indicated that data were not normally distributed which is what we commonly see in our Cochlear Implant Research so we report primarily on median and range in order to describe our variables. median differences and 95% confidence intervals were used as our measures of effect size and a mixed effects model was used to examine differences between those two groups. The less than 50% and the greater than 50% group throughout our study visits. Spearman's correlations were used to explore the relationship between speech perception and the self assessment questionnaires because, both us and CMS felt it was important for us to look at these self assessment questionnaires and determine functionally how these differences were represented in our questionnaires. So next, I'm gonna turn this over to Dr. Craig Buckman and he's going to take us through the results of this study as well as discuss with you the summary as well as what our next steps will be in regards to this important study. Thank you for your time.

- [Buchman] Okay, thank you very much Dr. Zwolan, we'll now move forward with the results. So, these are the results of our study and what you can see here in the table and the graph, as you see both best aided results as well as the using the cochlear implant alone for AzBio sentences, if you look here at baseline AzBio sentences in the

best aided condition, the median score was 53% and for AzBio score with the CI alone was 24 and then the six month interval you see just really a big change from 53 up to 91 and with the implant alone 79 so really big changes and similarly, we see these at 12 months and this is graphically represented here below, best aided, of course, it's between 40 and 60 pre-op 'cause that were our inclusion criteria and then following, it went up to as high as 90% best aided and you see nearly 80% in the ear implanted. So, to test the null hypothesis, a group, the median change in the best aided AzBio sentence score was 39% which is significantly greater than the 25 that we started with as our criteria and for the CI ear alone, for AzBio was 52% which is better than the 30% hypothesized. Importantly, 21 of 31 individuals or 72% demonstrated a greater than 25% improvement and when you looked at the two groups remember the first group was those that started with a 41 to 50% score and the second group was those that started with a 51 to 60% AzBio score and you can see 100% of those that started between 41 and 50% improved greater than 25% and nine out of 17 or 53% in group two, as you think about group two as you're starting with better and better scores, there does become the issue of reaching a ceiling effect.

So, this looks at a mixed model analysis and estimated marginal means for again, best aided testing here on the left and CI alone testing looking at AzBios and again, you see this median score of roughly, or mean score, excuse me, of around 50 prior to and then at six months upwards of 80% by six months and then 12 months, if you look at, and then similarly, for the CI ear, you see this large change which is of course significant. If you look at the 95% confidence intervals, which basically compares baseline to six months baseline to 12 months and then six months to 12 months, what you see is baseline versus six and 12 months are both significant but there's not a real difference between six and 12 months meaning that once people have reached their six months score, they're not having large changes between six and 12 months. Similarly for the CIA ear alone, you see a big change between baseline and six months but not as much of a change between six and 12 months, although this was significant, it'll be really close. So then, if you break the scores down by the group that they were

in meaning those that started with a 40 to 50% score, or those with a 50 to 60% score, what you can see is both groups had significant benefits so both groups had significant changes and really, whether you started at 40 to 50 or 50 to 60, you saw a significant benefit and that was true for both the best aided score as well as the CI ear alone. So, this shows the AzBio scores using the mixed model analysis and what you see is that baseline scores are again around 50% here and then by six months, they jump up to near 80% and this difference between six and 12 months is not significant, you can see that according to the 95% confidence intervals. Similarly, when you look in the CI ear alone, you see really, a large change between baseline in six months and then a much smaller change between six and 12 months. The other interesting thing is you see here, the baseline or the CI ear was certainly the poor hearing ear in most instances when these patients received an implant.

So, this looks at AzBio sentences broken down by the two different study groups, those that started with a 41 to 50% score and those that had a 51 to 60% score, on the left here is best aided, on the right is CI alone and just to sorta cut to the chase here, what you'll see is that both groups significantly benefited from the device, those that started with poor scores to begin with, meaning they were in the 41 to 50% group they had a larger change of course than those that started 50 to 60 but really significant changes for AzBio in both groups. So, this shows CNC word scores as well as the CUNY sentence telephone tests and what you can see here in the table above and then shown graphically below is that our CNC word scores in the best aided condition were 38, the median was 38, prior to surgery or prior at baseline and then by a six months again, big changes up to 78% by six months and then stable beyond that and the CI ear alone, they were generally starting somewhere between 10 and 20%, you see the median score there 16 with median score of 62 at the six and 12 month period. This was sort of a interesting test is the ability to do CUNY sentences across the telephone and you see really poor performance prior to with those scoring around a median of 24 at baseline and then a big change by six and 12 months. This shows the estimated marginal means or the mixed model analysis again for these particular

variables and CNCs had a big change between baseline and six months and then stable to 12 months and then you see here with the CI ear alone you see also a big improvement. Looking here as a breakdown between the two different study groups, the entry criteria, those that started with 41 to 50% and those that were at 51 to 60%, again, both groups, big improvements, these were statistically significant generally speaking by the six month time point most of the change had occurred and then between six and 12 months, not so much. These are the results of the CUNY telephone test and again, you can see with a mixed model analysis, big improvement by six months and then stable beyond that and then when you compare the two groups, those starting with 40 to 50 or 41 to 50 or 51 to 60 on their pre-operative AzBio again, both groups did well, sort of interesting that actually those that started with a slightly better score ahead of time actually didn't have quite as much delta but these are really not different.

So, on to subjective test, this was the APHAB, this is, of course, a test that many of you might be familiar with, it looks at a number of different hearing specific quality of life indicators and you see the APHAB is broken up into five different domains. The global domain is sort of a summary domain and then there's ease of listing reverberation noise and evasiveness, the important thing is all of these result in positive test results so the better you do, the more positive it is but then evasiveness is the better that you do, the more negative it is and just to say, what I think you can see here in the graph below is at baseline, you can see what the scores were and then following cochlear implantation, you can see a substantial improvement for each of the various domains. And then this is the estimated marginal means for each of the APHAB sub domains and generally speaking, there were significant changes over time for for many of these, again, similar to the other metrics, six months showed strong significance and differences between six and 12 months were much less apparent. This is the results of the HUI3 and the HUI3, again, looks at a variety of domains, one of which was really important, of course, is the hearing domain and then there's one that's the multi sort of a conglomeration of all of the other domains put together and you can see the raw

scores here are the medians and ranges here but I'll show you the analysis more specifically. So, this looks at HUI, you see here HUI vision, HUI hearing and HUI speech as compared to baseline six months and 12 months and you see that for each other these graphs and the long and short of this is that for HUI vision and for HUI speech, there were no significant changes but for HUI hearing, you see the significant change at six months and then 12 months, things were pretty flat. The other sub domains really had no significant change except HUI dexterity which was somewhat unusual. the reason is 'cause it dropped down just slightly and then came back up. And then here, it looks at pain cognition and multi and I think the thing to recognize here is that the multi had significant change because, each of the other domains really didn't change much significantly, the main change in the HUI multi was driven by the change in HUI hearing. the SF-36, which is a more global measure of quality of life really had no significant changes across the various domains. That's because it doesn't really have metrics that look at the categories that are really driven by a cochlear implant.

Importantly, this is probably one of the more important slides that you'll see, this looks at correlations between changes in the AzBio scores in the cochlear implant ear versus changes in the HUI3 and the APHAB so we're looking at quality of life changes relative to how a person improved on their speech recognition score and what you can see for both of these is really moderate to strong correlations for changes in AzBio sentence score in the CI ear here versus HUI3 multi, which as you know is driven by HUI hearing so that's nice to see that the objective measure of speech perception is correlating somewhat or correlating modestly with changes in quality of life. You can also see over here on the right, similar metric here changes in AzBio in the implant ear alone and then versus APHAB and again, really moderate to strong correlation suggesting that changes in your speech perception are good indicators that you'll have a nice change in quality of life. So, to summarize the findings of this study using all the available cochlear implant systems show effectiveness for treatment of hearing loss and Medicare beneficiaries with preoperative sentence scores that fall between 41 and

60%, adults in this study demonstrated significant improvements in sentence score and telephone recognition tests and improvements in the AzBio sentences in both the best aided and the CI alone conditions were significantly larger than the predefined clinically important changes of 25 and 30% respectively so we were able to accept our hypothesis. Improvements in speech recognition appear to be related to positive changes on the self reported assessments such as HUI hearing, HUI Multi and the sub domains of the APHAB. So, what does all this mean? The results of this support the following proposed changes to CMS criteria. Cochlear implantation may be covered for treatment of bilateral pre or post-linguistic sensorineural moderate to profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification would be defined by scores of less than or equal to 60% correct in the best aided listing condition on tape recorded tests of open-set sentence recognition.

This requested change if approved by CMS will increase access to cochlear implants for Medicare beneficiaries and will facilitate treatment of hearing loss in a more timely fashion, a factor that could help produce the impact that hearing loss has on patient's overall health and quality of life. So currently, the stage of this manuscript is it's been recently submitted for publication and if published a formal request for a national coverage determination which is an NCD for cochlear implants will be submitted. This will include opportunities for public comments so we'll be reaching out to many of you for you to be involved. Importantly, this has been a very, very long process that's been ongoing for a number of years, in addition to Dr. Zwolan, I'd like to recognize Dorina Kallogjeri who gave us statistical support for this work, as well as really importantly, John Niparko, who had a lot to do with this study getting started in it's early days in it's design and he was a staunch advocate for cochlear implants really worldwide. So, if anyone has any questions, you can certainly either email them to Dr. Zwolan or myself and thank you for listening.

- [Zwolan] My name is Terry Zwolen and I'm director of the Cochlear Implant Program at the University of Michigan. And my co-authors for this paper are Dr. Kara Schwartz Leyzac and Terence pleasant and our talk is titled Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Evaluation. I'd like to begin by acknowledging the team at the University of Michigan and as many of you know, access to cochlear implants is poor, it's estimated that less than 10% of adults who qualify for an implant actually end up receiving one and those numbers are very dire, we really want those numbers to increase, we wanna provide access to cochlear implants for as many adults as we can and there's many reasons that have been proposed for why this number is so low. We know that there's a lack of hearing screening for adults and we know how many times have you gone to see your primary care doctor and they rarely asked you about your hearing.

There's lack of candidacy awareness among primary care physicians, audiologists and the general population. We know that there are no current referral guidelines for audiologists who dispense hearing aids and that group is so important for us because they're the ones that really should be referring patients to receive a cochlear implant evaluation and Teddy McCracken has noticed a weak to moderate positive correlation between unaided word recognition scores and aided word recognition scores which we know, the first one, the unaided word scores are the ones that the hearing aid audiologists are using and the aided scores are the ones that the implant audiologists are using so there's a bit of a disconnect there which leads to actually, we have some poor communication between hearing aid clinics and cochlear implant clinics and I've heard from some potential referral sources that they're worried that patients will be upset if they travel all the way to a clinic only to find out that they're not a candidate for a cochlear implant and one of the things we're going to focus on in this study is that there are big differences in the test procedures that are being used by referral sources and the clinics that are doing the evaluations of cochlear implant candidacy. Evidence-based criteria is lacking regarding when to refer a patient for a cochlear implant candidacy evaluation. There are a few investigators who have published evidence

based criteria for when to recommend a CI and that's very different versus one to recommend a patient be evaluated for a CI. A Gubbels in 2016 examined medical records of 139 patients over a five year period and I love this study, it was extremely well done and they found that 86% of their patients with monosyllabic words scores at or below 32%, met criteria for a cochlear implant and they also concluded that a pure tone average that was greater than or equal to 75 dB or a word recognition score less than 40% have a high likelihood of being an implant candidate. The only thing with this study which was done four years ago, candidacy was based on different measures than what many clinics are using today, they base the candidacy on HINI sentences, AzBio sentences in quiet as well as AzBio sentences delivered in a plus five signal to noise ratio.

If we add into the mix that different implant clinics are utilizing different materials to determine candidacy really adds to the confusion that our referral sources have of who's a good person to send for a cochlear implant candidacy evaluation. And if we add into this that the implant scenario has changed recently, we know that MedEL in 2019, received approval for single sided deafness and asymmetric hearing loss and that many of our clinics are more likely to ask insurers to pre authorize implantation off label than we ever have in the past but we're still missing those traditional candidates, those patients who meet traditional criteria for an implant, our clinic sees a lot of these patients who've likely been candidates for a very long time that haven't spoken openly on the phone, even with familiar speakers for at least five to 10 years and we know that's a strong sign and they probably should have been in our clinic five to 10 years ago so we really wanted to focus on those traditional candidates that are coming to our clinic too late or who are being missed by the referral sources. So, the purpose of this study was to develop referral guidelines for traditional candidates. We know that the traditional FDA candidacy guidelines vary for commercially available devices so for this study, we decided to base our criteria on the most lenient FDA indications and those would state that patient should have a bilateral moderate to profound sensory neural hearing loss and that they should score less than or equal to 60% correct unrecorded

sentences when tested in the best aided condition. We also wanted to see if this referral guideline would be appropriate for patients involved in the Medicare population and we know that their criteria are a little stricter, Although patients need to have a bilateral moderate to profound hearing loss, their candidacy requirements regarded aided speech recognition are stricter and they must score less than or equal to 40% correct unrecorded sentences. So, a lot of our patients are coming in that are Medicare beneficiaries so we wanted to see if this was applicable to that population as well. And importantly, we wanted a guideline that would be clinically useful for referring clinicians so we focused on measures typically performed by referring audiologists that relate to measures used in the implant candidacy determination so we know based on that review of the guidelines that we're importantly looking at unaided hearing so we wanted to look at the unaided pure tone average of the better hearing ear and we picked the better hearing ear because of the FDA indication stating we need to look at the best dated situation which is greatly influenced by that better hearing ear. We also decided to look at the highest preoperative unaided, monosyllabic word recognition score because again, because of that best aided situation that the FDA indicates we need to look at.

So, for our methods, we reviewed the medical records of 661 adults who participated in a Cochlear Implant Candidacy Evaluation at the University of Michigan between January 1st, 2016 and September 30th of 2019. This timeline was selected because, we had a consistent use of a protocol where we would administer AzBio sentences in quiet or in a plus 10 signal to noise ratio and patients needed to score less than 60% on that measure, in order to be considered a traditional candidate using FDA indications and needed to score less than 40% in order to be considered a Medicare candidate. We examined the test results to determine if the patient's met these traditional criteria which we defined as a bilateral moderate to profound sensory neural hearing loss in the lows and a profound hearing loss in the mid to high speech frequencies as well as that score of less than or equal to 60% correct on AzBio sentences in quiet or a plus 10 SNR. So, of the 661 records that we examined, 250 of

our adults met traditional indications for a cochlear implant. 279 adults did not meet the traditional indications, that doesn't mean that they were sent away without an implant, some of those were candidates for off label requests to their insurer for coverage of a cochlear implant but for the purpose of this study, we indicated those as non candidates because they did not meet traditional indications. An additional hundred and 132 candidates were removed from the analysis, Several of them are non English speaking, Some of them had some mild cognitive impairments, some of them were inappropriate referrals that we all see, they maybe never tried hearing aids in the past or some of them were non traditional referrals such as those specifically referred for single sided deafness but we really wanted to develop a guideline and then we wanted to examine the hit and miss rates associated with that guideline. So, as a result of examining those records, we came up with 529 subjects who could be included in our study.

So then, we looked at the preoperative data for these candidates and non candidates and again, we looked at the unaided thresholds and then we looked at their best unaided monosyllabic word recognition score and when we did this, we looked at the information we received from the referral source so if available we use the score obtained at the referring clinic, if they sent us an audiogram and there was no word recognition score then we would use the score that we obtained as part of their audiometric testing as part of their cochlear implant candidacy eval, we accepted all comers for this meaning that no matter what test they used and if the test was administered, taped or live voice, they were administered at a variety of presentation levels because it was typically done at the MCL and we know that that varies for patients depending upon their hearing loss. So, because that's the type of information we receive from the referral sources, we decided to include all of the available speech recognition data. So, now we're going to move on to our results and here on this slide, we have the preoperative, unaided, better ear pure tone average for the traditional candidates so we really wanted to see what were the demographics of this group in regard to their unaided hearing and so what we have on this version A of this figure, on

the left hand side, you see that we're looking at the cumulative proportion of patients and we've got their better ear pure tone average broken down so the bar on the far left, we see if they're better ear PTA was between 30 and 120 dB, that included 100% of our patients. If we took it out to 40, then 99.5% of them had a pure tone average that fell somewhere between 440 and 120 and as the pure tone average goes up, the cumulative percentage goes down. On the right hand side, you see the proportion of patients who have various pure tone average so it was a different way of breaking down this data set so what you see here on the right hand side is that most of our patients have a better ear pure tone average, these traditional candidates that fell between somewhere between 70 And 90 decibels. If we look again at this data, we wanted to see where are most of our traditional patients falling? And we find that 95% of our patients presented with a better ear pure tone average that was greater than 60 dB So we look at that line on the A side of the graph on the left side and we see that 95% of our patients have a pure tone average greater than 60 dB and the vast majority of them had a pure tone average that was much greater than 60 dB so as we know, most of them had a pure tone average greater than 70 but we've got a lot with pure tone averages at about 110 or 120.

So, that was part of it so we're looking at, okay, most of them have that pure tone average greater than 60, now let's see where their word recognition scores fall and not everyone had a word recognition score. I'll be honest that when we do the candidacy eval, we don't always release previously, we didn't always test their unaided word recognition so in this slide on part A on the left, we again have cumulative proportion. so we have cumulative percentage data and we're break it down into a 10% chunks. So, 100% of patients scored between zero and 90 and as the word recognition score goes down, the cumulative percentage also goes down so if we then look at the right hand side, what we're seeing are the proportion of patients with various word recognition scores so what we see is the greatest number of our candidates are having word recognition scores that fall at about 34.4% and at 34.4% of them have a score that falls at about zero to 10%, that's a pretty low score but if we look and we break it

down, if we look at 60%, we find that 92% of our patients will have a score less than 60% and we're seeing that most of them fall here and very few fall above that. So, based on this data we developed this 60/60 referral guideline because more than 90% who qualified for an implant demonstrated a better ear pure tone average greater than or equal to 60 dB and more than 90% of them had a better ear word score that was less than 60%. When we look at our data based on 415 patients that had both pure tone average and word recognition scores our 60/60 referral guideline was accurate for 82% of the patients so that would be an 82% hit rate in our traditional candidates. Our miss rate, we would have missed 80% of our patients if we just determined if they would be evaluated or not based on the 60/60 guideline so based on these findings, we believe that patients should be referred for an implant evaluation if they meet that 6060 referral. One other way that we looked at the data is how effective is it as a 60/60 screening tool? So, there's a lot of different ways you can look at the the efficacy of this so the first way that we looked at it was we wanted to look at sensitivity, how sensitive is it? And we found that 212 out of the 220 candidates met the 60/60 guideline giving us a 96% sensitivity rate.

A specificity rate would be sort of the, looking at the non candidates in 67 of those met the 60/60 guideline but turned out not to be traditional candidates. So, that meant we had a specificity rate of 66% which the opposite of that would be a false positive rate of 34%. We can also look at it as a positive predictive value and when we calculate the positive predictive value, that comes up to a 76% PPV rate which means that a patient has a 76% probability of meeting traditional indications if they meet the 60/60 guideline and we also came up with a negative predictive value of 94% which means there's a 94% probability that a patient will not meet traditional indications if they don't meet the 60/60 guideline. So, with all of these different ways of analyzing this number, we felt pretty comfortable with this guideline. Importantly, we wanted to see also does this apply to Medicare beneficiaries? We saw that more than half of the 661 patients that we saw were 65 years of age or older so 392 of those 661. So then again, we wanted to see if this applies to Medicare beneficiaries and we looked at that group of people

who were over the age of 65 and of that group, we found that 37% met FDA criteria and 74% met Medicare indications. So, that meant that there were 26% who met the FDA but were turned away because they didn't meet Medicare's criteria. If we look at 66 patients over the age of 65 years, they had both word and pure tone average information available, we found that 94% of those patients met the 60/60 guideline and met Medicare indications. So based on those findings, we really feel that the 60/60 guideline is also appropriate for use with Medicare beneficiaries as it is with patients who have more traditional insurance. So, one possible reason for under referral might be the difference in test procedures used by referring professionals and audiologists who performed CICEs of all those records that we reviewed, we didn't run across a single record where sentence testing had been performed by the referring audiologist so it's a big disconnect when we're performing different tests to determine if someone should be a candidate versus when someone should be referred.

Professionals often indicate they prefer to recommend a patient for an evaluation when they're fairly certain they'll be a candidate and we're really hopeful that this guideline based on this data set will provide professionals with good justification for when they should refer patients for this. 34% of the patients seen in our clinic for an implant evaluation demonstrated an unaided word score in their better ear that was less than 10% so this really shows us that they were probably candidates way long ago, maybe five or 10 years earlier and Richard Dowell in 2016 reported that recipients chances of a good outcome are significantly better if we provide that person with an implant soon after onset of severe hearing loss and before they lose all of their functional auditory skills. So, this shows us that timing is important so it is important for us to catch these patients early. So, based on these findings, we recommend that patients be considered for a cochlear implant evaluation if they obtain a score less than or equal to 60% correct and an unaided monosyllabic word test in their better ear and if they demonstrated pure tone average greater than or equal to 60 dB HL also in their better hearing ear and it also should be noted that many of these patients who fall outside traditional indications still receive an implant and that this guideline only refers to

traditional candidates. It does not apply to patients who might be considered excellent candidates for an implant even though they don't meet traditional indications and we're sincerely hopeful that this simple guideline will result in an increase in the number of patients who are referred for a traditional Cochlear Implant Candidacy Evaluation so that we can change that bar on the number of patients who are receiving cochlear implants. Thank you for your attention.

- [Dunn] Good morning. I guess I don't know if it's gonna be morning when you're watching this but this is certainly a different kind of American Cochlear Implant Alliance Conference but we are so grateful that AudiologyOnline has offered to do this for us and it gives us an opportunity to still get some of our CEUs but it also gives us an opportunity to learn and I think that's what all of us are interested in going to the Cochlear Implant Conference for. Today, I'm gonna talk about benefits of a Cochlear Implant Registry. Specifically, I'm gonna talk about a study that we did where we looked at candidacy in quiet versus in noise. Recently, in the probably the past maybe five years, there's been an influx of doing cochlear implant candidacy testing using noise and I think that's very appropriate, We live our lives in noise and when a patient comes into our facility, the biggest thing that they complain about is they can't hear a noise. So, we're gonna talk about current testing protocol doing testing in noise versus in quiet and see what happens to our candidacy.

So, how many of us think of a question and we can't come up with an answer? This probably happens to me on a daily basis and if you think about something as simple as I have to come up with a password, an uppercase letter, lowercase, numbers, special symbol, you sit there and think about it for a while and have to come up with a solution. Likewise, when we wanna do research, we often have roadblocks ahead of us and some of those challenges, Maybe we don't have enough time. We can't collect research, there's no funding, it takes a lot of data to try to answer questions, personnel is limited, statistics are hard, where do I store my data for easy access? These are all things that come up if we have these underlying questions that we wanna ask and that

kind of segues into the purpose of this project. It was really to establish a database of CI outcomes to try to answer some of these big questions. So in this study, we're doing a CI research registry, where we have a lot of data in one data set and we're trying to address analytics related to CI candidacy, pre and post-operative CI assessment, patient management and perhaps even some counseling. The goal really is to generate a meaningful information using evidence based data to guide current clinical practice and I think I'm gonna really stress evidence based because so many of us have these ideas and we wanna employ them but it really needs to be backed up by data and so that's what we're trying to establish with the CI registry. So, what is a CI registry?

A CI registry is a resource where data from many different centers, many different demographics, geographic locations can dump their data into one database and it can be used to help us answer these big questions. HERMES is a web based application for centers to enter their outcomes. It currently has 32 centers and right now, I believe this HERMES database is pretty much status quo, they are in the process of trying to understand the next steps of this database but cochlear talked to the HERMES web people and asked if there was a way that certain databases from certain centers can be dumped into this HERMES web based application and we can try to answer some big questions. So, this study was primarily funded by cochlear. When cochlear put this together with HERMES, we ended up with nine different centers and you can see them on this map, pretty spread out across the geography of the United States and here are the centers so with a cochlear combined database and HERMES, we ended up with these nine centers, it ended up with 9,353 different patients which got funneled down based on certain criteria which are, had to be 18 years of age or older, implanted in at least one ear, all of the data that went in had to have a valid age at implant, they had to have an implant currently, we had to have information on the onset of their hearing loss, validation of duration of the hearing loss that they had and so all of these things were required because in order to answer some of these big questions, we had to have that information. And so, we ended up with greater than 3,500 patients to be able to

analyze some of these big questions that we talked about earlier. The data table descriptives as I said, there were 9,300 patients, four different manufacturers, different device, internal types, there were 55 and you can see the number for CNC word scores, we had 37,000 CNC word scores, AzBiOs, 39,000 so a really, really big data set and that was so important to try to answer some of those questions. When we look at pre versus post-operative, which is an interesting question, we wanna see pre-operative what we have for these demographic data but then we also wanna see through CNCs, AzBios, the Audiogram, how things change after they're implanted and so that's where some of the data points kinda break down, get a little bit smaller but we still have for CNC words, over 25 post-operative word scores that we can still analyze and use for data statistics. So, in this particular study, we're gonna explore the proportion of candidates who qualified for a cochlear implant in quiet versus in noise. We're also gonna look at the demographic characteristics of the cohorts and we're gonna try to examine that pre versus post-operative relationship between the condition that was used to determine candidacy for these implant patients.

So, for this particular data set, we started out with 7200 patients, that was funneled down to 2979 patients because, we asked the question from that original data set, how many patients in this data set had pre-op AzBio sentence scores? And then from there, we asked the question, how many have an AzBio sentence score, whether it's in noise or in quiet that was less than or equal to 40%? The reason we chose that 40% is probably pretty obvious to you, that's what the current CMS criteria is on sentence scores to qualify a patient for candidacy. From there, we wanted to stratify these groups. Okay, so we had 2183 patients and they were stratified into three different groups. These patients may have had a quiet score in the database and a noise score in the database but we wanted to assign the patient to the group, whether it was the quiet group, the plus 1015 group or the plus five group into one of these different categories. So, we took the score for the patient in the least adverse listening condition so that they scored under 40% so for example, if a patient scored 29% in quiet, or and 15% and a plus 10 dB signal to noise ratio, they were put into the AzBio quiet group so

even though they qualified to be in the noise group because they got 15%, that's under 40, that's not the least adverse listening condition that they were tested in that they were under 40% so we put them in the quiet group. So, this is how that kinda shakes out, we ended up with 1,479 of those patients in the AzBio quiet group, 198 in the plus 10 and 506 in the plus five signal to noise ratio group. The demographics for those three groups, you'll see along the horizontal axis down here, we have those different quiet groups based on the number of patients and then we have number of patients for each of these bars that represent aged implantation, duration of deafness, pure tone average, that's using a four pure tone average and then we just did the low frequency pure tone average so we wanted to try to dive into, if these were patients that were possibly gonna be EAS patients. So, you'll notice that aged implantation, there's no significant difference, duration of deafness between the three different groups is very, very close but the two areas where we have a significant difference is the PTA, the PTA is significantly lower for the group with a plus five signal to noise ratio and also the low frequency PTA for the plus 10 and the plus five are significantly lower than that of the quiet group.

So, this makes sense because that probably represents patients who have poor hearing loss, probably qualified under 40% in quiet, which is the least adverse listening group, where four of these patients that have a little bit more hearing in the low frequencies or across the Audiogram, it probably required at least a plus 10 or a plus five for them to qualify for a cochlear implant and so perhaps the plus 10 or plus five was the least adverse listening condition for them to be under 40%. So, this is how our data kinda shook out, when we look at this slide, I'm gonna take a couple seconds to kinda explain it here. We have pre versus post AzBio in quiet performance so as I mentioned before, a lot of patients had pre and post scores in quiet and in noise but we took and quote or stratified them into a group based on their least qualified but we wanna look at all of their scores. So, this represents patients who qualified in quiet, patients who qualified in noise but were tested in quiet for the plus five group and patients who qualified in plus 10 which is the blue but had testing in quiet and we just

wanted to look and see how, what their pre versus post-operative scores were. So, the pre-operative patients in the green, they started out at about 15% pre-operatively, the patients that had a plus 10 qualifying stratification in quiet, they scored about 63% and the patients that qualified in a plus five when they were tested in quiet, they were at about 71% pre-operatively so you can see why these noise qualifying groups even though they were tested in quiet, they didn't qualify for a cochlear implant until they were put in noise, when we look at post-operative improvement, again tested in quiet for each of these qualifying groups, we see that the patients tested in quiet, they improved to 71%, the patients that were tested in a plus 10, improved to 79% and the patients who were tested in a plus five, improve to 85%. Each of these asterisks by the percent score shows that they had significant improvement, okay?

So, from their pre to post, they had significant improvement in their scores, which is wonderful but what was interesting is that the quiet group was significantly poor than the plus 10 or the plus five group so even though we point out over here the pre to post-operative improvement, we show that the quiet group actually improved almost 60% so if we look at their pre to post-operative scores going from 15% to almost 70%, they improved 55% or almost 60%. So, that's a huge improvement for this group versus when we look at those patients that were tested in noise or that qualified and noise but were tested in quiet, their improvement was much lower. So, the plus 10 group, when they're tested in quiet only improved about 18% and the plus five group was about 15% so even though their post operative scores were significantly different, they were significantly higher than two noise qualifying groups had significantly higher post operative scores than the quiet qualifying group. The quiet qualifying group had a much more significant improvement, part of that could be because the quiet qualifying group or the noise qualifying group when we tested them in quiet, their scores were pretty high and they didn't have a lot of room for improvement. So, let's look at how they do, these two quiet or noise qualifying groups how they do when they're tested pre-operatively in noise and post-operatively in noise. So, the plus 10 qualifying group went from about 23% up to 65% so that's a huge improvement for them and the plus

five qualifying group went from 21% up to 53% so again, going over here to percent point improvement, the plus 10 qualifying group now has almost a 40% improvement and the plus five has almost a 30% improvement so that's much higher or much bigger improvement when you look at them tested in the same noise condition that they qualified for a cochlear implant in and we've seen much bigger improvement in their scores.

So, in conclusion, most patients derive significant benefit in speech perception and that's regardless of whether they are tested in quiet or they're tested in noise but it's especially true that they get a much bigger significant benefit if they're tested in the listening condition in which the patient qualified for a cochlear implant. Expectations and room for post-operative improvement differ for patients qualified in quiet than those qualified in noise and so I think if a patient qualifies in quiet, we can tell that patient that you can expect great big improvements in that same quiet condition but you might not see as big of improvement if you're a noise but likewise, if a patient qualifies for cochlear implantation and noise, then it's very likely that they'll see a big significant improvement in that same noise conditioned post-operatively. How does this translate to the general world? Or how they interact and function in their daily lives? You know, I think it's gonna vary, certainly the noise condition that were testing in are very different than the noise conditions that they're living in and so that needs to be a counseling component as well. Finally, I wanna acknowledge the research that supported the I will portion of the data that was dumped into this research registry. I wanna thank cochlear for funding the idea to formulate the big data to try to answer these big questions. And certainly I wanna thank my colleagues who helped put the study together looking at pre versus post-operative scores based on candidacy, Sharon Miller, Erin Schaefer, Christopher Silva, Rene Gifford and Jedidiah Grisel. Thank you so much, I hope you enjoyed it. Please reach out to me if you have any questions about this data and wishing you safe and to be well, thank you.