Health-Related Quality of Life Benefits with Hearing Aids, in partnership with the American Academy of Audiology

Presenters: Anna Jilla, PhD, AuD, Carole Johnson, PhD, AuD

At this time, it's my pleasure to introduce our presenters. We have with us today Dr. Anna Jilla. She is an assistant professor in the Department of Communicative Disorders at the University of Louisiana at Lafayette. Also with us today is Dr. Carol Johnson, who has retired as a professor in the Department of Communication Sciences and Disorders in the College of Allied Health on the University of Oklahoma Health campus in Oklahoma City, Oklahoma. As I mentioned, we invite you to read more about our presenters in your handout and on our course page.

And at this time, I'll turn the microphone over to Dr. Johnson.

Thank you, Carolyn. So we're going to go ahead and just give a little introduction from the American Academy of Audiology's past president, Tish Gaffney. Welcome. I'm Tish Gaffney, the president of the American Academy of Audiology and I'm here to share important information about the organization. The Academy is dedicated to achieving recognition of audiologists as the experts in hearing and balance care and the field of audiology as an independent clinical specialty that is integral to the healthcare team.

Through our partnership with Audiology Online, we're excited to offer courses like this one to help you broaden your knowledge and skills. We also offer the latest resources in practice management and evidence based clinical practice so you can grow professionally and improve patient care. We advocate for our members in Washington and across the country to ensure that the voices of audiologists are heard and we help connect audiologists to one another through our valuable networking opportunities like our annual convention. To learn more about the Academy, make sure to visit audiology.org thank you.

These are our disclosures, they're available on your handout as well as the limitations and risks for this presentation and also the learning objectives.

This is the outline or the agenda for our presentation and the first section is where we began reviewing chisholm et al. 2007.

So over 20 years ago, President Angela Lovenbruck decided to assemble a group of experts to really look at the non acoustic benefits of hearing aids. Those characteristics that go beyond just the fitting of the hearing aid, but what actually makes a difference in patients lives. And at that time, Dr. Terry Chisholm and Craig Newman were the ones who chaired the original task force along with Dr. Harvey Abrams, Jeffrey Danhauer, myself, Sharon Lesner, Patricia McCarthy and Laurel Ports.

And at that particular time you might remember some of the major movements in our field going through with evidence based practice. Dr. Robin Cox published the original article about evidence based practice in terms of amplification. And at that time our field was just moving forward to looking at the results of our studies and really making a mark in terms of what we do in the clinic and what our research indicates to us. At that time, many of our studies were just interested in P values or is there a significant difference in somebody's life between before getting a hearing aid and after a hearing aid? And so Dr. Terry Chisholm and Harvey Abrams have also worked at that time to try to write some articles to try to move us forward in terms of ratcheting up the levels of evidence, of research that support what we do in the clinic and in making differences in our patients lives.

And at that time we started to look at what was levels of evidence and that is in terms of rubrics that say to us how rigorous our results of our studies are. And of course at the very top we have systematic reviews of randomized clinical trials going down to expert opinion. And so at that time there were very few randomized control trials that that had been conducted on the effectiveness of hearing aids.

And with regard also Terry Chisholm and Harvey Abrams had written an article about how important it was for our clinic practice guidelines to think about graded recommendations for what we do. And so in order for our clinical practice guidelines to receive a grade of A, the level of evidence has to be

extremely high. And that is systematic reviews of randomized control trials and randomized control trials. And what's specifically unique about these types of studies are, is that there's random assignments of participants to treatment and control groups as well as double blinding of our, the researchers and the participants as to their assignment to particular whether they're in a treatment group or a control group. So this was the course of action that we wanted our profession to take.

And so at that time, President Lovenbruck didn't say you're to conduct a systematic review with meta analysis. Her concern was summarize the information out there that says that fitting of hearing aids and hearing aid use really makes a difference for our patients with sensorineural hearing loss. But Terry and Harvey and as well as Dr. Newman said, well, let's try to go ahead and do a systematic review with metaanalysis, which at that time took 2003 was relatively new to our profession. And so what we, what we did as a group was we met and looked at the steps that we needed to complete in order to do a really efficacious and conscientious review of the literature. And so we did not employ a library scientist.

And so what we did was we created for ourselves search strings to apply to the databases so that we could retrieve all of the studies that could possibly be used to answer our question what is the evidence that support that amplification makes a difference in our patients lives. And so we went through thousands of articles by hand and in the end we only had 16 studies that met the criteria for possible inclusion in what we call at that time a random effects meta analysis of generic and disease specific outcome measures. And so many of you probably use outcome measures in your clinic or if you're conducting research. But just as a review, generic outcome measures are those that are used across healthcare disciplines. For example, the Health Utilities Index number three, the SF36, the SF12 or the World Health Organization Disabilities and Assessment Scale.

And those have questions that tap into many areas of health functioning and also have subscales that can be used across healthcare disciplines. And many of them don't really tap into communication. And

then disease specific outcome measures are those that have been developed by us for use in our profession to show differences that we make with regard to auditory rehabilitation interventions. And at that time all of the studies involved analog hearing aids and digitally programmable hearing analog hearing aids. And there were very few randomized controlled trials that would be at that high level of rigor that's necessary for having a grade A recommendation for what we do and making an amplification fitting and also having the patient get use the hearing aid because we can fit them but we they don't always use them.

And so with at that. So basically the results of the findings for Chsim et al. This slide is kind of small, but we have the results at the bottom for generic on the left and disease specific on the right. The outcome measures. Different meta analyses were applied based upon the type of outcome measure as well as the type of experimental design.

And so the generic on the far left hand side, the first little symbol represents between subject studies, the randomized control trial and then the within pre and post same subjects measuring them before and after hearing aid fitting. And also this is the between subjects for the disease specific on the left and then the within subject on the right. And so at that particular time we were looking at the effect sizes and that's one of the differences that evidence based practice has taken us to in the past. We were looking at P values. Is there a significant difference between before someone gets a hearing aid and after for within subjects and between subjects, is there a significant difference between a group that was fit with hearing aids versus one that wasn't?

But evidence based practice requires looking at the effect size or what Is the degree of difference between those groups, how large is that difference? And that can get at not only beyond statistical significance but clinical significance. So with the results of the initial study, Chisholm et al. For within subjects designs and disease specific measures, there was a small to medium impact on health related

quality of life. And with between subjects designs, the randomized control trial, there was a small effect size for generic measures and for disease specific measures there was a medium to large effect.

And so effect size, you know, we may ask what's small, what's medium and what's large? And there are several effect sizes that are used in these studies, but generally 0.2 is a small effect size, 0.5 is a medium effect size size and Anything greater than 0.8 is a large effect size. And that will become important when we talk about the results of the current systematic review with meta analysis. And so because most of the studies were within subjects design and not randomized control trials at lower levels of evidence, the recommendation that hearing aid use a non invasive low risk intervention to improve the health related quality of life for adults with sensorineural hearing loss received a grade of B. And we were excited about that at the time because it was really the first time that we could really judiciously look at the results of the total body of literature and really be able to get a recommendation that we, we felt strong about.

And you probably have seen this article and part of the systematic review with meta analysis. The final article was not only the results of the study, but it was also kind of a piece to mark time where we were with evidence based practice in our profession. And there was a little bit left at the end to kind of talk about where do we go for the future. And the task force said that if we're going to raise our level of recommendation to a grade of A, we really need to have more studies done that are randomized control trials and that we need to systematic. We need to update the systematic review periodically and good gosh, 20, 25 years have passed and so we're now revisiting this topic.

And there's many reasons why this was really our time. This is really our window for to be able to get this done so that we can really make a statement for all of the technology that has improved and the awareness about the untreated effects of the effects of untreated sensorineural hearing losses. And just going through the literature in relation to hearing health, the concept of health related quality of life

has really expanded to broader aspects of health and well being. We see more outcome measures, both the generic type and disease specific, being used to measure or to mark progress with interventions for auditory rehabilitation. There's been many public health epidemiological studies that really are showing the association between untreated sensorineural hearing loss and other health care conditions.

The definition of health related quality of life have expanded to reflect these changes. When our group convened, that was one of the things that we really had to really think about and, and to, to show an expanded definition because the process of developing an effective search strategy with our library scientists was so important for her to understand, to be able to develop these Boolean search strings to put in, to be able to capture all of the richness of the literature that has been published in the last 20 years and more randomized controlled trials have been conducted. So our group back then had a crystal ball and said, you know, we really need more randomized control trials. And we're excited to say, and we'll say in a bit what we have found. And then also as Maya Angelou said, when you know better, you do better.

And so the original group was really boots on the ground where we are right now, conduction of a systematic review. And we really did work hard to do the best job that we can do, but we were kind of limited about where we were and where the research was. And again, most of the studies that were included in the systematic review were within subjects design. They didn't have the level of random assignment and they didn't have blinding in terms of reducing the amount of bias. We were so fortunate to be able to hire onto our team a skilled library scientist, Elizabeth Sanders, to conduct our search because it is a science in itself.

Also, meta analysis is really a complex process and so many of the meta analytic techniques that we used really reflected our emerging skills in this area. We lacked a little bit of sophistication and there

was a little bit of an incomplete picture about what has been portrayed. And it's not just the last study of the task force, but it's really, you can even look across disciplines and find that people are not really leveraging the power of meta analytic techniques like they can.

And we'll be talking about something called prediction intervals and heterogeneity assessments. But also too, when you're talking about thousands of articles, you need to have a way to organize this. And so competence has been an amazing platform to conduct a systematic review, which has allowed us to be able to have a team process all of the data through title and abstract review, full text review, and data extraction. And also there are software that enables us to be able to efficiently conduct meta analysis. And so that has made our job a lot easier.

But back in the day, you know, we're proud of what we did because we did the best with what we had and we, and we were able to move the ball forward.

And so the formation of the team, Dr. Anna Marie Jilla and myself have been so blessed to be able to work with this fantastic group of colleagues. Emily Gonzalez, Lindsey Jorgensen, Dr. Lakshmi, Dr. Lewis, Dr. Park, Elizabeth Sanders and Dr. Sullivan. And it does take a village to do this. And I would like Dr. Jilla now to be able to summarize our systematic review protocol. Great.

Thank you, Dr. Johnson. So I think that you've made some really great nods here as to where we were in the past. And we, you know, I say we, I wasn't on the committee, but the group was there in the past and how we've moved forward in terms of our methodology. So I think as we think about this new updated protocol, one of the first points to think about is how the definition of health related quality of life has expanded. You know, over the last 20 or 30 years, we've seen a movement away from defining health related quality of life as just an absence of disease.

We're really looking more at this as a wellness and well being model, which is multidimensional. This could be emotional impacts, communication impacts, impacts on physical functioning or mental functioning. So we tried to expand this more holistic definition of health related quality of life. And we did a quick cursory review of the literature to determine what that updated definition might look like from the broad health care perspective. And this is important when we think about developing a search strategy in each one of these databases that have the academic literature that your search is only as good as the search terms that you put in.

And so we wanted to be very mindful in being detailed and also multifaceted in the types of terms that we put into the search. So our goal for this project was really to determine what the graded recommendation is for hearing aid use among adults with sensorineural hearing loss and those impacts on health related quality of life. So as part of this project we really had kind of two aims. And today's presentation will touch mostly on AIM one. We will give some nods to AIM two towards the end, but our AIM one is twofold.

So we wanted to see what the impacts of hearing aid use were on those disease specific health related quality of life measures, the ones that we know and love, such as The Hearing Handicap Inventory for the Elderly. And similar to the previous task force, we wanted to also look at those generic health related quality of life measures. We felt that this was important to include yet again, because those generic health related quality of life measures, whatever outcomes we get, because it loads on to this broad terminology, we can compare those results against other chronic health concerns as well. So that bird's eye view is really helpful in kind of ratcheting us up and getting us ready to punch in our weight class in the house of medicine. So for AIM2, we'll talk about that a little bit later as far as the specific domains that we'll get into for that one.

But for the present study, our development of a pico rubric. So thinking about what population specifically do we want to study? Well, some of these things are pretty obvious, you know, adult sensorineural hearing loss. But we need to define these more specifically because as we're going through titles and abstracts and full text reviews, we have to set this pico rubric a priori. Right?

We have to say exactly what we're looking for before we look at the literature. So let's hop in and see what we came up with. So for the population here, we wanted to include adults, and we defined adults as 18 years and older. We wanted to look at that population with sensorineural hearing loss. We did have some considerations because some of the we anticipated, based on the last study that was done back in or published in 2007, there were some inclusion of some participants that maybe had mixed hearing loss that was primarily sensorineural.

So we did include those populations as well. Because the majority of the hearing loss component was indeed sensorineural. We included any severity of hearing loss, mild to profound. And for the adults that we were looking at, we wanted to make sure that we restricted this to those that were community dwelling or resided in assisted living facilities. That meant by extension that we excluded adults in skilled nursing facilities or acute care inpatient care.

We felt that these populations were a little bit different in terms of what their communication needs are, what their access would be. And so we left that for a future study, I suppose, and then any adults in correctional facilities. We had some of those similar concerns about heterogeneity of the actual sample.

When we started to ponder the intervention, so many, Dr. Johnson had given the nod to the previous study talking about analog and digitally programmable analog hearing aids. So we had to really think this through on what are we going to include in terms of the intervention? And we took a really broad approach. We Included any hearing aid style, any power source, any signal processing circuitry, any microphone technology, any fitting arrangement, monaural or binaural, whatever service delivery

method, whether that was more audiologist fit or direct to consumer. And we also included any payment type as well, because we know that there are many studies out there that maybe people are paying for their hearing aids or there may be other studies where their hearing aids were provided for free as part of the study.

So all hearing aids included. What we did exclude were any of those surgical options such as cochlear implants, bone conduction hearing aids or anything else like an auditory brainstem implant. We felt that those were just distinct and very different and we didn't want to muddy the waters.

So then what's the comparison? We have the intervention really well defined and we took a lot of time considering this and we ended up choosing to include non use of hearing aids as the comparison. And non use of hearing aids is exactly what that says. We did anticipate though that, you know, there's an ethical piece to that that if you say, okay, we're not going to give you hearing aids as part of this study, what are we going to do to help improve your health? And so we did include as a comparator any kind of controlled intervention such as a healthy aging education program, that they enrolled the participants who were not using the hearing aids.

But again, no hearing aids on the ears. And after much deliberation and consideration, we decided to exclude sham or placebo hearing aids. Part of the reason that we did this was because, well, if we know that the vast majority of hearing losses are mild and moderate and we have a sham or placebo hearing aid with a minimal amount of gain programmed, even something as small as 7dB could be meaningful and could confound our outcomes that we were looking at in terms of health related quality of life. So we felt that it was going to be much more clear cut if we used non use of hearing aids instead of including some of the studies that program sham hearing aids or placebo hearing AIDS. And as Dr. Johnson had alluded to earlier, we have these disease specific outcomes such as the hearing Handicap Inventory for the elderly.

And we're also looking at any generic health related quality of life measure such as the UroQual 5 dimension, which is a 5 dimension general health assessment. We also have the short form 12 and that's again just a generic health questionnaire and the 36 item version of that as well. We excluded any studies that didn't meet this specific inclusion criteria. So for instance If a study had one question on health related quality of life, it didn't come out as a validated measure. We did exclude those studies.

But so for our search and retrieval process we met with Elizabeth Sanders. She has a master's in library science and she was very instrumental in helping us to develop these search strategies based on our Pico rubric and this expanded definition, this holistic definition of health related quality of life. So we developed search strategies and you may notice that we added a lot more databases compared to the 2007 study because there are many more databases available now. So we were as exhaustive as we could possibly be. And we included all of these databases and queried them with our search strategy.

Some of these may look very familiar to you.

And in terms of study tools, Dr. Johnson had spoken about this earlier. We tooled up with as much tech as we possibly could. We utilize covidence, which is an online platform, one among many that can be used where you upload the records in and the study selection is systematized, all of the choices are documented, which is really great when you're thinking about the history of decisions. And this gets us away from paper based grading, which is absolutely fabulous. We also conducted our quality assessment using the risk bias tool, the Rob 2 from Cochrane.

And we also performed our data extraction in covidence as well. This included data extraction, forced study characteristics as well as the data that we're going into meta analyses. Then we use the comprehensive meta analysis software. Again, this is one among many options that are available to researchers. We use this one specifically because we've got a lot of great output that again was not

available in the 2007 study.

And as Dr. Johnson said earlier, when we know better, we do better. And so we're trying to boost out what that we're considering to be the standard practice for reporting and systematic reviews with meta analysis. So this will include things like the I squared statistic, prediction intervals, publication bias and reporting of standardized difference in means, which Dr. Johnson will talk about at length in just a little bit when we get to the results. And with that, I'll turn it over to you, Dr. Johnson.

Thank you, Dr. Jilla. So I had alluded to earlier that we dealt with thousands of records or articles and another 20 years added a lot more to that yield. And so we also wanted to say that we conducted our systematic review according to PRISMA guidelines. And this is our PRISMA chart, of course, way too much information and not really able to be read as well. And so this top part has to do with the identification.

So our search strings through our Boolean search strategies through all of Those databases yielded 9,620 articles and one was added through hand searching. And of course when you're using multiple databases, they're going to bring back with you to you a bunch of duplicates. So we after eliminating 5383 duplicates we had 4238 to go through to be screened for title and abstract, then for full text review. And so we had 76 articles for full text review and 22 articles after all of that were included. Now I want to remind you that our specific aim one had to do with had we moved the ball forward in terms of the research to get to a graded of a of our recommendation that hearing aid use enhances health related quality of life.

So we were looking specifically for randomized control trials. And so that's why the Yield was at 22 articles. And so 22 articles were included. That result yielded 13 randomized control trials or RCTs one systematic review of RCTs and then eight study protocols. And the study protocols were mostly from ClinicalTrials.gov or the clinical trials registry of other countries.

So those are the ones that are still under completion. They are not yet to the point of publication.

So for the the 13 randomized control trials this is just a summary of them and out of the 1310 were suitable for meta analysis and suitable means. Did they have the correct, did they meet the requirements of our Pico rubric? The publication date range was from 1990 to 2025. So Mulro's historical RCT looking at the effectiveness of hearing aids for health related quality of life was included all the way up until present day. The number of participants in the meta analysis.

Now recall back when I was talking about the results for chisholm et al 2007 that we're doing multiple meta analyses, one for disease specific and then for generic measures. So the number of participants data that went to contribute to the meta analysis was 1965. And then for generic the meta analysis for generic outcome measures was 2054. And that represents a huge movement forward for us because it's combining the results of multiple studies converging evidence. Participants age were greater than 65 years as we would expect.

And also the studies were conducted in a variety of settings, outpatient veterans health clinics, local health centers and so forth. The location of the studies, eight of the RCTs were in the United States with with the others being conducted in Europe and Asia as well. The disease Specific health related quality of life outcome measure was the hearing handicap inventory, whether in the long form or the short form. And you know, we didn't go out to seek that out. That just was the acceptable disease specific measure to use in these RCTs.

And it has been our tried and true measure for the social and emotional impact of hearing loss for the last almost 50 years. And then the generic health related quality of outcome measures, and we've mentioned a few, the Health Utilities Index, Self Evaluation of Life function and the SF36 SF12 in the World Health Organization Disability and Assessment Schedule 2.

And so our meta analysis included three separate meta analyses. One for disease specific measures and then two for generic measures. And you'll see in the graph there it sort of bifurcates into a mental component score and a physical component score. And that there were three randomized control trials that you can see the starred in the right hand box here, the starred outcome measures. The SF12, for example, doesn't have a composite score to put into a meta analysis.

They have a mental component score and a physical component score. And because at least three out of seven studies included in the meta analysis had these two different scores, we had two separate meta analyses to account for mental component and physical component. Dr. Jill is going to be talking about the Future of specific aim 2 that our team is tackling right now about Mental component and the importance of amplification for enhancing mental health.

Oh my goodness. This is definitely a busy slide here. But what I would like to do is to go ahead and draw your attention to the upper right hand corner that says forest plot here. And what we have are the first author and the year of publication for the randomized control trials included in the meta analysis for disease specific measures, the effect size or standard difference in mean here, their z value and probability level, and that all of this information is or much of that information is represented on this plot to the right. And this is the forest plot.

As you might see in the middle there is a line that goes vertically that says zero. To the right of that is results that favors hearing aid use enhancing health related quality of life life. To the left of that it says favors hearing aid non use. Thank goodness that all of our symbols are on the right side of the line here. And what these are are the depiction of the effect sizes here along with their 95% confidence intervals.

You'll notice that these symbols differ in their size and when they differ in their size. All of this results in the RCTs are boiled down into a Single cooled effect size which is 1.372. But the size of the individual symbols for each of the RCTs indicates or gives a visual representation of the proportion to which that score of that trial contributes to the overall schooled effect size. And you'll notice that there is that 95% confidence interval. And you notice right here in a clinical trial by you and colleagues 2025 that their 95% confidence interval kind of goes over that line which indicates that that is not a significant effect, even though most of it is to the right of the line.

It's kind of like football in that first down. And you can see here that their effect size was 0.4, but it did not reach statistical significance, which I will talk about in a minute. So when you boil all this down for these RCTs, the random effects meta analysis produced a mean effect size of 1.2 with a confidence interval of 1.104 to 1.640 Z score significant. What a Z score is is just if it's significant, it just means that the effect size is significant. It's greater than zero, of which you and colleagues did not because they had their confidence interval cross the zero line.

And this was based on seven randomized controlled trials with 1,965 participants. Other results from the meta analysis was the I squared statistic which indicates that 83% of the variance amongst these studies were attributable to true effects rather than sampling error. And before when I talked about the our skills with systematic reviews, inclusion of what we call prediction interval is extremely important. And our prediction interval went from 0.5 to 2.26. What the prediction interval indicates is that the true effect size in 95% of all comparable populations that would meet may be conducted in many more RCTs would fall within this interval.

And that's good news because 95% of studies that would follow after this in randomized controlled trials would have at least a moderate to very large effect size. So that really bodes well. And recall back from Chisholm et al. That there was a higher a medium to large effect for disease specific outcomes back

then. The same is true now.

But again this is randomized control trials and that is super exciting. And then I mentioned that we had two separate meta analyses for generic outcome measures. One for three of the studies using the mental component score versus the physical. And you know, the same things that I had talked about are true here with regard to the randomized control trials, their effect sizes and these symbols Right here. But notice how some of these symbols are really getting close to that zero line and some of them have their 95% confidence intervals crossing that zero line.

And. But nevertheless, we still had a small effect size for generic outcome measures with a 95% confidence interval going from 0.089 to 0.487. Based on seven RCTs randomized control trials with over 2000 participants, 74% of the variance was attributable to true effects. And the prediction interval, 95% of all comparable studies using this outcome measure would. The effect size would be from minus 0.3322.

So to the left of the 0 line to 0.9 to the positive side. And you know, we have been talking about that zero point. But not to worry because this is the 95% prediction interval for all comparable studies. It can go into the negative to the left of the zero. But remember, there just may be some comparable populations that they're not going to find significant effects for pre versus post hearing aids control versus treatment groups.

And that's to be expected. And we still got a small effect size, but many of these studies had participants who had early cognitive decline or other issues or you know, different healthcare systems. We don't know. But the main thing is we still have a small effect size for generic outcome measures. And then to go on to the physical component scores, I won't go into great detail, but we still had a small effect size and that for the seven RCTs with over 2000 participants, 74% of the variance was attributable to true effects.

And the prediction interval is similar that it does go to the left of zero, going from minus 0.305 to 0.918. But again, it's a prediction interval. And some studies using these measures that aren't so sensitive to changes in communication with hearing aids as our own disease specific measures. But rest assured, this is such positive news, especially on the previous meta analysis with mental health and also physical functioning. And that shows that hearing aids are making a difference in multiple areas of health functioning.

And we also use the rob2 risk of bias. It looks very, very colorful here, but our team went ahead and judiciously went ahead and assessed the risk of bias for these RCTs. The red indicates high risk of bias, the yellow some concerns, and then the green is low risk of bias. And there's just different dimensions having to do with randomization, deviations from the intended intervention, maybe some missing data measurement of the outcome and selection of what was chosen to be reported, what was selected to be reported. We're really doing well on randomization and accounting for missing data, for intention to treat analysis and also being judicious and following through on the reported results.

Areas for improvement included anything that was changed. When we're dealing with people and older individuals and life, maybe the protocol doesn't go on as exactly as we had intended. And also blinding is very difficult for hearing aids. Either you have a hearing aid or you don't have a hearing aid. And also the Robs tool is very hard.

It's very strict. And that is if you're high risk in any of these six domains, it results in high risk for the whole study. But in terms of how far our area of work and our researchers have come, that the RCTs were generally well designed and they didn't really represent a material bias in the conclusions that were made and the graded recommendation because it was our randomized control trials. Our findings indicate that we have raised the bar. We've moved the ball forward.

We have a large effect size for disease specific measures and a generic for small with a grade of A of recommendation and we have ongoing clinical trials right now. But what I'd like to do now is to turn it over to Dr. Jella to talk about conceptualizing results and looking Forward to specific aim 2. Great, thank you Dr. Johnson. Just to give a quick sidebar on the ongoing trials, there are indeed eight of those. And so previously we had talked a little bit about the what's coming next.

Right. This thing is always needing to be updated. So we've, we've got some good studies that will be in the pipeline for the next update. So what are these results actually telling us? Well, we know that for disease specific measures we're seeing seeing large impacts, positive impacts on health related quality of life.

We're also seeing those quote, unquote small impacts for generic health related quality of life. But I would like to go ahead and kind of hedge that a little bit that this may be indeed a measurement issue, not necessarily related to the impacts. So the reason that I say this is because many of those generic health related quality of life outcome measures and health questionnaires, few of them have questions about hearing specifically. And so we may be missing the actual impact just due to the questions that are contained within these measures. Indeed, there's only one of the generic health related quality of life measures that we used in the systematic review and meta analysis that distinctly asks about hearing.

Some of them may have questions about communication or participating in society, but There was only one of those that really dug deep in on hearing. So I do want to say that even though it's small for generic, this may be more of a measurement issue as opposed to the measure issue, as opposed to an actual impact issue. So hopefully in the future we'll find those measures that actually really can be sensitive to those impacts of health related quality of life benefits from hearing aids. So as we said, the clinical recommendations, so I know that there are many clinicians listening in right now and you can

say with great certainty that use of hearing aids can improve health related quality of life for both hearing aspects, those social and emotional aspects related to hearing, as well as overall generic health.

Keeping in mind here the definition of a Grade A recommendation is first the level of evidence that Dr. Johnson had shown, but also it requires narrow and overlapping effect sizes. So we had good consistency within our results. So it's not necessarily just the types of studies, but how those studies actually pan out in relation to each other. Dr. Johnson did a great job of explaining those differences between the confidence interval, which is basically the accuracy of the mean. Meanwhile, the prediction interval or PI is an actual dispersion of the effect sizes.

And so basically otherwise stated, our PI here is an interval within which a person with hearing losses health related qual of life outcomes would fall with 95% confidence in the true effect size among those comparable populations in the universe of all possible studies. I do also want to note here that some of these studies were international and include different populations. And so some variability in the findings may be due to the heterogeneity of the study populations as well. But I know that many of you may be thinking about, oh well, that prediction interval, you know, there may be certain populations that don't see those benefits with hearing aids. Well, let's go ahead and look at this as a glass half full.

And this means that there's many people that are doing well with hearing aids. And this also means on the flip side, that there may be people that do better than expected with hearing aids and have more positive impacts on health related quality of life than we would anticipate. So what are our clinical implications? Well, good news, if any of you were twinging at the idea of including monaural and binaural fittings, well, the preponderance of the fittings included in the meta analysis here were bilateral. So that is pretty standard and consistent with best practices and standards of practice.

Many of these RCTs actually used evidence based fitting procedures, which I think is an important point to note. Because these outcomes represent both the devices and those supportive services. So it's difficult to disentangle what's from the widget and what's from the audiologist. And so I think that the way that we can interpret these findings clinically when you're talking to your patients is that these outcomes occur in conjunction with rehabilitative services, not in the absence of. So when we counsel our patients, we can say that these hearing aids can improve your quality of life for certain things.

Some gains may be modest, other gains may be higher than anticipated. And some of this can vary by individual. But we know beyond a shadow of a doubt that these hearing aids can benefit individuals well being beyond just audibility.

So where can we go and take this information next? Well, some of you may be familiar with the United States Preventive Services Task Force and they are tasked with, you know, broad health recommendations within the US for screening and prevention and hearing. Screening for adults has come up for review twice among their organization, once in 2012 and another time in 2021. And both times they indicated that there was insufficient evidence that the screenings were effective. And they also noted in the most recent 2021 review that there wasn't sufficient evidence to note that hearing aids served as an efficacious treatment.

So there's two components to this USPSTF non recommendation for universal hearing screening. Of course, if you're going to screen for an issue, there needs to be a treat because screening just to screen is not really a good use of time or resources. So our paper that we've talked about today does check that second bullet point, that we do have strong evidence for efficacious treatment. And we know that other researchers are working on this screening component. So we're hopeful that next time this comes up for review among the USPSTF that we will get a favorable recommendation.

Another thing that this may be useful for clinicians who are advocating for insurance policy changes. This is a paper that you could send to your insurers to say we do have robust evidence. Hearing aids are not experimental, they are not just quality of life devices or something like that. These are really medical necessities that these are improving health and well being more broadly. So please note that many insurers actually review their payer policies these regularly.

And this paper, once published will be a great resource to include in letters where you're asking for review or providing input for review.

So some of the future research in this area, we know that this will be updated again in the future. So we want to give a couple of Nods to some of the things that we're seeing in our crystal ball. Recently, the National Academies of Science, Engineering and Medicine came out with this lovely recommendation report for a core outcome measure set in audiology. And they included auditory measures such as the quicksand. But they also spoke a little bit about some of those questionnaire measures and what they have recommended for use as a core outcome measure set and questionnaires is the Revised Hearing Handicap Inventory.

Casserly and colleagues in 2020 took a hard look at this HHI HHIA and wanted to see, like, are the questions still relevant? What is the sensitivity and specificity of this? Can we give it a refresh to kind of improve its utility? And they did, and they have improved the sensitivity and specificity of that measure and shortened it. So if you've got a whole bunch of copies of the HHI in your clinic that you're using on a daily basis, I'd strongly encourage you to take a look at this revised hearing handicap inventory.

With its great psychometric structure. We also need to address the blinding conundrum. So we know that in randomized controlled trials we can have single blinded or double blinded trials. Single blinded could be blinding of either the assessor or the person in the study. Well, what we found in the corpus of the evidence here is that it was pretty easy to blind the assessors, but I mean, to blind the participants.

But it was not so easy to blind the assessors. And many clinical audiologists who are listening to this right now, well, if you don't have a hearing aid on the ear, it's pretty easy to tell what group somebody's in. Same thing for some of those other studies that we didn't include as part of this systematic review where they utilize sham hearing aids. You as a research audiologist may bring this participant in and do a quick listening check and you look at the audiogram and you go, oh, well, that listening check on that hearing aid doesn't really line up with that hearing loss. They must be in the sham group.

So we really need to think thoughtfully about how we're going to address this blinding conundrum because we're halfway there and we need to get a step further. The other thing that we'd like to see is younger recruitment. The average ages across all of the studies were greater than 65. So we do want to know a little bit about the long term impacts and positive impacts of hearing aid use in those younger and middle aged adults as well. We know that there's a lot of information and evidence forthcoming and some of the trials that are going on right now comparing professional versus consumer driven driven fittings.

So we need a little bit larger body of evidence to go ahead and do a similar systematic review to this one that we talked about today to make any conclusions about the differences between those, if any. And we also need long term follow up. Most of these studies other than the ACHIEVE trial didn't really study out further than any two years. And we know that hearing loss is a chronic health concern and impact impacts people beyond two years. So knowing what those impacts are on health related quality of life in the longer term is going to be very helpful as well.

So just to give a quick nod to what comes next, we have this other specific aim and with this expanded definition of health related quality of life, we quickly found that there may be some areas that are very important to audiologists in demonstrating our interprofessional expertise in areas such as cognition, balance and mental health. I know that many audiologists do mental health screenings regularly. Many

audiologists do cognition screenings regularly. And we are also part of the fall risk care team. So many of you are also doing balance measures as well.

So we wanted to look at the impact of hearing aid use on these specific health related quality of life domains, hopefully to demonstrate that argument again that these are not just an optional thing, it's not a luxury device. This is really a medical necessity that can improve life and reduce, reduce risk for other health concerns. So we're looking forward to continuing our work on that specific aim too. And hopefully that'll get us in, in the arena with that complex care management among primary care geriatrics, psychiatry and neurology. So lots of really great things waiting ahead.

So with that, I think that that's all that we have for you guys today and we are more than happy to stick around for questions questions.

Thank you both so much. The amount of data that you showed was truly mind blowing. I have one maybe stupid question before we take from participants but now with AI, with systematic reviews and that kind of research, is it helping with those kinds of tasks?

I, I'm, I'm finding that these youngsters, Dr. Jealous generation of audiologists are so good with AI. I'm just amazed with what I, but I, you know, I imagine that they're a, that, you know, summarization and conceptualization. I, I've used chat, GBT even today. I'm just amazed at what. Dr. Jilla, what do you.

Yeah, there are actually AI tools available to do this. We, you know, health related quality of life in humans. We did the human resources aspect to this as opposed to employing a robot. But they do exist and there is some budding evidence. I can't say that, you know, this has been replicated or anything, but they're saying that the AI based kind of title and abstract review and summarization is actually pretty accurate.

It so it'll be interesting to see where we go from here. But I would really like to see some replication of those studies about accuracy before we hop in with both feet. Oh yeah, that sounds like a good approach. When I see the number of studies that were included in this research, I'm like, how does even one go about that? How long did this research take, start to finish, would you say?

Probably three years, three and a half years. And as soon as the search is done, it's already obsolete, which makes it difficult. But we weren't really thinking that 20 years would go by before an update. But Dr. Jill and I and the team have decided that we're going to keep up with this fairly regular. It was exciting to see those slides near the end where you talked about what's coming with the mental health and cognition.

So I don't see questions, but I see some wonderful comments. Comments here. A thank you. And another person indicated information packed talk. I appreciate the background story behind this research.

Wonderful. We'll give it another minute. I don't see anything else. Do you have any closing comments? Dr. Diller, Dr. Johnson, thank you so much for this opportunity for the team to be able to show its work.

And thank you for all the. I can't imagine what goes on behind the scenes, but I've always enjoyed Audiology online and it's interesting. I know Dr. Jill is a veteran and doing these, but it's been a while since I think I did one, but it's amazing and really brings us all together. Yeah. I'd also like to take a moment on behalf of myself and Dr. Johnson as well as our entire crew for the support from the American Academy of Audiology.

For this project. We had personnel support, tool support, etc. So this certainly would not have been possible without them. And we really appreciate them prioritizing this as a crucial piece of evidence for moving us forward in audiology. Well, thank you both.

It's been a pleasure to work with you and thanks to all of our participants. It's wonderful to see so many people turn out to hear this and thank you. Thanks to the Academy for organizing another wonderful webinar and bringing forth this information. We wish everybody a great rest of your day and that wraps today's webinar. Thank you so much.