A Quantitative & Qualitative Approach Towards Evaluating OTC Hearing Aids

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Presenter: Amyn Amlani, PhD; Kevin Liebe, AuD

- It's my great pleasure to introduce to you Dr. Amyn Amlani and Dr. Kevin Liebe. Today, they're gonna be presenting to us A Quantitative & Qualitative Approach Towards Evaluating OTC Hearing Aids. It's been said that innovation is seeing what everybody has seen and thinking what nobody has thought, so this month, this February on AudiologyOnline, we're celebrating innovation in our hearing industry and also leaders in our industry with our third annual Industry Innovation Summit. Thank you for joining us all today, and we hope that we see you in other Summit courses throughout this month. And you can find all the course recordings in our library. We would like like to thank our title sponsor CareCredit, and all the companies and researchers and professionals who are participating in this year's summit. And at this time, I'll hand the mic over to you, Dr. Liebe.

- All right, thank you so much Christy, and thank you everyone who has joined us this morning. It's morning for me, maybe afternoon for where you are. Amyn and I, Dr. Amlani and I, are really excited to have this discussion today, so we'd not only like to thank you, but thank AudiologyOnline for inviting us to give this discussion today. So these are our disclosures. And so this is obviously a CEU event, so we do have our learning outcomes that we're gonna go through real quickly. So after this course, participants will be able to describe the barriers faced by consumers that are seeking reliable information on different over-the-counter/direct-to-consumer models. We kind of use those terms interchangeably since this is still, you know, still kind of new for everybody.

Even though we've been talking about this for a while, OTC is still quite a new concept. So you'll be able to explain the value of using both a quantitative and qualitative measure to understand performance and perceptual benefits of OTC or DTC hearing aids. And also discuss the benefits and features provided to consumers and professionals that engage and utilize a digital platform that provides both an audible listening opportunity combined with perceptual written/graphical information as they

navigate through this evolving OTC/DTC space. Okay. So this is an outline, but before we really get into it here, I'd like to do a brief poll to kind of get an idea of where you all are practicing, for those of you that are practicing clinicians.

I'm assuming most of you are. So if we just take a minute here, if you guys wouldn't mind, just real quickly there indicating where you're at, so where do you practice? In an ENT office, hospital, private clinic, the VA, or maybe a retail chain? Or if you're not currently practicing, or maybe you're not a clinician, you can just indicate other. So we'll give that about 30 more seconds here just so we can kind of get a sense and we can steer the conversation to make sure we're addressing the kind of, you know, concerns you would have. Okay. Okay, so looks like a decent spread here actually, so we have about 6% of you in an ENT office, ENT setting, about 25% in a hospital setting, about 23% in private practice, we got one of you at the VA, so 1%, 20% in retail, and 25% in other or not applicable.

So, you know, pretty good spread, you know, pretty representative, actually, of the typical clinician. So, okay, so that kind of gives us an idea of who's attending here. Okay. So really the thing that we all are aware of, whether we give it a lot of thought or not, is that consumer behavior, we're all consumers, today's consumer is different, okay? Today's consumers has evolved quite a bit from when most of us were practicing, or I don't know, I should have asked how long you've all been practicing. But regardless, we all know consumers today are taking a much more active role in their health than they ever have in the past. And this is for a lot of reasons.

A big one that I think we can all agree with, you know, the last time we went to the doctor's office, for many of us here, at least in the US, probably all over the place, you know, the quality isn't as good as it was, you know? It feels a little more impersonal. People are frustrated, it's expensive, you know? So there's just a lot of just general frustration with healthcare as a whole. We have a lot more access to information than

we've ever had in the past, you know, particularly when it pertains to healthcare information. You know, prior to widespread internet adoption, a lot of that health information was really, you know, you'd have to go to the doctor to answer your questions.

And now people can go online, they can, you know, go on Google Scholar, they can do all kinds of things. They can look up Medscape, I mean, they can look up a bunch of stuff and be able to get information. Some of it good, some of it maybe not so good. We can have that discussion. But regardless, consumers just have way more information to make decisions for better or worse. Technological innovations, like I said, the internet. Now we have all this access to all these things. Look at the last three years with COVID, you know? You can have a Zoom call with your physician, you know? There's audiologists that are more routinely doing telehealth. So technological innovations have really opened up the door to allow consumers to be, you know, a little more in the driver's seat with their care.

And then that also has opened up new business models. You know, there's been a growing movement for mobile audiology, for example. That's not new exactly, but technological innovations, and, you know, just the general frustration with the current system has opened up the opportunities for new businesses and new models to thrive. Okay. And so how did we get from where we were to the state that we're in with OTC? Okay. I think it's important to be aware of kind of the trajectory. So number one is that we need to understand that these things didn't happen in the vacuum, okay? So the PCAST report didn't just happen out of thin air. It was all of these things that have built up over time, but it really was the shot across the bow to the status quo in our industry.

So for those that, you know maybe don't recall what the PCAST actually stands for, it's the President's Council of Advisors on Science and Technology, okay? It's an influential report, and they published a report called Aging in America and Hearing

Loss: the Imperative of Improved Hearing Technologies. And they essentially made four recommendations. The FDA should designate a distinct category of, quote, "basic hearing aids, non-surgical air conduction devices for mild to moderate hearing loss," and essentially allow those to be sold OTC. So that was one recommendation. The next one was that the FDA should withdraw its draft guidance on personal sound amplification products or PSAPs. Many of you are familiar with PSAPs. The third recommendation was analogous to its eyeglass rule, the FTC should require audiologists and hearing aid dispensers who perform standard hearing tests and hearing aid fittings to provide customers with a copy of their audiogram and, quote/unquote, "programmable audio profile for a hearing aid at no cost."

And number four was the FTC should define a process analogous to contact lenses by which patients may authorize a hearing aid vendor, in-state or out-of-state, to obtain a copy of their test results and programmable profile from any professional who performed such a test. And again, at no cost. So really PCAST was sort of the, you know, the foundation of where we started here. But shortly after that, we then had the NASEM report, and NASEM is the National Academies of Science and Medicine, or excuse me, Science, Engineering, and Medicine, and they released their report and actually had 12 recommendations. We'll just touch on a few of them here. One of them was to improve population-based information on hearing loss and hearing healthcare, which, you know, again, these are all very laudable recommendations.

So they wanted to remove the FDA's regulation for a medical evaluation or a waiver of that prior to a hearing aid purchase, which the FDA did get rid of that in, I believe, 2016 or '17. To improve access to hearing healthcare for the underserved and vulnerable populations. Improve affordability of hearing healthcare by actions across the federal, state, and private sectors. Evaluate and implement innovative models of hearing care to improve access, quality, and affordability. Implement a new FDA device category for over-the-counter hearing aids. So again, they're kind of echoing a lot of what the

PCAST report says. And basically those two reports combined are sort of the evidence or the foundation for what became the OTC legislation that was introduced by Elizabeth Warren and Chuck Grassley.

So that bill essentially would say that, you know, hearing aids could be sold to, you know, adults over the age of 18 with mild to moderate hearing loss, ask the FDA to issue regulations within three years, including safety and labeling requirements, and update their PSAP guidance. So we kind of know this story from there, but the OTC bill passed, you know, in less than a year, it was signed into law. And then late last year, the FDA published its rule in August, but it went into effect in October. So, you know, we're going on just a few months into quote/unquote "legal" OTC hearing aid sales. So here we are. And before we go to the next slide here, I'd like to do another quick poll.

So just to kind of get an idea for, you know, those of you out there, since we kind have a good spread of where you practice, just kind of curious, will you offer or recommend OTC hearing aids to patients in your clinic? So, yes, we already offer OTC hearing aids, or, yes, we plan to offer them but haven't yet, and then, we might recommend them but won't sell them, or, we aren't comfortable recommending OTC hearing aids, or, not applicable. So again, we'll give you guys about 30 seconds or so and then we'll take a look and see what the results are. Okay, so about 10% of you said that you're already offering OTC hearing aids at your clinic.

16% of you say, yes, we plan to offer them, but haven't yet. 30% of you said that we might recommend them, but won't sell them at our clinic, so that seems to be the majority, that's 30%. And then 16% said we aren't comfortable recommending OTC hearing aids. And so, you know, we'll leave that open-ended on why. And then about 27% said it doesn't apply. So, okay, we'll move on, but I thought that was interesting. So it sounds like a majority of you will be recommending them, but not everybody's gonna sell them, at least in their clinic as of now. So interesting. All right, we'll go here

to the next one. So this here is barriers to hearing aid adoption. And so really, we really wanna think about why people don't get hearing aids, okay?

Any professional out there is gonna know there's a lot more to it than cost, okay? So number one, let's talk about the patient side. So number one, you have to actually have the perception that you have a hearing loss. So we know that there's a lot of people, quote/unquote, "in denial," right? There's stigma, the fact that people don't wanna wear hearing aids. They feel embarrassed about hearing aids. Or, you know, the fact that other people know that they can't hear. There's a lot of psychology involved in just even recognizing you have a problem and then seeking a solution. But we can't deny, you know, I think a lot of providers out there have felt that a lot of the language used and the numbers thrown around during the OTC discussions were not fair.

You know, most clinics are not selling hearing aids at $5,000 a piece, I think you would all agree. However, cost is a barrier. So we all, I think, can agree on that. We also probably don't give enough airtime and discussion to accessibility to providers. For those of you out there who weren't aware, you know, we're about 9,000 audiologists, just as an example, short of where we should be at this point over the last, you know, couple of decades. The profession is not getting out enough providers. So that just compounds the issue with, you know, people in rural areas that are, you know, maybe have to drive an hour to go get a hearing aid or even just be evaluated, so that really is a barrier that probably doesn't get enough discussion.

So, you know, on the provider side, this archaic delivery model we have in the United States, you know, as somebody who's, you know, who works with patients every day, I can tell you it's just a pain a lot of times dealing with different insurances and, you know, referrals and all these things, and making sure you're on top of it now. For those of you that have kind of been paying attention to the news here in 2023, we do now, as audiologists, and I know there's, you know, multiple kinds of providers that are gonna

be watching this course, but for audiology, we just barely got our foot in the door for direct access, but it's still very limited at this point.

Now, reliance on insurance and third parties, you know, that's only gonna grow. So that does kind of, again, that is a barrier. And now we have this new prescription category, or what we're calling prescription category of hearing aids, and the reassignment of preemptions from the federal to state level. And that is worthy of discussion, but it's a little more than we can address today. You know, the other thing is too is that consumers often are finding biased resources. You know, manufacturers own a lot of retail clinics, so, you know, you could argue that those are not unbiased, you know, locations for patients. Resources that you often find online are, you know, not without bias. There's a lot of misleading advertising out there.

And, you know, a lot of people just aren't super savvy from a digital health or a digital standpoint. So there's a component here of health literacy, of digital health literacy. So, okay. So let's just for a moment kind of go over what the OTC legislation actually does. And I know a lot of this is review for you guys, but we're gonna get into this a little more here. So what does the legislation actually do? Okay, well, it makes over-the-counter hearing aids available for adults 18 and older who believe they have a mild to moderate hearing loss, even if they've never had an exam. But it's to be noted here that if a provider is fitting an over-the-counter hearing aid, it's very likely that the state licensure and state laws go into effect, so it's very complicated and people are very confused.

The OTC legislation sets specific technical requirements for devices to be considered as approved over-the-counter hearing devices. They do have labeling requirements, and the FDA has taken hearing aids off its restricted device list, which is a list that's reserved for products that can only be sold through licensed practitioners under certain conditions of sale. And again, I mentioned the preemption. The one thing that is to be noted is that the removal of hearing aids from that restricted list does impact warranties

and hearing aid returns. So again, this is something to be aware of, but we're not gonna really get into it here. So the intent, the intent, I think, was very admirable. The idea behind OTC, you know, increased competition, you know, I think people have been calling for that for some time.

There's different ways to go about that. You know, OTC, that was one thing that advocates believed would help. The idea here is to reduce prices for consumers, increase access for those, you know, in areas that don't have providers easily available, and reduce stigma by, you know, assuming that this is gonna open the door for a lot more people wearing hearing aids, and therefore the stigma will be reduced. And of course, empower consumers to kind of DIY, take it into their own hands, okay? So the reality is, I think, for many people, and, you know, it's still very early, but the jury is still out on whether the OTC legislation will actually prove to deliver on what it promises.

Depending on who you talk to, there are a number of concerns that people still have. I think a big one that makes providers a little bit uneasy is this whole idea of self-perceived, you know? How many patients have you ever seen have a severe hearing loss that just think they have an occasional mild problem? Yeah, so self-perceived mild to moderate does make a lot of clinicians a little uncomfortable. However, you know, I think most of us would agree, the goal being, hey, if they're getting help, that's good. Pricing. For approved OTC hearing aids thus far, are those price points really making it dramatically more accessible for the average consumer? You know, a lot of the price points right now seem to be floating in the $800-1,200 range for a set, which is lower, probably, than an average clinic, but it's not far off from a professionally fit set of devices on the low end.

So I think people still, I think the pricing still is a question. Of course, there's the, you know, it's been brought up many times, the concern about medical conditions being

missed. Of course, lack of counseling and support. So the whole purpose of OTCs, you can get these devices yourself, but as we all know, hearing care is a high touch, you know, field. Even people that are technically savvy sometimes need some counseling, and they need to be supported a little more than they may be able to do themselves. And of course, you know, a lot of, you know, anybody that's worked with patients with hearing loss knows that when you fit somebody with a hearing aid for the first time, they often don't wanna be fit at their prescriptive level.

They wanna crank it down, which maybe initially isn't bad, but if somebody's doing it themselves, you know, there's a concern they're underfit. There's also the concern it could be overfit or overamplified. So again, there's several concerns. And then the federal preemptions to state, again, another issue. And the creation of prescription categories kind of caused some confusion, so, again. So with over-the-counter devices, there actually is an ANSI standard now, and this was among some of the issues that were originally debated when the bill was being, you know, introduced, and, you know, modified and tweaked. So the ANSI standard for output is 111 dB for a linear device, 117 dB for a WDRC device. There's actually no limit for gain, believe it or not.

Frequency response, at least 250 to 5,000. You know, less than 5% harmonic distortion, less than 32 dB A for the EIN. User adjusted volume control, available tools or software to control and self-test, insertion depth needs to be greater than 10 millimeters from the eardrum, proper physical fit, and there is a labeling requirement. You know, they must have warnings on there. It needs to be for adults 18 and up. Usage cautions and suggestions to seek professional help. So this is the newly empowered consumer that we are continuing to see every day. Now, as of October, consumers have the option to purchase over-the-counter or through a licensed professional. Professional fitting and follow up, obviously we would all agree here is the gold standard, but we also need to be able to discuss this option with our patients.

Patients that aren't ready for a traditional hearing aid may want a situational device to use. And you know, I don't have to remind you, for those clinicians out there, you're the expert, right? So you go to your doctor, you know, you expect to get as unbiased information as you can. So consumers expect that. They wanna come to you to have a discussion. We need to be able to provide objective professional advice irrespective of, you know, brand and such. Okay. So now that we have OTC, how do we actually know the performance of the devices? Okay, so this is an issue for everybody, okay? And this is not a new issue. Prior to OTC, consumers already had difficulty navigating this whole system, like, right, just understanding like, you know, what makes a Oticon different from a Starkey?

Or, you know, what is this dual mic, you know, fancy, you know, directionality, you know, proprietary feature on this hearing aid? Why is that different than this one? There's just a lot of challenge for consumers to figure out, you know, even when they talk to a professional, navigating this whole hearing aid thing. And I would say that with OTC, most of our colleagues are likely to lean on brands they know that they could recommend to patients. I mean, most of us, that's where we're gonna feel the most comfortable, right? I mean, we know that this company makes good hearing aids. Well, if they make an OTC, we could probably recommend that, but how do we know which ones of those are actually best for our patient?

And, you know, that then leads to the level of hearing loss, the sound quality, what kind of features it has, how easy is it to use, you know? So it's just like anything we would do with a prescriptive hearing aid. You know, we wanna know, you know, how does this best match the patient's needs, the patient that's in front of me? So it's just important to note in this context this idea of health literacy. I touched on it earlier. So this is from the CDC definition. So personal health literacy is, "The degree to which

individuals have the ability to find, understand, and use information and services to inform health related decisions and actions for themselves and others."

There's actually an organizational definition, "The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health related decisions and actions for themselves and others." So then we have to kind of think about, well, what are those barriers in front of our patients to getting good information? Older Americans, so, you know, those of us out there primarily are, you know, the majority of us are probably working with adults 65 and over, as well as low income Americans are much more likely to lack access to reliable information. And that begs the question, who are they most likely to ask? With relating to health, hopefully, I mean, most likely, I would assume, they're gonna ask their doctor, you know, but they probably will ask their friends and other things as well.

So that's just kind of food for thought here. Who are they gonna ask and how are they gonna get this information? So on that vein, there's a Pew study just from last year. So by the way, this is two years, or a year and a half into COVID. This was in '21, I think summer of '21. So it asked, did this survey and it said, "Okay, so the percentage of adults who say they have the following based on income." Smartphone, based on income, if you make less than 30,000, about 75% of people making 30,000 or less have a smartphone. If you're making over 100,000, you're pretty close to almost 100%. So desktop or laptop computer, if you make less than 30,000, you are just below 60% of people in that category would own a desktop or laptop computer.

For those in the higher income brackets, it obviously goes up. And then high speed internet, less than 60% of people making less than 30,000 have access to broadband or high speed internet at home. So again, this is just relevant when we're thinking about, you know, is this patient or is this individual gonna be able to find reliable, quality information? And then how do they go about finding it if they don't have a

computer, if they don't have, you know, high speed internet? And again, from another survey at the same time. So based on age, income, and geography, the percentage of US adults who don't use the internet, so only 1% 18 to 29 don't use the internet, so that sounds about right.

Even between the ages of 50 and 64, only 4% say they don't use the internet. But those 65 and older that don't, 25%. That seems really high. I mean, I can think of a lot of technically savvy patients I've seen over the years that are well past their mid eighties. So that's pretty stunning actually, that this was taken in the middle, you know, a year and a half into COVID. So by income, again, if you make less than 30,000, 14% of those don't use the internet. Interesting. If you're rural, which I think that's not a surprise, but 10% of people that are rural apparently don't use the internet according to this Pew survey. And we'll kind of go through these here. I don't wanna go too long on these examples.

But again, talking about the digital literacy and kind of knowing how to obtain the, you know, quality information when you're looking online, as you know, okay, go to Google and just type in the word hearing aids. Your entire display is actually gonna be all ads. You have to scroll down about halfway down the page before you actually see results. And even when you see results, they don't actually necessarily get into any great detail. They're more just kind of informative articles. But then you say, "Okay, well let's type in OTC here." And it's the same thing. All we're really seeing here is several ads. And again, for somebody who's older, they're not real savvy on the internet, they just, you know, oh, they just click on one of these, and then who knows?

Who knows if the provider that they click on is reputable, you know? Obviously not unbiased if it's an ad. So it's definitely, you know, a real issue. So then, you know, if we go to Amazon for example, so say this person's a little more savvy and they know how to shop on Amazon, you know, we're talking like an older adult. So let's say they go on

Amazon. Okay, well, I'm looking on Amazon and I can't make heads or tails out of what I'm finding. These ones say they're a best seller and they're 199, and these ones are 799 and these ones are 59. Like, I don't know what any of this means, you know? So for those of us that live and breathe hearing health and hearing aids, like, we get it, but you just gotta put yourself in the shoes of the average person.

This is totally overwhelming and confusing. Okay, so, what's the difference between a 199 device, a 799 device, and a $99 device? Well, this $99 one says it's the best seller, so that means it must be good, right? So I mean this isn't news to anybody here, but it just kind of really brings out, okay, this, you know, this clearly is is a huge problem for people to really find good information. And kinda like I said earlier, so even with professional guidance, patients have a very hard time navigating available devices and options. There's multiple brands, there's a billion different kinds of features. All the features have different names. That industry jargon is really opaque and difficult to know. and like, what's what?

And I'll be quite frank with you, the clinicians have a lot of the same challenges, you know? Sometimes it's really hard to decipher if this new, you know, this new feature on this new hearing aid is actually gonna be worth that, you know, 200 extra dollars that the manufacturer wants me to pay for that device. So it's tough. So we have a lot of limitations really understanding this stuff. So there's some subjective reviews of hearing devices, like other consumer products. They can be very useful, but they do have limitations. Again, if you don't know how to take stock of, you know, how savvy are you online, or with what you're reading, like is that a trustworthy source?

Is there a motivation or a bias to present the information a certain way? So we don't know. We don't know. So you don't know what you don't know. Are any important factors being omitted or neglected? So it's just really challenging. You know, and for traditional hearing aids, you have data sheets that can be provided and they give us

specs on things like gain and frequency range, battery drain, whoops, battery drain. So this is a familiar, you know, familiar look. But I will say that even for professionals, you know, having, you know, worked on the training side, the education side for a while, I'll say that there's a lot of providers that have a hard time really translating some of this information into, you know, benefits for the patient, that kind of thing. So even when we're getting some of these things, it can be a little tough to interpret for some people. So I will hand this over to my colleague, Dr. Amlani, and I'll let him take it away.

- Great, well good afternoon, good morning. Kevin, thank you. And so as Kevin and I were talking about some of the things that he's shared with you thus far, the question became what can we offer the professional and the consumer so that they, right, 'cause it's a partnership, how can they, both parties, take this information and make the right decision? So it's not necessarily triaging because that's more of a medical term. What we wanna do is we wanna be able to collaborate to ensure that the consumer's getting the best product available, whether it's an OTC or DTC and/or prescription device, and, you know, ensuring that the provider remains a part of that patient's journey. So as we were looking at this, I'm a big proponent of working backwards because at the end of the day, the consumer is the person that's going to end up with this device.

And so as Kevin and I were talking, I said, "Let's look at some consumer purchasing behaviors and let's find a model that works that we can then use and then have that information be available." And I believe because the audiologist is also a consumer, you're a consumer in the sense that you're having to purchase these units that you're going to then work with in your clinic and then pass on to your patients. And so we wanted to make sure that we were able to get both sides of the coin. So having said that, I've done a little bit of work in consumer behavior. There are different models, and this is one of them. This is the Consumer Decision Making Model.

It's by Blackwell et al. It came out in the early 2000s. And it actually starts on the right hand side of the graph. And, you know, you're looking at the bottom here where it says, variables influencing the decision making process, which then lends to the decision making process. You then have to have information in order to process, and then you also have input, you have external input, whether it's your spouse, whether it's a friend, whether it's a newspaper, or what have you, that then collectively allows you to make a decision. And so the reason that I really like this model is it's all encompassing. It takes the internal and external factors, and then it's predicated on this thing at the very top that says need recognition, and you're having to make a decision based on desired versus actual state.

So this is a model that is used quite a bit actually in consumer purchasing, and used by very, very large companies. So going back to this area here where we talk about need recognition, this is what we're looking at here, okay? And what you have here at the top are different states and lifestyles, and basically what we're looking at is down here in the middle, where it says your desired state equals your actual state. So if where you wanna be, and in this case I wanna be able to hear, and my actual state are equal, well, you know, I hear well enough, this is that whole self-perception piece, then I'm satisfied and I'm not going to do anything, okay?

So in this consumer behavior, it's a moot point because the consumer's not going to move forward with the purchasing or the acquisition of this product or service. If the desired state is greater than the actual state, okay? Sorry, if the desired state is less than the actual state, you're not gonna move forward, okay? Because where I'm at is better than where I'm trying to go. It's only when you see that the desired state, where I wanna be, is better than where I'm at, then need recognition comes in and says, "You know what? I need to do something." So if you think about it, right, we just passed the new year, I put on a few pounds last year sitting at home with COVID.

I probably need to exercise. Well, you know, where I'm at now and where I wanna be are not the right place, I need to do something. Let me do a little bit of homework online. Do I need a home gym? Do I need to go and invest a couple hundred dollars or a couple thousand dollars and join a gym? What kind of gym? And so forth and so on. And that's what need recognition is. Now, need recognition is based on three main points here. The first is motivation, the second is the ability and the psychology, and then the third is the opportunity that presents itself. And so we believe that folks are going to enter our market needing and wanting help because there's more of a demand than there is a supply, as Kevin pointed out.

We have more people entering the market, and there's even gonna be more coming in with the graying of America, than we have providers to supply services to these individuals. And so this need recognition is going to be a critical component in their journey. Now, as they talk about need recognition, there's gonna be these environmental influences, you know, culture, your social class, your personal influences, the situation that you're in, finances and so forth and so on, and then also your individual differences. So what is your motivation? What is your attitude? The biggest factor here is going to be emotion, which in this particular model falls under attitudes. And then also what's your personality, what's your values, and what's your lifestyle?

You then put those into memory, and then from there you decide, this is the information that I need, and this is what's going to give me the desired outcome that I'm looking for to get me over my actual state. So this is kind of the model in which we started this conversation in the materials that I'm going to share with you. Now, we also now have these extrinsic factors, and that is what are all these tools that are available in the marketplace? And so if we just dichotomize this, we've got concepts that are FDA regulated and concepts that are non-FDA regulated. Concepts that are FDA regulated include OTCs, and we can dichotomize, again, OTCs into self-fitting and then presets.

So self-fitting is where you have a device, you might take a hearing test on it, and then you're able to manipulate the internal controls, the electroacoustics if you will, for tone, for gain, and so forth and so on to get the outcome that you're looking for. OTCs also come in presets, and this is typically a toggle switch, could be on a smartphone where it's memory one, memory two, memory three, and these are already constructed for you at the manufacturing level. So it may be, for example, a 3 dB increase in the highs with a flat in the lows. It may be a 3 dB increase in the highs is button two with a 3 dB increase in the lows and so forth and so on.

And those are preset for you. The prescription model is what Kevin just discussed with you. It's basically our old medical model. They've just given it a new name. And so this is where you would actually go into a practice, you would see a provider, a licensed individual, and then they would then dispense the device to you. On the non-regulated FDA side, we have PSAPs, which is personal sound amplification products. So these are non-FDA regulated. You have your hearables, and then you have your consumer audio, like your AirPods. And all of these are direct-to-consumer products that are certainly available to you. So again, folks have choices here, but the question becomes, what is it that they're going to choose?

Are they gonna choose A or they gonna choose B? Potentially it could be A or C or A or D or A or E. And that's what we have to figure out. And so as we're having more and more discussions about what we could potentially offer the market here, we needed to come up with some working goals. And so these are the two main tenets of our discussions. The first was we needed to bridge the divide between subjective and objective assessment. And what that means is, so when we have objective measures, so for example, Kevin talked about electroacoustics, we also need to combine those electroacoustic measurements with what is happening with the person and their reviews.

So is there a way to marry those two pieces together? And in a lot of times they're separated. So to give you an example, our family uses Yelp quite a bit when we're looking for new restaurants, and, you know, you've got the subjective ratings of, you know, "This Italian place was fantastic." But when you actually get there and you see what's going on, the objective assessment is that it's dirty, is that they have a really narrow menu. The food is cold and so forth and so on. And so what we wanna be able to do is marry these two things in a way where you're getting accurate information from what the person perceives and what the person is actually getting.

The second working goal was to provide quality information that, again, allows both parties to make informed decisions about their hearing health. And it's not to say that the provider should not be included as part of this discussion, and I'll talk about that in just a minute. The question becomes is, what is their starting point along this journey? We want folks to start treating their hearing loss at a younger age. I think right now the age is about, the average age is about 65 or 67, depending on the materials that you read. In some cases it's closer to 60. But we're finding that more and more younger individuals are experiencing hearing loss because they've got electronics in their ears all day.

I've got a young adult and two teenagers here at home, and these things are in their ears almost 24/7. They don't let their ears rest. And I personally would not be surprised if one of them came back and said, "Dad, I'm having a hard time hearing," and we found a high frequency hearing loss just because those things are always on and they're always turned up. Okay, so now that we have our goals, what's the vision? How are we going to achieve these goals? And so we're going to do it in four different ways. Number one, we wanna highlight the device performance and we wanna show that to you, as well as allow you to listen to it.

And we wanna do this under optimal conditions, which is your typical electroacoustic measures now, and we also wanna be able for you to see and hear this under speech and noise and speech and noise and reverberation, because that's what the individual is going to be wearing these devices in. The second point here is we want to provide you and the consumer with peer and user input on device performance in both of these conditions. So we are in the process of putting together some select groups of peers, those with normal hearing and those with hearing loss, who are audiologists and hearing healthcare providers to share their inputs on what these devices are doing, as well as provide you with what folks are perceiving these devices to do in the real world.

The third piece here is we wanna ensure that our protocols are scientifically valid and that you can actually take these protocols and apply components of them, there may be pieces which you can't apply completely, but you can take portions of this and validate what we came up with in your clinic. And what that's going to do is it's going to allow you to see whether or not one, our data's real, and then number two, if there's an issue, it will allow you then to troubleshoot what that issue might be, which then becomes a revenue generator for you. But we wanna make sure that we're using these protocols that are already designed, and that we're not making these things up, so they have to be valid.

And then the last thing is we wanna partner with advisors and colleagues to ensure that our vision is encompassing of all the different angles, and that it can be achieved clinically with efficiency. We don't want you to spend an hour and a half looking at someone's OTC when you're only gonna get paid maybe $200 for the time that you spent on it. And in reality, there's no markup on these devices because they can purchase them anywhere. And so we wanna be considerate of that and make sure that what we provide you can be done quickly and efficiently. So how are we planning on doing this? Well, the first thing is, is you're gonna need a test box, right?

Most clinics have a test box. Again, the test box is going to allow you to test out the output and the gain of a traditional hearing aid. I don't want to speak on behalf of any of the manufacturers of these units, but I would expect that at some point you'll see the CTA and the NCCTA standard for over-the-counter electroacoustics become a part and parcel of this test box. Again, I don't have any insider information, but I do expect that to happen sometime in the future. And then you'll be able to test gain and output frequency response. You'll be able to run multicurves for compression. So as you put in different levels, what happens to the frequency response?

You'll be able to run multicurves for noise reduction. You know, if you have it on a weak setting versus a strong setting, how much of a gain reduction is there? And then also look at the efficacy, if you will, of your directional microphones in this particular environment. Okay, then we wanna take the test box, and we are in the process of experimenting, if you will, with different WAV files and playing them out in the Verifit 2 at this point. Eventually we'll do this with other equipment, but we're using the Verifit 2 at this point and looking at how hearing aids perform in the speech map mode in the test box. And we're doing this in quiet. And so right now we have a, I believe it's a 15 second sample of the Arizona passage, which was part of the acceptable noise level test.

So we're looking at a passage there, 15 seconds again. We then take the passage and add in competing noise, and we're looking at different signal to noise ratios. So we'll have one that is favorable, so maybe a plus five or a plus 10, and we'll have another one that's more adverse, so maybe it's a zero that you can test out. And then we'll add a reverberation. And we're trying to find a balance of what is a good reverberation time? Is it one second? Is it 250 milliseconds? Is it half a second? And so we're playing with that at this point in time. And then what we'll do is we'll provide you with this stimuli. You can then take these stimuli and apply it to the device that you have your

hands, that the patient has brought in, or that you're testing to put on your shelves and see what's happening.

Now, what we're also going to do is provide you with these WAV files so that you can listen to them. And as I said earlier, you're gonna be able to visualize what these devices are doing. And I'll show you in just a second what I mean by visualize. Now, we're also working with the folks at AHead Simulations. We have an Audio Carl, which just became available, and we're going to make real world measurements on this mannequin. We're in the process of determining what is the best loudspeaker array, so speech in front, and then how many noise speakers, or are we gonna set speech off to a side and look at head shadow effects? We're still playing with those kinds of things to figure out what those are.

But then what we wanna do is once we've scientifically validated the best model for that, take the output of the amplified signal and compare it to the original signal to see how much of a modulation or change there is in that signal so that, again, you can listen to and visualize changes that are occurring with that particular sound. Now, that's the objective piece. The subjective piece is a rating of device performance. And right now we are leaning towards the Self-Assessment Mannequin. It's a test by Bradley and Lang that came out in 1994. The test actually has three different variables. It has arousal, it has valance, and then there's a third one. The third one is not as sensitive to ratings, and so we won't be using it.

So we'll be looking at arousal versus valence as a function of different emoticons that are here on the right, and these are not exactly them, but you'll be able to rate what you think that sound is. And so we'll do this for the reference, the original sound, plus the amplified sound. And that will then allow us to plot on this graph what the individual is feeling. So for example, if in the original sound, we are up here at excited and happy, that's a good thing because you have high arousal and high valance. The likelihood of

that emotional trigger being excited is good, okay? But if you now amplify the signal and it's depressing, the likelihood of that individual then moving forward with that device is not very high, okay?

Now, I talked about emotion, and the question begs, why are we having a discussion about emotion? Well, as I shared with you when we were looking at the consumer decision model, one of the primary factors in acquisition or moving towards needs recognition and moving towards your desired state is the emotion. And I'll give you an example. When you are purchasing and you are overanxious, unless you're an irrational individual, right, the likelihood of you purchasing or moving forward with that acquisition is low. I'll give you another example. If you are having a good day at clinic and you have to stop at the grocery store on the way home, the likelihood of you making better informed decisions is higher.

What research shows is that you're more likely to not buy junk food, you're less likely to buy salty and chocolatey goods, and you're less likely to buy alcohol. You're more likely to buy things that are good for you. If you've had a bad day in clinic or something has upset you, right, you know, if you're a football fan and your team just didn't take the next step, or Tom Brady retired today and that's upsetting to you and you decide to go to the grocery store today, you're gonna end up with alcohol, chocolate, and probably potato chips when you should have been in there buying salad, bread, and peanut butter, okay? So emotions are what really drive your abilities to purchase.

And so really, that's the reason that we are leaning towards this rating of emotion, because we believe it's going to give you the best information as to how that patient feels about not only unaided hearing, but also amplifying hearing. Now, I said earlier that we want to ensure that you as the provider are on this journey with your patient. And what I want to talk about real quick before I lose this train of thought is, moving up a couple of slides, is new research is suggesting that patients want your support. So

this is figure eight out of the most recent MarkeTrak, so MarkeTrak 2022. And what it shows here is that a large majority, about 70, 71%, want the hearing healthcare provider as part of the decision making process in the journey for their devices.

This study came out in JAMA a couple days ago, or a week ago. This was an assessment of consumer attitudes towards the OTC market. This is by Singh & Dhar, so this is at Northwestern. 84% indicated pursuing hearing health in person, and older adults were less likely to pursue hearing healthcare online. So again, we want you to be a part of that whole process. Now, as you're a part of this whole process, there's a couple things that you need to consider, okay? Number one, emotions are going to influence a person's consumer behavior, okay? We are also learning from research that's coming out of Vanderbilt in particular that hearing loss and amplification characteristics have the potential to influence and evoke an emotional response, whether it's positive or negative.

And then the last thing is, is that emotionally related perceptions have the ability to represent a new outcome measure that assesses the efficacy of a treatment for hearing loss. So maybe we need to start thinking about different ways of looking at how people are not only purchasing devices, but what their thoughts are before they purchase these devices. And just to give you a little insight, you actually have seen this, or been a part of this, if you've purchased a car, if you've purchased a home, and, you know, if you've shopped in any other way where you're able to buy something, try it, and send it back. Now, we have this model in hearing care, but we really aren't making measurements, if you will, of what the person thinks emotionally.

We tend to base everything on the electroacoustics and on these handicap scores. And I'm not dismissing these handicap scores, they're very important, but I think we need to dive deeper into the person's intentions in order to determine how they're gonna move forward, particularly given what Kevin has talked about with these

individuals now having more information and the fact that we don't have enough of a supply for these individuals and the fact that healthcare is really changing, and not in a positive way, where these individuals are starting to take their healthcare into their own hands. The other piece that we're also going to include in this is something called patient readiness. So this is from Catherine Palmer's group.

It's a simple question. They ask on a scale from 1 to 10, 1 being the worst and 10 being the best, how would you rate your overall hearing ability? And you'll notice that if they report a one, there's a 96% probability that they're gonna move forward with hearing health treatment. If they report a 10, it's gonna be 6%. Anything above a five is really good, six is chance, and anything seven or below is pretty bad. And we are in the process right now of taking all of these things, working them into a dashboard that will be available to you from the patient so that you can see what their emotions are, what their readiness is, what the product comparison is between the test box and the mannequin head, And then in order to visualize, we will take the acoustic properties, we will run them through a spectro-temporal assessment, and look at the spectral differences so that you can see how much of a change in modulation or distortion is occurring in that signal so you can then help guide that patient with the right information and the right product, and then, again, serve as a conduit in them getting the right, and more importantly, the help that they need in order to move forward with their hearing health.

So kind of to put all this into a summary, we want to take the qualitative and quantitative data, and we wanna make sure that we are affecting the consumer in their decision making process in a positive way. We wanna be sure that we're providing a holistic picture of the benefits provided for the product and the professional support that you are going to provide. And then we also want to deepen the relationship between the provider and the consumer, lending to an increased likelihood of them purchasing a device from you down the road as you become, you know, a partner on

this journey with them through their hearing care. So that's it. Here's our contact information. If you have questions or comments, we're certainly happy to answer those. I believe we're a little bit over on time. And there's the references. So with that, I will stop. And Christy or Kevin, I'll turn it back over to you.

- [Christy] Thank you, Dr. Amlani. So we do have a question here from Brenna. Brenna mentioned, "Can you explain more about what you mean by reassignment of preemptions?"

- Yeah, so very, very briefly, so let's take the medical clearance. That is a federal preemption, and so as we all have been trained, the person can come in, we can share with them what their test results were. If they're a candidate for amplification, we can tell them, you know, "You can either go see your physician, or you can sign this waiver." Well, now what has happened is those federal preemptions, including this medical clearance, are being shifted down to the state level. And each state then is going to decide how they're going to implement, in this example, the medical clearance. And what I'm learning, I'm on the Academy of Doctors of Audiology Board, and what we're seeing at different states is some states are keeping with the old federal preemption, right, where you have the option to waiver out, the patient has the option to waiver out.

There are other states where there is a huge medical community, and they are now forcing the consumer to go in and get a medical evaluation before they're fit with a hearing aid. All of this is going to develop over the next several years as state licensure laws open up. My advice to you is if you are concerned or you're not sure what's going on, please, please, please contact your state organization and get involved at that level, because that is where it's going to come back to affect you most importantly. So I hope I answered that question for you.

- [Christy] Thank you, Dr. Amlani-

- Okay, so it looks like-

- And thank you, Dr. Liebe.

- Go ahead.

- [Christy] It doesn't look like there's any other Q&A in the queue, but I know that you provided both of your contact emails, so if anyone in the classroom has to log off and, you know, things happen to pop into their mind, feel free to reach out to either Dr. Amlani or Dr. Liebe. I'm gonna hand it back over to you for any last closing comments.

- Yeah, I just wanna say thank you to everybody who stuck around. I mean, we had about 150 people still here at the end, so thank you for listening to, you know, our thoughts on this. Really, we're trying to make something that's gonna be valuable to everyone involved. And as Amyn pointed out, that research that just came out indicating, you know, a vast majority. So, you know, we need to put all the fear about OTC aside. I think most of us have moved on from that. But just realize that regardless, even the most savvy patients, they still wanna make sure they're doing the right thing. So we just need to be prepared to be the objective professional that's gonna give them good advice.

Because, I mean, just in the last few years, just since OTC passed, I mean, I've seen a number of patients who've, you know, bought hearing aids online, and at the end of the day, what most of them say is, you know, "I bought this device. I could tell it helps me a little bit, but it's just not quite right. And I knew I needed to come see a professional." So if you are that professional who has helped guide them from the beginning, you're just gonna help build that trust and that long-term relationship. So

again, what we're trying to do is we're really trying to make something that's gonna be of value, you know, and hopefully be able to unveil some of this here in the next few weeks.