Design Considerations for Fitting OTC Hearing Aids, presented in partnership with the American Auditory Society

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- It is my pleasure to introduce today's presenter, Dr. Andrew Sabin leads the research division of the hearing aid group at Bose corporation. Prior to this, he also led efforts at a startup that was focused on hearing aids self fitting. With no further ado I'll turn it over to you Dr. Sabin.

- All right, thanks. Well, first it's a privilege to be able to speak to this audience. I really admire audiologists and I think they have a really critical role to play with this sort of new market that we think is gonna open up at some point. So, yeah. Please ask questions throughout, it'll feel better if I'm not just speaking into a void. So I would love any feedback throughout if there's anything I can clarify. But before we kick things off I do wanna just have a little bit of a sense of who am I actually talking to, who's on the call. And one way to do that is by doing a silly poll. So Anna, if you wouldn't mind bringing up the first poll, are you guys wearing sweat pants?

I mean, we're all kind of wearing sweatpants these days or at least those of us who have the ability to work from home. I just wanna have, you know, a mental image of who I'm actually talking to. So I don't have any visibility into how many people have submitted their answers but maybe we'll give it just a few more seconds. It was a lighthearted way to kick things off and potentially you're seeing the results. So well, it looks like there's enough people who've responded, maybe we can show the results to everyone. Interesting, only a third, okay. There's probably some people actually at clinic today. I'm wearing sweatpants for what it's worth. Okay, and then just one other question just for my own sense of the disposition of who I'm talking to.

Maybe ask the second question. So can you pop up the second poll please, Anna. Are you willing to sell an OTC hearing aid in your clinic? I promise my feelings won't be hurt if the answer is no. But I'm just sort of curious about what the disposition is of the folks who are on this meeting. So same story, Anna, well, it looks like there's folks who are, well the results have kind of leveled out. I'm curious what the disposition is of folks

here. Maybe show the results. Okay, so two thirds, about two thirds say yes and one third says no. And it's interesting to speculate about whether then there's a relationship to the sweatpants, but yeah, not for now.

All right. Let's get into the meat of it. Thank you for doing that poll. Now I have an image of who's actually listening. Oh, all right, so there's a disclosure, I worked for Bose. I should say I'm not talking on behalf of Bose, I'm talking on behalf of me. Everything that I'm talking about today is publicly available. You can, you know, a lot of it is published research or policy documents, things like that. I do work for Bose though, so take that for what it's worth. And there are these other disclosures that you can read if you want to get bored. The learner outcomes you've probably already seen. So I'm just gonna jump to sort of how I'm thinking about this presentation.

So there's three things I'd like to just sort of, big picture things I'd like to focus on for you guys. So one is, what does the actual regulatory landscape look like today? Cause it's weird. And it's also, it's funny to be giving this presentation now because if I gave this presentation a month from now or six months from now or a year from now, it would probably be different. So I do wanna say that, like, what I'm gonna talk about is sort of what the current state of things is, current state is, but you know, as we'll talk about, you know, it's gonna change pretty soon. And then, you know, there's this question of like, all right, if there is an OTC hearing aid, how the heck does a user fit it?

And of course what I mean by fit in this case is electro-acoustic fit, right? How do they choose the gain that's right for them? And then the third question is how do we know if that fits any good? What can research say about that? So those are gonna be the three big blocks of the talk and I'll sort of keep coming back to the slide to tell you when I'm changing blocks. All right, so let's talk about regulation, everyone's favorite thing. But it is sort of a weird and interesting time and I'll say I've learned quite a bit about how the US government works that I had never learned before. But you know, back in the

ancient history of, you know, five years ago and a lot of times, you know, when I started paying attention to this, it was very simple.

There were basically, there was basically a hearing aid and technically there were two, there was a wireless and wired hearing aid. But those were medically regulated devices and the thing that made them special was you could make medical claims about them in marketing, right? And this is what you're all used to dealing with in selling that's the big five hearing aids and they can make medical claims. And then there was this other sort of recognized category by the FDA that was not regulated, all PSAP, personal sound amplifier products. And really the thing that made those different was, you are not allowed to say anything medical, right? You could only talk, you know, the classic example that people would point to are things like birdwatching, right?

The thing that can amplify sounds around you but not to actually make any claims about whether you can help people with hearing loss hear better. And there were attempts to actually narrow that even further to not even mention like situations where people with hearing loss and have problems, but those sort of went out the window. But the regulatory space has changed, no shocker to the people on this call. And my sense is it kind of looks like this or at least the hearing aid side of it kinda looks like this right now, where there's the sort of fragmented hearing aid concepts. And they're actually not even all categories in the FDA but hopefully I wanna dig into this that'll be clear, but what I'm gonna talk about are the over-the-counter hearing aids and that's probably the thing that's gotten the most press and you might have the most opinions about.

There's also a different category called self fit hearing aid which you may have seen a couple of years ago, but has got a De Novo FDA approval. And that's actually not an over-the-counter hearing aid or at least not yet, and it's a little bit fuzzy and weird. And then of course there's still a traditional hearing aid which you're also familiar with. There is still the PSAP category, I will say just a couple of things about it but really the

new stuff that I wanna talk about are these first two categories, the over-the-counter hearing aids. So over the counter hearing aid you have a picture of Elizabeth Warren and Chuck Grassley who are the co-sponsors of this bill.

It was interesting 'cause it's a very rare case of bipartisanship. Elizabeth Warren of course is a Democrat, Chuck Grassley is a Republican and they did pass a bill called the over-the-counter hearing aid act of 2017. And let's do what everyone wants to do, which is, you know, actually read legislation. I won't say I have never actually read a bill from Congress before, so it was educational for me to actually see what what's the actual text of it. And I think what you'll find is there's not a whole lot of text in it, there's a lot that's not defined in it. And you know, the punchline is we're still kind of waiting for the FDA to fill in the gaps of what's not defined in this.

So yeah, there's this bill called the over-the-counter hearing aid act of 2017 that was passed in Congress, signed by, you know, lame duck president. And what did it actually say? It was very short bill. I encourage you to actually read it, it's kind of interesting, but I'm gonna highlight a few things that I think about when I think about this bill that was passed. One thing, and by the way, you might hear some of the craziness of my family, apologies for that, but that's just what's happening with the time. All right, who's it for? Well, it's intended to be used by adults over the age of 18 to be compensated for perceived mild to moderate hearing impairment.

And I think that, you know, the word that's doing a whole lot of heavy lifting in that sentence is the word perceived, right? Because it is intended to be sold directly to the consumer and so doing a diagnosis, audiogram, tints, whatever, is not required. So if you just think you have mild to moderate hearing loss, you are, you know, that's the intention of this legislation. And of course, oh, sorry, this next thing it's available over the counter without supervision, prescription or other order involvement or intervention of a licensed person. That's you guys, I promise it's not that scary we're gonna get into

it but that part it was probably scarier to you and it can be sold in person or by mail or online.

One thing that's, you know, probably boring to you guys but actually is a really important piece of this legislation is that there's this concept of that the federal law preempt, there's a magic word, preemption state law. So right now the regulations are, you know, prior to this, there were regulations are weird where every state had its own legislation about who can dispense and fit hearing aids. The OTC regulation say, at least with respect to OTC hearing aids, this thing takes precedence over all of that. So it is a federal law, that preempts the state law. And then there's other bet to say, hey, so this doesn't say anything about the stuff that we care about, nothing about gain, nothing about output, nothing about UI, nothing about usability support, all those kinds of things that we know are critical to making a successful product.

It says, hey, FDA, you got to figure that out. And by the way, you get three years to figure it out. Not later than three years after the date, and three years after the date is August, 2020. And of course we all remember in August, 2020, when the FDA actually announced these regulations, I'm joking. Of course they haven't released any detailed regulations yet. Now, I'll give you a sense of what those regulations might look like when we talk about the Bose self fitting product. But we're still waiting. And by the way, it doesn't just happen that the FDA announces it, the FDA announces it and then there's 180 day period where the public, including you all get, to comment on it.

And then at the end of that, 180 day period those regulations are finalized. So we're at least 180 days away from the FDA announcing, oh, sorry, from this actually becoming a real category. So what happens when, you know, the federal government says you have three years to do this and you don't do it. It turns out nothing, really. All that happens is in this case, you know, you get letters, angry letters from Congress people. So yeah, here's one headline that Senator Warren has sent the FDA, actually a few letters at this point saying, hey, what's going on? You're supposed to do this by now,

why is it taking so long? And my friends at the FDA are working as hard as they can and have cited, you know, the pandemic as a totally reasonable reason why things are taking a little bit more time than we might expect.

But, you know, we're hoping 2021 is the year where, again, the FDA will announce the details like the meat of what does that actual category going to look like. And then 180 days after that it will be finalized. All right. So that's what I have to say about OTC legislation. The next thing so sort of like a compliment to that, there's a self fitting hearing aid which Bose has gotten approved. I will admit to having a part in that. And I, in fact, I'll talk about some of the clinical research that I did to support that application. And what you'll see in this is much more detailed specifics about what what does it take to actually be an FDA approved hearing aid that can be sold direct to consumers?

And I think hopefully what you'll see is the bar is fairly high, I think. So, you know, there's a lot of effort that you need to do to actually convince the FDA that what you're doing is safe and effective. So again, you might remember that in 2018 Bose got granted what's called a De Novo FDA approval which is the approval of a new medical product. So it is not any of those hearing aids that proceeded it and it is not a class one air conduction or class two wireless hearing aid, it's its own thing. And what you can look at is the De Novo classification. This is again a document that I just took right off of the FDA's website.

And there's a few things that sort of jump off of these like sort of exciting parts of yet another government document, what is the indications for use? And so what you'll see here is something that looks very similar to the OTC regulations. So it's intended to amplify sounds for individuals 18 years of age or older with perceived mild to moderate hearing loss. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct to consumer sale and use without the assistance of a hearing care professional. So at least in terms of the indications it's very similar to the OTC concept. And certainly there

are people who have speculated that this De Novo classification is sort of a framework that the FDA might use for the OTC category.

I have no intelligence on this one. You know, the FDA gets to make their decisions in private and we'll find out. But there's another really interesting part or another part of this document that you might find interesting, I should say. And that's these things called special controls. And, you know, if I'm being sort of a colloquial about it, it's sort of like, what are the hoops that a company needs to jump through if they want to be in this category. And some categories you don't actually have to do anything. You just have to sort of document stuff so if the FDA audited you, you would show that you did your good hygiene with your software and hardware development.

So what has to happen? Well, the first thing that is gonna jump off the page is, you need clinical data to evaluate the effectiveness of the self fitting strategy. That's something that we should all care about, right? You need to actually run real studies with real patients and do a good enough job that the FDA is going to believe that what you're doing is effective. That's not a low bar. That's something, you know, I'll talk about what we did but, you know, that is, I think an important bar and I think one that maybe our community should really push for as the OTC rags come out. Obviously it's self-serving to say that, but I do, I honestly believe that like, look, there could be a lot of, there is a lot of garbage out there, we all know that there's a lot of garbage out there and so this FDA approval should matter.

And in one way it could matter would be, hey, you've actually run clinical studies to say that this thing is effective. Electro-acoustic parameters, they don't specify any limits but they do say that you have to disclose maximum output, distortion levels, equivalent input noise, latency, frequency response. So you have to specify it and test it. There's a whole bunch of stuff around wireless. This is true about most FDA devices but you have to, you know, make sure that all your wireless stuff is not causing any problems. Now I'm on number four here. There's a way in which you have to do medical device

development that is fairly cumbersome but appropriate given that you know, that you're dealing with someone's health and that has to do with how you'd actually do your software development, all kinds of testing and validation, hazard like you have to, yeah.

Hazard analysis, can you see any opportunity or any cases where someone might get hurt and how do you mitigate that? Number six is, hey, you have to do yet another study, usability testing. So this is more like human factors research, a little bit less like the clinical one in number one here. But you have to actually show that people can understand this interface. And again, this is, you know, they don't define like here's the test that you need to run but you have to a good faith test and submit it to the FDA and the FDA has to decide, hey, was that a good test? So that's yet another hoop that folks have to jump through we did jump through and other folks might have to jump through if they wanna be in this category.

And then, you know, there's a labeling requirements. So how can they self identify as a candidate? Where do they seek professional help? You guys something about loud environments, I think there's a concern about over amplification and a few other warnings you can read on this page. But I think the points that I wanna make here is, there's a lot of hoops you have to jump through and it's not, you know, it's not something that the FDA has taken lightly. I mean, I think that, like if someone who is sort of casually paying attention to this space might say, OTC hearing aids, it's just gonna allow anyone to sell any kind of junk to our patients. And the answer, I think the answer to that is no, it's like, hey, look, you have to do your homework, you have to get some clinical data, usability data, you have to do all kinds of more rigorous development.

And hopefully that standard will keep some of the junk out of the market. So, that's a self fit hearing aid. In the fullness of time a self fit hearing aid might be the same thing as an OTC hearing aid, that's what I was saying at the beginning, all this stuff is in flux.

We don't really know what the OTC regulation is gonna look like, but hey, pay attention. We'll find out, hopefully, you know, and then your future. I'm gonna skip this ones. That basically their conclusion is the benefits outweigh the risks for the Bose hearing aid, whether or not that's true for others will be determined by what they do. Okay, so, you know, again, zooming back out the new regulations we have these over-the-counter hearing aids in theory, but the FDA hasn't actually defined what they're going to be.

Hopefully they'll define that soon. There's the self fitting hearing aid which is much more defined. You have to jump through all these hoops and then you could be, you know, if the FDA thinks you've successfully jumped through them you can be a self-fitting hearing aid. And of course the categories that existed before for traditional hearing aids haven't changed. And then one thing I think is worth pointing out is, yeah, there still is this like PSAP category. And, you know, one example that I would point to is we're starting to see consumer products happened to have a hearing assistance feature. I think the most notable of them is our friends over at Apple. Sorry, I see the question, did Bose actually receive FDA approval?

The answer is yes. Yeah, one thing that's really also sort of confusing with all this is like FDA approval versus FDA registered. In fact, if you ever watch John Oliver on HBO he's got a great episode on this. Basically FDA registered means nothing, it just means you send some paperwork to the FDA and they filed it away. FDA approval, that's a really hard thing to get. And so you might consider, if you're going to recommend something to your patients using the FDA approval as a bar, 'cause it's not an easy one to overcome. FDA registered means nothing. And there's a lot of people who have used that. Okay, so back to this PSAP thing, so yeah, AirPods pro have a feature called headphone accommodations and basically you can use your AirPods pro like a PSAP.

And what does it do? Wide dynamic range, compression, feedback, canceling, steady state noise reduction, that sort of stuff. And they get, you know, from, well, you can

measure it yourself but I think there's some folks who have published that you can get about 20 DB of gain there, but they, as far as I'm aware, have not done anything with the FDA. So they're playing in that murky space where, you know, it's a hearing aid but they're not calling it a hearing aid even though you can also import an audiogram which is sort of surprising. But I think that we will see a whole lot more of that. Just looking at, you know, where our friends have been hired.

You know, I think a lot of consumer electronics companies are going to put hearing assistance as a feature in some of their earbuds. And I will just say, you know, I'll offer my opinion that, you know, I think the hope is to just get more people into the market and potentially, you know, one thing that I've seen happen is some of these sorts of things can sort of turn on a light bulb in people's head and they can say, hey, did you, you know, I didn't know what I was missing. Right, I hear the birds chirping, I hear the crunch of the vegetables, that kind of stuff. And because of that, hey, maybe now I'm gonna go get a real hearing aid 'cause, you know, there's a pretty significant drawback to using an AirPod, for instance, as a hearing aid, it's big and battery life is not great that including all that sort of stuff.

All right. That's all I have to say about regulations. Hopefully it was thrilling to you all. Moving on block two, how does the user actually fit in OTC hearing aid? I mean, I think you're all used to fitting software where there are a ridiculous amount of parameters and of course a user can actually adjust all those parameters. So if we simplify the interface, what would that actually look like? And I'm gonna sort of reduce the question here, sorry, I got some redundant slides. At least the way I like to think about this problem these days is what you're really trying to do is balance coverage with simplicity. So of course you want the simplest interface possible.

Typically our users are not tech savvy, but that's in direct conflict with coverage. And what I mean by coverage is saying, hey, can this thing actually deliver prescriptive gain targets that are appropriate for as wide of a population as possible. So the shorthand

for coverage is like how much, what percentage of the hearing loss population could you reasonably fit with with a particular interface? So I'm gonna talk about some published research in that space and I'm gonna start by talking about how do you even approach this problem, right? It's a really challenging problem. And it turns out that our taxpayer dollars have actually helped us with this. And the CDC has this really awesome database that's free for anyone.

You guys can download it right now, we refer to as NHANES and I guess that means nutritional health and, sorry, National Health And Nutrition Examination Survey. And it's really an attempted to get health data from America. They do really try to randomly sample America, not just, you know, in terms of like an online survey but I believe they even have like trailers that go around and can do medical exams. And part of that medical exam is an audiogram. And what you'll see here is one of the, this is just a screenshot of their website. Again, you could just download this yourself and and play with it. And what you'll see is, hey, you've got air conduction thresholds for America, right?

And it's not like they did it for everyone in America but they tried to do a random sample of America. And in the database there's this quantity called a sample weight and basically you can use that to figure out to what extent is this particular individual representative of America. One limitation of it is that it's air conduction thresholds only. There is tymp data as well tympanometry data. So you can get some guests as to whether it's a conductive or sensory neural hearing loss but there are not bone conduction values. So you do have to be a little bit careful about how you pick and choose. There's also some survey data. It's a really cool database. It's wonderful that we have it.

But basically this database is the basis that typically researchers use when they try to answer questions about coverage, because it is maybe the best, it is definitely the best database out there that I'm aware of in terms of sort of a representative sample of

audiograms. So, well, this is interesting. Okay. There's a really good paper, came out this year from some of our friends over at the university of Iowa. And what they did is they took this enhanced database and they said, all right, we all know about like a preset based device or programmed device. If I had a device that can do three different presets or one preset or 10 presets, how much of the hearing loss population could I cover for real?

And so what they did is they first took a subset of that enhanced database, people with mild to moderate sensory neural hearing loss. And then they ran a cluster analysis on that set of audiograms or prescriptive targets, they actually did it both ways. And the clusters basically say, hey, you tell it how many clusters you want. I want there to be three clusters. And the algorithm spits out and saying, okay, if you're gonna have three clusters, here's the best way to cover the most population if you just have three presets. And what you could do then is repeat that analysis for any number of clusters you want. And if you do that, you get curves that look like this.

So let's spend just a little bit of time understanding this graph. This is right out of their paper. So first thing is if you just choose a single preset, oh, and I should make you make a distinction between tight fit and loose fit. So it's basically, can you hit nail on all two targets for an individual? If it's a tight fit that's for three input levels, 55, 65, 75 DB input, and for the loose fit they focused only on the 65 DB input cause maybe that's the most common input level. But so yeah, if you have one preset and you're trying to have a tight fit you could be in this sort of 20% range, or you could get up to 30% coverage with a single preset.

30% if you're willing to use the loose fit criteria. And as that, you know, as you increase the number of clusters, the coverage also increases surprise, surprise. So we might look at something like a three preset device because that feels to be like, maybe it's about the most that the user can handle three or four. And in that case, if you wanna use the tight criteria you're in the sort of 35 to 45% coverage range meaning you could

cover about 35 to 45% of the mild to moderate hearing loss population or if you're willing to use a loose fit, sorry, I got a weird message, if you're willing to use a loose fit then that goes up to about 60 or 70%. So, you know, and then there's this increasing function that sort of saturates, you know, in the, I don't know, 10 or you can interpret this curve how you want, but you know, with a few presets, it seems like you could cover, you know, roughly half of the the population of people with mild to moderate hearing loss.

Moving on. Ah, and then, you know, the thing that people always ask me is like, well, who can't you fit with something like that? And they did a really good job in this paper of pulling out some of the audiograms that couldn't actually be fit. And you know, this won't be a shocker to you guys but it's the rarer audiograms, right? You have your cookie bite up here, you have the reverse cookie bite, you have a rising loss, you have flat losses. The stranger losses are the ones that typically you can't fit when you're trying to build an interface based on population data, because those account for such a small portion of the population. I'm gonna move on.

So, you know, my self-serving question has been, well, you know, presets are one simple interface but there is another simple interface that might be able to cover a broader swath of the population. And that's giving people just a few simple controls where, you know, to them it feels like a volume control for instance, on this left wheel, but what's actually happening behind the scenes is that it's, you know, selecting between a whole bunch of presets that fall out of an analysis that's being applied to the enhanced database. So, you know, even though, so one important constraint on this is that it's monotonic, which just basically means that as you turn this wheel up, all the gains go up.

And I think that's important if we want users to actually understand it. It has to kind of feel like a volume control if you're stretching it and maybe they can also handle a tone control, but, you know, I think there's this open question of saying, all right, well, if you

give someone a wheel that's like this, does that actually increase coverage at all? And I get to give you guys a sneak preview of some work that I'm doing. Hopefully we're going to submit it to a journal very soon in collaboration with those folks at Iowa. But before we do that, I do wanna just talk a little bit about what's going on behind the scenes on this interface.

So, you know, when we made this interface we really wanted to sort of stand on the shoulders of giants here and use as much of the sort of best practices from audiology as we can, forgive me if you've seen this before. But the basic idea is that this world volume wheel is our approximation of fitting to wide dynamic range like basically prescriptive targets, gain targets. And the other wheel is just about fine tuning. The sort of comments you get from users, you know, it's too tanny, it's too hollow. We're trying to sort of capture some of that, whatever we can with this other wheel. So I'm gonna show a really awesome animation here about what's actually going on behind the scenes.

So before I actually show the animation I just wanna orient you to the axes. Hopefully this is a very familiar graph to you guys. We've got frequency on the x-axis and real ear insertion gain on the Y axis. And if you look there's a little number of insight into the curve. So, you know, for a quiet 50 DB input, you get the top curve and for allowed ADB input, you get up the bottom curve. And as the user is turning this world volume wheel, forgive me, something kind of happens like this, when they're increasing the world volume you get curves like that and when you're decreasing the world volume you get, you know, curves that are smaller.

So one thing that you'll see is, let me see if I can come back to that. So, you know, as you increase the gain you're also increasing compression. So you can see out here like the curves are further apart. So that means there's more compression. There's also more high-frequency emphasis. And again, this is just something that falls out of the end of HANES database if you apply something like a principal components analysis to

a big population of audiograms. And then with this fine tuning, it's basically just a spectral tilt. There's nothing magic to it. It just, it seems like from a number of analysis that we've done, that a simple spectral tilt could account for a decent share of people's typical complaints during fine tuning.

So what happens as you move that wheel is, you know, you take this whole family of curves and you just tilt them basically around a kilo Hertz. And that's what's going on in the Bose interface. And the question that I had for the folks at Iowa was do we cover anything more than just a few presets because it wasn't necessarily a given that we would, and the answer is yes. So don't take this graph too seriously because it's, you know, hasn't gone through peer review yet. But what I would say is that we are, you know, where if you use a tight fit criteria, if you have three presets you can fit about 50%, four presets you could fit, you know, just under 60%, but with the Bose method, you could fit over 80% of the mild to moderate hearing loss population using the tight fit criteria and more than 90% using the loose fit criteria.

There's a slight twist on this to say, you know, when they compute their clusters they're sort of computing their clusters and then also testing on the exact same database. And we didn't do that if we actually did develop through the principal component analysis on the exact same database as those folks in Iowa did, we would get even more coverage in the 90% range using the tight fit criteria. So it does seem, you know, I know of course, you know, I have my own biases here, but it does seem like if you use something that has more of a continuous controller you can actually cover a broader swath of the population than if you just had three presets.

And in fact, if we go back, so if we look at like 82% and we compare that to that curve, sorry, forgive me, from these folks, you know, you need, you know, at least I don't know what 11 presets or so just to have the same amount of coverage and to me 11 presets is way too much to have a user just cycle through on their own. I'll say, you know, there's lots of solutions to this. You know, we are biased of course, to the

continuous controllers but there's certainly people who have tried, you know, AB comparisons that are adaptive trying to do in C2 audiograms and prescribing based on that. For the sake of simplicity I'm just not talking about those in this presentation.

All right. Okay, so how does a user fit an OTC hearing aid? You know, there's lots of answers to that, again, I'm just for the purposes of this talk, focusing on presets and simple continuous controllers, monotonic controllers you might even say. Alright, and then the last block of this talk, I'm asking about how do we know if this fits any good, right? I mean, just because you have precepts doesn't mean the user is actually gonna choose the right one. And just because you have simple UI controls, you know, it doesn't mean the user is actually going to choose something that's reasonable for them. And so I'm gonna talk about some of the research in that space.

So again, I'm just gonna focus on presets and simple UI controls. I'm not saying those are the only solutions, there's plenty of other solutions out there but I think those are the two that in my opinion have had the most, you know, the hardcore research behind them. And the first one I'll talk about is I'm just gonna talk about presets and this is work that came from Larry Humes back in 2017, I would say maybe controversial work, but he had tried to do a randomized clinical trial of various delivery models for hearing aids. So in one case, so he had AB was one group and CD was the other group. So AB is audiologist best practices, this is what you guys do every day.

And then CD is consumer decides and it's basically a preset kind of approach. And one thing that came out of this, sorry, a bit of a busy figure, but the score here is the P-H-A-P which is the longer version of the APHAB but it's a measure, it's a survey, a questionnaire of hearing aid benefit. And so the, I guess they're not showing a benefit score, sorry. This is a case where the, as the bar is taller the user has more hearing complaints. And what you can see is in the audiologist benefit, sorry, audiologists best practices group. There is a, you know, reduction in problems. So the red curve is lower, the red bar is lower than the black bar.

The, sorry, there's a question about the MPO of the Bose hearing aid. I think that's in the De Novo and I don't know what off the top of my head. The thing that's interesting here is that the consumer decides group also has some benefit. The red bar is lower than the black bar. So the difference between these two, you know, you might say, hey, they got more benefit in the audiologist best practices group, true, but there's also a significant amount of benefit in the consumer decides group and there's basically no benefit in the placebo group. And it's very interesting to think that there was a placebo group in this experiment. So these are people who are actually sent out with a hearing aid that was basically turned off, a bummer to be in that group but you could see that, you know, there is actually better than a placebo.

So I think the conclusion of this paper is yeah, you know, presets kind of work for some people, in this case not as good as audiologists best practices but certainly better than placebo. Then one of the things I wanna talk about in this space and this is something I just kinda squeezed into the presentations, but it, I think it's an interesting point and Larry's been making this point more publicly lately in a few, actually at the AAS conference was one time where he said this. But sort of this idea of using audiograms as a metric for who's going to actually benefit from hearing aids leaves a lot of people behind that don't necessarily need to be left behind.

And so I'm just gonna grab one figure from that paper, but I encourage you to read it, it's a really thoughtful paper. And of course Larry has trained tons and tons of audiologists. He's, you know, just trying to take an honest look at it. But, okay, in this case, we're looking at another questionnaire. This is called the Hearing Handicap Index for the Elderly HHIE, again, up is I have more problems but now he's broken it down by the audiogram. And he's specifically uses the WHO benefit, or the WHO classification for audiograms. And if we just look at the audiologist best practices group, if we look at the top bars, now we can look at benefit which is the bar on the right of this cluster.

And you'll see that the benefit score really doesn't change whether your audiogram is normal, mild, or moderate. And so he's really been making the point of saying like, hey, these are people who actually have normal audiograms they still get just as much benefit as these folks with mild to moderate loss. And that's also true when the consumer decides to group down here, but, you know, for simplicity you could just look at the top panel. And, you know, he said provocative things like who are we to, you know, deprive this person of a hearing aid, because these people really do could actually benefit from hearing aids. So, you know, the hearing aid benefit it seems at least from these papers, isn't really well predicted by the audiogram.

And I think that, you know, anecdotally I've certainly heard other audiologists tell me that, you know, it's really hard to predict who's gonna be successful with the hearing aid and sometimes, you know, give it to people with a normal audiogram and they'll actually have some benefit. I don't know why, but that does seem to be the case. In fact, in general, I like the idea, one thing that I like about direct to consumer hearing aid is that it does kinda let the user decide, you know, does this actually help me? If so, I'll use it, if not, I won't. And, you know, we don't necessarily need to rely, in terms of fitting on the prescription derived from the audiogram.

It's more about, does it work for you? Moving on, all right. So now back to some shameless self promotion, again, forgive me for this but we actually published a paper and this was some of the work that we submitted to the FDA, at least some of the same data. And it just talks about what's the actual clinical trial that we did to see if there is a benefit of, you know, these self fit hearing devices. Yeah, and I'll just, maybe before I get into it, just say that it's really easy to have an idea that you think is good and it's really hard to actually prove that it's good or test whether it's good. And I've had plenty of ideas that I thought were brilliant that when I actually put them in front of customers, just really fell apart.

And so I'll just say that as you are considering recommending an OTC device to your users or to your patients really take a good hard look at the clinical evidence behind it. I think that's really an important role of audiologists in this new market as the sort of arbiters who read these papers and say, hey, I buy this method or I don't buy this method. And ideally, everyone who actually submits a product into this category will publish their articles and you can decide for yourself. All right, so what did we do? This one I'm not going to go into a little bit more detail largely because I just know a lot about it. It was a two group design.

There was a group that we called it, the clinical group, and it's basically audiologists best practices. We did give everyone these Bose hearphones which are sort of similar to a hearing aid in the sense that, you know, there's microphones, wide dynamic range compression, all the sort of algorithms that you would typically associate with the hearing aid. So the clinical group ideally we tried to match these two groups but they're not identical, but they're identical enough. They tend to have mild to moderate hearing loss. They were almost all new users that just sort of naturally happened from the way we were recruiting. And they were typically a little bit younger than hearing aid customers. I think the average age of first purchase of hearing aid is like 71.

Someone can correct me if I'm wrong on that one. So they're a little younger, a little bit more mild hearing loss and new users. But we had two groups, but every group actually started with the exact same treatment. So we tried to give everyone the sort of gold standard audiologist treatment where at Northwestern, they came in, they got their audiograms measured, they had now NL2 prescriptive targets program for them. They were verified with real ear fits in the clinic. Then they went home for on average about five days and came back and did a fine tuning session where they raise their complaints and a licensed excellent audiologist at Northwestern tried to address those complaints. So at the end of the fine tuning session these folks had what I would consider to be like a gold standard fit of the hearing aid.

And I should say the audiologist had an interface that was fairly similar to a hearing aid fitting interface where they can control gain and compression in 12 channels, same with limiter, that sort of stuff. But then these two groups different where the clinical group just use the audiologist fit for the next 30 days and the self fit group, we basically, you know, threw away this fit and said, hey, here's some wheels go figure it out on your own. And in fact, those wheels were starting at zero DB real air insertion gain. And then they actually wore the hearing aid in their lives for 30 days on average. And our instructions to them were adjust those wheels as much as you can.

And every time you adjust those wheels hit this star button in the middle of the screen and the star button will give you a little survey and I'll talk about the results of the survey. And one thing that I think is sort of nice about this design is that like something like an APHAB you know, really relies on the user's long-term memory. You know, how did that thing sound across the whole last month of activity is a very different question than how does it sound right now in this particular moment. And we really did try to capture what was going on in that moment. I should say also the clinical group did have an app as well but it was a much more D featured app, you, roughly trying to approximate what a big five hearing aid would do primarily a volume control and the ability to switch through a few different programs.

Okay, so that's the setup, what actually happens in the real world, well, the thing that I would assume that most of you care about is, you know, what gain did these people actually choose? So again, every time they made some sort of an adjustment and this is your machine interface, this is the one that proceeded the Bose hear interface but behind the scenes it's basically the same thing. So yeah, they said, you know, movies, wheels and when you're done hit that star button, and when you hit that star button we record the gain settings that you had selected. And then for each individual we took the average gain that they selected. We got to boil it down to a number to do some of these analysis and so we just did the four frequency average gain that the user selected for a 60 DB input tone.

And one thing what you can do is just compare to what did they choose in comparison to what the audiologist chose for them. And so what I'm about to show is an audiogram of that data, if in terms of this gain metric the users chose the same thing as the audiologist, they would be in the zero DB bucket. If they chose more gain than the audiologist they'd be in the positive and if they chose less gain, they'd be in the negative. And here's what the data looked like. So one thing that's kinda cool is the thing that jumps off the chart to me is the biggest bar is a zero. So on average, roughly speaking users tend to choose gain that's very similar to what the audiologist chose for them.

And then the other thing that I like to point out is that the next tallest bar is lower gain than what the users chose than what the audiologist chose for them. And I'll say that, you know, having paid attention to sort of user-driven self fit for a while, people used to raise the concern quite often of like, oh, aren't people just gonna over amplify for themselves and cause more hearing loss and wouldn't that be a problem? And I think that, you know, what the data tend to show is that if anything people choose they under amplify, if you accept that premise, on average users tend to choose a little bit less gain than what the audiologist chose for them.

So that's the gain, but we can look at other things. For instance, one thing we can look at is sound quality. So how happy are you? So after they hit that star button, they had to rate their sound quality on a scale of zero to five stars. And the clinical group tended to be, this was the distribution of the data in the clinical group. So on average, they were, most people were about three and a half stars out of five. And if you look at the OTC group they were actually slightly higher. So, and it is statistically significantly different, not a huge effect, I'm not gonna like hang my hat on it but there's certainly no reduction to sound quality in the OTC condition.

And there's some evidence that it's actually improved sound quality when you give people the ability to choose the settings that sound good for them. And, you know, one sort of hypothesis I've had going as I've done some of this work is that, you know, people know what they want and our job is to sort of help them get there. And I think the greatest audiologists do a great job of that. And hopefully the greatest interfaces do that as well. I was able to see a question coming in but I'm just gonna close to the end so I'll come back to it. One of the things that we did on sound quality is we had people do a blind AB comparison.

So, you know, they fiddled with the wheels, they find the settings that sound good to them and then while they're doing the previous, goodness, while they were doing the other questions, the hearing aid was muted. And then the hearing aid turns on and you hear two different settings the user can switch back and forth, A and B, and it's randomly determined which is which, one of them is a setting that the audiologist chose for them, for the user. You know, there was what they had just chosen with the wheels, and then they indicate their preference, which one do they actually like more by moving the slider. So in this case, the user has a slight preference for B and, you know, again B is randomly determined which is which.

So I'll show you the results here, again, to orient you, if the users had no preference at all they'd be in the middle of this graph. If they greatly prefer the clinical fit will be on the left and if they greatly preferred what they chose for themselves, they'll be on the right. And this is what the data looked like. So again, there's a slight tendency to prefer the settings that they chose for themselves over what was chosen for them by the clinician. So, at least on the sound quality side, it does seem like if you give people, at least our controls, they do tend to improve their sound quality. Now, does that come at the cost of audibility?

Maybe, I will say, I don't have the results here but we did do a QuickSIN for both groups and there was no difference, but I will admit that QuickSIN is not a great tool to

detect the benefit of amplification. Last thing I'll talk about is we did also do APHAB even though it's not my favorite, you know, it relies too much on memory, but we did have both groups. We computed an APHAB benefit score, here's what the clinical data looked like, these are the gray bars. And so, you know, I should say these people tended to have mild like pretty mild losses. So the benefits scores in general are fairly low and there's really no difference whatsoever between the clinical and the OTC group.

So there was no reduction to benefit but there's no indication that there's any more benefit in any of the two conditions. Okay, so with that, I'll just let you know. So those are the three big blocks. Hopefully we covered a lot of ground. Hopefully you're able to follow it but we talked about the regulatory landscape. It's sort of weird and changing right now. The only direct to consumer hearing aid that's FDA approved is the Bose one but that's gonna change once the OTC regs are announced and hopefully that'll be very soon. A user can fit an OTC hearing aid by using presets or simple controls but you know, not everyone. And you know, the more presets the more people you, in theory could fit or if you do something clever with controls, hopefully you can fit even more.

And how do we know if that fits any good? Well, you know, there's lots of different ways you can measure it. You know, you can look at the gain, you can look at sound quality, you can look at typical measures of benefit. You know, I think that the research seems to say, hey, it's certainly, I think it's very easy to defend and say it's better than nothing. And then, you know, in some cases you might say that at least for the right population, it's, you know, they can have similar outcomes as they get through the audiology channel. Okay, with that, I do wanna just ask that same poll question one more time, just for my own curiosity.

So Anna, if you're still hanging on there, can we ask that OTC question again? I'm just curious if I've made you all more interested in OTC devices or less interested in OTC

devices or no change at all. So if you guys can launch that poll, that would be great. So hopefully there are responses trickling in here.

- And Dr. Sabin, maybe while she's getting that and while people are responding, you know, how do we manage the MPO dilemma and making sure people aren't getting it too loud. Is that gonna be incumbent upon the device developers to make sure that there is output limiting or what's your thoughts on that?

- Yeah. I'm thinking. So, you know, in the, well, let me answer the question then we can see the results. In the, oh, hey, it went up a little bit, alright. 75% from I think it was like 66%. All right. In the both De Novo approval it just says you have to specify the MPO, it doesn't say what the MPO should be. I think it's possible that the OTC regs would specify an MPO. I don't particularly have a strong opinion on that. I mean, one thing that I think about, at least a fair bit is that there's some pretty good symmetry data actually from the folks in Iowa but also from others looking at what kinds of SPLs people actually experienced, hearing aid users actually experience.

And they spend the vast majority of their time in quiet environments. And so the, and of course these devices are compressive as well. So as you get into those loud environments you're applying less and less gain. So I think it's pretty rare that you're actually hitting your MPO, but yeah, of course, you'd want to have some sort of an MPO in place to make sure you don't deliver damaging sounds. But I'll say, we'll see what the FDA decide, right? I'm certain that's something that they're considering.

- Are you ready for a couple more questions that came in?

- Yeah. Okay, I see another one. Do you think the first fit and fine tuning experience in the self fit group would have influenced what they selected on their own? Maybe, you know, that's certainly a criticism that I've heard of this work in the past, and I'll just talk about the sort of design decision about why we chose that. And that is, we thought

that those comparisons in the field were really important. Again, I don't love questionnaires. And so if we wanted that comparison to happen in the real world, that AB comparison we needed that gold standard fit to compare it to. And the only way that I know of to get to that gold standard fit is to do that first fit and fine tuning.

And so we needed to do that so that we can do that comparison. Now, someone could criticize the experiment, and folks have and saying, well, they only chose good settings because they knew what good sounded like because the audiologist chose good for them. Hey, this is a really active area of science. I hope that there could be some followup studies to try to sort of counterbalance that. But yeah, we haven't done that. And, you know, I think that's a totally, it's a smart question and we'll see if somebody answers it.

- Another question that came in, you know, what sources are out there for clinics to obtain OTC devices to be able to sell in their clinic? Can you speak to that just a little bit?

- Yeah, this is another one, you know, I'm just weird who does research it both, I'm not necessarily too involved in the sales but I do know that at least so right now we're actually not selling earphones. We sold out, but, you know, we have expressed an interest to sell future devices and we've worked with distributors the typical hearing aid distributors in the past. And we are certainly have, we would love it if our products were sold through audiologists through the typical channels. There is not that I'm aware of a, you know, any sort of formal organization there. I think it's just sort of a case by case basis as new manufacturers get into the space and they're gonna have to make their own deals with manufacturers or with the buying groups as well.

- What about bone conduction in OTC? Are you seeing any developments in that area or, you know, certainly we've seen some bone conduction headphones out there, but in the OTC landscape do you see that being an Avenue? I think that the regulation specifies air conduction, you can look at the regs yourself. That's a tough one to get into. I think, you know, bone anchored hearing aids certainly you know, that's an operation. You can't do that in your home. And typically if you're not going to bone anchor aid you just can't get that much gain out of it because you really need to have really good coupling to the head. So that doesn't feel like an area where I expect to see a lot of work.

Yeah, maybe I'll just leave that there. Hopefully that answers your question.

- Let's see. A couple of the other comments, you know, most earbuds do have some kind of limiter device in them now, you know, doesn't seem like that will be a much different in the OTC or self-fitting device as we've talked about that MPO thing before, you know, I would imagine that those would continue to be true in the OTC space as well.

- Yeah. The EU actually has a nice standard for output limits of consumer electronics headphones. And gosh, I wish I had that number at the tip of my tongue but it's something like 115 DB free field equivalent. It's actually more stringent than the typical regulations on hearing aids. And so to the extent that the company actually abides by the EU limits, they will also abide by a typical hearing aid limit. Yeah, I mean, you should expect that every device that you would ever give it to a customer is gonna have a limiter in it. The specific value of the limiter, maybe as a design decision by a developer but also could just be something that comes out of the regulations.

And certainly something that as you know, the FDA as we have that 180 day period of being able to comment to the FDA, you know, certainly something that audiologist if we feel passionately about MPO limiting, you know, we should push for that, that's

something that they have to report on their clinicals but on their spec sheet. And so, you know, I think as we're all going through this process and looking at what things would be important to us on OTC devices, you know, what are the things that you wanna know about a specific product, like their output limiting, like their use of cell fitting strategy, like their recognition to the national database? You know, those are all things that hopefully are going to be already included in the FDA period.

- Absolutely, and that's, I totally echo that. Like that is the time to chime in those 180 days like they do actually pay attention to what people write. So, you know, get out your word documents. Hey, one last thing I know we're over time, but there's just one other fun graphs that I wanted to show that I think about sometimes and our friends over at hearing health and technology matters have been serving audiologists about their opinions towards OTC hearing aids. And I think that a lot of us remember 2017, a lot of anxiety about OTC and you can see from the yellow bars here that most people thought OTC hearing aids would hurt their clinic, but I'm very pleased to see that in 2020 most people actually think that OTC hearing aids would have no effect on their clinic.

I actually would love it if more people thought they would help their clinic, right? But my goal here is just to make the pie bigger. I just want there to be more people getting amplification. I don't want to take away, like I have extreme respect for audiologists and I wouldn't not wanna hurt the clinics. So hopefully as things are shaking out, some of the anxiety about OTC hearing aids is decreasing.

- Well, Dr. Sabin, thank you so much for giving us very good overview today of, you know, just the process that companies have to go to in order to get to that FDA clearance point of view but also just greater knowledge, you know, knowledge is power and I think the more that we learn and understand on the ever-growing changes in this space the better off all audiology will be for it. So thank you so much, Dr. Sabin, thank

you for everybody that participated today. I know a bunch more questions came through that we didn't have time to get to, but that's the the nature of this and maybe that means we need to do another course on OTC and self fit hearing devices in the near future.

Thanks so much everyone and we look forward to seeing you again on audiology online. Thanks Dr. Sabin.

- Okay, thanks everyone. Stay healthy.