The OTC of OTC: Opportunities, Threats, and Challenges Associated with Over-the-Counter Hearing Devices

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- Okay, we'll go ahead and get started. Welcome to my course, The OTC of OTC, which stands for the Opportunities, Threats, and Challenges Associated with Over-The-Counter Hearing Devices. My name is Brian Taylor, and for the next about hour, we're gonna be reviewing several facets of these new, this new category of hearing aids called OTC. Before I dive into the material, just a couple of housekeeping items. My course is gonna go probably just under an hour. There aren't any CEUs attached. Hopefully, you'll find the information helpful, even though it doesn't have any CEUs attached to it. A couple other things, we'll take questions at the end, so be sure to ask the questions and save those, and I'll try to address them at the end.

And if you want to download the handouts, there's an article, a copy of the slides, and also the FDA OTC guidelines in the chat box. I'll go ahead and get started. Thanks for attending, either live or on the recorded version of this. I'm the Senior Director of Audiology at Signia, also the Editor of Audiology Practices, which is the quarterly journal of the Academy of Doctors of Audiology, Editor-at-Large for the Hearing Healthcare Technology Matters blog, and an Adjunct Professor at the University of Wisconsin. Really, the title of this course could be OTC Devices are here, now what do I do? You see there on the right, that's a pair of OTC devices that I have in my desk that arrived in the mail a few weeks ago.

And we're gonna talk about maybe how you would implement those kinds of devices into your practice. The primary objective of this material today is to kind of give you a general lay of the land. I want to, whenever possible, use published peer reviewed research to illustrate a point to talk about the emergence of OTC devices, how they differ from personal sound amplification products, and traditional what we now call prescription hearing aids, and how all of these devices could fit into a thriving clinical practice. And I've really divided the course up into two parts. The first part is really about the ins and outs of this new category of devices, and the second part is really

related to how these devices might impact both people in your community and your practice.

I like to show this slide at the beginning of the presentation because it uses you hear the term disruption a lot around OTC, I think it's an overused term, and OTCs in a lot of ways are a disruption that are a decade or more in the making. Here, you see a timeline around some of the key landmarks related to the emergence of the OTC category. We go all the way back to 2009 where there was a working group of researchers across different professions that basically rose the red flag and said, "Hey, there's an access and affordability issue around hearing care, and we need to do something about it." That led to some other scientific groups, some congressional initiatives, the OTC Act being signed in 2017, and then finally, several years later, this year, 2022, the final eight rules were issued by the FDA and it went into effect in October.

So, here we are. These are the five questions that I wanna try to address today, and I hear these questions a fair amount. I am lucky enough to speak at many state and regional kinds of meetings, I've been to several places over the last couple of months and I've heard all of these questions in some form several times. What do OTC, why do OTC devices exist as a category? What are OTC devices and how do they differ from other types of amplifiers? How do OTCs differ from prescription hearing aids? What are the opportunities, threats, and challenges associated with OTC devices? And how might you integrate those devices into your practice? So, I'll try to address each one of those questions over the next several minutes.

Let's look at question number one. Why do OTC devices exist as a category? And as I've already mentioned, access and affordability are the key drivers behind this, but let's look at it in a little more, let's look at this question a little more deeply. I think that OTCs device, this category has come into existence largely because we have quite a lot of research that tells us that untreated hearing loss is not a benign condition, that

somebody who's older that might have a mild-to-moderate hearing loss in addition to having difficulty with communication, that untreated hearing loss is linked to a lot of other chronic conditions that can be quite restrictive and sometimes harmful. We know the research tells us that untreated hearing loss is linked to cognitive decline, depression, loneliness, social isolation, the risk of falling.

And the schematic I show you on this slide on the right looks at some data that was published in The Lancet a few years ago, looking at the different modifiable and unmodifiable conditions that are linked to dementia, looking at it through the course of a person's lifespan from early life through middle age and later in life. And as hopefully all of you know, untreated hearing loss is the largest modifiable risk factor. And I think intuitively we know that if we can identify and treat something early, other more harmful conditions are less likely to occur. And so, that Lancet data that you see there, illustrated on the right-hand side of my slide, I think tells a really important story about hearing loss as a modifiable risk factor for people in the middle age category.

Another reason why OTC I think exists is we know and the data varies from study to study, it depends a little bit on how you define hearing loss, but traditional hearing aids, I think we can all agree are undervalued and underused. About 25 or so million Americans with some degree of hearing loss could benefit from hearing aids and they don't own them. And I think that's a big problem for the reasons I mentioned in the previous slide. We know, I think, or we can say with a fair degree of accuracy, again, opinions may vary depending on how you design the study or interpret the results, but I think it's fair to say that about four in five people who could benefit from amplification don't seek help from it, and that can be a problem.

Another factor about why we have OTC is if you look at why people maybe don't flock to their local hearing care provider to at least look into hearing aids, there are a number of reasons, and you see those listed here. This is data that comes from the MarkeTrak

2020 survey that was published a couple of years ago in seminars and hearing. And you can see there's sort of a long tail here, meaning there are a lot of maybe smaller reasons why people don't go to see one of us for hearing aids. But the ones I wanna point out here on the left-hand side of the graph, people say that they hear well enough to get by.

Maybe they've developed some coping strategies and they're able to, maybe they think it's kind of normal for their age and they're fine with that. And the other reason, of course, is driven by cost. But you see here, there are a lot of maybe smaller reasons that kind of add up to keep that uptake rate relatively low. As you look through this data, the other thing I would encourage you to think about are what are some of these reasons for a low uptake of traditional hearing aids that could be maybe addressed with a device that's self-fitting, that's able to be purchased online without any direct involvement from a hearing care professional? And I'm thinking that there are some of these reasons that could be addressed with an OTC delivery system.

So, that's question number one, why we have OTC? Largely driven by access and affordability, and also driven by the fact that we know that untreated hearing loss in middle-aged and older adults is not a benign condition. Let's look at questions two and three, we'll kind of combine these together. What are OTC hearing aids and how do they differ from other types of amplifiers? And how do OTCs differ from this kind of new term, prescription hearing aids? Let's look at the landscape from the 1970s. You could probably go into even before that even, I'm just gonna use the 1970s to the current day, 2022. And you can think of any kind of amplifier that might go in, around, or near your ear as falling into these two different siloed categories.

We'll call one on the left, medical grade hearing aids, and the silo on the right, non-custom amplifiers, things that maybe you could buy through the mail, personal sound amplification products, and ALDs. Let's look at up until this year, what type of

amplifiers would fit into each one of these categories? We know medical grade hearing aids, what we've been dispensing in our clinics for decades have been regulated by the FDA as a medical device since 1973, meaning that when a manufacturer brings one of these devices to market, there's some regulations that they have to abide around the manufacturing process, quality control, advertising, labeling. We know that they require the involvement of a licensed professional in the buying process.

And, of course, that licensing is done or overseen by the state rather than the federal government. I use the term medical grade because we really didn't have a term for it, they were just hearing aids. And also since at least the 1970s, we've had this maybe broader term called direct-to-consumer devices. I think of Lloyds as sort of the number one player in this market, been around for many, many decades, based out of Rockford, Illinois. We're always sending hearing aids in the mail.

Now that, of course, they've been doing that online for a long time. And in the same category, I think you see over the last 15 years, the emergence of companies like Hearing Planet, Hear.com, Eargo, Lively, some of them having this hybrid business model where they combine in-person and remote care all kind of falling into this broader, more general direct-to-consumer category where maybe there's a licensed professional available over the phone or online to assist in the acquisition process. And also we have this other category that's been around for a number of years called PSAPs. To the consumer, they look in many cases exactly like hearing aids, but they're not a medical device. They are not regulated by the FDA, although the FDA back in 2013 issued what's called draft guidance, which tells us the intended user of these kinds of devices are people that have normal hearing that want sound in their specific listening situation to be accentuated.

And, you know, I think of the proverbial bird watcher as somebody who might be an intended user of a PSAP. But I think we all know that many people that buy PSAPs

have hearing loss and they're looking for a low-cost solution. So, PSAPs are essentially unregulated, and I don't think they're going away anytime soon. Maybe some over-the-counter hearing aids over the next few years were yesterday's PSAPs and will be tomorrow's OTCs if they can meet the FDA's new OTC regulatory requirements. But the point I wanna make now are PSAPs, which in many cases look exactly like hearing aids, quality is very uneven and they're not going away. And then, of course, an even broader category of unregulated amplifiers would be things like TV Ears, Pocket Talkers, amps apps that you can download on your smartphone that amplify and shape speech, maybe connect through your wireless earbuds, voice to text apps.

There's many of those on the market now that are quite good. Tunable earbuds, those are all kind of general categories that maybe sound is shaped and amplified that are unregulated, and nevertheless, patients may try and use and some may be effective. Which brings us to today, as I mentioned a minute or two ago, we had these two siloed categories, medical grade hearing aids and non-custom amplifiers. And I think what you see today is illustrated on this slide where you have on the left what we call prescription hearing aids. And I used that term deliberately because that's in the new FDA guidelines. And we still have these non-custom amplifiers, but in the middle we have this new emerging category called OTC.

And for those of you that want the details, I would have you look at the guidelines from the FDA, it's about a 60-page document that is in the chat notes here. But a couple of highlights that I think are important to mention about OTC. There you see the actual act that authorizes the FDA to establish this category and to ensure that they have standards that meet safety and effectiveness. And to remember that the intended user of these devices are adults aged 18 or older and people with perceived mild-to-moderate hearing loss. And as you all probably know, what somebody may perceive as a mild hearing loss in actuality could be quite significant. But nevertheless,

it's important to note that the intended user is somebody who perceives their hearing loss to be mild or moderate.

Some other terminology to know that's in the guidelines and just sort of generally out in the ether is when we talk about direct-to-consumer devices, which have again been around for a long time, think of that as more of a blanket term that describes how devices are purchased. And like I mentioned, companies like Lively, like Lloyds, Hearing Planet, those are all direct-to-consumer kinds of devices, Eargo. But now, we have this specific carefully defined category called over-the-counter devices. And as we'll talk about over the next few minutes, over-the-counter devices can be divided up into different subcategories. There are self-fit over-the-counter devices and there are other, what we will call non-self-fit OTC devices.

I'll show you some details of that in a moment. Another important piece of terminology that you all should know that's a big focus of the FDA guidelines around OTC is this term input controlled compression or simply input compression. And not all OTCs are required to have this, but many of them will have it. And it's really there as a safety mechanism to ensure that the maximum output never gets above a certain threshold. And remember, with any input controlled input compression circuit that that MPO or maximum output is tied to the volume control. In other words, the user can manually adjust the gain and the MPO with their manual switch or wheel or app. A few other technical details about OTC, we know that there are some output limits depending on the type of product, the type of OTC, it's the output limit is either 111 or 117 dB SPL.

And of course, that was a topic of a lot of debate over the last few years, but that's what the FDA settled on, what you see on this slide. We also know there are no gain limits, which in a lot of ways makes sense because we know that preferred gain settings of individuals has a lot of variability, and it's good to know that the product is going to provide enough gain for those that maybe need more than you might think.

And I think the problem with maybe a low gain setting was it would have a device that wouldn't be very effective for a lot of users. So, output really protects the person from harmful sounds, gain is there as something that people can kind of find their own preferred setting for inside these OTC devices.

A few other design requirements, the innermost component of the device must be at least 10 millimeters from the eardrum. And no assessment of the hearing loss is required, you don't have to have a hearing test before you buy the device. Even though the intended user clearly states adults 18 and over, there's no way to verify the age when you buy one of these devices over-the-counter. In other words, nobody's asking for your ID, so they trust that people will kind of follow what the labeling says. And then I think a really important point and something that I think is a positive is all of these devices, OTC hearing aids, must have an adjustable volume control either on the device itself or accessible through a smartphone app.

Just a few more details, I'm not gonna spend a lot of time on this. Some of my references in the notes get into a lot more details. But the labeling on the device, on the outside of the package lists the red flag medical conditions that would pre prevent you from using the device. And another important technical detail is the quality requirements, the manufacturing process, what they have to do to ensure that the device meets a certain quality threshold are pretty, I would say, stringent around distortion, latency. And that's a good thing, that means the quality control process meets some relatively high standards. You know, and that I think will keep some of the more maybe fly by night lower quality companies out of the OTC market.

I think the problem, of course, is many of those devices would be available as a PSAP, but at least if it's labeled as an OTC, we know that it's gonna meet some a fairly high bar with respect to the way it's manufactured. Now, this is a really, I think, useful slide. This was created by Vinaya Manchaiah and Cory Portnuff at the University of Colorado

Medical Center. They published this recently in an article they wrote for consumers, and it kind of shows you the landscape. You have the higher cost devices on the left, the lower cost devices on the right, and you notice you have three categories of FDA-regulated hearing devices. And their intended user, of course, are people with hearing loss.

Those are prescription hearing aids, self-fitting OTC, and pre-set OTC. I'll get into some of the details of the differences in a minute. And then on the right, you see some of these more nebulous kinds of fuzzy terms, consumer audio devices, hearables, and PSAPs. So, devices that maybe don't meet the quality FDA requirements around manufacturing and labeling can still come to market as a PSAP or a hearable. When I think of hearables, I think of things like the AirPods Pro, certain versions of that have a amplifier built into it, or I think of consumer earbuds that might have an amplification feature that has some, maybe some customizability. The point is, is there's still a very broad landscape around devices that amplify sound.

We do have clarity around what OTC are, and how they should be labeled, and who the intended user is, but we still have some of these other essentially unregulated categories that people might buy. So, I think the key point here is although their consumer labeling is alike, as we'll talk about next, not all OTC devices function the same way, meaning there are self-fit OTC and there are non-self-fit OTC. This is some data that David Akbari, who is one of the, I think, real experts on OTC devices, he's an audiologist that is with Intricon who shared with me a few weeks back. And so, I wanna make sure he gets credit as the source here.

But it shows you on the far left, you have the self-fitting OTC. And then remember all of these device or some of these devices have input controlled compression, therefore they can have a higher peak output of 117. But there are other linear OTC devices that don't have input controlled compression that would be required to have an output

that's lower at 111. But here, you see sort of a breakdown. Linear OTC, meaning they don't have input compression and customizable OTC, meaning that the user can do some shaping of the frequency response or the gain, and those devices have input controlled compression. Now, those are some of the important differences. Regardless of what category the OTC would go into, all of them require a user adjusted volume control.

I think that really in your clinic, it's important to kind of differentiate what's gonna be a self-fitting OTC, one that where a person could really fit the entire thing using the audiogram versus what's a customizable or linear OTC that doesn't fall into that category. And maybe the self-fitting OTCs, maybe they are going to be sold at a higher price point. I think those are some things we don't know yet. So, the point I wanted to make is that not all OTCs are self-fitting. And there's some very specific categories around OTC that you need to know. A couple other key points I think that are worth repeating due to the FDA regulations, the quality and reliability of OTC devices I think is comparable to prescription hearing aids.

Now, it may not have all of the features in it, but it has the output, the gain, the latency, the distortion. I think all of those key functions are comparable to what we've been fitting in our clinics for a long time. And I think the good thing about that is it provides confidence that these devices are safe and effective. One last thing, I think that it's really important to know about OTCs as a broad category, and that is there are three different self-fitting approaches that we're seeing in these devices that you have to know. Now, I'm talking about self-fitting approaches, it doesn't necessarily mean that these devices are labeled as a self-fitting hearing aid, but I wanna share with you three different self-fitting approaches, which are how the person would fit, adjust, or fine tune the devices.

So, the first self-fitting approach, I'm gonna call it the audiogram-based because with this type of an approach, and I have a couple of examples listed here on the slide, you have to do a hearing test of some type before you wear the hearing aid. Now, it's doesn't have to be a traditional pure-tone audiogram, but it's some version of a hearing test that's done to determine sort of what the gain and the frequency response has to be as a starting point. The second type of self-fitting approach is what I'm gonna call pre-set programs. For those of you that are old enough to remember the matrix approach, where you would ask the manufacturer to send you a hearing aid with a certain output gain and slope, you can think of, I'm showing you a piece app that's been on the market for a number of years here called the Clik EZ, that essentially has five different matrices built into it.

You should see the different colors there on the audiogram, and the patient can toggle between those five matrices to determine which one might sound the best. That's an example of a pre-set program or as far as a self-fit approach. I'm showing you one example here. There's actually been some research done on how many pre-sets are effective, how many pre-set programs would you need inside the OTC to fit, you know, a reasonable number of mild-to-moderate hearing losses. A study done at the University of Iowa published last year says that four pre-set gain programs provide enough gain to meet the needs or match the target of 68% of people with mild-to-moderate hearing loss.

So, that's a fairly high number of those, of people that are in that mild-to-moderate category. Another thing to note is in the FDA guidelines for a hearing aid, to qualify as and labeled as a self-fitting OTC, it has to have more than three pre-sets to qualify. So, you could have a device with two or three pre-sets, it would be an OTC hearing aid, but it wouldn't be a self, it wouldn't be labeled as a self-fitting OTC hearing aid. So, I know that gets a little confusing, but the number to remember is more than three pre-sets and it qualifies as a self-fitting device. And that doesn't mean it has, it can be labeled

that way necessarily, they have to qualify and they have to be, the FDA give them an approval, but you need to start with at least more than three pre-sets with using this approach if you wanna be labeled as a self-fitting device.

And then finally, we have the direct adjustment method. This was pioneered, at least one approach was pioneered by the folks at Bose several years back, that interface, the Bose direct adjustment approach, which does not require any kind of a hearing test, is in found in some versions of the Lexie OTC device that's on the market. This is probably the most interesting and the most novel of the three self-fit approaches because it doesn't require any kind of hearing testing. And this 2020 study that was published in Trends in Hearing from some individuals at Bose and Northwestern showed that for this method, it yielded patient outcomes that were comparable and quite similar to people that were fit in a clinic using traditional best practice methods.

So, there's some data to show that this approach has some effectiveness, right? Again, for the right patient or the right candidate. So, that's kind of part one, and some of the key points that I wanna summarize before we move into part two, and that is there are, I think, three different types of OTC devices, and not all of them are self-fitting. But regardless of what specific type it is, I think we can have confidence that these devices are safe and at least somewhat effective, you know, for mild and moderate and high frequency moderate hearing losses. It's important to remember that PSAPs, which are a highly uneven category of uneven quality, they still exist and that quality is still uneven.

And there are numerous studies that suggest that tech-savvy consumers can get in the ballpark of an audiology-based fitting much of the time. And if you want the details of those studies, they're in the end of my presentation, I have a whole page of references. And probably the best source that summarizes all of those different types of self-fit and consumer decides approaches is the Almufarrij paper that was published earlier this

year that did a really nice review and a competitive comparative analysis. So, if there's one paper you wanted to read that kind of that summarizes all these different direct-to-consumer and self-fit approaches, it's the paper that you see listed here as a bullet point.

Okay, so that winds up part one, let's now move in to part two. And in part two, I really want to, I want this to be more of like a practice management, more of a strategy session around the people that you serve and with what you do in your practice. And I think the best way to think about this section is to think about your geographic footprint of your business. And I just sort of randomly picked a city in the middle of America, Wichita, Kansas as an example. So, if I have a practice that's in Downtown Wichita, I might think that there are about 400,000 people that are within my geographic footprint that are within driving distance of my practice, that I am there to serve with professional hearing care services.

And so, my challenge to you is to think about your community, your geographic footprint, who might be within an hour's drive of your practice, or if you live in a metro area, maybe a 30-minute train ride or whatever it might be. Those are all of the potential people that you're going to serve and that might value what you offer and your practice. And so, with that, through that lens, I want us to address question number four, which is what are the opportunities, threats, and challenges associated with over-the-counter devices? And to do this, it helps to know what a SWOT analysis is. This is done commonly with business consultants. If you work with a buying group or maybe a practice management specialist and a manufacturer offers you, they might do a SWOT analysis of your practice, strengths, weaknesses, opportunities, and threats.

And it's a great approach to develop a more systematic strategic plan. I'm gonna change it little bit and call it a SCOT analysis, strength, challenges, opportunities, and

threats. And with this approach, it will kind of maybe uncover what we want, how we might wanna offer OTC in our practices. Let's first start with some challenges. The first challenge that comes to mind if you're in a practice and you're thinking about offering OTC is what's the probability that if somebody buys one of these products that maybe I provide on my website or in my practice, what is the possibility that I've missed a possibly very serious condition that requires a medical referral? I think that's a legitimate concern all of us should have.

And to address that question, I wanna point to some data that Dave Zapala, who's a audiologist at Mayo Clinic in Jacksonville, presented at an one of the meetings at the time called the IOM, National Academy Science Engineering Medicine now, and used to be called the Institute of Medicine back in 2014, that looks at the prevalence of ear diseases in adults aged 50 and older. And you can see here, the prevalence of some really serious ear conditions that would require and necessitate a referral to an otolaryngologist. And I think the concern here is that if somebody buys something OTC, it's a possibility that these conditions could be missed. Also in red, you see just the sheer high prevalence of age-related hearing loss, it's over half versus some of these other conditions that are quite, I don't, I know what the term is rare, but don't occur very often.

So, I think knowing this, even though some of these conditions are unlikely, I think it's really important that if anybody comes into your office, and this is my opinion based on this data, that if somebody was coming into your office, this is a reason why you'd wanna do comprehensive audiometry before offering them any device that they might wanna put in their ear. That kind of speaks to the value and the importance of good comprehensive audiometry for identifying these conditions. So, that's a challenge I think that we have to think about in our practice and then really the importance of doing tests the right way to find cytolesion. Let's look at some other additional challenges that I see with OTC being in the market.

I think OTC buyers that are in need of service, maybe they bought it somewhere else, maybe on Amazon or some other website or in Best Buy, that they might be even though they might have a really whoever is offering the OTC might have a real systematic customer service phone line, some of these patients still might find their way in your door and some of them, enough of them could take away from other revenue-generating opportunities in your practice. Along those same lines, I think that given that there are many PSAPs still in the market, hearables, more and more OTCs, I think it's really challenging for a single practice to know the ins and outs, the technical specifications, the fitting processes of so many of these that would take away time and resources in your practice.

You know, if you had a lot of people coming in with many different types of devices. So, those are some of the additional challenges that I see. And then also kind of determining what type of OCT it might be, is it a PSAP, is it a hearable? I think all of those things can really drag on on a busy practice. Probably the biggest challenge though with OTCs, and there's some data to back this up, is lack of service delivery. There was a poster presented last year at the AAS meeting, the lead author was a student by the name of Auriemma, I think, at the University of Iowa. The poster is actually in the notes at the end, they found that lack of service delivery was the most significant barrier to consumer satisfaction.

That a high number of people that were trying OTC devices in this study were frustrated and kind of turned off because there was a lack of education and a lack of personal assistance. So, it's sort of I have this OTC and I'm kind of stuck with it, what do I do next? And that really, again, no surprise to any of us in this field, knowing that service is such an integral part of it. But if you buy OTC, you know, you might be stuck with the device. And I think as we'll talk about in the opportunity sections, there's huge opportunities to offer personalized service for people that may have bought something

elsewhere. What are some ways to address these challenges besides practicing at a high level, following best practice protocols?

I think using assistants, so block scheduling, remote care, making sure you have really well vetted up-to-date educational information on your website, offering a fee-for-service menu for people that might come in. And maybe something that flies under the radar, I think it's really important that in your practice that you have a clear definition of a quality amplifier. When you put something in someone's ear and you're evaluating it, what's your definition of quality? Smooth broadband response, low distortion, and being able to evaluate that and talk about it with your patients. So, this slide kind of talks about how you address the challenges associated with OTC. What are some things that you can do to make it less or more efficient and less of a potential drag on time and resources in your practice if people are coming in with these devices and they're needing some type of service.

So, I think of those as more challenges, now let's look at some threats. Threats to the margin of your practice, threats to the cannibalization of business, and how you can address those threats. So, the first one is, "Because of their lack of full customizability and the lack of follow-up service, outcomes from OTC devices will be inferior." This is a quote I'm saying, I'm not saying this is true, I'm saying this is a quote that kind of paraphrasing what I hear out in the field, "And negative word of mouth about outcomes create barriers for other people seeking help." Or maybe a slightly different variation of that that I hear in the field is, "People who try OTC devices and fail will give up and stop looking for help, and this delays necessary treatment even longer."

I would argue that even though there's a limited amount of data, I think it suggests otherwise that there are a group of people, according to the way I interpret one study about a third of people that have tried, I'll call them OTC-like devices, needed no assistance from a professional and they were achieving what I would call good enough

outcomes. They had not have been the best, but they were able to do it themselves and they were happy with it and that was fine. And I also think that the Larry Humes studies suggest that a lot of people that try to self-fit, when they know that there's an audiologist or a hearing care person available for assistance, they may seek that person out and take advantage of the personalized service.

I know that he found that about half of the people who decided to return their customer decides devices when they were offered a trial with an audiologist, many of them took up that opportunity and that led to successful outcomes. So, the fact that people might have a bad experience with OTC, I don't think there's really any data to support that that happens in a huge way. Maybe there's some outliers of course, but systematically, if people know that there's an audiologist or a hearing care professional available and they're offered assistance to them, that many of them will take them up on it. And that's certainly, I think a positive for all of us. Perhaps a bigger threat is this one.

Again, here's a quote or a paraphrase of some of what I hear out in the field, "Because of their low price point and the ease in which they can be purchased, OTC devices will cannibalize my existing business, cannibalize the number of patients I see, cannibalize my margins." And I think that let's kind of look at that question more systematically. And again, let's look at it through the lens of our SWOT or what I call SCOT analysis, strength, challenges, opportunities, and threats. And let's talk about how we can turn any potential threat into an opportunity. And so, let's move into some of these threats that I just mentioned and how we might be able to turn them into opportunities.

And opportunities I think are, that's why we have the smiley face. So, again, I want you to imagine your geographic footprint, all the people within an hour's commute of your practice, how many people that you serve, because maybe more people than you think could potentially value your services if you think more broadly about what you offer. So, one way to think about these opportunities is through this little chart that I think many

of you have seen. This looks at the number of device users as a function of degree of hearing loss. And this slide's been around for 10 or 20 years in various forms, it's accurate information, but I'm gonna argue that it's myopic or at least it's a little bit shortsighted because it's only looking at people in your community that have a hearing loss.

We know, for example, that about 10% of people out there that have a hearing loss are in the severe/profound category, and 70% of them are hearing aid or cochlear implant users. We know about 30% of all the people out there in your community with hearing loss have a moderate loss, and about half of them are device wears. And we know about 60% of people in the hearing loss community have a mild condition, and 90% of them are not wearing hearing aids. And, of course, the argument here is all those 90% of people don't value the services of an audiologist, they think hearing aids are too expensive. And that's not wrong, but that thinking is a little bit myopic as I'll talk about over the next couple of slides.

And I wanna share with you, I think some really powerful information that was actually something I read from Brent Edwards, who's the Director at the NAL in Australia, very well respected, renowned hearing aid expert that heads up NAL And he talks about, and I think this is a much broader, more accurate view of the people that you serve in your community, and that is just imagine all of the adults in your community, they fit into two overlapping categories, many of them do at least, they have self-reported hearing difficulty, meaning they struggle with communication, maybe they avoid situations because they don't hear very well or they have a lot of challenges in background noise, and others or maybe some of the same people, these are overlapping categories, have a hearing loss as measured objectively on the pure-tone audiogram.

And you take those two broad overlapping categories and you cross them together like I did right here, and now you have four distinctly different patient populations. And I think this is a great way to think about what different segments of the market might value from your clinic. And also kind of helps you understand where OTC might fill a potential gap. So, you see here we have self-reported hearing difficulty, that could be measured on something like the Hearing Handicap Inventory. And we have measured hearing loss, which, of course, is measured on the pure-tone audiogram. Now, when you cross those two categories together, you get this four quadrant matrix and five different segments of people in your community.

Let's look at each one separately and then we'll talk about the ones that might be, that what segment might value OTC in your practice. So, if you look at category A, and I'm gonna get my little handy telestrator out here so I can draw, we're over here at category A. Those are people that have normal hearing on the audiogram and no self-reported hearing difficulty. And because of those two things, many of them probably don't know that your practice exists. And, of course, most people in your community probably fall into category A, younger, middle-aged adults, healthy don't know or don't need or value your services. So, most people we would say fall into category A.

Let's move to to category B, those are people that have an hearing loss on the audiogram, but they express no hearing difficulty. And maybe they're in denial, maybe they're unaware, maybe they're just developed coping strategies. And we know from several reports that around 8-10% of the adult population in the US would fall into category B. Let's move to category C down here, those are people that have no hearing loss on the audiogram or maybe a hearing loss that's better than a 25 dB pure-tone average, but they report hearing difficulty. So, they have self-reported difficulty mainly in noisy social situations. We know from a couple of different reports that about 12-15% of the adult population falls into category C.

Category C, we might call them people with hidden hearing loss, subclinical hearing loss. Those are some of the terms that you hear in category C. And then, we have two different subcategories down here in the bottom-right, those are all individuals that have a measured hearing loss on the audiogram. We would look at their audiogram and say, "You're a hearing aid candidate," and they also have self-reported hearing difficulty. And those are people that typically know that you exist and they have come to your office seeking help. And you can see subcategory D are people that are hearing aid owners, people that you've actually seen. And then people in subcategory E are people that maybe came into your office and for whatever reason decided not to do anything.

Also notice the percentages. We think that about 3% of the population, hearing aid owners, 2% non-hearing aid owners. What's interesting here is think about again, your geographic footprint, how many people might value your services that are within an hour commute. And take those percentages and you get a rough idea of who might be out there that would need services from you or value services from you, which brings me to the next slide. Now, that's the terms you see here for each one of the four or five categories are terms that I made up. I think of category A, those are people with normal hearing, no self-reported difficulty, the majority of people in your community. You could turn them into preventive care apostles, people that really need to be educated about the ins and outs of protecting their hearing, periodic hearing tests.

Category B, people that might be in denial, people that have developed coping strategies that are unaware that their problem is maybe as bad as it really is, I would call them fence sitters. Category C, I would call those people with subclinical hidden hearing loss maybe people that have a 500 or $1,000 problem and we offer them traditionally a 4 or $5,000 solution. And because of that, I would call them technology overshoots. We're offering them more than they really need in situational places where they have hearing difficulties. And then down in categories D and E, we have the

familiars, people that are already working with you that probably are really happy and satisfied with their hearing aids and the services that you provide.

And then the rejectors, people that for whatever reason have decided not to pursue amplification from the clinician. Now, the lesson here I think is all of these categories or a couple of these categories might benefit from OTC. Let's take fence sitters, these are people that maybe if given the opportunity to try something from the comforts of home without having to take the risk of going out and having to talk about their condition, allowed to dabble with something kind of quietly behind the scenes, they may find that that is beneficial. And of course, they may also find that it's not meeting their needs and they come down here and they see one of you. Let's take technology overshoots, people that are likely to have situational difficulties.

I would argue these are patients that may be rather than OTC devices, they might be more amenable to maybe a multitasking device that allows them to stream music and listen to podcasts and then turn it into a hearing aid when they get into a challenging situation. So, maybe some type of a high quality multitasking tunable earbud like the AirPods, maybe some type of an OTC device down the road would fall into that category. But I would argue people in C and B might want different kinds of offerings relative to each other. And then finally, we have category E that for whatever reason rejected the audiologist or the hearing care professional being involved. And maybe OTC might be something that would be for them, assuming that they meet the criteria around hearing loss and other things.

Anyway, this is a nice way, I think, to think about what different segments of the hearing care market might value from you. And to realize that maybe OTC has a place in your practice, which is what we're gonna get into next. Now, I apologize, we're going a little long, over than I thought. I hope you hopefully you're finding the information to be helpful. So, I'm just gonna go ahead and dive right into our fifth and final question,

which is how you might integrate OTC into your practice and talk about three different types of, I think, patient opportunities that maybe didn't exist to the extent that they will now that OTC are available. And I'm gonna talk about the three different types of patients around them, and put them into categories around the questions they might have for you when they come to your practice.

So, the first patient category or the first question would be patients that come in and say, "What's best for me?" They're being seen for an in-person appointment and maybe they've done their homework and they know that OTC devices are out there and maybe they're thinking about buying one of them, but they know that you're the expert. Maybe they've been referred by a friend or a family member and they want to get an opinion from you. And I think this is an opportunity to offer a service package around the concept of help me help the patient decide. And maybe it's a one hour or a half an hour block of time where you do comprehensive audiometry, you maybe do QuickSIN testing, and you do one of these validated self-reports that systematically evaluate the patient's perception of their communication ability like the HHI questionnaire.

I also think it's an opportunity to sit down with these patients and to do some sort of a cost-benefit analysis. You know, assuming that they know or they've come to you knowing that they're or they're thinking about buying OTC, maybe you show them, "Here's what an OTC pair costs, you get no service, but you can do this, but you'd pay as you go with us with for the service," versus and you pick the price point, I arbitrarily pick $2,000 for a pair of entry-level prescription hearing aids where maybe you get a limited number of service visits, which involve in-person follow-up care and you show and you kind of do a cost-benefit analysis with the patient.

This one costs twice as much, but maybe you get twice or three times as much service. So, I think that's a handy kind of an approach for people that might come in wanting you to help them decide and haven't worn anything. Let's talk about the

second patient question that might come in. These are patients that might come in already have purchased OTC or maybe more likely someone has purchased them, purchased for them as a gift and now they wanna know if it's right for me and maybe they've really struggled and they wanna know what their other options might be. If this is the patient, I think it's a slightly different service package where you're helping the patient make the most of the device that they already have.

And maybe it's a one hour block of time where, again, I think it's really important for us to not forget our role as disease detection specialists around comprehensive audiometry, speech and noise testing, one of those validated questionnaires. And because they already have a device, the possibility exists that you might wanna do some goal setting, some counseling around orientation, and certainly real ear measures to see how that device might be working in the ear, demonstrate noise reduction features, maybe even compare it to a prescription device that you have on your shelf to show the patient what some of the differences are in the ear. I think it's also a possibility that there might be a way to maybe offer some type of a rebate if it's a person that maybe bought a device off from your practice or maybe off of a website that you're affiliated with.

I also think given all of the service concerns in that Auriemma poster that I mentioned briefly a while back, patients that come in already having purchased an OTC set of devices, you can think of it as an opportunity to create an on-ramp to best practice care. That's a term that David Akbari uses, you know, when you think of all the cosmetic concerns, lack of perceived benefit, the service concerns that I've already mentioned, now's the time to maybe create an on-ramp so people see the value of the extra expense associated with in-person best practice care. That brings me to the third and final patient that I think you're likely to see in the OTC world, and that is people that come in with the question, "How do I get the most from this device now and in the future?"

And these might be patients that are maybe perfectly happy with the good enough benefit, but they're interested in some type of preventive care and maintenance. They may realize that devices, it helps to get them cleaned professionally, maybe have their ears looked at, maybe have a professional test done every once in a while. And it's an opportunity again to create an on-ramp to best practice care, where you're helping the person even though you didn't dispense these devices and you might know that there are some shortcomings around benefit, but the patient is happy with them, satisfied with them, that you're gonna help them keep them in their ears at least over the next year or two by offering them some type of a service contract that involves an annual hearing test, maybe a cleaning of the devices, cleaning, and maybe it's an opportunity to offer some type of a trade-in program.

So, for X amount of dollars, they can trade their OTC devices in for a pair of prescription devices that have some professional service associated with them. Which kind of brings me to the conclusion here, and remember our SWOT or what I call our SCOT analysis where it's really important to focus on our strengths as a profession. And and I love this quote from Mike Valente. The source of this quote is in one of the videos in my references, and the quote is this, "We carry OTC and we do it better than anyone." I think that's a mantra that all of us in the clinic should have. We should embrace OTC as just another tool in our toolbox.

And if we think about our strengths as a profession, hopefully these are strengths in your own practice. It's the strengths of things that we can do that really can't be duplicated in the OTC device world, and that is our ability to help a patient make an educated, informed decision by focusing on education, by focusing on increasing or boosting a customer's hearing health literacy by providing really well designed high quality educational materials both in our practices and on our website so that all of our patients can make a better informed decision about treatment, about intervention. And

then along those same lines, I think another important strength is our ability to implement and execute best practice standards, including the use of patient-centered communication because we know, and there's data to support this, that the use of best practice care yields the highest outcomes for those that desire that.

And if you don't know about it already, I would go to the Audiology Practice Standards organization website and you can read the practice standards that that group has developed around adult hearing aid intervention and follow those standards. So, as we wrap up here, some things to think about, you've heard me mention Dr. Akbari a few times. Here are some quotes from a really excellent article he wrote in the consumer layman's press a few months back where he talks about how we're kind of embarking on the golden age of hearing healthcare, where people have a lot of choices and innovation and interventions available to them that he believes we're going to see over the next few years, more innovation and consumer choice than has been available to previous 50 years.

And that allowing consumers to choose the product that's right for them and to take ownership of their health condition will not only improve health literacy, but it will reduce health disparities and outcome around Americans of all stripes. I think that's excellent advice and words of wisdom from him. And again, a reason why it's important to practice at a high level and to focus on education and best practice standards. And so, when we think about our geographic footprint, it's really, I think, important to think about how we can promote early intervention and preventive care to the entire community and to think about how your practice can be known for service and support, education and prevention, comprehension, comprehensive and patient-centered care.

And that OTC is just one of many tools that are available to you to achieve this. That doesn't happen on its own, it takes a deliberate effort to focus on turning a challenge

and a threat into an opportunity and a strength inside of your practice. And again, that doesn't happen just by hoping it, it happens by having a deliberate strategy that focuses on creating those strengths that I talked about. And I'll leave you with one final point. And if it was my practice and I worked with a group or a team, I would focus on conducting my own SCOT analysis and I would have a plan, how are you gonna position these OTC devices compared to prescription devices?

How are you gonna talk about them with your patients? What kind of fee-for-service packages are you gonna provide? How much are you gonna charge? And what OTC devices might you carry either in your office or on a website? And what's the profile of a patient that you might recommend those to? Because we're kind of limited in time here, some of the written, there's one little short article that you might wanna look at that gets into what devices you might wanna recommend and what's the profile of a patient that might benefit from that. Here are all the references and the further readings. I encourage you to take a look at these. You wanna check my work?

I even included some old, some PSAP studies. Remember, yesterday's PSAP might be tomorrow's OTC, so it's good to know about some of those. Here are some videos. You can click on the links in the PDF and it'll take you right to the videos, some of them in AudiologyOnline. Here are some of the more recently published OTC articles. Some of them in the trade press, some of them in the layman's press. There's a poster there that you can click on and read really good information about barriers to care. And with that, I wanna thank you for watching. If anybody wants more insight on conducting a SWOT analysis in their own practice, I'm happy to facilitate that process. You can contact me at that email, and I wanna thank all of you for watching and we'll take any questions that you might have.