Implications of an Over-The-Counter Approach to Hearing Healthcare: A Consumer Study

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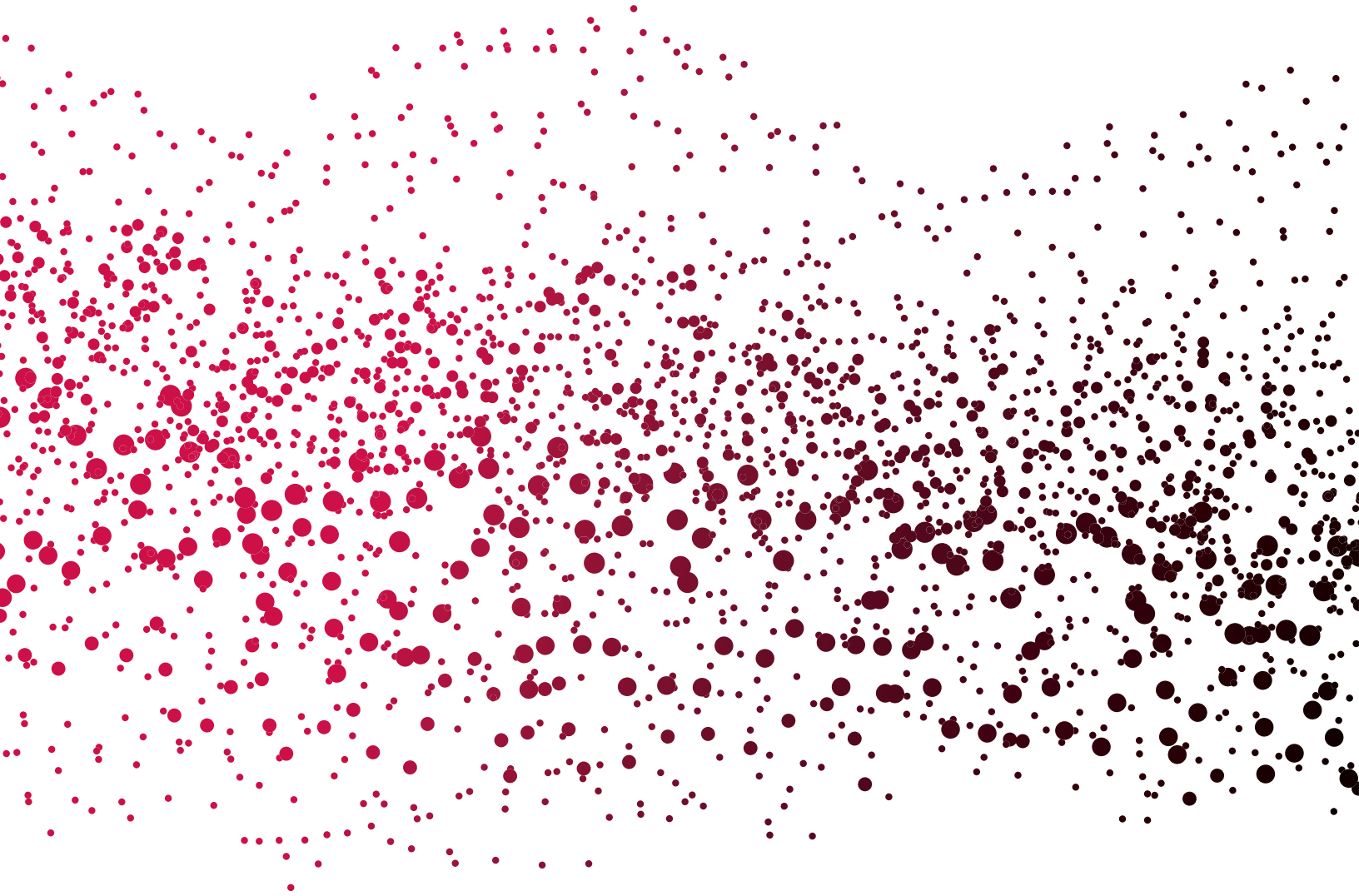

Implications of an Over-the-Counter Approach to Hearing Healthcare: A Consumer Study

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Preliminary results from a pilot study comparing OTC devices to hearing aids

By Thomas J. Tedeschi, AuD, and Janette Kihm, MS

> *This pilot study indicates that individuals supported by a hearing care professional experienced significantly better participant outcomes across all metrics, including daily usage of the hearing solution; how well each solution met expectations; overall satisfaction rates; the incidence of individuals who stopped using the hearing solutions before the end of the trial period due to dissatisfaction (ie, "instruments in the drawer"); and willingness to recommend, a strong indicator of patient outcome and also of perceived success.*

In the last couple of years, there have been many discussions surrounding solutions to improve access and affordability for hearing aids and hearing healthcare. Several of these discussions have focused on the technology-side of hearing instruments, and they have included proposals that the FDA create a separate category of "basic hearing aids"[1] or "wearable hearing devices"[2] approved for over-the-counter (OTC) sales to adults with mild-to-moderate hearing loss.

Over-the-counter (OTC) products are defined as products that are safe and effective for use by the general public without seeking treatment by a health professional.[3] By definition, this "classification" assumes that consumers can self-diagnose, self-treat, and self-manage without professional guidance.[4] Proposals to introduce an OTC category of hearing aids make the assumptions that individuals can appropriately:

- Self-diagnose the presence of a mild or moderate and a bilateral or unilateral hearing loss (without undergoing any type of hearing evaluation);
- Self-identify the need for any type of medical evaluation if they self-detect any red flag condition (as defined by the current FDA rules[5] and practice standards), and
- Self-select and self-manage an effective treatment option or product for their impairment.

To the authors' knowledge, little or no evidence-based research exists or has been referenced to support these assumptions. Similarly, few studies or published data evaluate the OTC experience (with no professional involvement) from the consumers' perspective.

Given the absence of supporting data and the significance of these proposals, we launched a pilot consumer study with the objective of generating evidence-based data to inform and support the public discussions on how to reduce barriers and improve access to hearing health care. This study was designed to provide insights about four key questions related to the above assumptions:

1. Can individuals properly self-diagnose and classify their level of hearing loss, and they identify red flag conditions that would require medical attention?
2. How well can individuals self-select a hearing instrument without professional guidance? How easily and successfully can individuals properly use and maintain hearing instruments without professional support?

3. How easy, effective, and satisfactory is an “over-the-counter” approach for an average consumer to address their hearing care?
4. How does an “over-the-counter” experience compare to the traditional process, which involves a hearing care professional providing guidance?

It is important to note that this study was designed as a pilot study that can be refined and replicated in other markets to provide additional evidence and to allow for deeper analyses in the future. Here we present the overall design and the preliminary insights gained from this pilot.

Study Design

This pilot study was complex and required carefully planned, designed, and managed steps across multiple phases. At a high level, participants were given opportunities to participate in two distinct phases. Each phase had a duration of 6 weeks and was set-up as follows:

- **Phase 1 (OTC Process).** Qualified participants were invited to self-treat their perceived hearing loss by selecting and using a Personal Sound Amplification Product (PSAP) or ready-to-wear hearing aid without professional guidance or support, and evaluate their experience at two points in the process.
- **Phase 2 (Hearing Care Professional Process).** The same participants were given a hearing evaluation which was followed by counseling, fitting of the hearing aid, instructional information, and aftercare services. All these steps were provided by a licensed hearing care professional. As in Phase 1, they were also asked to evaluate their experience at two points in the process.

Participants were not informed of the Phase 2 opportunity until after they had completed the final evaluation for Phase 1, so as not to introduce any anticipatory bias.

Online surveys were used to collect data at 3-weeks and 6-weeks within each phase. The online process was chosen because it offers the researcher control of the order and presentation of questions, and can help to manage, minimize, and remove the effects of various forms of bias.

Brand/Model	Price	Type	Volume Control	Bluetooth	Battery Type	Feedback Cancellation	Noise Reduction	Battery Life	Max. Output	Peak Frequency
MEDCA	$11.99	BTE	Yes	No	1.5v mimi Alk. (not rechargeable)	No	No	Unknown	125dB	1.00 kHz
NewEAR	$24.73	ITE	Yes	No	#10 zinc air (not rechargeable)	No	No	Unknown	115 dB	1.5 kHz
Stealth	$29.39	BTE	Yes	No	Lithium rechargeable	No	No	10 hours	132 dB	0.34 kHz
ZDB-100M	$39.99	BTE	Yes	No	Nicek-hydrogen rechargeable	No	No	12-16 hours	127 dB	1.33 kHz
ClearHear	$49.99	BTE	Yes	No	niMH rechargeable	No	No	45 hours	125 dB	1.10 kHz
Britzgo BHA220	$59.50	BTE	Yes	No	#675 zinc air (not rechargeable)	No	Yes	Unknown	126 dB	1.70 kHz
Tweak Basic	$144.99	BTE	Yes	No	#312 battery	Yes	Yes	7-10 days	117 dB	0.8 kHz
EaReader	$195.00	BTE	Yes	No	#13 zinc air (not rechargeable)	No	No	Unknown	124 dB	0.75 kHz
Tweak Mini	$249.00	BTE	Yes	No	#312 battery	Yes	Yes	7-10 days	117 dB	0.8 kHz
Etymotic BEAN	$299.99	ITE	Yes	No	#10 zinc air (not rechargeable)	No	No	10-12 days	98dB	2.66 kHz
CS50+ Sound World	$349.00	BTE	Yes	Yes	Lithium-ion rechargeable	Yes	Yes	18 hours	114 dB	5.60 kHz
SoundHawk (T)	$399.99	BTE	Yes	Yes	Lithium-ion rechargeable	No	Yes	9 hours	106 dB	4.0 kHz
GH Simply Soft	$400.00	ITE	Yes	No	#10 zinc air (not rechargeable)	Yes	Unknown	145 hours	108 dB	2.70 kHz
GH Simply Slim Smart	$479.00	ITE	Yes	No	#10 zinc air (not rechargeable)	Yes	Unknown	145 hours	104 dB	2.70 kHz
GH Simplicity	$499.00	BTE	Yes	No	#10 zinc air (not rechargeable)	Yes	Unknown	141 hours	105 dB	2.50 kHz

Table 1. List of Personal Sound Amplification Products (PSAPs) and ready-to-wear hearing aids and features included in product profiles shown to the participants. Products in red (exceeding 120 dB maximum output) were listed as choices for study participants, but were not available for use during the trial period due to safety concerns (if these were selected, participants received their second (safer) choice).

Products. Since the “OTC market” does not exist for hearing aids today, this environment had to be “simulated” to allow consumers to choose and safely try these products. In order to do that, we selected 12 PSAPs and 3 ready-to-wear FDA-approved hearing aids **(Table 1)**. The products ranged in price from less than $100 to approximately $450 per device. To prevent any harm to the hearing of the participants, we excluded any products with a maximum output of 120 dB or higher from the trial portion of Phase 1 (and we will refer to these products as “prohibited” here). However, 6 of the 15 devices the participants were shown as potential choices up-front did exceed the 120 dB maximum. This was done to understand how consumers evaluate choices and what they would likely choose if this range of options were available to them. (More about the order and presentation of information shown to the participants is described below.)

Sampling, screening, and recruitment. When describing it to the participants, this study was intentionally framed fairly broadly during the screening and recruitment process; it was introduced as being about senior health and wellness, and no emphasis was placed on hearing loss or hearing instruments upfront. This kept the objective of the study blind to the respondents at this stage in the process. The study specifically targeted adults aged 60 years or older residing in the greater Minneapolis and Saint Paul, Minnesota metropolitan area, and recruiting was conducted by working through an on-site research facility in the area.

A sample of 991 individuals met the age and location requirements within the research facility database. They were invited to participate in the initial online screening survey. These individuals were asked a series of questions about their characteristics, potential conditions, and current treatments and devices in use. This determined who met the basic criteria to participate in the study, which included:

- Self-reporting a mild or moderate hearing loss;
- Not using a hearing aid, a PSAP, or any other hearing instrument or device to compensate for their hearing loss;
- Not receiving a recent (last 2 years) hearing test.

From the initial sample, 130 individuals met the criteria above.

Also in this screening survey was a profile page for each product listed in **Table 1** designed to mimic what consumers might find when shopping for hearing solutions in an OTC environment. These profile pages included a photo of the product, the price, and some key technical features that could be used when deciding between options. The technical features included: style of the hearing instrument, battery type and life, maximum output, peak frequency, feedback cancellation, noise reduction, volume control, and Bluetooth capabilities (see Table 1 for a summary of this content). Participants who met the basic criteria above were asked to view the product profiles and indicate which product, if any, they would be likely to buy (if available in the market). If they selected a “prohibited” instrument (ie, output of ≥120 dB), they were asked if there was a second option they would try if their initial choice was out of stock. In this second pass, there were only options in the set that would be allowed for trial. At no point in this initial screening process were participants told that some products were “prohibited” and for what reason, nor were they told there would be an opportunity to try the product they selected.

Those who indicated they would be likely to buy a qualifying device, if available in the market, were then told about the opportunity to participate in a follow-up study to try and evaluate such a product. At this point they were given an opportunity to schedule an in-person session at the research facility, where they would be given a hearing test and the hearing instrument to take home and try for 6 weeks.

From the pre-screened sample, 30 individuals qualified and could participate in an on-site session during the allotted time window. We established the goal of completing on-site appointments with 30 individuals to keep the process manageable, but still have a sample size that yielded reasonably stable overall estimates and directional insights.

The on-site appointment included an in-person interview to gather some in-depth qualitative insights and a hearing evaluation conducted by a licensed hearing care professional. The two key goals of the hearing evaluation were to:

- Ensure that a red flag condition did not exist that would require medical attention or preclude the use of any hearing device (as per the current FDA provisions5), and
- Determine if the participant had a hearing loss, and establish the type and the degree of hearing loss.

During this process, we monitored all the interactions between hearing care professionals and participants to ensure that the professional would not provide any consultation or interpretation of the results, as well as not provide any expert opinions about the best solution or perceived efficacy of any hearing instrument or aid.

The hearing test results were shared with the participants only after the completion of the 6-week survey at the end of Phase 1. An exception was made for participants who had a red flag condition uncovered during this evaluation. These participants were told about the condition and immediately referred to a physician.

Of the 30 who participated in the in-person session, 4 individuals were referred to a physician for a red flag condition; 3 of them obtained medical clearance for inclusion in the study. Thus, 29 participants were cleared to participate in the study. These 29 participants were given the PSAP or the ready-to-wear hearing aid they chose online (so they would each try and evaluate the one they would likely buy in the real world). There was no assistance provided by a hearing care professional or a researcher. They also did not have a chance to change their choice once they knew they would be allowed to try a product.

The 29 participants covered a broad range of socio-demographics:

- **Gender.** The sample was fairly equally split between women (52%) and men (48%).
- **Age.** All participants were aged 60 or older, as per the screening criteria. 69% were between 60-69 years and 31% were 70 years of age or older.

- **Household income.** 31% of the participants estimated their annual household income at lower than $50,000; 28% at $50,000-$74,999; 17% at $75,000-$99,999; 21% at $100,000-$149,999, and 3% at higher than $150,000.

Results from Pilot Study

1) How well can individuals identify red flag conditions, and diagnose and classify their level of hearing loss?

As noted earlier, the 30 participants who took part in the in-person interview were evaluated for the presence of any red flag conditions, as required by FDA provisions.5 A total of 4 of these individuals (13%) were referred to a physician or an ENT for the following conditions:

- ***Participant 1.*** History of sudden or rapidly progressive hearing loss within the previous 90 days and unilateral hearing loss of sudden or recent onset within the previous 90 days;
- ***Participant 2.*** History of sudden or rapidly progressive hearing loss within the previous 90 days and presence of a PE tube in the contralateral ear;
- ***Participant 3.*** Unilateral hearing loss of sudden or recent onset within the previous 90 days;
- ***Participant 4.*** Outer ear infection in both ears.

The first three participants obtained medical clearance and were able to participate in the study.

		Self-Reported		TOTAL
		Mild	Moderate	
Hearing Test Results	No Loss (25 dB HL or less)	2	1	3
	Mild (26 – 40 dB HL)	2	0	2
	Moderate (41 – 60 dB HL)	8	5	13
	Severe (61 – 80 dB HL) *or* Profound (81 dB HL or higher)	3	8	11
TOTAL		15	14	29

Table 2. Comparison between self-reported perception of hearing loss and results of the hearing tests (n = 29).

As reported in **Table 2**, a significant number of participants were unable to precisely self-diagnose their type and degree of hearing loss. As per the study design, all 29 participants had reported having either a mild or a moderate hearing loss as defined by the World Health Organization's scale6; however, the results of the hearing test performed during the on-site interviews revealed that:

- 3 participants had no loss. Hearing evaluation results revealed thresholds to be less than 25 dB at octave frequencies, bilaterally;
- 11 participants had hearing loss that was more severe than what they self-reported;

- 15 participants had evaluation results which revealed a mild or moderate hearing loss (ie, correct identification within mild-to-moderate);
- Of the above 15 participants, 7 correctly identified if their hearing loss was mild or moderate.

Authors' Note: WHO defines slight or mild hearing loss as 26-40 dB HL; moderate hearing loss as 41-60 dB HL; severe hearing loss as 61-80 dB HL, and profound loss as ≥81 dB.[6]

		Self-Reported			TOTAL
		Unilateral Loss	Bilateral Loss	Not sure of type	
Hearing Test	No Loss	1	1	1	3
	Unilateral Loss	0	5	0	5
	Bilateral Loss	4	14	3	21
TOTAL		5	20	4	29

Table 3. Comparison between self-reported discrimination of unilateral vs. bilateral loss and results from the hearing test (n = 29).

Many individuals were also unable to correctly determine if their hearing loss was unilateral or bilateral. **Table 3** shows that most participants (20) reported their hearing loss to be bilateral; however, after their hearing evaluation, only 14 self-reported correctly. Four individuals were not sure if their hearing loss was unilateral or bilateral.

When examining these individuals' ability to self-report whether their loss was bilateral or unilateral and their ability to differentiate between a mild or moderate hearing loss versus other degrees of hearing loss, only 1 in 4 were able to correctly self-diagnose their hearing loss.

2) How well can individuals self-select a hearing device for their needs without the guidance of a professional, and how easily and/or successfully can they get started using it?

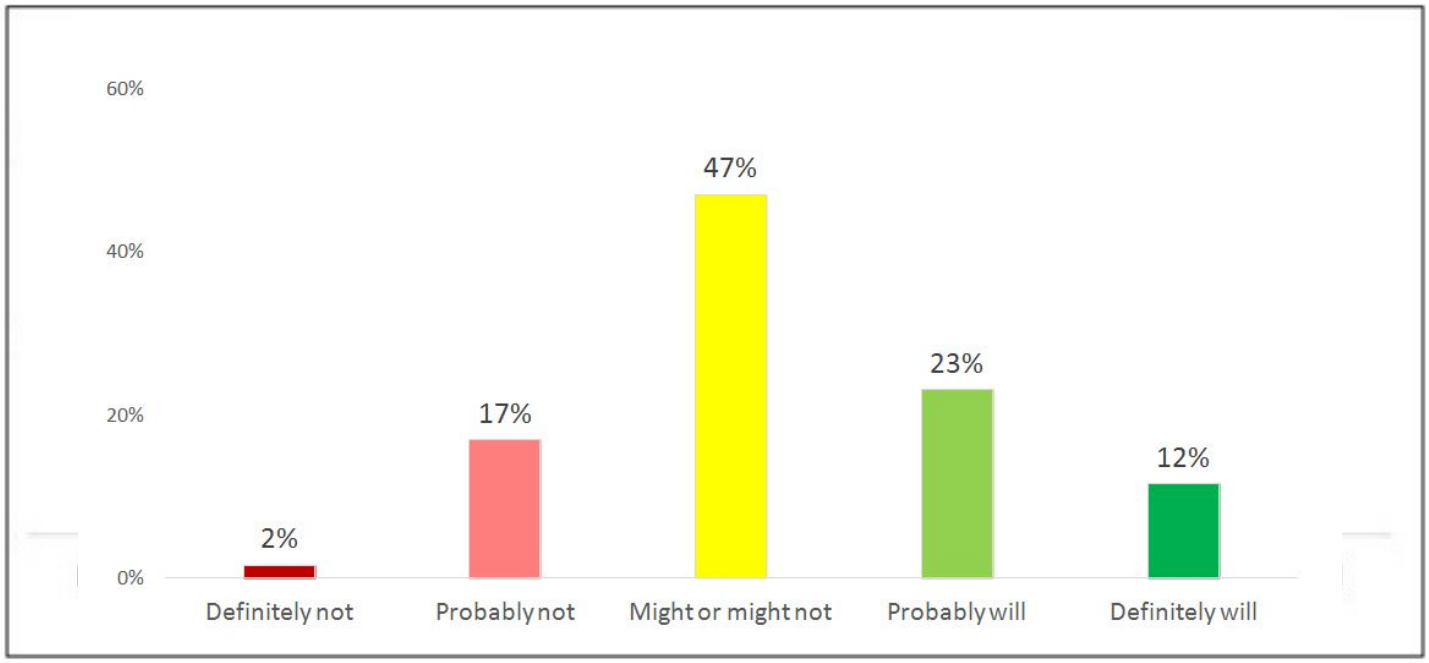

Figure 1. Top of mind likelihood to try a "hearing solution" in the next year (n = 130). Note: "Hearing solution" was not defined in the question.

As shown in **Figure 1**, about 1-in-3 participants (35%) indicated they were probably or definitely likely to try a "hearing solution" in the next year. Approximately half (47%) of the respondents were unsure if they were going to seek assistance for their hearing loss. About 1 in 5 (19%) were probably not or definitely not likely to seek a solution for their hearing loss within this time frame. Among this last group, more than two-thirds did not feel their hearing loss was significant enough to need a "hearing solution"; one-in-five mentioned barriers to purchase as reasons for not acting, which included cost, insurance coverage, and access.

The hearing device selection process revealed several interesting points. One-in-five initially selected a hearing device model with a maximum output of 120 dB or higher. This selection then caused the participant to identify a second choice (as described above). The products selected by and delivered to the 29 participants were balanced between medium priced PSAPs (priced $100-$250 each), premium priced PSAPs ($251-$400), and the ready-to-wear hearing aids being sold online ($400-$450). Only one participant selected a PSAP priced lower than $100 per unit.

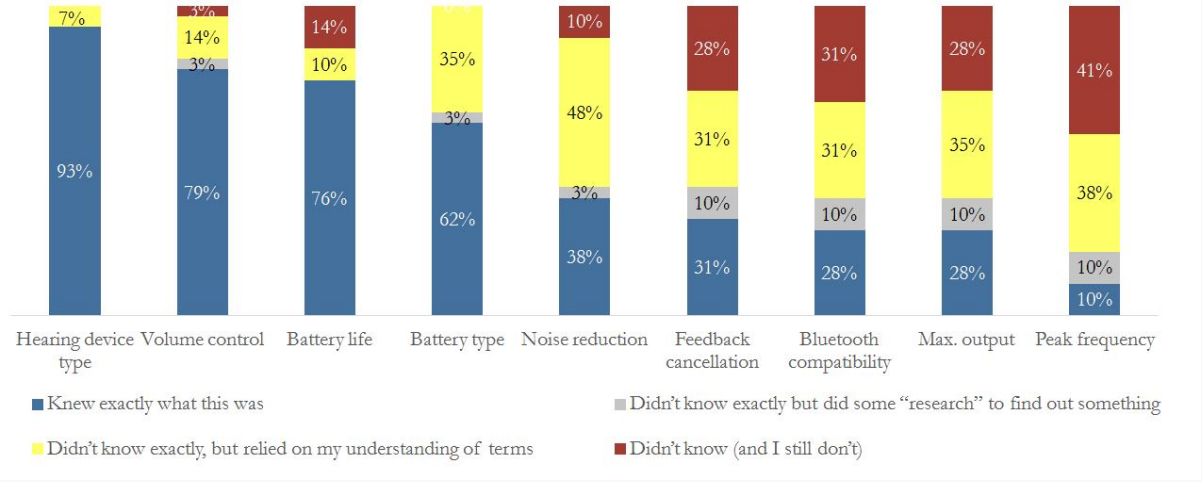

Figure 2. Familiarity of product features shown in the selection process, recall of what knew when choosing the product upfront – this was asked at the 3-week survey (n = 29).

The initial 3-week survey investigated how familiar participants were with the different technical features noted for each device and which features were considered when choosing the device. As shown in **Figure 2**, most participants were familiar with only the basic and most intuitive features, including: hearing instrument style (93%), volume control (79%), battery life (76%), and battery type (62%). Two-in-five (38%) participants knew exactly what noise reduction was, but approximately half (51%) relied on their understanding of the term or researched it further to understand the meaning.

Less than one-third of participants were familiar with features, such as feedback cancellation, Bluetooth compatibility, and maximum output; for those features, an equal proportion of participants declared that they did not know anything about the specific feature at the time of the screening survey. Peak frequency was the most unfamiliar feature with only 1 in 10 knowing what it meant at the time of device selection. More than 4 in 10 did not understand the meaning of peak frequency at 3 weeks into the trial period.

Hearing instrument style, price, and appearance were the three primary factors considered by at least half of the participants when selecting their device. Among these top features, price needs more explanation to fully understand the dynamic. When participants considered price, not all were looking for the lowest-priced option. Most participants did not select the lowest-priced options (as indicated by the mix of products they chose as the devices they would likely buy in the real world). During the in-person interviews, participants explained that they saw price as an indicator of quality, and they avoided the lowest-priced options because they felt low cost was a sign of poor quality.

Conversely, features that have a direct impact on performance of the hearing device (eg, peak frequency, maximum output, Bluetooth compatibility) were less likely to be considered. This behavior was likely due to a lack of familiarity or knowledge concerning these features.

The 3-week survey, also evaluated the ease and ability of the participants to begin using the device and steps taken in the process. Prior to using the device, 86% of the participants read some or all the instructions included in the device packaging; 17% utilized the troubleshooting instructions, and 14% sought the advice of an individual person who was currently utilizing a hearing aid. Some asked a family member or a friend for help with inserting the device or for assistance in determining how to use the device.

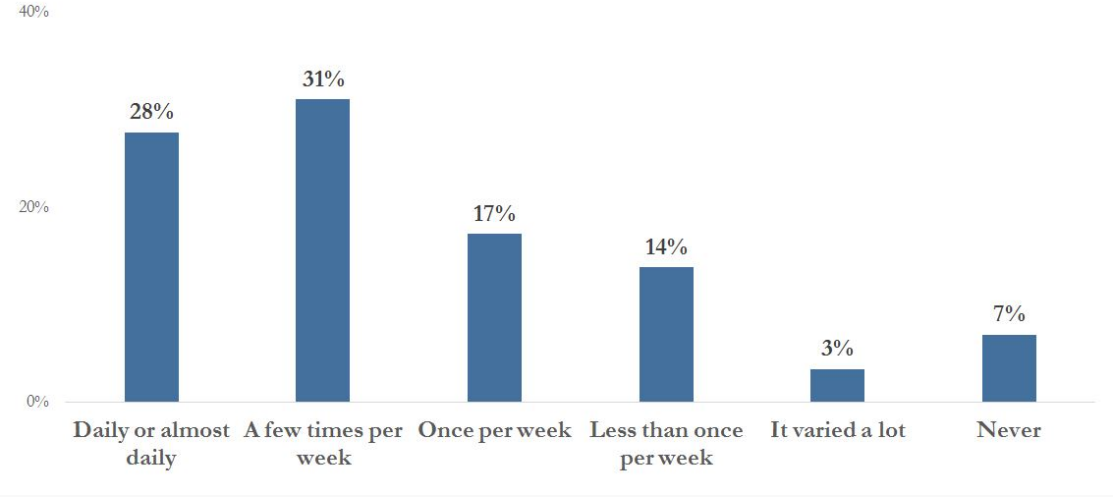

Figure 3. Level of usage of the Personal Sound Amplification Product (PSAP) or ready-to-wear hearing device during the 6-week trial period in Phase 1 (n = 29).

At the conclusion of Phase 1, the 6-week survey revealed that 90% of the participants felt that having some assistance from a hearing healthcare professional would have been at least somewhat useful when getting used to the device. A sizable percentage of the participants (40%) felt that this type of assistance would likely have been very useful.

Less than one-third (28%) of participants used the hearing device daily or almost daily, with an average usage of about 8 to 8.5 hours per day among the daily users (**Figure 3**). One-third (31%) used the device a few times a week, and the remaining one-third used the device sporadically. Usage declined over time and 2 participants discontinued use after the first evaluation at 3 weeks into the study.

3) How effective and satisfying is an "over-the-counter" approach for individuals in need?

Expectations. In both the 3- and 6-week surveys, the study examined how well the experience met the expectations that the participants by asking the question, "How does this hearing instrument compare to whatever expectations you had before you tried it?" using a 5-point scale (1 = "Much Worse Than Expected"; 5 = "Much Better Than Expected"). Perceptions varied over time. The 3- and 6-week surveys revealed that the longer participants experienced the over-the-counter approach, the more individuals felt that their expectations were not being met. At 6 weeks, 1-in-2 participants rated the hearing instrument "much worse" or "somewhat worse" than expected compared to 1-in-3 participants at the 3-week survey. The biggest shift was from the "about as expected" category to the "somewhat worse than expected" category.

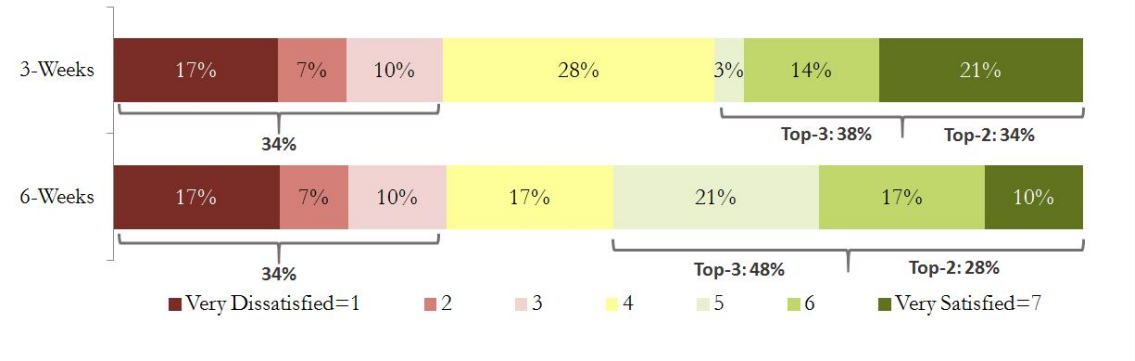

Figure 4. Satisfaction rate with the over-the-counter hearing instrument at 3 and 6 weeks in the study, rated on a seven-point satisfaction scale (n = 29).

Satisfaction. Both surveys also asked “Overall, all things considered, how satisfied are you with this hearing instrument” on a 7-point scale (1 = “Very Dissatisfied”; 7 = “Very satisfied”). The overall level of satisfaction varied over time, as well. But, as **Figure 4** shows, approximately one-third of the participants (34%) were consistently dissatisfied with the OTC instrument at both the 3- and 6-week surveys.

There were some shifts in ratings on the neutral and positive parts of the scale. For example, some participants who were in the neutral position at 3 weeks moved to the positive end of the scale; however, fewer participants were very satisfied, and more had moved from the top rating to being only marginally satisfied.

The study also evaluated satisfaction rates for specific listening situations. The OTC instruments seem to work best when watching TV (which had a satisfaction rate of 75%), in conversations with small groups (68%), and with one person (68%). Conversation in a noisy environment, like a restaurant, received the lowest satisfaction ratings at both the 3-week survey and 6-week survey (with a 48% and 34% satisfaction rating, respectively). This category also revealed the largest decrease in satisfaction between the 3- and 6-week surveys.

At the conclusion of the 6-week trial period, approximately one-quarter of the participants stopped using the hearing device. About half felt that the OTC hearing device helped some or all the time, and they would recommend one to a friend or family member with a hearing problem.

4) How does an “over-the-counter” experience compare to the traditional process of getting a hearing aid with the guidance of a hearing care professional?

At the end of Phase 1, all the 26 participants whose hearing test showed some degree of hearing loss were invited to participate in Phase 2. As described earlier, this phase consisted of the use of a hearing aid which was fitted by a hearing care professional. A total of 18 of the 26 accepted and participated in the Phase 2 of the study. This phase was designed to gain insights about how usage and satisfaction levels might change when the same individuals receive the care and support of a hearing care professional and utilize a hearing aid (ie, compared to self-managing their hearing healthcare with an OTC device).

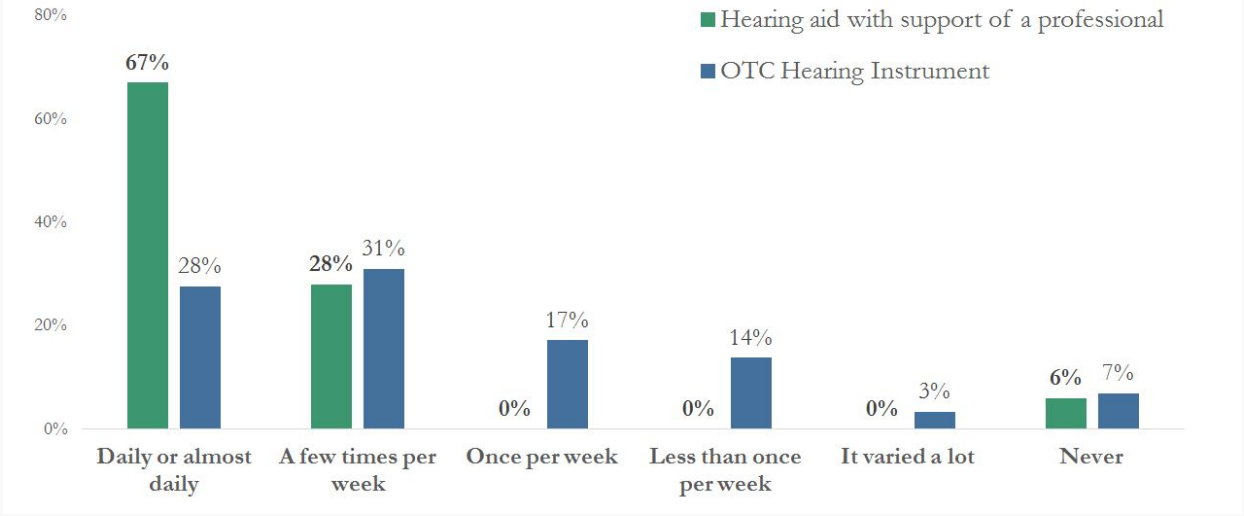

Figure 5. Level of usage of hearing aid during the 6-week trial period with professional guidance in Phase 2 (n = 18) compared to the level of usage of a PSAP or ready-to-wear hearing device during the 6-week trial period in Phase 1 (n = 29).

Level of Usage. As shown in **Figure 5**, two-thirds of the individuals (67%) who participated in Phase 2 wore their hearing aid daily (with an average of over 11 hours per day among daily users). This is in contrast to the OTC hearing instrument usage where less than one-third reported daily usage (with an average of 8-8.5 hours per day among daily users). All participants in Phase 2 believed that the hearing care professional played an important role in the process of getting started and using the hearing aid. Two-thirds felt the role of the professional was very important.

Expectations. At both the 3-week and 6-week evaluation points, two-thirds felt the experience with their hearing aids (along with the support of a hearing care professional) exceeded their expectations. Only about one-in-six said it fell short of expectations (and only “somewhat”). None of the participants rated the experience as “much worse” than expected. What is interesting to note is that more than half of the participants rated their experience with the OTC instrument as falling short of expectations (52%), and a significant percentage of participants rated that experience as “much worse than expected.” The size of the gap between the ratings of the two experiences grew wider at 6 weeks compared to 3 weeks (with a much larger proportion feeling the OTC products fell short by the end of the trial).

Figure 6. Comparison in satisfaction rate between the experience with an over-the-counter hearing instrument (n = 29) and a hearing aid fitted by a hearing care professional at the 6-week survey (n = 18).

Satisfaction. At the 6-week survey, the level of satisfaction with the hearing aid fitted by a professional was considerably higher than the level noted for the OTC instrument (**Figure 6**). More than four-in-five (83%) were satisfied with the hearing aid fitted by a hearing care professional, compared to less than half (48%) for the OTC hearing instrument. The number of participants who were very satisfied went from one-in-ten for the OTC hearing instrument to one-in-three for the hearing aid with the support of a hearing care professional.

Conversely, the rate of dissatisfaction with the experience decreased almost six-fold. Approximately one-third (34%) were dissatisfied with their experience with the OTC hearing device, whereas 7% were dissatisfied with the hearing aid fitted by a professional.

During Phase 2, more than three-quarters were satisfied with their hearing aids in each of the listening situations assessed. These areas were all rated considerably higher for the hearing aid than they were for the OTC hearing device. Specifically, it should be noted that the ability to hear a conversation in noise received a high satisfaction rate of 88% with hearing aids, compared to only 48% for the OTC hearing devices (when using top-3 box percentages). It is important to understand that conversation in noise is the situation hearing-impaired individuals with mild-to-moderate hearing loss struggle with the most.

At the conclusion of Phase 2 of the study, two-thirds felt the hearing aids helped them some or all of the time, compared to about half who felt the same about the OTC device. It is important to note that not one participant stopped using the hearing aid because they did not like it, compared to one-in-four with the OTC device noted in Phase 1. The “willingness to recommend” the product went from about half in the OTC environment to more than nine-in-ten with the hearing aid with the involvement of a hearing care professional.

Conclusions and Recommendations

This study provided several insights on how consumers may react to and behave in an over-the counter (OTC) environment for hearing health care. There have been other studies that have examined the electroacoustic analyses of PSAPs and studies evaluating the performance and satisfaction rates for PSAPs when selected and fitted by a hearing provider or other trained healthcare professionals.[7-11] However, to our knowledge, no consumer study has been conducted that “simulates or mimics” an OTC environment for hearing solutions and investigates consumers’ reactions to this market approach.

A key objective of this study was to provide fact-based evidence from the consumer perspective. This information can provide a valuable and unique contribution to the current discussions concerning an OTC approach for hearing aids. It is our opinion that these discussions need to focus on the consumer, consumer safety, consumer satisfaction, and outcome efficacy rather than on just the technologies that are (or will be) available at some distant point in the future.

This study raises several questions about the assumptions behind the proposal of an OTC market approach (without the involvement of a hearing care professional) with regard to public safety and patient outcomes.

Public safety. The results of this study indicate that a sizable portion (13%) of the participants were not able to self-identify red flag conditions that would have otherwise required immediate medical referral by a hearing care professional prior to accessing and utilizing any hearing instrument.

It was also apparent that about half of the participants were not able to correctly self-assess the degree of their hearing loss, or to self-determine if their hearing loss was unilateral or bilateral. When we combine both assessments (ie, self-identify a bilateral, mild or moderate hearing loss), only one-in-four were able to correctly self-diagnose. About 1 in 10 who self-reported a mild or moderate hearing loss had normal hearing. The benefits for these individuals buying a hearing solution are questionable.

One-in-three participants who were diagnosed with a degree of hearing loss higher than moderate potentially would have delayed seeking proper hearing care. This point is also valid for individuals who stopped using the OTC device due to a negative first experience with a hearing solution. Delaying proper care can potentially create other healthcare costs (eg, depression, non-compliance with medical recommendations, cognitive dysfunctions, etc).

During the online survey, when participants were provided with the various hearing device profiles and asked to choose one, most of the participants were only familiar with very basic elements such as style, price, and battery life. Participants had very little knowledge of important technical features, such as noise reduction, feedback cancellation, and maximum power output. Consequently, they tended to select devices without factoring in the pros and cons of most of the features provided. When they had to select between the solutions made available, one-in-five selected a device with a max output higher than 120 dB which is harmful for any normal-hearing individual or potentially for a hearing-impaired person with mild-to-moderate hearing loss.

Patient outcome. If the true intent of the National Academies of Sciences' proposed changes in regulation are to increase access and the "timely use of personal health services to achieve the best possible health outcomes,"[12] then results on participant outcomes and satisfaction reported in this study should not be disregarded.

In summary, in this pilot study, when individuals were supported by a hearing care professional in the testing, counseling, fitting, and aftercare of hearing solutions, significantly better participant outcomes were reported across all metrics, including (but not limited to):

- Daily usage of the hearing solution;
- How well each solution met expectations;
- Overall satisfaction rates;
- The incidence of individuals who stopped using the hearing solutions before the end of the trial period due to dissatisfaction (ie, "instruments in the drawer"), and
- Willingness to recommend, which is a strong indicator of patient outcome and also of perceived success.

Interestingly, the results on patient outcome and satisfaction from Phase 2 (ie, the experience of trying a hearing aid with the guidance of a hearing care professional) are comparable to the larger MarkeTrak 9 study which examines the hearing aid industry in the United States.[13] It should also be noted that patient outcome and satisfaction ratings

in Phase 1 (ie, self-treatment with a hearing instrument) were comparable to markets where the delivery of hearing care and the dispensing of a hearing instrument is not regulated, like Japan.[14] In those markets, satisfaction and adoption rates are about half the level achieved in the United States.

We acknowledge that more data is needed to better understand how consumers could behave in an OTC environment for hearing aid acquisition and to more precisely estimate rates and differences, but feel this pilot study is extremely revealing relative to the value of professional hearing care for consumers.

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