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Audiology PRACTICES



The Power to Practice

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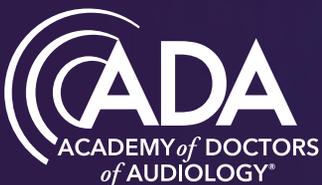


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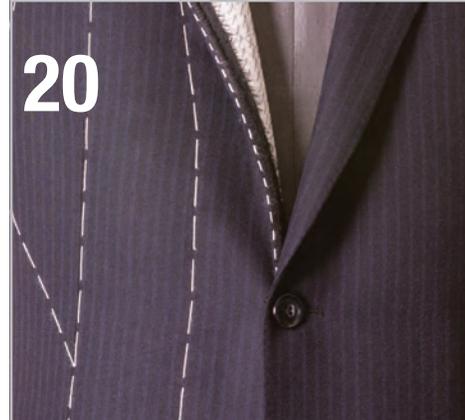
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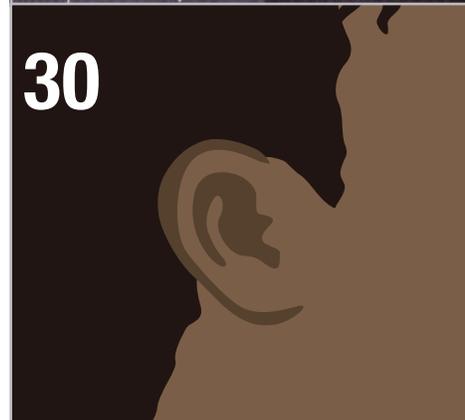
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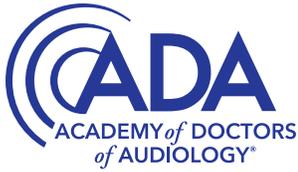


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A Defining Year for Audiology

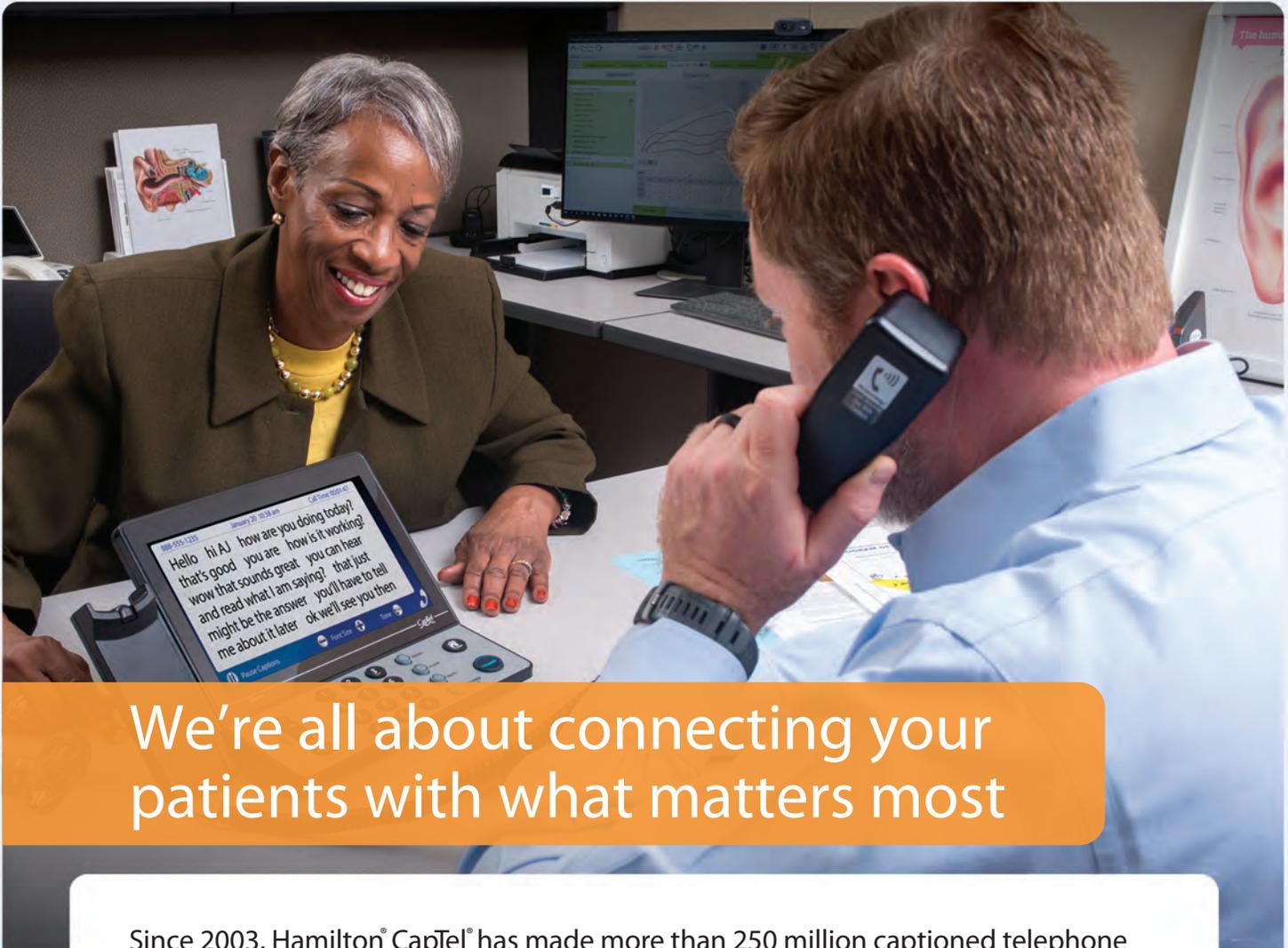
As 2022 began, hearing healthcare remained top of mind in the media, with the public, and in Washington, D.C., from Medicare expansion in the form of the Build Back Better bill to the FDA Proposed Rule for OTC Hearing Aids. Beginning my term as your ADA President, I must admit I felt a little like a novice in the gladiator ring. The upheaval in audiology and the hearing aid industry has sparked a recurring debate regarding the future of the profession of Audiology. This is not a new topic but has gained attention in the past few months as it is being discussed on social media, in our professional journals, during networking at conferences, and in the classrooms of our future doctors of Audiology. The debate centers around the external versus internal threats to our profession. What are they, which are the most potentially harmful, can we control any of them, should we have seen them coming? Will Audiology survive??

The most popular cited *external* threats include lack of perceived value for our services, poor consumer understanding of Audiology as a profession, and not being viewed by the public as a healthcare profession. Managed care, vertical integration, the exorbitant tuition costs to enter our profession, and lack of cohesion as a profession also commonly make the list. In addition, the cost of technology remains high for independent audiologists and therefore patients, while insurance reimbursement for audiology services remains extremely low. Finally, there is the common complaint of Costco and now OTC hearing aids. These have all been with us for a while or we have seen them coming; they should not be a surprise to anyone.

Popular choices for *internal* threats are audiologists' refusal to accept change, continued audiology participation in managed care programs, lack of diversity in our profession including lack of education and training regarding diversity, and our inability to unite into one national professional organization. In my view, *we are the number-one internal or external threat that we face*. We, as a collective group, have been unwilling to acknowledge that change needs to occur—and to embrace it! Audiologists have not even implemented best practices in totality. We must act like a doctoring profession to expect to elevate our profession to that level. How do we expect to reach a consensus on messaging to the public, implementation of OTC, certification, and so on if we can't even check best practices implementation as a profession off our list?

A critical step in saving Audiology is to complete our transformation to a doctoring profession. The passage of MAASA is key! ADA, AAA, and ASHA have been working collaboratively the past couple of years to move MAASA across the finish line; but the work is being done by a minority of audiologists. We need to stop complaining about there being more than one Audiology organization and reflect on why that is. Our profession is truly diverse. We have military audiologists, academic

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Best Practice is Good Business

A trend ten-plus years in the making, we continue to await the arrival of over-the-counter hearing aid legislature and the impending shifts in the marketplace resulting from it. While there is no shortage of naysayers spouting doom and gloom for the profession when OTC and self-fitting hearing aids arrive, investors, whose job is to study market forces and their impact on future business, are worth paying attention to during uncertain times. This recent quote from the UK investment group, A/B Bernstein is a particularly good example.

“We do not expect OTC to disrupt traditional hearing aid market volumes in the long-term, given the critical role the audiologist plays in helping users through the selection and fitting process. However, in the short-term we do think there could be significant disruption to traditional hearing aid sales in the U.S., as users are attracted by the low prices of the devices to give them a try. Meanwhile, over the long-term we believe OTC prices could prove problematic for traditional retail pricing (\$4,000-\$7,000 per pair), enabling the likes of Costco (\$1,400-\$2,400 per pair) to gain further share in hearing aid retail.”

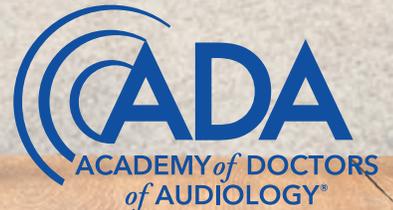
—A/B Bernstein Report, February 9, 2022

The main message from this investor’s analysis is that once customers have their fling with OTC, the market will settle back to business as usual with one critically important exception: Margins for the private practice audiologist will substantially erode. Besides finding alternative revenue streams from services such as tinnitus and balance, and improving efficiency by seeing more patients over the same amount of time (topics we will continue to cover at *Audiology Practices*), audiologists must identify ways to add value to the traditional model of hearing aid dispensing. In this issue of *Audiology Practices* you will find three articles that shed light on how value can be added through the dedicated application of clinical standards as well as the ability to customize various components of the hearing aid selection and fitting process. For the conscientious audiologist, following best practice is good business. ■



Contact Your Legislators!

Urge them to support the **Medicare Audiologist Access and Services Act**
(H.R. 1587 and S. 1731)



The Medicare Audiologist Access and Services Act of 2021 (H.R. 1587 and S. 1731) will remove unnecessary barriers, allowing patients to receive appropriate, timely, and cost-effective audiologic care. This legislation can improve outcomes for beneficiaries by allowing direct access to audiologic services and streamlining Medicare coverage policies so that audiologists can provide the full range of Medicare-covered diagnostic and treatment services that

correspond to their scope of practice. The legislation would also reclassify audiologists as practitioners, which is consistent with the way Medicare recognizes other non-physician providers, such as clinical psychologists, clinical social workers, and advanced practice registered nurses.

Support the future of audiology!

Contact Congress today and express your support for H.R. 1587 and S. 1731.

Visit chooseaudiology.org/support and contact your congressperson today!



MAASA Means Medicare Policy Parity for Audiology Services and for Women as Clinical Doctoring Professionals

Women make up approximately 85 percent of practicing audiologists in the United States.^{1,2} While tremendous strides have been made to increase the percentage of women in medicine and other clinical doctoring professions in recent years, there continue to be significant disparities.^{3,4} Audiology is well ahead of other clinical doctoring professions in terms of female representation—and way behind in terms of salary and stature, despite the high demand for audiology services, and the scarcity of audiologists. These disparities are borne out in Medicare reimbursement policies.

Beneficiary Direct Access is More Readily Achieved, and with Fewer Restrictions for Male-Dominated Professions

Medicare Part B regulations impose fewer restrictions on beneficiary “direct access” to clinical doctoring professions that have low percentages of females as shown in Table 1. Further, additional requirements and restrictions increase proportionately to the percentage of females in the profession.

Medicare Provider Classification Favors Male-Dominated Professions

- *Physician:* The clinical doctoring professions that Medicare recognizes as physicians coincide exactly with professions that are predominantly male.⁵ Of those professions, optometry has the highest representation of females in clinical practice at 43%.⁶ Optometry was also the last profession to be categorized among Medicare physicians in 1987.⁷
- *Practitioner:* Clinical psychology is classified by Medicare in the practitioner category. Women account for 65% of practicing clinical psychologists today, up 10% from 1990 when Medicare first added them as eligible providers.⁸ While not included in the physician category, clinical psychologists are eligible for reimbursement of medically necessary, Medicare-covered services at 100% of the Medicare Physician Fee Schedule.⁹
- *Supplier:* Medicare classifies physical therapy and audiology, the clinical doctoring professions with the highest percentage of women (68%¹⁰ and 85% female respectively), as suppliers. Suppliers are frequently left out of important policy advances—for example, they are not included among the providers who are eligible by statute to deliver services via telehealth.

1 Hearing Health Matters (2017) <https://hearinghealthmatters.org/hearingviews/2017/sex-and-audiology/>

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4 Searing, Linda. *The Big Number: Women Now Outnumber Men in Medical Schools.* The Washington Post. December 23, 2019. https://www.washingtonpost.com/health/the-big-number-women-now-outnumber-men-in-medical-schools/2019/12/20/8b9eddea-2277-11ea-bed5-880264cc91a9_story.html

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9 Social Security Act, Title 18. https://www.ssa.gov/OP_Home/ssact/title18/1842.htm

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CUSTOMIZING REAL EAR VERIFICATION OF HEARING AID GAIN AND OUTPUT

An Interview with Gus Mueller, PhD

TAYLOR: As many of our readers probably know from the recent This Week In Hearing episode, our first contributor recently celebrated his 50th anniversary as an audiologist. It's hard to believe that Gus Mueller was fitting hearing aids before audiologists could ethically "sell" them (he was in the military at the time and ASHA wouldn't allow their members to engage in selling, anyway). By now, most of you are also familiar with his popular column at AudiologyOnline, 20Q with Gus, and if you've been around as long as I, you know he authored the first book on real-ear verification measures in 1992, as well as the more recent, *Speech Mapping and Probe Microphone Measures*.

In June 2020, in the middle of the pre-vaccine COVID-19 pandemic, Gus published a highly informative review and update on real-ear verification that I am sure many people missed. The reason they missed it, however, had less to do with coronavirus and more to do with the fact that the article was published in a German Audiology Journal. Fortunately, the folks at *GMS Zeitschrift für Audiologie - Audiological Acoustics* have granted *Audiology Practices* permission to reprint it.

Gus, thanks for agreeing to have us reprint your article.

MUELLER: No problem, Brian. Your readers are the very people who could make change happen. There probably isn't much in the article that hasn't been published somewhere else before, but sometimes repetition is a good thing. You know, each year we have added emerging information regarding the importance of providing appropriate audibility and real-ear output when hearing aids are fitted, for both children and adults. There is considerable evidence showing that "getting-it-right" will lead to better outcomes for our patients. The general theme of the article is that if fitting hearing aids is what we do --why not get-it-right?

TAYLOR: I don't see how anyone could disagree, especially when it is likely consumers will be able to purchase hearing aids without the help of an audiologist very soon. It's been two years since you wrote this article that we are reprinting. Has anything changed since then that you'd like to mention?

MUELLER: Well I'd like to tell you that there has been a huge surge in the use of probe-mic real-ear verification, but unfortunately, that isn't true. About the only thing new that I can think of is that we now have a hearing aid fitting standard, developed by the Audiology Practice Standards Organization (APSO), which was published last year. In many respects, it simply states what has been published in fitting guidelines for the past 30 years, but importantly, it is a standard, not a guideline. And yes, of course, it emphasizes the importance of probe-mic verification. Will having a standard move the needle? We'll see. Let's hope.

TAYLOR: I am pleased you mentioned the APSO, because in addition to reprinting your 2020 interview we are also re-printing APSO's first two published clinical standards in this issue of *Audiology Practices*. John Coverstone and Patricia Gaffney have written a brief introduction to those two standards that explains why clinical audiologists, especially those in private practice should support APSO standards.

Perspective: real ear verification of hearing aid gain and output

Abstract

It is the role of the audiologist to ensure that hearing aids are programmed and fitted to optimize benefit. Research has shown that haphazard fittings lead to reduced performance for the hearing aid user. This paper reviews the evidence supporting the use of validated prescriptive methods such as the NAL-NL2. The use of prescriptive methods includes ensuring that the fitting targets are met relative to ear canal SPL. This verification only can be made using probe-microphone measures; current techniques and procedures for this verification are discussed.

Keywords: probe microphone measures, real ear measures, hearing aid verification, prescriptive hearing aid fittings, NAL-NL2

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Introductory remarks by the editor

We are using a somewhat different format for this special Review Paper. H. Gustav Mueller, PhD, has been a leading advocate for the real-ear verification of hearing aid performance for over 40 years, and has published numerous articles and book chapters on the topic. He authored the first book on real-ear verification back in 1992, and recently, a second textbook, *Speech Mapping and Probe Microphone Measures*. Dr. Mueller also is known as the editor of the popular column “20 Questions” that appears each month at *AudiologyOnline*. For this invited Review Paper, we’re going to turn things around and ask Dr. Mueller the questions.

Interview

ZAUD: We hear that you might be one of the pioneers of the real-ear verification of hearing aid performance. True?

Mueller: I’ve been at it for a long time, so I guess that does make me a pioneer. We started looking at the practicability of these measures in 1979 when I was at Walter Reed Medical Center, Washington D.C. In those early days, we actually placed a small hearing aid microphone down in the ear canal. It was a procedural nightmare, but we were able to obtain some meaningful measures, and were excited about the potential of this procedure. At the time, we were using pure-tone aided testing in the sound booth to verify our prescriptive fittings. We were well aware of all the negative issues and pitfalls surrounding these measures, and were anxious to abandon them. We presented a paper on our early experiences with real-ear measures at the 1980 conference of the American Speech and Hearing Association [1] – that was 40 years ago, so this certainly isn’t something new.

ZAUD: This was before we used probe tubes to assist in the ear canal measure?

Mueller: Yes, the “probe-tube” version wasn’t introduced until 1983 or so (the Rastronics CCI-10), and was not really commercially available for another year (at least in the U.S.). The probe-tube approach was a life saver – throwing away a plugged tube was a minor thing compared to the gummed-up microphones we had in the past. By 1985 we had all our fitting rooms at Walter Reed equipped for probe-mic verification, and we were off and running. We of course expected this to soon become the best practice standard for fitting hearing aids, and commonly used by all audiologists. After all, why wouldn’t you want to know the SPL at the ear drum?

ZAUD: You say “the standard.” But that never happened?

Mueller: No – I guess that’s partly why I’m here with you today. I can’t speak for other countries, but in the U.S., my best guess is that no more than 30–40% of audiologists who fit hearing aids conduct probe-mic verification routinely, and that hasn’t really changed since the 1990s.

ZAUD: Why do you think there is a reluctance to use this verification tool?

Mueller: It’s a combination of several factors. Some say that they simply don’t have the time, a weak excuse I believe. One issue is that I don’t think the concept of verification is well understood. To verify something, we start with a set of standards to verify against – in the world of fitting hearing aids that would be an evidence-based validated prescriptive method. On social media, I often read long discussions among audiologists regarding whether or not to do REM (a popular term for probe-microphone measures). In these online discussions, audiologists talk about “REM” as if it were a way to fit hearing aids. It isn’t. It’s simply a verification of the “best known way” to fit hearing aids. I know clinics where the audiologists use the manufacturers’ default fitting, conduct

probe-measures but do not change the programming, and then tell their colleagues that they “fit by probe” (whatever that means). That isn’t the way it works. We have to buy into the fact that an evidence-based standard is the starting point, and go from there.

A second factor is that audiologists often are encouraged by manufacturers to use the manufacturer’s proprietary fitting. They sometimes are told that certain hearing aid features do not work correctly unless the manufacturer’s first-fit is selected in the fitting software. Audiologists tell me that they follow this guidance. There are no ear-canal targets for the manufacturer’s fitting available on probe-microphone equipment, so it’s impossible to do real-ear verification. Recently, some manufacturers, through the use of autoREMfit, have made it possible to use real-ear data to fit to their proprietary targets. The problem of course remains, that these targets have not been validated.

A third factor is that some audiologists believe that combining their clinical experience with comments from the wearer will provide a fitting more optimal than that of a prescriptive fitting approach. Denis Byrne, was the developer of the original National Acoustic Laboratories (NAL) prescriptive fitting approach, dating back to 1976 [2]. He passed away in 2000, and a year later Harvey Dillon gave the Denis Byrne Memorial Lecture at the annual meeting of the American Speech and Hearing Association. Harvey paraphrased Denis’s thoughts on relying on clinical experience to fit hearing aids as follows [3]:

- If you can’t write down the rules you use, you probably don’t understand what you do.
- If it’s not written down, no one else can do it, and no one can test whether it’s better or worse than some alternative approach.
- If you can’t evaluate your procedure you can’t improve it.

Another important point is that when fitting a hearing aid, you have to start someplace. Why not with a validated approach? In his 2012 article, Earl Johnson [4] reviewed the problem of going rogue when selecting the best frequency response for a new hearing aid user. He suggests that an experienced clinician can rule out a large number of possible frequency responses, so we can assume that the optimal frequency response falls within a 20 dB range in each of the 16 channels of a typical modern hearing. We also know that there is a need for a somewhat “smooth” response across the side-by-side channels of adjacent frequencies – we wouldn’t put 20 dB of gain in one channel, and 0 dB of gain in the adjacent channel, nor is it even possible due to overlapping channels. When we construct somewhat smooth frequency responses, we eliminate 99% of the available 16 channel, 20 dB range frequency response choices. We then apply further logic, only selecting frequency responses that in theory could simultaneously provide the best speech intelligibility, acceptable loudness and sound quality. After all of which, there are still 1,430 possible frequency responses from which to choose for any particular hearing aid user!

And that is only for one input level. Sounds like the fitting process is going to require more than one office visit.

ZAUD: You mention the need for verification of the “best known way.” But do we know that there really is a best way?

Mueller: Well, we certainly know what *isn’t best*, and that is what is commonly used, and I’ll be happy to talk about that later. There probably are several “equally-best” ways. There are three or four prescriptive fitting methods that have been rigorously validated. Let’s talk about the NAL approach, simply because it’s been around for the longest, is the most researched, is used around the world, and for adults, the current version is very similar to the other methods available. It started with the original NAL [2], which then led to the NAL-R [5], followed by the NAL-NL1 [6] and we now have the NAL-NL2 [7]. I published an evidenced-based review of the earlier NAL methods in 2005 [8].

One method to evaluate the appropriateness of a given prescriptive fitting is to fit individuals accordingly, provide them with highly trainable hearing aids, and then allow them to adjust the products to what they prefer based on real-world use. We have these types of studies for the NAL prescriptive method. Ben Hornsby and I were curious if previous experience with a given hearing aid fitting would influence preferred gain with new instruments [9]. We often hear that hearing aid users want new hearing aids that sound like their old ones. We specifically selected participants (n=20; all bilateral wearers) who had used their current hearing aids for at least two years, and who we knew had been fitted to a specific manufacturer’s proprietary fitting, which tended to provide gain substantially below that of the NAL-NL1. We fitted these individuals bilaterally with trainable hearing aids (e.g., input-specific gain training, and a treble adjustment) to the NAL-NL1 prescriptive method. The participants used the hearing aids in the real world for two weeks. They had a diary to complete, which included a variety of assigned listening situations that potentially would encourage gain adjustments (note: on follow-up, data logging showed that all participants had at least 130 gain adjustments during the trial period).

The results are shown in Figure 1. Displayed are the mean NAL-NL1 targets, and the mean values for the REARs for the hearing aid user’s present instruments, the original programmed output, and the trained output, for both low and high frequency bands. As predicted, the participants had been fitted substantially below NAL-NL1 targets – nearly 10 dB for the 55 dB SPL input. Observe, however, that following training, they did not train down to what they had been using, but rather, used significantly more gain (p<.001), only 2–3 dB below NAL-NL1 targets. It may simply be coincidental, but these were NAL-NL1 targets, and the NAL-NL2 targets are roughly 3 dB lower.

The Mueller and Hornsby [9] study was with experienced hearing aid users. Perhaps even more compelling data is from a study using trainable hearing aids conducted by Catherine Palmer [10]. The participants in this study

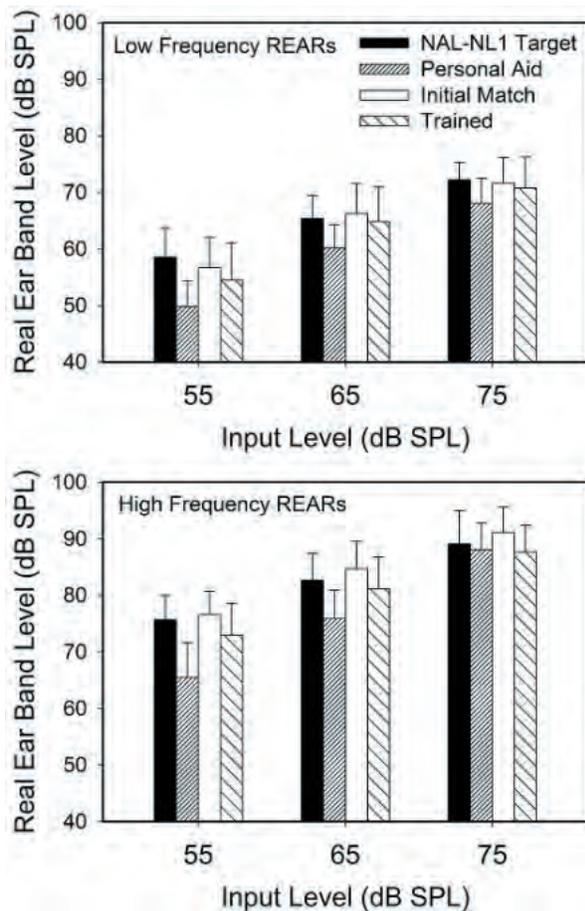


Figure 1: Mean real ear aided response (REAR; ear canal SPL) shown for the averaged low-band and high-band frequencies for the real-speech inputs for three levels. Data shown for four conditions: NAL-NL1 target, NAL-NL1 best match to target, trained gain, and average gain for the patient's personal hearing aids.

were 36 new users of hearing aids. One group of 18 was fitted to the NAL-NL1, used this gain prescription for a month, and then trained the hearing aids for the following month. The second group of 18 was also fitted to the NAL-NL1, but started training immediately, and trained for two months. Importantly, these individuals were using hearing aids that had input-specific training, and had the potential to be trained up or down by 16 dB – providing ample opportunity for them to zero in on their preferred loudness levels. In general, after two months of hearing aid use, both groups ended up very close (within 1–2 dB) to the NAL-NL1 targets for average inputs. Palmer reports that the Speech Intelligibility Index (SII) for soft speech was reduced 2% for the first group, and 4% for the group that started training at the initial fitting. Again, this was with NAL-NL1, not the current NAL-NL2.

The NAL-NL2 prescriptive method was evaluated in a trainable hearing study by Keidser and Alamudi [11]. In this research, 26 hearing-impaired individuals (experienced hearing aid users) were fitted with trainable hearing aids, which were initially programmed to NAL-NL2. Following three weeks of training, the authors examined the new trained settings for both low and high frequencies, for six different listening situations. That is, the training

was situation specific based on the hearing aid's classification system; a given participant could train increased gain for music, and decreased gain for speech-in-noise. The participants did tend to train down from the NAL-NL2 for all six situations, but only by a minimal amount. For example, for the speech in quiet condition for the high frequencies, the average value was a gain reduction of 1.5 dB (0.95 range = 0 to –4 dB), and for the speech in noise condition, there was an average gain reduction of only 2 dB (0.95 range = +0.5 to –4.5 dB). The trained gain for the low-frequency sounds for these listening conditions was even closer to the original NAL-NL2 settings.

These studies all suggest that on average, the NAL prescription is a reasonable starting point. A skeptic, however, might point out that in all three studies, the starting point was the NAL prescription, which could have influenced the ending point [12]. Let's then look at a recent study from Sabin et al. [13]. These authors evaluated the outcomes of self-fitting hearing aids that were initially set to 0 dB REIG, so the starting point was not biased toward any fitting rationale. For later reference, the hearing aids were programmed to a real-ear verified NAL-NL2. The real-world performance of the self-fitting approach (n=38) was evaluated via a month-long field trial. There was a strong correlation between user-selected and audiologist-programmed gain ($r=0.66$, $p<.0001$). On average, the user-selected gains were only 1.8 dB lower than those selected by the audiologists based on the NAL-NL2 prescription.

These studies all have used the NAL prescription as the reference, but it seems unlikely that the findings for DSLv5 would be much different, simply because for adults, this prescription method is very similar to the NAL-NL2. Johnson and Dillon [14] compared these two methods for five different mild-to-moderate sensorineural hearing loss configurations. Rarely did prescribed gain for the key frequencies of 500–4,000 Hz differ by more than 3–4 dB, and when the SII for an average-level input were averaged for the five different configurations the difference between the two methods was 0.01 (DSL SII=0.70; NAL SII=0.69).

ZAUD: Given that many audiologists choose not to verify to the NAL-NL2 targets, what do you believe is their concern?

Mueller: In some cases, for some products, fitting to the NAL-NL2 will cause a feedback issue, but by far, what I hear the most is that NAL-NL2 prescribed targets provide more loudness than what the average wearer wants. This just doesn't match with the research evidence. I've already reviewed that when hearing aid users have the opportunity to train away from the NAL fitting, they don't. But we can go back to the research that led to the NL2 modification of the NL1 [15]. At the time, there were data that suggested that indeed NL1 called for slightly more gain than desired by the average user. For this reason, gain for average inputs for NL2 were lowered by about 3 dB. Based on the preferred loudness level data from

nearly 200 hearing aid users, it was shown that by lowering the gain by this amount, about 60% of individuals would fall within a ± 3 dB window of the fitting target. So yes, we then would expect about 20% to say that an NAL-NL2 fitting was too loud, but also, 20% to say that the NAL fitting was too soft. From my experience, this seems about right.

Now, I can think of some reasons why clinicians might state that their NAL targets call for too much gain – two of them involve procedural issues:

- Prior to the testing of each individual, the probe-mic software must be set to correspond with the specifics of the fitting. The two most important factors are whether the fitting is bilateral or unilateral, and if the person being fitted is a new user, or experienced. I'll use an example from Johnson [4] to illustrate the importance of setting up the equipment correctly when using NAL-NL2. Our examples are a woman obtaining her first set of hearing aids, and an experienced male user, obtaining a new set of hearing aids. To make it easy, let's say that they have the same hearing loss; 20–30 dB HL in the low frequencies sloping down to 70 dB HL at 2 kHz and above. While their hearing loss is the same, the prescribed insertion gain at 2,000 Hz for the female for a 65 dB SPL speech input would be 16 dB, whereas for the male it would be 21 dB. If the equipment was not set up correctly, you could think that you are at the NAL-NL2 target (for the woman) when in fact you were 5 dB over target – possibly big enough difference to exceed preferred loudness and impact the success of the fitting. The greater the hearing loss, the bigger the differences will be.
- A second procedural issue concerns the equalization method used by the clinician. Most probe-mic systems default to concurrent equalization – that is, the reference microphone is active during the presentation of the test signal. This helps correct for minor head movement during the 10–12 seconds that the signal is presented. But, this equalization method cannot be used with open fittings. Consider that for nearly all probe-mic systems, the reference microphone is located at the ear lobe, just below the ear-canal opening. The amplified signal leaks out of the ear, is picked up by the reference microphone, and if it is louder than the input signal (which it usually is) this will prompt a reduction in the input signal. The audiologist might think that they are presenting a 65 dB SPL signal, when in fact it's only 60 dB SPL. This will likely generate an output that is below the 65 dB target, so the audiologist now increases gain by 5 dB, which causes 5 dB more to leak out of the ear, and the input signal goes down another 5 dB. It is very possible that the ear-canal output would appear to be at target, when in fact it's 10 dB or more over target. This usually is observed in the 2,000–3,500 Hz region, because of the residual resonance of the ear canal. This is why stored equalization, not concurrent needs to be used, even when the fitting is only partially open (see Mueller

et al. for review [16]). This then is a possible reason why an audiologist might report that his or her hearing aid users believe the NAL-NL2 targets are too loud – they are not fitting to the target. We talked about it back in 2006 [17], but it still seems to be a reoccurring problem.

- A third issue relates to the understanding of the prescriptive target. The target is not a “dot” on the fitting screen, but rather a range. At least one probe-mic manufacture has a \pm vertical bar at the target for each frequency to remind us of this. How big is the range? As mentioned earlier, we would expect that about 60% of individuals would be okay falling within ± 3 dB of the center of the target. At least two different fitting guidelines have used ± 5 dB as acceptable (International Society of Audiology [18]; British Academy of Audiology [19]), and we know that 5 dB would probably not be more than two JNDs for a broadband signal [20], so a ± 5 dB range would seem clinically acceptable. The point being, that if a given hearing aid user preferred 5 dB below the precise target, they are still *fitted to target*. It remains important, however, to maintain a smooth frequency response that more or less follows the precise prescriptive pattern – we would not want to be 5 dB over at 1,000 Hz, then 5 dB under at 2,000 Hz, and then back over at 3,000 Hz.
- The final issue is related to counseling. Yes, it is true that when we first program the hearing aids for a new user, the first thing we often hear is, “Wow, everything seems loud.” But this does not mean that we immediately grab our mouse and start turning down gain. Rather, the follow-up comment from the audiologist would then be something like, “Yes, that is the expected perception, it should sound loud; you haven't been hearing these sounds for many years. You'll adjust to this after a few days of use.” Of course, there are some cases where the new user simply will not accept an output level that is close to target, but most will experience at least some acclimatization to loudness after some listening experience. For these individuals, therefore, it's usually possible to increase gain during post-fitting visits, or implement an automatic gain increase in the fitting software, so that in the end, audibility is acceptable for both the user and the practitioner.

ZAUD: You mentioned the common use of manufacturers' proprietary algorithms. How do they compare with the generic prescriptive methods?

Mueller: Let me first talk a little about why I think these fitting algorithms exist. I'll start with an example from the mid-1990s. I was serving as a consultant for a major hearing aid manufacturer, and the DSL[i/o] had just been introduced [21]. Our clinical audiology advisory team convinced the R & D folks that this should be the default fitting for WDRC instrument that was soon to be launched (WDRC was a big deal in those days). They bought off on it, and it was part of the fitting software. Within months,

the sales staff was inundated with complaints from the field that the new product was not well received, and sales were dismal. The report from the field was that the new product had too much gain, sounded “tinny” and was feedback prone. New software was soon introduced and the fitting screen now showed “DSL [i/o]*”. The note for the asterisk simply stated that the DSL had been modified. In the background, overall gain was reduced, and gain above 2,000 Hz rolled off considerably (solving both the tinny and feedback issues). Sales increased immediately. The point of the story is that manufactures, to stay profitable, have to satisfy a wide range of fitting goals for dispensers around the world – some with PhDs and others with no college at all. Sometimes decisions are not based on science.

Many individuals fitting and dispensing hearing aids want a “click and go” solution. That is, one click on “First Fit” and the wearer is happy. What makes the typical new user happy on the day of the fit? Something that doesn’t sound like a hearing aid, something that sounds “natural,” and certainly, something that doesn’t sound “tinny”. It is therefore to no one’s surprise, that propriety fittings under-fit (compared to generic methods), and in particular, roll off gain above 2,000 Hz.

In 2015, a group of us compared the proprietary fittings for the premier products of the five leading manufacturers [22]. Our mean results (REARs; 16 ears) are shown in Figure 2, for inputs of 55, 65 and 75 dB SPL. This was for a downward sloping hearing loss, going from 25 dB in the lows, to 70 dB in the highs. The NAL-NL2 fitting targets also are included for comparison purposes. Granted, the proprietary methods aren’t geared to meet NAL-NL2 targets (you could simply use the NAL algorithm if they were), but this provides a reference.

Notice that we do see a 5–8 dB difference among manufacturers, but the pattern of the output for all the proprietary fittings is similar, and considerably different than that of the NAL-NL2. For the higher frequencies, output above 2,000 Hz falls 10 dB or more below the NAL prescription for the 55 dB SPL input (a level just slightly below average speech [23]). This could be a holdover from the days when feedback reduction systems were not very effective. We see it today, however, even for moderate losses in the high frequencies – the high-frequency loss for the sample audiogram in this study was only 70 dB, a level where feedback would not be an issue for most modern hearing aids, even with an open fitting.

If you follow the mean output values (1,500–4,000 Hz range) for a given manufacturer for the 55 to the 75 dB input levels (20 dB input difference), you see a change in output of ~17–20 dB – in other words, these are essentially linear fittings. This helps explain why they under-fit for soft inputs, and over-fit for high intensity levels.

We also recorded the SII that was present for each participant. The group mean values for the three input levels compared to a NAL-NL2 fitting are shown in Figure 3. There is a sizeable difference between the SII of the proprietary fittings compared to the NAL-NL2. As the input goes up, the differences become smaller. The most con-

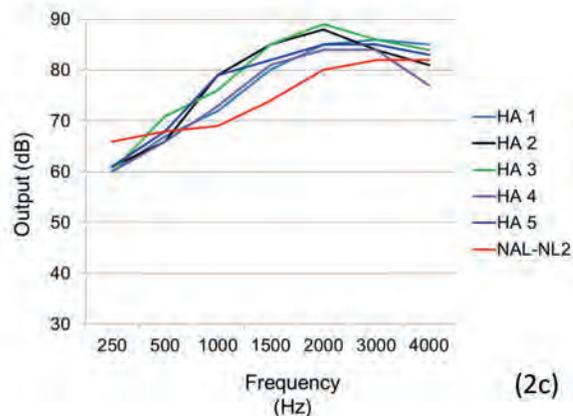
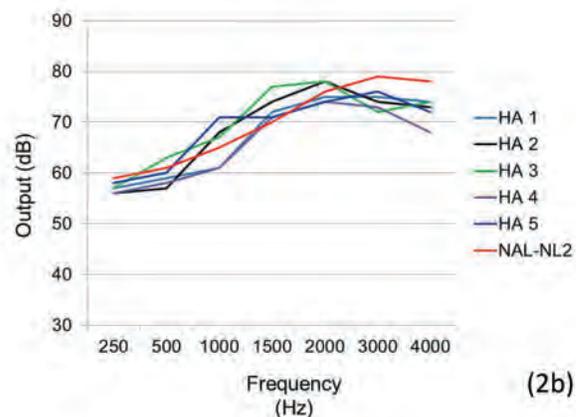
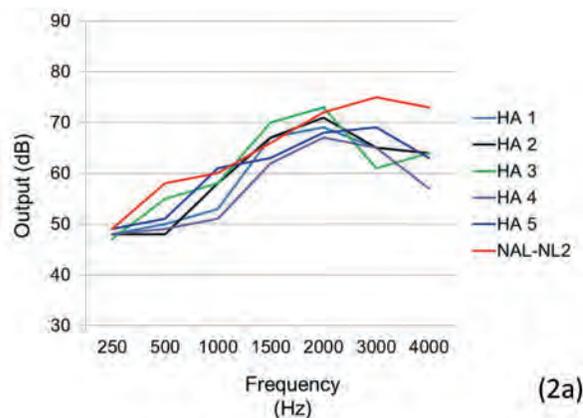


Figure 2: Mean ear canal SPL output for the proprietary fitting (experienced user, bilateral fitting) of five leading manufacturers for a mild-to-moderate downward sloping hearing loss. Data shown for inputs of 55 dB (2a), 65 dB (2b), and 75 dB (2c) SPL. The NAL-NL2 targets are displayed as reference. Adapted from Sanders et al. [22].

servative fitting for the 55 dB input was HA-4, with an SII of only 0.25, compared to 0.47 for the NAL-NL2. For some listening situations, going from an SII of 0.25 to 0.47 can improve speech recognition substantially.

For the 75 dB input, the SIIs are similar to that of the NAL, but this value is misleading for real-world use (assuming the wearer has a method to lower gain). If we go back to Figure 2, note that for some instruments, the output in the mid frequencies (1,000 to 2,000 Hz) is about 10 dB greater than the NAL prescription. Given the amount of research by the NAL to determine preferred loudness

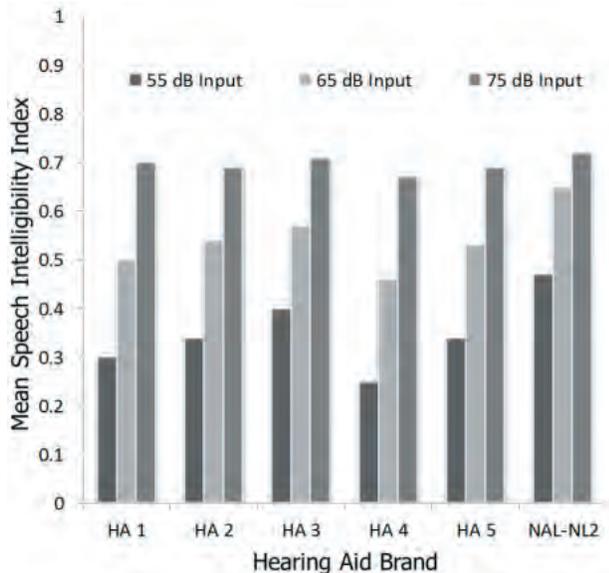


Figure 3: Mean SII values (as calculated by Audioscan Verifit) for the proprietary fitting (experienced user, bilateral fitting) of five leading manufacturers for a mild-to-moderate downward sloping hearing loss. Data shown are for inputs of 55, 65, and 75 dB SPL. The SIIs for a precise fitting to NAL-NL2 targets are shown as a reference. Adapted from Sanders et al. [22].

levels, it seems likely that a hearing aid user would find this too loud, and reduce gain. This would then lower the SII for this input level, and of course would make the SII for soft speech even worse than it already is.

The reduced audibility for the manufacturer's default fitting was illustrated more recently by Valente et al. [24]. These researchers reported that for soft speech, the mean gain for the proprietary fitting fell 15 dB below NAL-NL2 targets for 3,000 Hz and 21 dB for 4,000 Hz. For average level speech, the mean differences were 9 dB and 13 dB respectively.

ZAUD: This would seem to have an effect on speech recognition.

Mueller: I think even a beginning student of audiology would predict that this minimal audibility would reduce speech understanding for individuals fitted in this manner. They would be correct. Ron Leavitt and Carol Flexer [25] fit hearing-impaired individuals (typical downward sloping losses) who were experienced hearing aid users with seven different pairs of hearing aids and conducted aided QuickSIN testing [26]. The QuickSIN sentences were presented at 57 dB SPL (roughly average speech [23]). Six of the seven pairs of hearing aids were the premier models from the leading hearing aid companies. Special features such as directional microphone technology and noise reduction were activated. The seventh pair were 10-year-old analog, single-channel, omnidirectional hearing aids with no noise reduction features. Each of the six premier hearing aids were first evaluated while programmed to the manufacturer's first fit, and then also when programmed to the NAL-NL1. The old analog hearing aids were only tested programmed to the NAL-NL1.

The results of this study are plotted in Figure 4, which are the mean QuickSIN scores for the participants for all the aided conditions; the QuickSIN is scored in "SNR Loss" – the difference between the SRT-50 value for a given individual and that of the QuickSIN norms for individuals with normal hearing. In Figure 4, a -10 dB SNR would indicate that mean performance is 10 dB worse than expected for normal hearing individuals (in other words, down is bad).

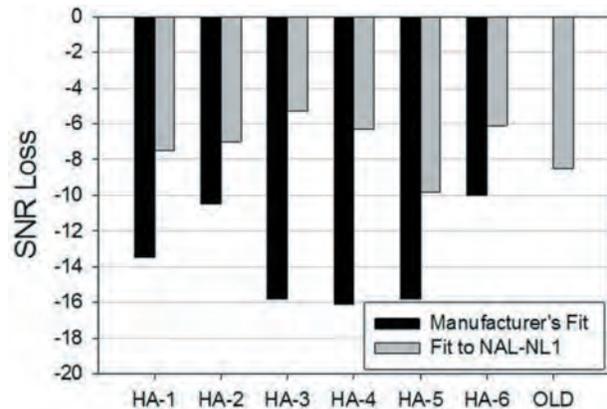


Figure 4: Mean QuickSIN scores (SNR-Loss) for hearing impaired individuals fitted with six different pairs of hearing aids. One pair (labeled "old") were 10-year-old analog single-channel products; the other six pair were the premier model of the six leading hearing aid manufacturers.

If you first look at the far right bar, you see that the mean SNR-Loss for the old analog instruments was around 8 dB SNR-Loss. Compare this to the mean performance for the manufacturers' recommended fitting for the six different new premier hearing aids (dark bars). The results for HA-6 are fairly similar to those of the old analog hearing aids, but note that when the participants used HA-3, HA-4 or HA-5, their scores were about 8 dB worse.

As we would predict, when the premier hearing aids were programmed to the NAL-NL1 rather than the manufacturer's recommended first fit, you now see that most of the new products are performing 2 dB or so better than the old analog instruments. Note that with HA-3, for example, the mean QuickSIN score improved by over 10 dB simply by changing the programming from manufacturer's fit to NAL. This is clearly a good example that it's not the brand of the hearing aid that matters so much, it's the person who programs it. A 10 dB SNR improvement could be a life changing difference for some hearing aid users. Similar findings for speech recognition in quiet were reported by Valente et al. [24]. Shown in Figure 5 are the speech recognition scores for a NAL-NL2 fitting compared to the manufacturer's proprietary fit. Observe that the 25th percentile of the proprietary fitting exceeds the 75th percentile of the manufacturer's fit.

As you might expect, these speech recognition advantages for the NAL-NL2 carry over to the real-world, as evidenced by self-assessment inventories. Valente et al. [24] report there was a significant advantage for the NAL-NL2 fitting (compared to the proprietary) observed with the self-

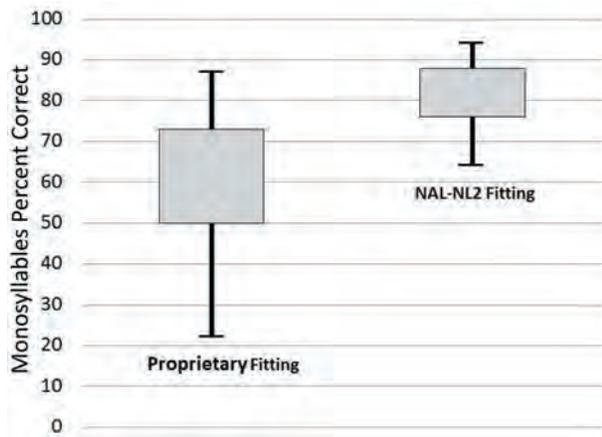


Figure 5: Percent correct performance for speech recognition in quiet for the manufacturer’s proprietary fitting compared to a verified NAL-NL2 fitting. Data from Valente et al. [24].

assessment ratings of the Abbreviated Profile of Hearing Aid Benefit (APHAB) – it was a cross-over design, so all 24 participants had both conditions. The APHAB findings from Valente et al. [24] are plotted in Figure 6, and for interest, the APHAB norms for elderly individuals with normal hearing from Cox [27] have been added. Two things are apparent: The NAL-NL2 fitting is superior to the proprietary default, and when fitted to the NAL algorithm, the real-world performance for this group of hearing aid users was equal to individuals with normal hearing.

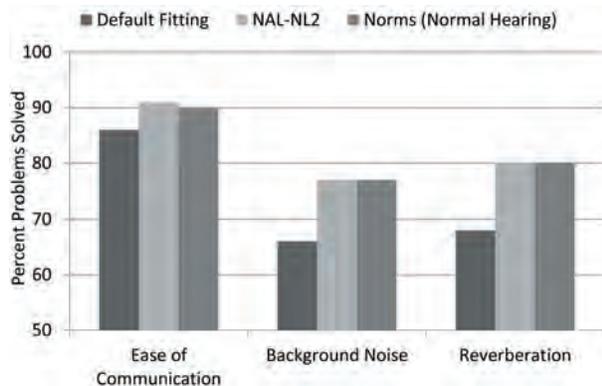


Figure 6: APHAB performance (percent problems solved) for the Ease of Communication, Background Noise and Reverberation subscales comparing the proprietary (default) fitting and the NAL-NL2 fitting, from Valente et al. [24]. For comparison, also shown are the normative data from Cox [27] for elderly with normal hearing.

Is all this talk about proprietary fitting really necessary? Are they really being commonly used? We have a good idea that this is the case, at least in the U.S., and probably in Europe as well. Here is a snapshot. Leavitt et al. [28] reported on probe-mic measures for a total of 97 individuals (176 fittings) who had been fitted at 24 different facilities within the state of Oregon. The participants were current hearing aid users and were wearing hearing aids that came from 16 different manufacturers; the average age of the product was 3 years. These researchers found that in general, all the hearing aid users were under-fit.

When RMS errors were computed, they found that 97% of the wearers were >5 dB from NAL-NL2 targets, and 72% were >10 dB.

ZAUD: You have been talking about proprietary fittings, but all manufactures have the option of using either the NAL-NL2 or DSLv5.0 in their fitting software. Does this reduce the need for verification?

Mueller: In a word – make that two words – absolutely not! “A rose is a rose is a rose,” is a commonly used phrase dating back to the early 1900s. I can assure you that the NAL is *not* the NAL is *not* the NAL, regardless what you might see on a manufacturer’s fitting screen. First, we would not expect the software fitting to the prescriptive target to be a perfect match in the real ear. We would expect variance above and below based on the individual’s RECD. That is, if the average RECD for a given frequency is 8 dB, and the individual’s RECD when fitted with a given earmold is 11 dB, then we would expect the output to be 3 dB above target. But the problem is bigger than this. Much bigger. Shown in Figure 7 are data from our comparative lab study mentioned earlier [22].

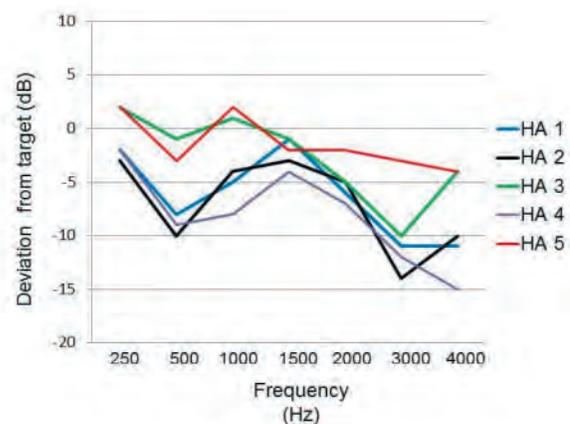


Figure 7: Mean deviation from NAL-NL2 target based on real-ear measured output (55 dB input signal; n=16) for the premier hearing aids from the five leading manufacturers. Hearing aids programmed to the manufacturer’s NAL-NL2.

These are the results for a 55 dB SPL speech-signal input, averaged over 16 ears for the premier product of five different manufacturers, programmed to NAL-NL2 (according to the software). What you see is the mean measured REAR deviation from the NAL-NL2 target. The deviations are similar to what we saw for the proprietary fittings. It is important to mention, that in all cases, *the deviation from target on the manufacturer’s fitting screen was no more than 1 dB*. Imagine audiologists, looking at the software fitting screen simulation and patting themselves on the back for being a good person and fitting to target, when it’s very possible they could be missing target by 10 dB or more in the high frequencies. Amlani et al. [29] reported very similar results. They found that the manufacturer’s NAL-NL2 fitting, on average, fell nearly 10 dB below real-ear NAL targets, for both soft and average speech inputs. This led to speech recognition

(Connected Speech Test) to be significantly poorer when their participants were fitted with the manufacturer's NAL-NL2 compared to a real-ear-verified NAL-NL2.

Are things better in 2020? As part of a larger study, we recently conducted probe-mic measures on 2020 premier hearing aids using 2020 software. Figure 8 shows the REAR findings for soft speech inputs (ISTS) for 16 NAL-NL2 fittings, all to the same mild-to-moderate hearing loss sloping from 30 dB in the lows to 70 dB in the high frequencies. We were careful to match the settings of the software to that of the probe-mic equipment; bilateral fitting, experienced user, gender neutral, closed earmold. As shown, and similar to previous reports, REARs fall well below NAL-NL2, with mean deviations of 10 dB or more. We did not sample all brands, so it's possible some manufacturers have a better match than this, but in the past under-fitting for the NAL-NL2 has been common.

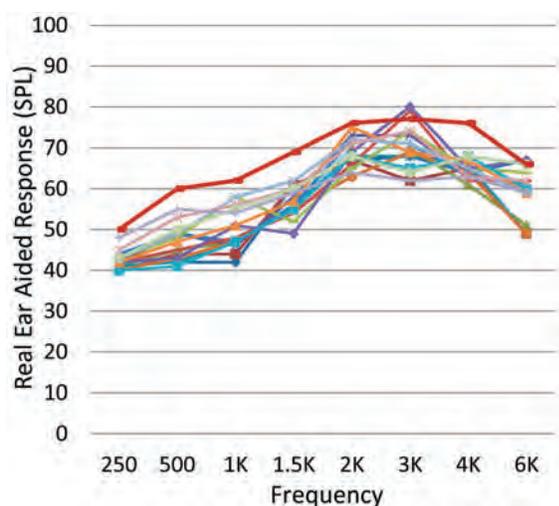


Figure 8: REARs of 16 fittings, programmed to the manufacturer's NAL-NL2 (Input: 50 dB SPL ISTS). Upper line is NAL-NL2 prescriptive target.

All of this is not really news. Going back to 2003, Hawkins and Cook [30], testing 12 hearing aids from different manufacturers, reported that gain in the high frequencies was 8–10 dB below the software simulation. Aazh and Moore [31] used four different types of hearing aids and programmed them to the manufacturer's NAL-NL1 using the software selection method. When probe-mic verification was conducted, only 36% of fittings were within ± 10 dB of NAL targets. Aazh et al. [32] conducted a similar study with open fittings. They reported that of the 51 fittings, after programming to the manufacturer's NAL in the software, only 29% matched NAL-NL1 targets within ± 10 dB. And this problem doesn't appear to be unique to the NAL methods. Folkeard et al. [33] reported that the manufacturer's DSLv5.0 fell ~ 7 dB below target for both soft and average inputs.

The bottom line is pretty simple. If we consider that our primary fitting goal is to optimize speech recognition, hearing aid users do the best when fitted to a validated prescriptive fitting. We also know that the software fitting screen is not correct, and therefore, the only way to know

the fitting is appropriate is to conduct probe-mic verification.

ZAUD: Perhaps your discussion here might encourage some clinicians to make probe-microphone verification a more routine part of their hearing aid fitting. For readers who have been away from probe-mic measures for a few years, is there anything new?

Mueller: If we look at the last 10 years or so, there have been some definite trends. While I believe audiologists still use the REIG for verification in some parts of the world, nearly everyone in the U.S. uses REAR targets; this provides a clear picture of audibility, and of course eliminates the need to conduct an REUR. Another area of change is that we finally have all agreed on a good speech signal for testing, the ISTS [34], [35], which is available on most all equipment and commonly used.

In more recent years, some changes include:

- The use of simultaneous bilateral measurements. Each hearing aid of course still needs to be programmed independently, but the bilateral measures do save some time. For example, if AGCo kneepoints were originally adjusted correctly, only one REAR85 presentation may be necessary.
- Some systems now have an automated method to inform the examiner if the probe tube is within the desired 5 mm of the eardrum. This relieves some apprehension for inexperienced examiners, and helps ensure valid measures.
- Most hearing aid companies have partnered with one or more probe-mic manufacturer to offer autoREMfit [36], [37]. This is when the hearing aid software and the probe-microphone equipment communicate with each other, and the fit to target is automated – only a few mouse clicks from the audiologist are needed. This isn't really new, as it's been available for 20 years [38], but only recently has it become widespread. There are still some minor issues to work out, but research shows that it is valid, and reduces the time spent on verification by about $\frac{1}{2}$ [33].
- Finally, from a procedural standpoint, more and more audiologists are conducting an initial RECD, and then using these values for the HL-to-ear-canal-SPL conversion along with the RETSPL (rather than the average RECD stored in the probe-mic equipment). This adds accuracy to the displayed ear canal audiometric thresholds (for audibility decisions), and in turn, adds to the accuracy of the prescriptive targets, which are calculated from these thresholds.

ZAUD: Is there a specific verification protocol that you recommend?

Mueller: In our most recent book, we have step-by-step guidelines for all types of probe-mic measures, which include verification of direction technology, noise reduction, frequency lowering, the occlusion effect and other fun-to-do measures [16].

Regarding basic verification, I would first pick my favorite prescriptive method (either the NAL-NL2 or DSLv5.0) from the fitting software and initially program to that. Then make programming changes to obtain a match to target for soft (55 dB SPL), average (65 dB SPL) and loud (75 dB SPL). Some people use 50–65–80 dB SPL, which is okay too. The key is to start with the soft input level – for some reason, people like to start with average, which I think is a mistake. Soft will nearly always be under-fit, so if you start with average, and obtain a target match for average, and then go to soft and make appropriate adjustments (increase gain), average will then be too loud, and you'll need to go back and re-program average. So why not start with soft? After soft, I would then go to loud (75 dB SPL). After programming loud, average should be pretty close to okay, as it falls in the middle of the two levels that already have been programmed correctly. At some point, I would probably also do an REOR, just to ensure that the degree of openness or tightness of the eartip meets my fitting goals.

It is then important to do an REAR85 to ensure that the MPO is set correctly. We used to be concerned that the MPO would be too high, but recently manufacturers have become pretty conservative in their default MPO settings, and now it's more common that we need to move our AGCo kneepoints up rather than down. Hopefully the audiologist doing the fitting has conducted pure-tone LDLs, and entered them into the probe-mic software, so we then have targets for the REAR85 measure. Finally, I'd present some of the obnoxious noises available on the probe-mic equipment at 85 dB SPL, to ensure that the output is "Loud, But Okay" and did not reach the hearing aid user's LDL (using the Cox 7-point loudness chart [39]). That's about it.

ZAUD: In closing, let's go back to the underlying issue, that many audiologists do not see the need for real-ear verification of gain and output. Is this something that should be addressed by professional organizations?

Mueller: To some extent, it already has been. Most organizations do have best practice guidelines regarding the fitting of hearing aids, such as those of the EUHA. All the guidelines I have seen over the past 25 years state that probe-microphone verification should be conducted. In guidelines published in 2005, the International Society of Audiology went so far as to state what variation from prescriptive target was allowable [18]. But – these are *guidelines*; there really is no penalty if they are not followed. I did hear that in the province of British Columbia in Canada, disciplinary action can be taken for not conducting verification routinely – perhaps the loss of a person's dispensing license. But this, unfortunately, is not common.

In the near future, over-the-counter (OTC) hearing aids will be available in the U.S. It's going to be important that audiologists differentiate themselves from what can be purchased in Aisle 7 of the neighborhood Big Box store. It's expected that some of these OTC products will come with smartphone apps for the prospective user to fit

themselves. As I mentioned earlier, at least one study has reported that hearing aid users will fit themselves to gain that is quite similar to the NAL-NL2 prescription [13]. If audiologists are not conducting real-ear verification, and not fitting to the NAL-NL2, logic would suggest that for individuals who can navigate the fitting app successfully, they would be better off to fit themselves!

Several years ago, Catherine Palmer, now the President of the American Academy of Audiology (AAA), wrote an article describing how the failure to do verification is an ethical violation [40]. I agree. Consider that most professional audiology organizations and licensure boards have a Code of Ethics. Here is an example from the Ethics Code of the AAA [41]: *Principle 4: Members shall provide only services and products that are in the best interest of those served.* I fail to see how charging someone a sizeable amount of money, and then sending them out the door with a fitting that has little or no audibility for soft speech, is in the best interest of the patient. I think we can do better.

Abbreviations

- AGCo: automatic gain control for output
- APHAB: Abbreviated Profile for Hearing Aid Benefit
- DSL: Desired Sensation Level
- ISTS: International Speech Test Signal
- JND: just noticeable difference
- LDL: loudness discomfort level
- MPO: maximum power output
- NAL: National Acoustic Laboratories
- NL1/NL2: non linear
- OTC: over-the-counter
- REAR: real ear aided response
- RECD: real ear coupler difference
- REIG: real ear insertion gain
- REM: real ear measures
- RETSPL: reference equivalent threshold in sound pressure level
- REUR: real ear unaided response
- REOR: real ear occluded response
- RMS: root mean square
- SII: speech intelligibility index
- WDRC: wide dynamic range compression

Notes

Competing interests

The author declares that he has no competing interests.

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PRESIDENT'S MESSAGE

Continued from page 3

audiologists, private practice audiologists, educational audiologists, rehab audiologists—find the organization(s) that meet your needs and get involved! Appreciate the importance of education and advocacy in the hearing healthcare space.

Acting like a doctoring profession means practicing to the top of our scope of practice and following best practices. Then we provide true value. Understand the importance of collaboration with other healthcare specialists to optimize patient outcomes, refer when appropriate, educate healthcare providers and the public on the importance of hearing healthcare to overall health and wellbeing including how it relates to other comorbidities. Fight for your scope of practice and for recognition of treatment and rehabilitative services for insurance reimbursement, and donate your time, talent, and funds to facilitate change. I may sound like a broken record, but the importance of audiologists completely evolving to a doctoring profession and differentiating ourselves is crucial to the survival of the profession and cannot be overstated.

There is no longer time to procrastinate. It is time for audiologists to wake up! Apathy, resulting in lack of action and negativity, is nibbling around the edges of audiology, and if we aren't careful, it will eat our profession alive. The GOOD NEWS is that we control what happens next. The answers lie within us, and only we can do the work. As I sit here with my cup of coffee reflecting on the past two months, instead of feeling apprehension, I feel anticipation and excitement for the year to come.

Let's stop complaining and get involved at the state and national level! Let's spread positivity and empowerment to students, not fearmongering. Let's evolve our service and delivery models to meet the needs and desires of today's patients. Let's employ innovative thinking to reinvent and grow awareness of Audiology and hearing healthcare. ADA has always led and been the champion for our profession; this is what we do! Let's make 2022 a defining year for Audiology! Who is ready to do the work with me? ■



TAILOR-MADE EAR COUPLING

The Forgotten Science of Customization

By Brian Taylor, Au.D.

In Chapter 9 of the Studebacher and Hochberg textbook *Acoustical Factors Affecting Hearing Aid Performance* (second edition), esteemed professor, Margo Skinner¹, wrote, “Before any hearing aid evaluation, it is essential to optimize the coupling of a hearing aid to the ear.” Published in 1993 during the seminal days of prescriptive fitting methods — an era when hearing aids were still often selected and fitted in the clinic using the now outdated comparative method, Skinner highlighted a critical aspect of the hearing aid fitting process: When an earmold is properly customized to the individual’s ear it results in four key benefits:

- ✓ Long-term physical comfort of the device on the ear
- ✓ Minimal feedback at desired amplification levels²
- ✓ Gain out to 6000 Hz is likely to be maintained
- ✓ Reduction of the occlusion effect

In the same chapter, she went on to write these four criteria should be met by all hearing aids on the day of the fitting, and that although it might be difficult to meet these goals, to achieve the best possible outcome for the individual, it is essential to fulfill these four conditions. Today, given the popularity of instant fit ear tips, many of us seem to have minimized (or even forgotten) the advantages of a customized coupling system and how these four conditions contribute to wearer benefit.

In 1993, getting Skinner’s four factors right required the fitting of a customized earmold – it was, after all, really the only coupling option as instant fit ear tips didn’t really exist. Back then, a successful physical fit of the earmold was determined by the amount of time the clinician could spend with the patient, good clinical judgment, and no small dose of luck. First, a custom earmold had to be tailored to the shape of the individual’s ear – a process that could take a few in-person visits. Second, once the earmold was comfortable, the process of finding the proper vent dimensions to minimize occlusion while maintaining high frequency gain without feedback was sometimes an arduous tightwire act — one requiring patience from both the wearer and the clinician. What has changed in thirty years is that few clinicians routinely order custom earmolds today.

Open-canal, thin tube mini-BTEs with instant fit ear tips and automatic feedback cancellation were gamechangers for audiologists when they were introduced in the early 2000s. The combined effects of these two features made the customized earmold process much less daunting. Instant fit ear tips and automatic feedback cancellation, two features introduced to the market at about the same time, are a little bit like the chicken and egg. It's difficult to know which of the two caused the other to happen. On balance, you often cannot achieve reasonable levels of high frequency gain open-canal BTE using instant fit ear tips without effective automatic feedback cancellation.³ And as a standalone feature, automatic feedback cancellation is not all that interesting unless it is implemented in a smallish, open-canal type of device. This focus of this article is to demonstrate the advantages of customized ear coupling for the receiver in-the-canal (RIC) devices. Commonly known as custom RIC molds, there are several often forgotten advantages of using RIC molds — advantages that cannot be found in any instant fit coupling system.



Figure 1: An example of an open-canal, thin tube mini-BTE with an instant fit ear tip

The combination of these two features: automatic feedback cancellation and instant fit, open-canal mini-BTEs took the market by storm around 2003. As Figure 2, created and published by Karl Strom at the Hearing Review last summer keenly demonstrates, the popularity of BTEs began to grow then. Note in Figure 2 the big uptick in “traditional BTEs” beginning around 2006. This uptick, of course, was largely driven by sales of the open-canal, thin tube mini-BTEs, which really weren’t all that traditional when compared to their bulkier cousins – the much larger, conventional BTE. Also notice in Figure 2, around 2009, the “traditional BTE” was supplanted by the even sleeker thin-wire, receiver in the ear (RIC) BTE.

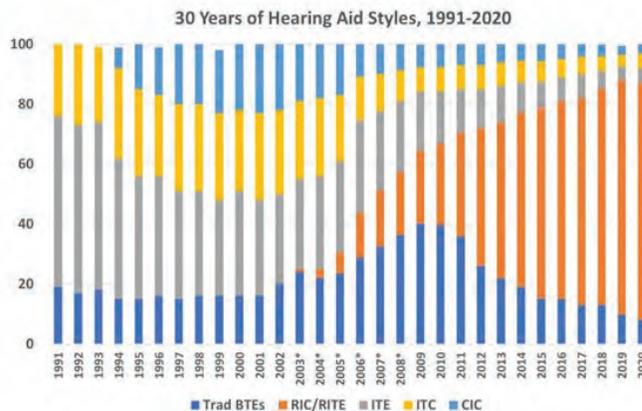


Figure 2. June 2021 Hearing Review data from Karl Strom. Reprinted with permission.

GOING ALL-IN ON COMFORT

For the past several years, about 80% of total hearing aids sales have been RICs. A clear trend away from the use of custom-fitted earmolds, as with few exceptions, most RICs are dispensed with instant fit ear tips. Available in five or more options, from completely open and flanged to double-domed and closed. As their name implies, instant fit ear tips are fitted in a few minutes and they are usually extremely comfortable for the wearer. Instant fit ear tips enable hearing care professionals to fit cosmetically appealing and comfortable devices with minimal occlusion. But they come with a potential downside: Instant fit ear tips are the coupling method of choice for on-line hearing aid retailers. Additionally, two the key benefits of custom coupling — minimal feedback at desired amplification levels and a smooth frequency response out to 6000 Hz with sufficient gain - can be difficult to achieve with instant fit ear tips for many high frequency hearing losses.

Instant fit ear tips are comfortable and who isn't looking for more comfort in their life. Plus, instant fit ear tips are a convenient, off-the-shelf solution. But perhaps too often we are sacrificing many of the benefits of a custom earmold at the altar of comfort and convenience. Given the variability associated with how ear tips fit in an individual's ear, however, clinicians roll the dice when it comes to optimizing the benefits of RIC devices. Without customized coupling, when hearing care professionals overprescribe instant fir ear tips, they are prone to making three critical mistakes that could affect wearer benefit.

- 1. Underfitting the low and mid frequencies.** Yes, many types of the instant ear tips effectively overcome the occlusion effect, but in many cases, they roll-off excessive

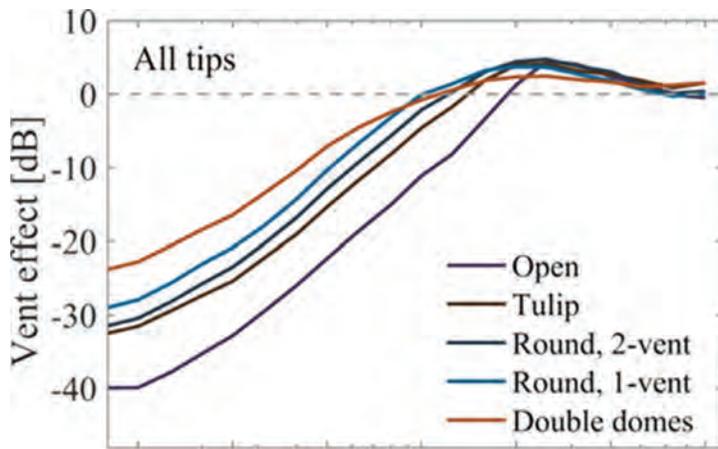


Figure 3. The venting from instant-fit tips and domes is often much different than advertised. “Closed domes is not always closed in the ear”

amounts of low – and even mid-frequency gain. For example, as shown in Figure 3, Balling and colleagues⁴ found that completely open ear tips had an *average* vent loss of about 20 dB at 500 Hz and 10 dB at 1000 Hz, with considerable individual variability – many wearers had substantially more roll-off at those frequencies. Even the more occluding double dome ears tips, according to this study, have an average vent loss at 500 Hz of about 10dB, with a few wearers experiencing 10 to 15 dB of roll off at 1000 Hz.

This excessive low and mid-frequency roll-off can negatively affect the audibility of speech and the performance of directional microphone systems for wearers with more than a mild hearing loss at 500 and 1000 Hz.

2. Not accounting for the clear path noise has to the eardrum. Often when a more open, instant fit ear tip is used, the resonance of the unoccluded ear canal is maintained, usually around 2000-3500 Hz. This peak is often as large as 15-20 dB in many wearers. Now, imagine a listener with cocktail party-like background noise of 60 dB SPL in the 2000 to 3000 Hz range coming from behind the wearer. It’s possible that good directional microphone technology will reduce the amplification for this noise by 15-20 dB, compared to speech from the front. But when a more open, instant fit ear tip is used this noise has a clear path to the eardrum. And because of the boost from the ear canal resonance when this noise reaches the eardrum it won’t be 60 dB SPL, but 75-80 dB SPL. Therefore, one advantage of a closed fitting is to alter the clear path of noise and minimize this problem. Yes, this also means that the desired speech signal from the front doesn’t receive the resonance boost, but that easily can be accounted for by programming the appropriate amount of amplifier gain to maintain the natural ear canal resonance of the wearer.

Additionally, if the fitting is more closed with a custom RIC mold, another advantage will be that the earmold is more likely to act as an earplug for surrounding noise. This more closed coupling system does not impact the desired amplified speech signal, as it has a different pathway to the ear canal via the hearing aid receiver. This effect is depicted in Figure 4 where it is clear to see that as the coupling becomes more closed, the directional benefit improves.

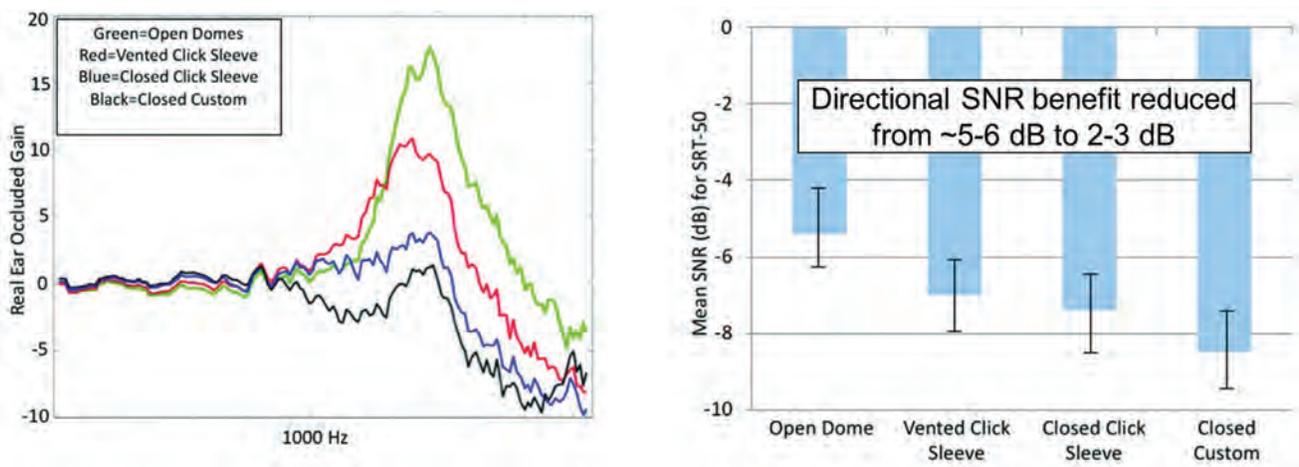


Figure 4. Note in the left panel, top to bottom that the real ear occluded gain (REOGs) corresponds to the speech recognition in noise results, which are shown from left to right in the right panel.

The ear coupling also affects the performance of processed-based digital noise reduction (DNR) algorithms. When noise has an open pathway to the eardrum and there is also leakage out of the ear of the amplified speech signal, both these factors reduce the signal to noise ratio (SNR) at the eardrum. An SNR that might be +10 dB or better in the lower frequencies with good noise reduction processing and a closed earmold, likely will be 0 dB SNR if that same fitting is open. Stated differently, steady-state, diffuse noise such as the hum of a refrigerator or the drone of a humidifier are primarily low frequency sounds. When the coupling system is completely open, these sounds remain unprocessed by the hearing aids, take a direct path to the eardrum and are not attenuated by the DNR system. Just how much the openness of the ear coupling effects the performance of DNR is shown in Figure 5. The bottom line is that if we want the sophisticated processing of the different features to function optimally, then we do not want direct sound to have a pathway to the eardrum - a result much more likely to happen with many instant fit ear tips – even double domes.⁵

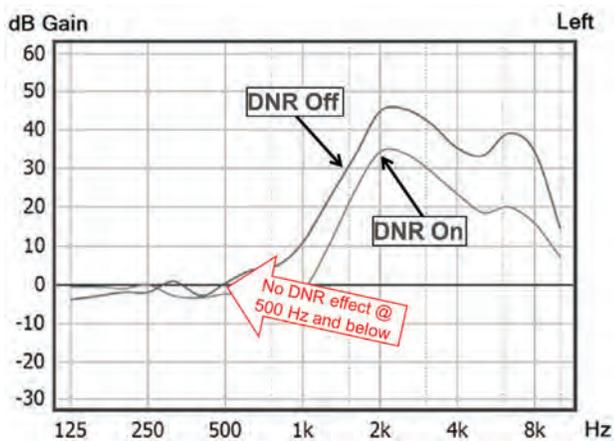


Figure 5. Openness of coupling also can adversely affect DNR

3. Underuse of the feedback canceller. Maybe not directly related to the use of instant fit ear tips, but nevertheless a common problem associated with fitting hearing aids today. I’ve examined a lot of real-ear measures over the years and invariably upon first fit, RIC devices coupled to the ear with instant fit ear tips are more than 10 dB below the high frequency NAL target. Of course, it is easy to bump up the gain when you see this, but I think we can be more confident when bumping up the high frequency gain if a custom earmold is used in combination with modern feedback cancellers.

Hearing aids have had effective feedback cancellers for more than a decade that enable them to easily match many high frequency gain targets without feedback. The best feedback cancellers allow you to squeeze another 10 dB of high frequency gain from the device, which expands the fitting range up to 20 or 25 dB. But when clinician’s rely on first-fit settings, and don’t verify a validated gain target with real ear measures, it is common to underfit in the highs, Therefore never really pushing the automatic feedback canceller to squeeze additional gain from the device. In many cases, when the high frequencies are underfit, the audiologist is essentially not engaging the feedback canceller – a feature that wearers pay for when they purchase devices, but one that may never ever have to do its job.

Here a word of caution is warranted. Even though the automatic feedback canceller may allow you to turn up the high frequency gain, only increasing the high frequencies without an appreciable boost in low frequency gain can result in-wearer perceptions of poor sound quality or “tinniness” – another important observation from Margo Skinner and a task more easily accomplished with use of a custom earmold.

CHECKING ALL THE BOXES

Given the variability in the quality of physical fit associated with ear tips, it’s worth revisiting Skinner’s four benefits of customized coupling.

- ✓ Long-term physical comfort of the device on the ear
- ✓ Minimal feedback at desired amplification levels
- ✓ Gain out to 6000 Hz is likely to be maintained
- ✓ Reduction of the occlusion effect

Although instant fit ear tips provide outstanding comfort for the wearer without occlusion, and they are quick to fit for the clinician, they come with a tremendous potential downside. Beyond a mild hearing loss, it can be next to impossible to meet all four of Skinner’s criteria with today’s RIC unless it is coupled to the ear with a custom-made earmold – a task that must be conducted by a licensed professional and cannot be duplicated by on-line OTC retailers.

For many wearers, you cannot readily achieve these four benefits without a customized coupling system. You could, in fact, argue that nearly all wearers benefit from customized coupling – that it is worth the time to take an ear scan (or ear impression) and carefully tailor the physical fit to the ear canal dimensions of the wearer.

But wait there's more. There are two additional benefits of a customized coupling system, often overlooked by hearing care professionals – benefits that transcend the magnitude of hearing loss.

- ✓ Easier for the wearer to insert into the ear canal
- ✓ Stays secure in the ear

The intent of this article is not to bash instant ear tips. Of course, for the appropriate candidate they are tremendously effective and should remain an integral part of the clinical “toolbox.” Rather, the point here is to remind audiologists of the forgotten benefits of customized earmolds – benefits audiology pioneers like Margo Skinner promoted more than 30 years ago that seem to be getting lost in the maw of ever-improving hearing aid technology.

As OTC device options loom, audiologists' ability to customize the coupling of earmolds of all devices could be a key differentiator in their success. All things considered; clinical best practices warrant that variability be driven out of the decision-making process. Routine use of customized coupling, even for RICs, is one more way to reduce this variability and improve the probability of excellent patient outcomes. ■

Brian Taylor, Au.D., is director of scientific and product marketing at Signia, a division of WS Audiology. He is the editor of *Audiology Practices*, the quarterly journal of the Academy of Doctors of Audiology, and an editor-at-large for the *Hearing Health and Technology Matters (HHTM)* blog. He has written five textbooks and numerous articles and lectures extensively on topics related to clinical practice, hearing aids, and business management.



FOOTNOTES

1. Margaret “Margo” Skinner was a professor of otolaryngology and director of the Cochlear Implant and Hearing Rehabilitation Program at Washington University. She was the author of the 1988 textbook, *Hearing Aid Evaluation*. Skinner died in 2008.
2. Desired amplification levels should be interpreted as both gain at a preferred loudness level for the patient and prescribed gain that closely matches a scientifically validated target, like the NAL-NL2. Often, according to research, these are similar values.
3. Although all major hearing aid manufacturers employ automatic feedback cancellation, there are considerable differences across product lines. For example, one key metric of a feedback canceller is additional gain before feedback (AGBF). Based on the findings of Marcrum et al (2018) * there is an 8 to 10 dB advantage on AGBF for some hearing aid manufacturer's feedback canceller compared to others. This 8 to 10 dB advantage on AGBF can expand the fitting range of the instrument by 15-20 dB. This means that a hearing aid with a mediocre feedback canceller can match high frequency gain targets for losses up to 50dB at 4KHz, while a high quality feedback canceller can match high frequency gain targets for losses up to 65 or 70dB at 4 KHz.

*Marcrum, S. C., Picou, E. M., Bohr, C., & Steffens, T. (2018). Feedback reduction system influence on additional gain before feedback and maximum stable gain in open-fitted hearing aids. *International Journal of Audiology*, 57(10), 737-745.
4. This is one of the few published studies that has examined the variability of instant fit ear tips, which is surprising given the popularity of RIC devices.*

*Balling LW, Jensen NS, Caporali S, Cubick J, Swital-ski W. Challenges of instant-fit ear tips: What happens at the eardrum? *Hearing Review*. 2019;26(12) [Dec]:12-1
5. For a more in-depth analysis of the problems associated with a more open fit and the benefits of a more closed fit, please see this AO Signia Expert Series course from Gus Mueller at <https://www.audiologyonline.com/audiology-ceus/course/signia-expert-series-ten-or-36750>



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As part of an ongoing commitment to help hearing healthcare providers achieve their business goals, CareCredit and Allegro Credit continue to develop educational resources featuring industry experts sharing innovative solutions and strategies to enhance the patient experience, optimize cash flow and foster successful partnerships. In this whitepaper **Dr. Keith Darrow, PhD, CCC-A**, Clinic Owner and cofounder of AuDExperts, discusses the importance of cash flow and how creating useful and valuable partnerships can help you build your business.



Q

Can you share why you recommend hearing healthcare providers focus on cash flow to help achieve their business goals?

Cash flow is core to running your business. I like to think of it as the gasoline that keeps your business running. Cash flow is that amount of money that comes into your business each month, quarter or year. Cash flow is important because it determines if you can pay your employees and meet your bills. Every practice needs a certain amount of cash flow to sustain it. To stress the importance of cash flow, I like to use the patient experience as an analogy. Treating hearing loss is expensive, and one concern for patients is paying a large sum for hearing devices. Many patients can't afford to give a large sum of money upfront, so they may

"You'll need a consistent stream of income — you can't depend on spikes in cash flow to grow your business long-term."

prefer to finance their device using a CareCredit credit card, Allegro installment loan or Allegro lease every month. Patients want a monthly payment that fits into their budget. That is exactly how cash flow works. We all know that accounting can be a nightmare. But by focusing on cash flow, you can determine

continued >>

what money you can reinvest in your business to grow and help meet your business goals. Just like a patient, you'll need a consistent stream of income — you can't depend on spikes in cash flow to grow your business long-term.

Q What is your recommendation for calculating cash flow?

One thing my father told me before he passed was, "You need a good lawyer and a good accountant." Owner operators put their heart and soul into helping patients get the care they need by diagnosing and recommending treatment. However, there are some instances where the owner may not have the business knowledge to calculate and analyze this. There's nothing wrong with that. If you asked me to develop an accounting system with proper controls and forecasting, there is no way that I could do it at the level of a Certified Public Accountant (CPA). Partner with an accountant. Bring in an outside CPA and start by going through financials to determine your practice's cash flow. From there, your CPA partner can give you ideas on how to innovate and optimize your cash flow to help set your practice up for success. From my experience, I've never seen a practice grow without one, knowing their cash flow and two, having negative cash flow. One thing that can shrink your practice is to stop reinvesting in your business, stop reinvesting in marketing, stop reaching out to patients and stop innovating your practice because your cash flow does not allow it.

Q Are you talking about the importance of having partnerships in practice — assembling a team of experts to help guide the practice owner to the right direction and help them achieve their goals?

Absolutely. One thing I stress with all my providers is that treatment is a team sport. It goes beyond the Audiologist, the ENT or the Hearing Instrument

Specialist. We can even think bigger than in the practice. What partners are you bringing into your practice that help enable care? Could it be someone like AuDExperts who can help you develop a plan to grow your practice and achieve your goals? Could it

"Treatment is a team sport. It goes beyond the Audiologist, the ENT, or the Hearing Instrument Specialist."

be someone like CareCredit or Allegro that provides innovative financing solutions that patients can choose from? Or could it be another provider in another specialty like a dentist who refers patients to your practice? Treatment is a team sport and the practice owner is the quarterback.

Q How can a practice help convert their tested-not-treated patients to enhance their cash flow and increase the average patient revenue?

Tested-not-treated — these are some of my favorite words in the hearing industry. Why? Because they present a unique opportunity to help a patient with their hearing healthcare. One way to identify these patients is to go through your Practice Management Software (PMS). This software can help you take a data driven approach to your practice. It can help you mine data and identify opportunities within your patient base. Once you identify those opportunities, you can find ways to bring those patients back to the table and leverage your partners in practice to help move forward with care. You could use your manufacturer partners by highlighting their latest technology and how it meets their lifestyle needs. You could use your financing partners like CareCredit or Allegro to discuss innovative financing options you now offer. You could even do a combination of partners to help move the patient forward with care. Many patients are fearful of what they don't understand. You can use your PMS partner to identify those patients who are dealing with

continued >>

uncertainty and leverage your other partners to help alleviate it. Ultimately, you want to use those partners together to help connect patients to a higher quality of life where they see the value in hearing healthcare.

Q Do you see value in investing in a PMS system as an owner-operated practice?

Absolutely. I do like the value of having a PMS system. Frankly, if you use paper you might just want to close your doors. One of the many things that your practice should invest in is the best technology for your practice — and that includes the best PMS system for your practice. A PMS system can help you see what's

“One of the many things that your practice should invest in is the best technology for your practice — and that includes the best PMS system for your practice.”

happening in your practice including your cash flow and trends, help you set goals for your practice, and measure how you are building towards them.

Q Based on your experience with helping practices nationwide, how does in-house financing affect cash flow?

Hearing professionals are in patient care to help people. That is the fuel that gets them up every day. As a result of this, there are instances where providers may bend the rules a bit so they can help every patient. This is where in-house financing may have been born. I actually have an experience with this firsthand. I met this amazing couple during my time as a clinical audiologist. They could not afford to pay for the hearing devices up front. I decided to create an in-house financing program for them that would meet their needs and help them move forward with care. They were great people and even invited me to their wedding. However, it took me 16 months to cover my cost of goods sold — let alone to pay for the front office and my fixed expenses. What

I learned from that experience is that in a business with a high cost of goods sold, like a hearing practice, in-house financing doesn't make sense. You may have a large accounts receivable, but it may not help you cover your cost of goods sold or your fixed costs when those bills become due. Options like the CareCredit credit

“As a business owner, I've learned the faster your cash flow comes in, the easier it is to pay for bills and reinvest in your business.”

card and the Allegro installment and lease programs let patients select which financing option works best for them — but they can also help providers optimize their cash flow, because they may not have to wait weeks or months to get paid. It can happen in a matter of days. As a business owner, I've learned the faster your cash flow comes in, the easier it is to pay for bills and reinvest in your business.

Q What are some other ways practices can innovate to help optimize cash flow?

As I said earlier, I believe that treatment is a team sport. It's important to look at how we can help patients achieve the best outcomes by approaching treatment together. It really extends past the four walls of any hearing practice clinic. When it comes to running a great clinic where you are looking to reduce tested-not-treated patients and create more cash flow, you need to invest in great partners. You may need a great CPA, attorney, marketing agency and other advisors. That's why I'm so proud of the work and the community of like-minded practices we've established at AudExperts. I've been doing this for over 20 years and my partnerships have helped me grow my business, because they all came together with a singular goal to help me have patients move forward with treatment and build my cash flow.

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Things you can do in your practice today

- Analyze your operations. Identify what partnerships you can bring in to enhance your business.
- Keep learning. Seek out information that helps you innovate your practice and empowers you to take care of your patients.
- Review your technology. Are you using a PMS system that meets your practice's needs?
- Make time with your CPA partner to review your cash flow and ask for advice on how to achieve your business goals.

CareCredit and Allegro Credit can help you manage uncertainty along your patient journey. Each patient has unique financial and lifestyle needs. The more options you can offer, the more likely patients may be able to move forward with care.

Not a CareCredit provider yet? **Call (800) 300.3046 (option 5)** to enroll today.



To learn more about how to use financing partnerships to grow your practice, **scan** the QR code to make an appointment.

Data fees may apply. Check with your service provider.



Dr. Keith Darrow is the cofounder of AuDExperts, a company that helps private hearing practices streamline their operations and build their legacy through community. His clinical experience includes a fellowship at the Brigham and Women's Hospital, and he is the co-founder of the Hearing and Brain Centers of America. Dr. Darrow is a nationally recognized speaker, coach and trainer, and researcher with his work being cited multiple times.

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Racial and Ethnic Diversity in Audiology

By Carolyn Smaka, Au.D., Debbie Abel, Au.D., Jerald James, Au.D., and Kate Witham, MS

The United States is becoming more racially and ethnically diverse according to data from the U.S. Census Bureau. It is projected that by 2045, no single racial or ethnic group will be the majority in the U.S. (Vespa et al., 2020).

Diversity in audiology is critical to meeting the needs of an increasingly diverse society. Several studies indicate that health disparities exist in hearing care (e.g., Nieman et al., 2016; Mamo et al., 2016). Healthcare teams who reflect the diversity of their patient populations have a clear advantage in their efforts to deliver culturally competent care (Tulane University School of Public Health and Tropical Medicine, 2021). Diversity among healthcare professionals can promote better patient care as well as a sense of belonging, comfort, and trust for patients. There has been interest in diversity in healthcare for at least the past few decades. In 2003, the Institute of Medicine (IoM) of the National Academies Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care proposed increasing the proportion of underrepresented racial and ethnic minorities in the health professions as part of a multi-level strategy to address health disparities. The IoM publication, *In the Nation's Compelling Interest, Ensuring Diversity in the Healthcare Workforce*, cites a multitude of evidence-based studies indicating that increased diversity in the health professions is associated with improved access to care, greater patient choice and satisfaction, higher patient trust and compliance with treatment, and better educational experiences for healthcare students (Institute of Medicine, 2004). More recently, a 2021 JAMA study looking at diversity in healthcare concluded that additional policies are needed to strengthen and support a healthcare workforce that is more representative of the population (Salsberg et al., 2021).

Phillips (2014) summarizes decades of research concluding that diversity is also good for business. She reports that teams that are racially and ethnically diverse have enhanced creativity, better problem solving and decision making, and show more innovation. Diversity in the workplace has also been reported to foster increased employee morale and retention (Tulane University School of Public Health and Tropical Medicine, 2021).

Racial and Ethnic Diversity in Audiology - By the Numbers

Today, the profession of audiology lacks racial and ethnic diversity. Estimates of racial and ethnic diversity in audiology can be made by comparing survey data from audiologists to public sources for U.S. demographic statistics. Currently, of the 13,727 audiologists certified by the American Speech-Language-Hearing Association, 92% are White, 3.7% are Asian, 3.3% are Hispanic or Latino, 2.5% are Black or African American, 1.4% are Multiracial, 0.2% are Native American, and 0.1% are Native Hawaiian or Other Pacific Islander (ASHA, 2021). According to the U.S. Department of Health and Human Services Administration (HHS), in the U.S. workforce, 64.4% are White, 16.1% are Hispanic, 11.6% are Black or African American, 5.3% are Asian, 1.8% are Multiracial, 0.6 are Native Americans, and 0.2% are Native Hawaiians or Other Pacific Islander (U.S. Department of Health and Human Services, 2017). These data are displayed in Table 1. As can be seen in the table, racial and ethnic groups other than White are underrepresented in audiology as compared to the U.S. workforce.



A lack of diversity is not unique to audiology; disproportionate representation of racial and ethnic groups is seen in many healthcare professions (U.S. Department of Health and Human Services, 2017; Salsberg et al., 2021). How does audiology compare to similar healthcare professions? In speech-language pathology, 91.6% of clinicians are White, and the distribution of other races/ethnicities is similar to audiology (ASHA, 2021). According to HHS (2017) data, among dentists, 74.8% are White, 6.1% are Hispanic, 3% are Black or African American, 14.3% are Asian, 0.1% are Native American, and 1.7% are multiracial. HHS also reports that of optometrists, 78.4% are White, 3.9% are Hispanic, 1.8% are Black or African American, 13.7% are Asian, and 1.8% are Multiracial.

Table 1 shows the numbers compared across professions. Like audiology, dentistry and optometry have a higher percentage of White professionals proportionally and lower percentages of Hispanic, Black, and Native American professionals as compared to the U.S. workforce. Dentists and optometrists have higher representation of Asian professionals as compared to the U.S. workforce. From the data, we see that audiology is predominantly a homogeneous profession, even more so than these similar healthcare professions.

Is there more diversity in the pipeline for audiology? The 2020 Audiology Student Census, a survey conducted by the Student Academy of Audiology, included 418 responses from 83 universities (Tittle et al., 2020). Of audiology students surveyed, 81.9% are White, 4.6% are Hispanic, 2.9% are Black or African American, 6% are Asian, 0% are Native American, and 4.3% are Multiracial. The survey data suggest that there is more diversity in the audiology student population than among audiologists, although an underrepresentation of Black students, Hispanic students, and Native American students and an overrepresentation of White students as compared to the U.S. workforce is seen. Data is displayed in Table 1.

Table 1. Race/ethnicity of the United States workforce across three healthcare professions.

	White	Hispanic	Black or African American	Asian	Native American	Multi-racial
U.S. Workforce^a	64.4%	16.1%	11.6%	5.3%	0.6%	1.8%
Audiologists^b	92%	3.3%	2.5%	3.7%	0.2%	1.4%
Dentists^c	74.8%	6.1%	3%	14.3%	0.1%	1.7%
Optometrists^c	78.4%	3.9%	1.8%	13.7%	NR	1.8%
Audiology Students^c	81.9%	4.6%	2.9%	6%	0%	4.3%

^a Data from U.S. Department of Health and Human Services Administration, National Center for Health Workforce Analysis (2017).

^b Data from ASHA's 2020 Member & Affiliate Profile (ASHA, 2021).

^c Data from 2020 Audiology Student Census (Tittle et al., 2021).

Initiatives to Increase Racial and Ethnic Diversity in Audiology

Federal legislation to address diversity in healthcare was introduced in 2021. The Allied Health Workforce Diversity Act (H.R. 3320/S.1679) was modeled after the Title VIII Nursing Workforce Development program that has successfully increased the percentage of racial and ethnic minorities pursuing careers in nursing. The goal of the legislation is to increase the number of minority professionals in allied health to address underrepresentation in audiology, physical therapy, occupational therapy, respiratory therapy, and speech-language pathology. This legislation would enable the Department of Health and Human Services to provide grants to accredited educational programs in these professions to increase diversity. Grants may be used to support evidence-based strategies shown to increase the recruitment and retention of minority students such as outreach programs in the community, mentorship and tutoring programs, and student scholarships and stipends.

There also have been initiatives within audiology for improving the diversity deficit in the profession. The three leading audiology professional associations, along with hearing industry companies and practice management companies, have Diversity, Equity, and Inclusion (DEI) committees (or Multicultural Boards) that are seeking solutions. Mentoring programs have been established or expanded. Hearing industry manufacturers have donated scholarships to support Black audiology students and those attending Historically Black Colleges and Universities (HBCUs). This is not an exhaustive list and does not include any work being done in audiology academic programs to promote diversity and to recruit and retain students from underrepresented groups.

Academy of Doctors of Audiology DEI Committee

The Academy of Doctors of Audiology (ADA) recognizes the current lack of racial representation in the profession of audiology. In August 2020 the ADA sought to make an impact by establishing a Diversity, Equity and Inclusion Committee (DEI) task force. The task force was composed of ADA and non-ADA members of diverse backgrounds. The task force was charged with the following tasks.

1. Assess the current professional landscape of audiology and ADA to identify gaps between the existing state and the desired state outlined in the *ADA Commitment to Diversity, Equity, and Inclusion*.
2. Identify DEI initiatives that will help eliminate identified gaps and are consistent with ADA's vision outlined in the *ADA Commitment to Diversity, Equity, and Inclusion*.

3. Evaluate and prioritize DEI initiatives using the following criteria:
 - a. Alignment with ADA's mission and resources
 - b. Alignment with ADA member capabilities and interest
 - c. Ability to address areas of greatest need/or make the greatest impact for the effort/resources required
 - d. Will be enhanced through collaboration but will not require it for success
 - e. Will not duplicate the efforts of other organizations
4. Provide recommendations to ADA Board of Directors for strategic DEI focus areas that should be incorporated into the ADA 3-year strategic plan.
5. Provide recommendations to the ADA Board of Directors for specific DEI projects within the areas of focus to be considered for 2021-2022 project cycle.

The task force met over the course of several months. In February 2021, the task force made two recommendations to the ADA Board: 1.) Increase Racial Diversity in the Profession of Audiology; 2.) Promote Audiovestibular Health Equity in the Community.

ADA's Diversity, Equity and Inclusion committee began working on these tasks in September, 2021. Separate sub-committees were formed to focus on each of the two recommendations. Each of these main areas of focus involved various subtasks.

The sub-committee focused on the recommendation to increase racial diversity in the profession are addressing the following subtasks.

Task: Create resources for audiologists and AuD students to use for viral or in-person outreach to high schools (videos, toolkit, information about audiology).

Task: Advocate for a holistic approach to AuD program admissions (without reliance on GRE).

Task: Develop an outreach and recruitment program specifically targeting undergraduate students at historically black colleges and universities to increase awareness of an interest in audiology as a career path.

The sub-committee working on promoting audiovestibular health equity in the community is addressing the following subtasks.

Task: Create a toolkit of resources for practices seeking to develop and implement alternative business models/models of care to foster health equity in their communities.

Task: Create advocacy resources for audiologists to use in their communities to advocate and eliminate inequities that disproportionately increase risk of audiovestibular harm and delayed treatment in underserved populations.

Task: Identify/develop alternative business models and models of care for practices seeking to deliver audiovestibular services to underserved populations in their communities.

Task: Create templates for employee and patient-facing forms, communication and other resources that audiology practices can adopt and modify for use to promote inclusion and equity.

Summary

Racial and ethnic diversity in audiology is a longstanding issue that requires complex, long-term solutions. ADA is committed to diversity, equity and inclusion in audiology and advancing positive change. We believe that the initiatives of the ADA Diversity, Equity, and Inclusion Committee can have a significant impact in enhancing our profession by leveling the playing field and improving access to audiology, for both students as well as for people who need our care. ■

Carolyn Smaka, Au.D. is editor in chief at *Continued*, an online continuing education company whose professional learning spaces include *AudiologyOnline* and *SpeechPathology.com*. She has worked in many clinical settings and in the hearing industry. She is passionate about educational access and volunteers with *ScholarMatch.org* and other initiatives that address inequity in higher ed. Carolyn serves on ADA's Advocacy committee, DEI committee, and is a past recipient of the Joel Wernick award.

Debbie Abel, Au.D. is the manager of Coding and Contracting Services for Audigy after serving as staff at the American Academy of Audiology and is a Past President of the Academy of Doctors of Audiology. She has also had her own private practice in Alliance, OH.

Jerald James, Au.D. is a Clinical Assistant Professor of Audiology in the Communication Disorders department at the LSU Health School Center in New Orleans, Louisiana. He is the audiology clinical coordinator. His areas of interest include adult aural rehabilitation, audiology business development, hearing conservation and tinnitus management. He currently serves as the Chair of the Diversity-Equity-Inclusion (DEI) Committee for the Academy of Doctors of Audiology. Dr. James is also a Lieutenant Colonel in the U.S. Army Reserves. He currently serves as the Commanding Officer of the 7242 Medical Support Unit in Gulfport, MS.

Kate Witham, MS is a 4th year audiology student at Gallaudet University and is currently completing their residency at Berkshire Medical Center in western Massachusetts. They are the co-chair of the ADA DEI committee and a past president of SADA. Their interests in DEI include neurodivergence, cultural competence, and accessibility.

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My Google Search History

after 10 Hours of

Hearing Aid Research



By Blake Cadwell

I realized that I had hearing loss around my freshman year of high school. I struggled to hear my friends on my Motorola Razr cell phone and realized that I was reading lips in every conversation. My hearing loss wasn't a total surprise since my mom had discovered her hereditary loss in her 30s and started wearing hearing aids in her early 40s. Later, my younger brother and three other siblings were diagnosed with varying levels of hearing loss.

I spent my teens and 20s asking people to repeat themselves and developing hacks for getting people to talk louder. Fun fact, when you speak loudly early in a meeting, everyone else gets louder to match the volume.

I didn't seriously consider hearing aids for 15+ years for a few reasons.

- 1 I am a young guy in the creative industry in LA, and hearing aids didn't feel like me.
- 2 My mom was paying \$8,000 for a pair every few years, and I couldn't stomach the cost.
- 3 It all felt like a lot of effort, making it easy to kick the can down the road.

In 2020 I turned 30, my wife and I learned we were expecting a daughter, and everyone everywhere was wearing masks. No more lip reading. It was all enough to get me off the fence and onto Google to start researching my options.

What I found was really confusing. I saw \$99 hearing aids, \$8,000 hearing aids, and no apparent differences. There were blogs, audiologists, and YouTube channels all talking about hearing aids, but I had the feeling that I was walking in on a conversation that was already in progress, and it took me more than a day to get my bearings.

Eventually, I started blogging about my experience at HearSoundly.com and connected with many fellow hearing aid seekers who shared my experience.

I'm convinced that now, more than ever, audiologists and experts in hearing technology are critical to showing the way in a changing and often confusing category.

In this article, I'll recount my first 10 hours of research, hoping that all of us can chip away at the mass confusion customers face on the start line of hearing health.



The start: What are my options?

When I sat down in front of my laptop in 2020, I had a pretty simple question. What are my options? Not just my professional options. I want to understand all of my options.

I searched for “how to get hearing aids” and then “best hearing aids.”



The middle: Who can I trust, and how much are my hearing aids going to cost?

Even as a young, tech-savvy consumer, I spent hours in the middle of my research process stuck in a slog of reviews, videos, and manufacturer spec sheets. I didn’t know what I was looking for, and the crazy thing was that no one shared prices. I now understand that this is par for the course, but I couldn’t figure it out in my first few hours of research. I felt sure I was missing something. How was I supposed to pick something off the menu without prices? Was this one of those “if you have to ask, you can’t afford it” type places?

I searched ten variations of “how much do hearing aids cost” and Googled “most common hearing aid styles.”



The middle continued: Am I ready for this?

In the middle of my search, I started second-guessing this whole thing. Maybe I wasn’t ready after all. So many of the products felt clunky, and my hearing isn’t SO bad.

I started searching for things like “invisible hearing aids,” “modern hearing aids,” “innovative hearing aids.”



The decision: Close my eyes and point.

After a fresh cup of coffee, I regained my resolve and picked Eargo. They had good reviews; I could see they had raised a lot of money, and their prices were easy to find. Importantly, Eargo had a return policy, so I could send them back and revisit this whole thing in a few years if they didn’t work.

Now two years later, I most often wear my ReSound One hearing aids that were prescribed by a local audiologist. The tech and custom program are much better suited for my cookie bite hearing loss but the experience of my first 10 hours is still fresh in my mind.

It took me 15 years to start my search, and then moments before I accessed treatment, I almost gave up.

The solutions to the broken entry point to the hearing health care world aren’t simple, but they require our attention. I hope my experience can inspire a renewed focus on simplifying the customer journey.

The hearing health world will get more complicated before it gets clearer. The collective opportunity is to make thousands of small patient-focused decisions across websites, social media, and in-person care. Together the industry can make hearing healthcare more straightforward, welcoming, and transparent. The rest will follow. ■

Blake Cadwell shares his hearing loss experience and research on his blog at [HearSoundly.com](https://www.hearsoundly.com). After waiting almost two decades to take his hearing loss seriously, he got hearing aids in 2020. Blake has become passionate about sharing easy-to-follow research on hearing aids, hearing technology, and accessible care. Blake has spent the last decade in the creative field working for brands like Gatorade, Southwest Airlines, and Nike. He hopes to put this experience to use in destigmatizing hearing health.

Why We Need Practice Standards

By Patricia Gaffney, Au.D. and John Coverstone, Au.D.

Practice standards have existed in most professions for many decades, if not longer. It is important for a profession to define standard methodologies for services commonly provided. When providers perform tasks differently, it leads to chaos in a healthcare system: other healthcare providers have difficulty coordinating care, teamwork becomes difficult for support staff, and patients notice inconsistencies in outcomes. Taken further, payers become uncertain as to the efficacy of care and education of new professionals becomes increasingly more chaotic as the disparities multiply with successive generations. Finally, the healthcare system loses faith in the profession.

Standards reduce risk for providers by minimizing adverse events. They promote faith in a profession because patients and other providers know what to expect. They support education and help to codify routine tasks for payers and regulators. They do not restrict practice because we recognize that all patients are different, and providers must utilize an array of tools to meet their needs. For this reason, we have clinical guidelines. Clinical guidelines provide a framework for patient care that allows for individual differences and multiple pathways to achieve positive outcomes.

The profession of audiology has not had standards describing the tasks we perform in clinical practice. In 2012, the American Academy of Audiology published *Standards for Practice in Audiology*. While this was a needed document and described the full breadth of what an audiologist might do within our scope of practice, many felt we needed standards that include more detailed descriptions of what audiologists do in specific areas. As a result, Audiology Practice Standards Organization (APSO) was founded in 2017 to develop and maintain clinical standards in audiology.

Individual practice standards serve as a foundation for guidelines, accreditation, licensing and education. They describe what a typical provider does with a typical patient in each situation (such as a diagnostic hearing evaluation or a hearing aid fitting). Practice standards describe the minimum tasks considered acceptable by the profession. Practice guidelines, on the other hand, describe how those tasks are performed and often include variations for different populations and hierarchies of preferred methods.

APSO standards are developed, reviewed and edited by two groups of subject matter experts prior to release for public comment. All audiologists are invited to review and comment on the standards, with substantiating evidence solicited when possible. After final revisions by the development SMEs, each standard is also subject to review by an ethics panel and legal team before publication. Each standard is freely available to download on the APSO web site at www.audiologystandards.org, as is the standards creation process.

The first two published APSO clinic standards begin on page 37 in this issue of *Audiology Practices*.

The profession of audiology is committed to providing auditory and vestibular care through ethical and evidence-based clinical practices that lead to optimal patient outcomes. Standard of practice documents outline basic services that audiologists are expected to include in the provision of quality healthcare. They reflect the values and priorities of the profession, providing direction for professional practice and a framework for the evaluation of practice. Standards of practice are prepared by subject matter experts, based on available evidence, peer-reviewed and subject to periodic updating.

AUDIOLOGY GENERAL PATIENT INTAKE STANDARD

1. During intake, information to be collected as applicable from the patient and/or the patient's family member/legal representative will include but is not limited to:
 - a. Demographic and contact information
 - b. Legal and financial documents (e.g., consent to treat, insurance, HIPAA, release of medical information, prior authorization, medical referral and/or medical order when required)
 - c. Chief complaint, history of present illness, and current symptoms including functional impact of hearing or balance deficit
 - d. Information related to medical and surgical history (including comorbidities), current medications, allergies, medical/specialist team members, and cognitive and developmental concerns
 - e. Social history to include marital status, sexual orientation and gender identity, employment history, recreational history of alcohol, drug, and tobacco use and environmental factors such as noise exposure history (military, occupational and recreational)
 - f. Screening for the red flags of ear disease²

- g. Tinnitus and falls risk including nature, onset and impact on patient's quality of life sufficient to develop a care plan which may include referral to an appropriate healthcare professional
 - h. Audiologic history (e.g. previous hearing examinations, hearing amplification devices) as available
2. The following should be considered:
- a. Questioning may be completed in written or oral format
 - b. Information shall be provided to and collected from the patient and/or patient's family member/legal representative using methods required for effective communication (e.g. written, oral, or signed language and appropriate level to ensure understanding) in accordance with clinic policies.
 - c. Specialized questionnaires may be completed if relevant to appointment type (see standards for specific areas of evaluation)
 - d. Questions shall be tailored to patient characteristics (e.g., age, cognitive function, reason for visit)
3. Following collection of information, the audiologist shall determine plan for evaluation
4. Intake information collection will continue throughout course of the initial appointment and subsequent visits. This should be updated at least annually.

RESOURCES:

Audiologists are encouraged to familiarize themselves with the measures outlined in MIPS available at <https://audiologyquality.org/measures/>

Red Flags-Warning of Ear Disease: <https://www.entnet.org/resource/position-statement-red-flags-warning-of-ear-disease/>

The profession of audiology is committed to providing auditory and vestibular care through ethical and evidence-based clinical practices that lead to optimal patient outcomes. Standard of practice documents outline basic services that audiologists are expected to include in the provision of quality healthcare. They reflect the values and priorities of the profession, providing direction for professional practice and a framework for the evaluation of practice. Standards of practice are prepared by subject matter experts, based on available evidence, peer-reviewed and subject to periodic updating.

HEARING AID FITTING STANDARD FOR ADULT & GERIATRIC PATIENTS

1. The hearing aid selection and fitting process is based on a comprehensive, valid audiological assessment. Each step of the selection and fitting process and the rationale is documented, where appropriate.^{1, 2, 3}
2. Patient communication is conducted in a clear, empathetic manner consistent with the patient's communication mode, comprehension, and their health literacy level. Patient-centered and family-centered care is provided. The patient is encouraged to include communication partners (e.g., family members, significant others, companions) throughout the selection, fitting, and follow-up process.^{4, 5, 6, 7, 8}
3. A needs assessment is conducted in determining candidacy and in making individualized amplification recommendations. A needs assessment includes audiologic, physical, communication, listening, self-assessment, and other pertinent factors affecting patient outcomes.^{9, 10}
4. Pre-fitting testing includes assessment of speech recognition in noise, unless clinically inappropriate, and frequency-specific loudness discomfort levels. Other validated measures of auditory and non-auditory abilities are considered, as appropriate for the individual patient.^{11, 12, 13, 14, 15, 16, 17, 18, 19}
5. Fitting of bilateral hearing aids is the recommended protocol if the patient is a candidate for hearing aids in both ears and it is supported by the needs assessment.^{20, 21, 22}
6. The hearing aid style and the ear coupling are chosen to be appropriate for the degree and configuration of the hearing loss. Style and coupling should reflect any physical limitations of the patient. Patient input regarding acceptable styles is taken into account.^{23, 24, 25, 26, 27, 28, 29, 30, 31, 32}

7. The recommended hearing aids include signal processing and features that support the patient's listening needs. They have the appropriate gain and output, including reserve gain, to meet frequency-specific fitting targets as defined by a validated prescriptive method.^{23, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43}
8. Assistive technology and accessories are considered to facilitate accessibility to other devices and to satisfy the patient's listening and communication needs.^{23, 44, 45, 46, 47, 48}
9. An assessment of initial product quality is completed, using standard electroacoustic measures to verify either manufacturer or published specifications.^{34, 49}
10. Hearing aids are fitted so that various input levels of speech result in verified ear canal output that meets the frequency-specific targets provided by a validated prescriptive method. The frequency-specific maximum power output is adjusted to optimize the patient's residual dynamic range and ensure that the output does not exceed the patient's loudness discomfort levels.^{50, 51, 52, 53, 54, 55, 56, 57}
11. Following individualized verification of hearing aid gain and output, if the fitting is not acceptable to the patient, minor deviations in gain and output may be necessary.^{58, 59}
12. Orientation is device- and patient-centered and includes use, care, and maintenance of the hearing aid(s) and accessories.^{60, 61, 62, 63}
13. Counseling is conducted to ensure appropriate adjustment to amplification and to address other concerns regarding communication. Additional rehabilitative audiology is recommended if deemed appropriate.^{64,65,66,67,68,69}
14. Hearing aid outcome measures are conducted. These may include validated self-assessment or communication inventories and aided speech recognition assessment.^{70, 71}
15. Short- and long-term follow-up is conducted to ensure that post-fitting needs are addressed. This includes updated audiological assessment, hearing aid adjustments and routine maintenance as needed to ensure the devices are functioning properly and appropriately for the patient.^{23, 33, 72, 73, 74, 75}

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February 1, 2022

STATEMENT FROM ADA ON THE FDA OTC HEARING AID PROPOSED RULE PROVISIONS FOR MAXIMUM SOUND OUTPUT AND GAIN

I. THE BIG PICTURE

Following the release of the Food and Drug Administration (FDA) Over-the Counter (OTC) Hearing Aid Proposed Rule (Proposed Rule) in October 2021,¹ the Academy of Doctors of Audiology (ADA) convened an internal task force for the purpose of evaluating whether the Proposed Rule (i) meets the statutory requirements outlined in FDARA (FDA Reauthorization Act) and (ii) supports evidence-based practices, professional autonomy, consumer access, and competition.

During this process, the ADA OTC task force conducted a comprehensive literary review of scientific presentations, research articles, the President's Council of Advisors on Science and Technology (PCAST) report (2015)² and National Academy of Science Engineering and Medicine (NASEM) Report (2016)³, FDA regulations, ANSI standards, and the "Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness" (2018 Consensus Paper)⁴ to assess the Proposed Rule provisions for technical and performance standards for OTC hearing aids.

ADA advocates for public policies that improve consumer access to audiology services and access to safe, effective, and affordable treatments for hearing loss, including OTC hearing aids. ADA believes that through the evaluation of science and the application of the information found, consumers and the profession of audiology will be best served by a legal framework that is evidence-based.

After a careful evaluation of the evidence, the ADA OTC task force and the ADA Board of Directors concluded the original methodologies used to justify the 25 dB (decibel) gain limit and the 110 dB output limit in the 2018 Consensus Paper—published as a consensus paper from several hearing healthcare organizations, including ADA—was flawed. In January 2022, ADA subsequently submitted the following recommendations to the FDA:

- ADA **supports** FDA's proposal to allow an output limit up to 120 dB OSPL90 for OTC hearing aids with input-controlled compression and user adjustable volume control.
- ADA **urges** the FDA to implement a general output limit for OTC hearing aids of 110 dB OSPL90 when the hearing aid *does not* include input-controlled compression and user adjustable volume control.
- ADA **supports** FDA's proposal to forgo gain limitations for OTC hearing aids.

¹ <https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22473.pdf>

² https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf

³ Hearing Health Care for Adults: Priorities for Improving Access and Affordability: <https://www.nationalacademies.org/our-work/accessible-and-affordable-hearing-health-care-for-adults>

⁴ Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness, Consensus Paper from Hearing Care Associations, August 14, 2018. <https://hearinghealthmatters.org/hearingnewswatch/2018/consensus-otc-hearing-aid-classification/>

ADA continues to endorse several portions of the recommendations contained in the 2018 Consensus Paper's five major areas. However, after a renewed and objective review, ADA maintains strong concerns and no longer agrees with two specific recommendations.

ADA **does not** support the 2018 Consensus Paper recommendations regarding maximum gain and maximum output:

- The 2018 Consensus Paper working group recommended a high-frequency average full on gain (HFA-FOG) limit of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI standard S3.22-2014.
- The 2018 Consensus Paper working group recommended a peak (or maximum) 2cc coupler OSPL90, per ANSI S3.22-2014, not to exceed 110 dB SPL.

Furthermore, ADA remains committed to collaborating with other professional organizations to ensure that federal and state laws for OTC hearing aids are implemented responsibly, transparently, and in a manner that maximizes consumer access to audiology services.

II. THE TIMELINE

A multi-organization opinion paper, "Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness," was released in August 2018 (2018 Consensus Paper). This 2018 Consensus Paper is a 35-page document from three associations representing audiologists (ADA, the American Academy of Audiology (AAA), and the American Speech-Language-Hearing Association (ASHA)), and one association representing hearing instrument specialists, the International Hearing Society (IHS). While the hearing aid industry trade association, Hearing Industries Association (HIA) was not credited with authorship, several employees of their member companies (i.e., industry personnel) were included in the 2018 Consensus Paper working group and HIA immediately endorsed the paper upon release.

Throughout the development of the 2018 Consensus Paper, there was strong debate among participating organizations regarding recommendations for maximum sound pressure level (SPL) output and gain. Despite best efforts to align on assumptions, evidence, and a rationale supporting one recommendation or another, in the end, every organization, including ADA, made concessions to arrive at the 110 dB SPL (output) and 25 dB (gain) recommendations.

The 2018 Consensus Paper had five key recommendations to the FDA regarding OTC hearing aids:

1. Establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment.
2. Define concise, out-of-the box labeling appropriate for OTC, with strong recommendation to consult with a hearing health care professional.
3. Define comprehensive, inside-the-box labeling appropriate for over-the-counter medical devices.
4. Define the new OTC category so that it is easily comprehensible by consumers and in line with risk class requirements for safety and effectiveness.
5. Adequate provisions for consumer protection, in coordination with the Federal Trade Commission (FTC).

ADA was pleased that the FDA addressed all five areas in the 2021 OTC Hearing Aid Proposed Rule.

ADA STATEMENT: FDA OTC HEARING AID PROPOSED RULE PROVISIONS FOR MAXIMUM OUTPUT AND GAIN

The 2018 Consensus Paper provided a valuable “strawman” framework for regulators to consider as they implement the OTC Hearing Aid Act (a subsection of FDARA, the FDA Reauthorization Act of 2017). The conclusions drawn, however, were simply an amalgamation of the positions and opinions supported by selected evidence put forward by the authoring organizations and other stakeholders, including the Hearing Industries Association (HIA), and should not be confused with or portrayed as a peer-reviewed research publication.

Following the release of the FDA OTC Hearing Aid Proposed Rule in October 2021, ADA convened an internal task force for the purpose of evaluating whether the Proposed Rule meets the statutory requirements outlined in FDARA and supports evidence-based practices, professional autonomy, consumer access, and competition.

During this process, the ADA OTC task force conducted a comprehensive literary review of scientific presentations, research articles, the PCAST report, the NASEM report, FDA regulations, ANSI standards, and the 2018 Consensus Paper to assess the Proposed Rule provisions for technical and performance standards for OTC hearing aids.

In a meeting of representatives from AAA, ADA, ASHA, IHS, HIA, and the American Academy of Otolaryngology-Head Neck Surgery (AAO-HNS), and the Hearing Loss Association of America (HLAA) (2021, December 2), the question was put forward to all organizations as to whether all organizations would use the 2018 Consensus Paper as an agreed-upon starting point for harmonizing comments on the FDA OTC Hearing Aid Proposed Rule. At that time, ADA notified the other organizations that ADA was not prepared to do so without first completing the full review by its own task force.

Following the completion of the work by the ADA task force, ADA held a member town hall webinar (2022, January 12) on “Analysis of FDA Proposed OTC HA Rule.” Here, ADA presented a scientifically supported response to the request from the FDA for comments on the proposed rule, including some positions that differed from the 2018 Consensus Paper.

Specifically, ADA **does not support** the 2018 Consensus Paper recommendations regarding maximum gain and maximum output.

- The 2018 Consensus Paper working group recommended a high frequency average full-on gain (HFA-FOG) limit of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI standard S3.22-2014.
- The 2018 Consensus Paper working group recommended a peak (or maximum) 2cc coupler OSPL90, per ANSI S3.22-2014, not to exceed 110 dB SPL.

After a thorough review of the science related to electroacoustic performance, ADA concluded that the original methodologies used to justify the 25 dB gain limit and the 110 dB output limit in the 2018 Consensus Paper was incomplete. In January 2022, ADA submitted the following recommendations to the FDA:

- ADA **supports** FDA’s proposal to allow an output limit up to 120 dB OSPL90 for OTC hearing aids with input-controlled compression and user adjustable volume control.
- ADA **urges** the FDA to implement a general output limit for OTC hearing aids of 110 dB OSPL90 where the hearing aid does not include input-controlled compression and user adjustable volume control.
- ADA **supports** FDA’s proposal to forgo gain limitations for OTC hearing aids and notes that this was not a statutory requirement under FDARA.

Following the member town hall webinar, ADA received immediate and strong written (2022, January 14, *enclosed*) and oral (2022, January 17) criticism from representatives of the hearing aid industry regarding ADA's revised position on the 2018 Consensus Paper. In the January 17, 2022, virtual meeting with industry representatives, in which multiple issues were discussed, it was explained by the industry representatives that ADA's continued endorsement of the 2018 Consensus Paper recommendations (with lower limits on gain and output) was important to support the "traditional hearing aid business to ... remain the traditional hearing aid business." ADA views the Over-the-Counter Hearing Aid Act of 2017 as an opportunity to improve on the traditional hearing aid business and ADA supports new methods to increase access to hearing care services and affordability of hearing devices.

III. THE DETAILS

ADA diverges from the 2018 Consensus Paper on the gain and output recommendations as follows:

Comments on "Definition of intended users for OTC hearing devices" (pp 4-7 of the 2018 Consensus Paper):

- The OTC Hearing Aid Act of 2017 covers hearing devices "intended to be used by adults aged 18 and older to compensate for perceived mild to moderate hearing impairment" (page 4). The 2018 Consensus Paper states that "older individuals tend to underestimate their hearing loss" (page 6). The combination of these two statements is that a person with a perceived mild-to-moderate hearing loss may also be in the audiometry confirmed category of what many, but not all, American audiologists would term "moderately-severe hearing" loss of up to 70 dB HL. This issue is addressed in the section "Unintended but foreseeable users" (page 7) where it is stated "Considering that this will be sold over-the-counter, this group may include adults who perceive they ... have a more severe hearing impairment (56 dB HL or higher)." ADA agrees that these are foreseeable users but disagrees that these are unintended users. The legislation expressly states that the devices are for user-perception of mild-to-moderate hearing loss and does not state the devices are for users with \leq 55 dB HL hearing loss.
- A second point is whether to use any concrete number, or what number, for degree of hearing loss, when intended users have "perceived" hearing loss. The selection of a flat 55 dB HL hearing loss (page 5) as the designation of maximum degree of hearing loss that is applicable for OTC hearing aids is controversial, as many audiologists, organizations, hearing aid and cochlear implant manufacturers categorize moderate hearing loss up to 60 dB HL or 70 dB HL. This conversation was further complicated when the FDA, in their 2021, December 7 webinar on OTC hearing aids, displayed an audiogram categorizing moderate hearing loss up to 70 dB HL. Selecting 70 dB HL hearing thresholds as the limit of "moderate" hearing sensitivity are consistent with a global view of "moderate" hearing loss but are inconsistent with some US-oriented audiometry classification systems where hearing threshold responses consistent with of 56 – 70 dB HL are referred to as "moderately-severe."

In summary, ADA does not propose that *perceived* mild-to-moderate hearing loss be defined as 55 dB HL, 60 dB HL, 70 dB HL, or indeed any audiometry-confirmed level. ADA submits that using any audiometry-defined limit moves away from "perceived" as an inseparable part of the candidacy criteria and is inconsistent with the congressional intent of the legislation. A generalized definition that promotes discussions on gain and output limits would lead to flexible recommendations, and ADA believes this would be consistent with the Congressional intent of the OTC Hearing Aid Act of 2017.

Comments on “Gain requirements” (pp 7-11)

- ADA has objections to the underlying assumptions used to determine the maximum gain limits for a 55 dB HL hearing loss. The assumptions include binaural usage by new users to amplification as one example (page 9). These assumptions exclude monaural users, experienced users, and users with any type of hearing loss other than sensorineural. These exclusions are highly questionable as the assumptions could have easily included monaural, experienced users, and users who may have mixed or conductive hearing loss that does not require medical intervention.

The real-world impact of the modeling decisions of 55 dB HL hearing loss and only binaural, new users with sensorineural hearing loss is an inappropriate limitation on the maximum permissible gain limit to 25 dB HFA FOG for OTC hearing aid fittings, thereby reducing the number of potential users with hearing impairment who would benefit from an OTC device. An example of the consequences of these exclusionary assumptions can be seen in Table 1 (page 9), where a monaural, experienced hearing aid user with 55 dB HL thresholds is prescribed 30.1 dB HFA FOG using the National Acoustic Laboratories, Non-Linear Revision 2 prescriptive fitting rationale (NAL-NL2),⁵ the most common method of fitting prescription hearing aids in the United States.

If the 25 dB HFA FOG recommendation is implemented by the FDA, this individual with a moderate, sensorineural hearing loss would only be able to have their amplification needs met with a prescription hearing aid. This is a clear example of where the 2018 Consensus Paper does not meet the congressional intent of the OTC Hearing Aid Act of 2017 by conflating concerns over safety with a demonstrable impact on effectiveness.

- ADA further considered the algorithmic analysis referenced in the 2018 Consensus Paper regarding a mathematical model using the NAL-NL2 prescriptive use-gain target. The use-gain targets were translated into a 2cc coupler HFA FOG values, serving as the proxy for a maximum gain limit. This procedure ignores the clinical mandate that hearing aids are not to be fit or worn at the maximum setting, or full-on gain (FOG).

Hearing aids should be fit to user gain targets and have reserve gain available so the device user can increase the volume (gain) when they desire to hear sounds of low intensity (soft sounds). A typical amount of reserve gain in hearing aid fittings is greater than or equal to 5 dB but less than or equal to 10 dB. The lack of accounting for reserve gain means that the effective performance limit of these devices will be less than or equal to 20 dB HFA FOG, not the intended 25 dB HFA FOG. Devices with usable gain of less than or equal to 20 dB are appropriate for persons with mild hearing loss and will meet the needs of some, but not all, individuals with moderate hearing loss. This is another clear example of where the 2018 Consensus Paper does not meet the Congressional intent of the OTC Hearing Aid Act of 2017.

In summary, ADA does not support the 2018 Consensus Paper use of exclusion criteria, based on assumptions from most-common device usage for determining a gain limit. Instead, ADA supports using an inclusion criterion that would account for all intended device usage. As such, ADA supports FDA taking a more flexible position insofar as gain limitations may negatively impact competition and innovation for new OTC devices. A low gain limit, as was recommended in the 2018 Consensus Paper, would reduce

⁵ Keidser, G., Dillon, H., Flax, M., Ching, T., & Brewer, S. (2011). The NAL-NL2 prescription procedure. *Audiology Research*, 1(1), e24. <https://doi.org/10.3390/audiore.2011.25>

device effectiveness for the large population of individuals who could benefit from OTC devices, is not a statutory requirement under FDARA, and is inconsistent with the Congressional intent of the Over-the-Counter Hearing Aid Act of 2017.

Comments on “Maximum Power Output Limitation” (pp 11-17)

- ADA maintains the 2018 consensus document misconstrues the relationship between the maximum output for any single pure tone and that for a broadband signal. In the 2018 Consensus Paper, it was written (pp. 15-16):

“... when a broadband signal (such as speech or music that includes energy over a broad range of frequencies) is presented to the hearing aid, the output of the hearing aid is the sum of the energy at all the frequencies. Indeed, the maximum output of the hearing aid will be limited by the peak OSPL90 at each frequency but summed across all the frequencies of interest. Thus, a sinusoid or a very narrow band of noise of the same spectral level presented at a 90 dB SPL level may have an overall output closely related to the value of the peak OSPL90. However, a broadband signal (such as speech or music) of the same spectral level at all frequencies will have an overall output level far exceeding the value of the peak OSPL90.”

This conclusion is not accurate. Broadband signals can be output from the hearing aid only at average (e.g., root-mean-square or RMS) levels that will be well below the OSPL90 value. Even if care is not taken to prevent peak clipping distortion, output from the hearing aid will still not exceed OSPL90.

- ADA maintains the 2018 Consensus Paper misinterprets and misapplies the information from the Johnson (2017) paper⁶ used to justify an unnecessarily low maximum output level in OTC hearing aids. The 2018 Consensus Paper rationale for the 110 OSPL90 limit is as follows:

“Johnson estimated limit standards to determine the safe output sound pressure level (SPL) for sound amplification devices to preserve hearing sensitivity after amplification usage. In this study, the author developed an algebraic restatement of the correlation between hearing loss threshold and safe output limits. For example, the author’s results determined that for a hearing loss threshold with flat 55 dB configuration, a safe overall output SPL would be no greater than 111 dB.” (page 13)

“One reporting parameter that characterizes the maximum output of a hearing aid is the Output Sound Pressure Level at 90 dB SPL input (OSPL90, ANSI S3:22-2014). The OSPL90 measurement is done using a swept frequency (i.e., one frequency at a time) presented at a 90 dB SPL input level. The OSPL90 curve represents the maximum output of the hearing aid when a single frequency is employed. Indeed, when the input signal is a pure tone, the maximum output of the hearing aid is limited by the OSPL90 of the hearing aid.” (page 15)

“Thus, considering Johnson’s (2017) recommendation of an overall output level lower than 111 dB SPL as a safe level for a moderate degree of hearing loss, and considering that the 2 cc coupler OSPL90 is a required parameter in reporting the characteristics of a hearing aid, the Working Group recommends that the peak OSPL90 not be greater than 110 dB SPL in order to avoid the

⁶ Johnson, E. (2017). Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss, *International Journal of Audiology*, 56: 829-836.

potential of an output greater than 111 dB SPL. Balancing the issues of sound quality (such as in music appreciation), optimal speech intelligibility, listening comfort and minimal risk of discomfort and over-amplification for the intended users of OTC, the Working Group makes the following recommendation.”

“The Working Group’s recommendation is that the peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, not be greater than 110 dB SPL.” (page 16)

The 2018 Consensus Paper refers to Table 1 (page 834) in the Johnson paper where 4FA threshold values from 0 to 120 dB HL correspond to safe output SPL (overall dB) values from 90 to 136 dB (RMS). The 2018 Consensus Paper identifies that a person with hypothetical hearing sensitivity of 55 dB HL corresponds to 111 dB of prescribed device output and concludes from this data that the 110 OSPL90 value is the maximum safe output level. ADA contends that the two values [111 dB from Johnson (2017) and 110 dB OSPL90 from the 2018 Consensus Paper] are fundamentally different and any attempt to make a direct comparison is inconsistent with a correct application of the mathematics of acoustics. The 111 dB value is dB (RMS) for average speech level in the ear canal whereas the 110 dB value is for peak pure tone output level in the 2cc coupler at the single frequency of greatest intensity. This is a misleading comparison that ADA seeks to clarify in diverging from the 2018 Consensus Paper.

- ADA has another criticism of the 2018 Consensus Paper justifying the 110 dB OPL90 value from the Johnson paper. In the Introduction to his paper, Johnson writes “MPO levels have two basic uses. One use is to limit the amount of intermittent, short duration sounds to levels below those that are uncomfortable for the wearer. The other purpose is to limit the amount of amplification to higher level inputs occurring more consistently over a long duration (e.g., ≥ 8 hours). This second use was the perspective taken by the study.”^{7, 8, 9} (page 830)

First, Johnson’s line of reasoning is endorsed in the 2018 Consensus Paper (page 13).

“The proper adjustment of maximum output is the critical parameter that serves the purpose to limit the output of:

- *Intermittent, short duration sounds, to levels that are neither damaging nor uncomfortable to the wearer, and*
- *Overamplification of higher level inputs occurring more consistently over a longer duration (e.g. over six-eight hours).”*

To determine a hypothetical peak SPL value (appropriate to create an OSPL90 value), both the first point (intermittent, short duration sounds) and the second point (long duration sounds) must be considered. The 111 dB SPL (RMS) is only the long duration value for speech. Johnson addresses this issue and cautions that “The safe output SPL in Table 1 are RMS levels so that peak levels 15 dB higher could be allowed to preserve the sound quality of incoming speech inputs so as not to clip the speech and perhaps allow higher peak levels for other inputs like music.” This second factor discussed by Johnson (2017) is

⁷ The Occupational Safety Health Administration (OSHA) and National Institute for Occupational Safety & Health (NIOSH) limits for exposure are applicable only to industrial noise in a sound field for age-adjusted normal hearing persons. For these occupational standards to be applicable to hearing aids, in-ear (ear drum referenced) levels would have to be diffuse field referred and then adjusted for the hearing loss.

⁸ <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.95>

⁹ <https://www.cdc.gov/niosh/docs/98-126/pdfs/98-126.pdf?id=10.26616/NIOSH PUB98126>

not considered in the 2018 Consensus Paper. If it had been, the result would have been far above 110 and closer to 120 dB.

ADA agrees with Bose Corporation in its FDA comments, “...real-world signals are dynamic, unlike steady tones. Speech at a constant level has a crest factor (dB ratio of instantaneous peak to RMS level) of about 15 versus that of 3 dB for a tone.¹⁰ Music often has crest factors that are even higher.¹¹ These crest factor differences (re: a tone) correspondingly decrease the highest level that these signals can be played without distortion (from clipping) and consequent poor sound quality. Therefore, due to the frequency dependence of OSPL90 and the above crest factors, an OSPL90 limit of 120 dB SPL will allow actual speech (and music) to be played only up to around 105 dB SPL. While listening at such levels is not common, it does occur occasionally, and the proposed OSPL90 limits of 115/120 dB SPL are needed to ensure there is adequate headroom for undistorted outputs in these situations.”

In summary, on the issue of maximum output power limitation, ADA does not support several statements, assumptions, and rationales that led to a recommendation for a hard limit of 110 dB OSPL90 for OTC hearing aids. ADA supports the more flexible FDA position with an allowance of 120 dB OSPL90 to promote device efficacy including sound fidelity, when combined with user-controlled methods to lower device output, promoting device safety.

IV. CONCLUDING COMMENT

ADA has been heavily criticized for changing its position regarding key recommendations contained in the collaborative 2018 Consensus Paper. ADA must, however, prioritize accuracy over unity. Promoting and advancing the autonomous practice of audiology, guided by evidence-based practices, requires an adherence to scientific principles that withstands social pressure. A regulatory framework, built upon independently verifiable scientific methods and the earnest application of the evidence found, will deliver accessible, affordable, effective, and safe OTC hearing aids to consumers with hearing loss. ADA welcomes constructive discussion on this issue and maintains that the best way to advance the profession of audiology is by prioritizing the needs of those we serve.

¹⁰ American National Standards Institute (2020). ANSI S3.5-1997 (R2020). *Methods for the Calculation of the Speech Intelligibility Index*. New York: Acoustical Society of America.

¹¹ Chasin, M. (2003). Music and hearing aids. *The Hearing Journal*, 56(7), 36-41.

The Importance of Using Notices of Non-Coverage in an Audiology Practice

BY KIM CAVITT, Au.D.

Notices of Non-Coverage are forms that are almost always required by managed care entities, through their agreements, medical policies, and guidance (when you are in-network) and frequently required by many state governments (when you are an out of network provider). In this notice, you are informing the patient of the recommended items and services to be rendered, why your practice anticipates that these items and services will be non-covered, and the usual and customary costs for the items and services. The patient will acknowledge, through their signature, the receipt of the notice and acceptance of its associated financial responsibilities.

In-network providers typically have contractual responsibilities to inform patients, in writing, of non-coverage of items and services and to document the patient's acceptance of the financial responsibility for the costs of these items and services. Commercial plans (Indemnity, self-insured, PPO, POS, HMO) typically allow you to use a practice created and generated form. The Academy of Doctors of Audiology (ADA) offers a form, for purchase, through their Forms Library (<https://www.audiologist.org/practice/forms-library>) that was created by myself and ADA's legal counsel. This form should be used for ANY items and service, including but not limited to hearing aids, tinnitus management, auditory processing evaluation and management, evaluation and management services, cerumen management, auditory prosthetic device fitting, orientation, and troubleshooting, auditory rehabilitation, etc. The form should be provided to the patient prior to services being rendered and should clearly indicate the patient's financial and professional rights and responsibilities.

Advance Beneficiary Notices (ABNs) are the traditional Medicare (red, white and blue Medicare Card) notices of non-coverage. They have required (where you cannot collect payment from the patient without the form being in place before the service is rendered; when using 92700 , L9900 or when a local coverage determination is in effect in your locality) and voluntary (items and services that are statutorily excluded from Medicare coverage or that do not meet the definition of a Medicare benefit). You can learn more about ABNs at <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN> and you can get a pre-filled ABN for required or voluntary uses, at no charge, through the ADA Forms Library.

Medicare Advantage (Part C) plans have their own, unique notice of non-coverage requirements (organization predetermination). This can vary plan to plan and state to state. These requirements can often be found on their websites or in their portals. Some of these plans offer their own, specific notices of non-coverage that are to be used with their members. Others will allow for the use of the practice created and generated form.

Finally, out of network providers need to realize that they are not immune to patient notification responsibilities, especially when dealing with Medicaid beneficiaries. The Federal government, through the No Surprises Act (<https://www.cms.gov/newsroom/fact-sheets/no-surprises-understand-your-rights-against-surprise-medical-bills#:~:text=The%20No%20Surprises%20Act%20protects,network%20air%20ambulance%20service%20providers.>) and state governments, through similar legislation and state balance billing protections (<https://www.commonwealthfund.org/publications/maps-and-interactives/2021/feb/state-balance-billing-protections>) have set forth patient notification requirements that can impact out of network providers. Practices need to seek legal guidance, get assistance on their rights and responsibilities within these laws and determine what needs to be provided to out of network patients and in what settings.

Notifications of non-coverage can go a long way in providing patient's with pre-determination and price transparency. It also can help alleviate confusion when the patient is interpreting their third-party coverage and benefits and, after claims processing, understanding their explanation of benefits. These completed notices also offer provider's legal protections in the event of consumer and patient complaints on billing and insurance. ■

Dr. Kim Cavitt was a clinical audiologist and preceptor at The Ohio State University and Northwestern University for the first ten years of her career. Since 2001, Dr. Cavitt has operated her own Audiology consulting firm, Audiology Resources, Inc. She currently serves on the State of Illinois Speech Pathology and Audiology Licensure Board. She also serves on committees through AAA and ASHA and is an Adjunct Lecturer at Northwestern University.

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Avoid costly surprises for your practice—This live session will provide a comprehensive overview of NSA provisions and key information that audiologists need to know to stay compliant with its provisions. Template forms will also be available for ADA members after the event.

Learning Outcomes

Upon completion of the course, attendees will be able to

- Describe new requirements for health care providers and how those requirements will affect provider reimbursement and costs for patients
- List the pricing information that audiologists must provide to self-pay and uninsured patients,
- Describe when and how the information provided by audiologists to self-pay and uninsured patients must be provided

Course Leaders



Daphne Kackludis is a healthcare attorney at Brennan, Manna, & Diamond (BMD), where she leads the firm's Columbus, Ohio healthcare practice. She specializes in health care service delivery and payment systems.



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Medicare Reimbursement Restrictions Disproportionately Impact Audiology and Other Female-Dominated Professions

Archaic Medicare reimbursement restrictions disproportionately impact audiologists, other clinical doctoring professions with a high proportion of females, and the Medicare beneficiaries who need their services. While we do not know whether the association between the gender composition of the profession of audiology and the overregulation of audiology services is a causal relationship, it is nonetheless concerning.

What We Do Know

- What we do know is that while the OTC Hearing Aid Act allows consumers greater autonomy to self-assess and self-treat their perceived hearing loss—Medicare Part B coverage rules continue to prohibit beneficiaries with perceived hearing loss from going to their audiologist for a professional diagnostic examination, without first obtaining a physician order.
- What we do know is that Medicare Part B continues to categorize audiology services as “diagnostic other,” outright prohibiting reimbursement to audiologists for the Medicare-covered treatment services that they are licensed to provide. This policy is anti-competitive, expensive for beneficiaries (in both time and money), and a wasteful use of Medicare system resources.
- What we do know is that the Center for Medicare and Medicaid Services (CMS) continues to classify audiologists as suppliers, despite their education and training, which is commensurate with other clinical doctoring professions recognized by Medicare as physicians and practitioners, and despite evidence and outcomes from other government programs and commercial insurance that supports broader deployment of audiologists within the Medicare program.

The Medicare Audiologist Access and Services Act (MAASA) will help close the gap between the outdated Medicare policies governing audiology and the Medicare policies that apply to clinical doctors in male-dominated professions.

MAASA (H.R. 1587/S. 1731) will provide streamlined beneficiary access to audiologists by eliminating the physician order requirement, will authorize CMS to reimburse audiologists for the treatment services that they are licensed to provide, and will reclassify audiologists from suppliers to practitioners. MAASA supports Medicare policy parity for the profession of audiology and with it, parity for women in clinical doctoring professions.

TABLE 1: SELECTED CLINICAL DOCTORING PROFESSIONS BY PERCENTAGE OF WOMEN AND MEDICARE POLICIES

Clinical Doctoring Profession	Percentage of Women Practicing in the Profession	Medicare Direct Access	Classified in Medicare as Practitioner or Physician
Audiologist	85%	No, the beneficiary must have a physician order.	Neither
Chiropractor	32% ¹¹	Yes	Physician
Clinical Psychologist	65%	Yes, but must consult with the patient's primary care physician (Psychiatrists do not have do this for reimbursement). Physician must sign off on plan of care. ^{12,13}	Practitioner
Dentist	36% ¹⁴	Yes	Physician
Medical Doctor	36%	Yes	Physician
Optometrist	43%	Yes	Physician
Physical Therapist	68%	Yes, but plan of care must be filed and signed off by a physician. ¹⁵	Neither
Podiatrist	25% ¹⁶	Yes	Physician

Contact Stephanie Czuhajewski at sczuhajewski@audiologist.org for more information. ■

¹¹ American Chiropractic Association (2021) <https://www.acatoday.org/news-publications/aca-roundtable-explores-the-experiences-of-women-chiropractors/>

¹² American Medical Association (2020) <https://www.ama-assn.org/practice-management/scope-practice/congress-plays-name-game-redefine-physician-under-medicare>

¹³ Centers for Medicare Medicaid Services Reimbursement Handbook <https://www.cms.gov/files/document/medicare-mental-health.pdf>

¹⁴ American Dental Association (2021) <https://www.ada.org/resources/research/health-policy-institute/dentist-workforce#:~:text=How%20many%20dentists%20are%20female,2021%2C%2035.9%25%20are%20female.>

¹⁵ Web PT: <https://www.webpt.com/blog/medicare-and-direct-access/>

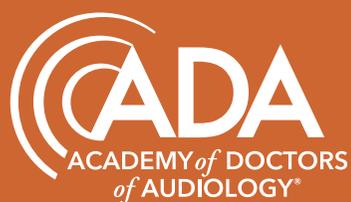
¹⁶ Kent State University, Women in Podiatry. <https://www.kent.edu/cpm/news/women-podiatry#:~:text=According%20to%20the%20American%20Podiatric,cited%20in%20Delzell%2C%202016.>



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