Addressing OTC via unbundling, counseling, remote care and remote fine-tuning

Michael Valente, Ph.D.

Professor Emeritus of Clinical Otolaryngology

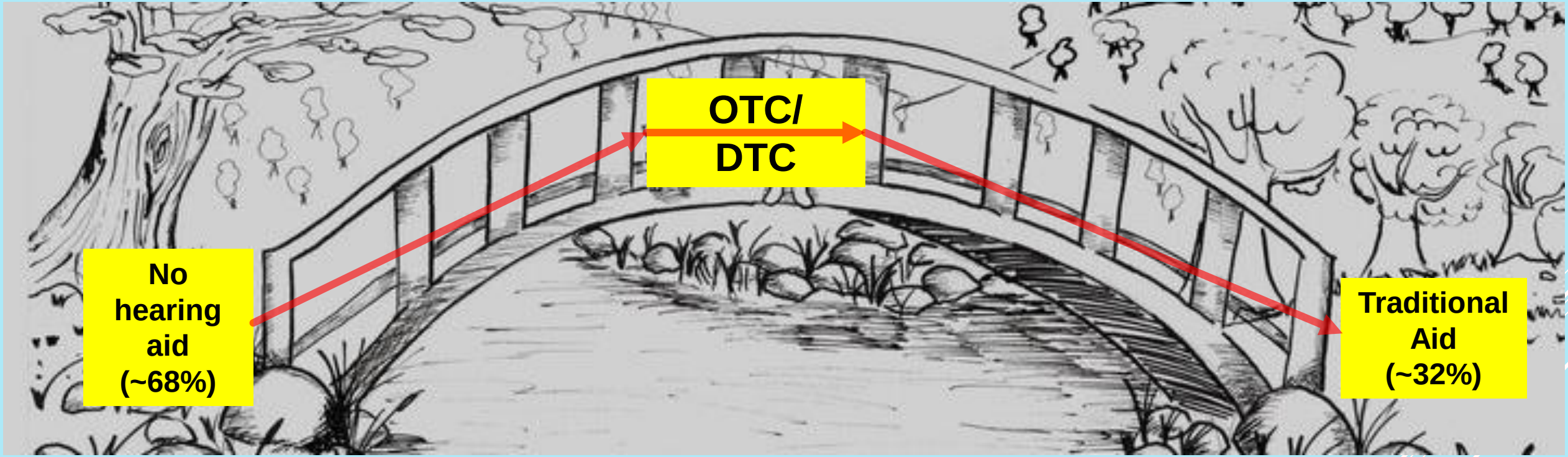
Washington University School of Medicine in St. Louis

valentem@wustl.edu

Outline

- General overview
- Discuss how OTC/DTC's evolved and why OTC/DTC's are an opportunity and not a threat
- Demonstrate how a clinic, in **2018-19**, addressed the changing environment created by OTC/DTC by:
  - Adopting an **intelligent unbundled** option to address **cost**, but at the same time maintained a **bundled** option
  - Integrating a **low-cost entry level** aid based on research as an **alternative to OTC/DTC** and combine with improved **counseling**
  - Providing **remote care** and **remote fine-tuning** to address **accessibility** and **convenience**

As audiologists we want all patients needing hearing aids to have hearing aids



I view OTC/DTC as a bridge motivating those who haven't pursued amplification to pursue amplification.

If OTC/DTC is the path patients seek I support this **informed** decision, but I hope the path is through **audiologists** and **not on-line**, **Big Box** or **drug stores**. In time, these patients may seek better technology as hearing loss progresses or device satisfaction doesn't meet expectations. This is already happening.

Via OTC/DTC, hopefully, the 68% "box" will deflate while the 32% "box" will inflate.

As early as 2015 I felt OTCs were inevitable and began thinking about how I might need to alter our practice to accommodate it's possible impact.

My first step was to better understand what led to OTC's so I don't repeat the same mistakes.

A. **President's Council of Advisors on Science and Technology (PCAST) (2015)**: ***"greater accessibility," reduced cost***

B. **National Academies of Science, Engineering and Medicine (NASEM) (2016):** "***cost*** is the primary reason," hearing aids are not ***accessible*** and ***convenient*** to patients.

C. **FTC workshop (2017):** ***access and convenience, affordability*** of hearing aids, competition and consumer protection.

D. **Warren et al: OTC Hearing Aid Act (2017)**

Is **cost** really the primary reason for the low (~32%) adoption rate of hearing aids in the US?

I'd argue cost is important, but not the primary reason as I'll address in a moment.

But, I'd also argue that the **bundled** model created the impression that hearing aids, dispensed by audiologists, are excessively expensive. We failed to educate the public that our **bundled** model is the **sum** of the **cost of the product** + the **cost of the service** for the duration of the warranty (1+ years).

$6.00 $10.00 $30.00

Product

Product & Service

This is why hearing aids dispensed by audiologists are more expensive than OTC, DTC or Big Box

Note = the chicken (product + service) to right is 5x cost of chicken (product) and consumers don't balk about this. I use this as a "talking point" to counsel patients on cost + with service compared to cost of device alone

As I will demonstrate later, when our patients are **counseled** on the differences between our **alternative** to OTC's using a **unbundled model** and **traditional hearing aids** using the **bundled model**, **93%** elected the bundled traditional hearing aids. I believe our new **counseling** was the key as I'll share with you later.

I strongly believe practices should offer patients both options. This is especially true if the clinic was using a bundled model.

So, is cost the primary reason consumers have not pursued hearing aids?

Valente and Amlani (2017) in response to Grundfast and Liu (2017)

VIEWPOINT

Cost as a Barrier for Hearing Aid Adoption

Michael Valente, PhD
School of Medicine, Washington University in St Louis, St Louis, Missouri.

Amyn M. Amlani, PhD
Department of Audiology and Speech Pathology, Consortium Program between University of Arkansas for Medical Sciences and the University of Arkansas at Little Rock, Little Rock.

Grundfast and Liu[1] recently provided otolaryngologists with an overview of the hearing aid market. While their viewpoint addressed valid points, some points did not accurately reflect the hearing aid market. In this Viewpoint, we hope to provide otolaryngologists with a more accurate representation of hearing aids as part of audiologic service delivery.

Grundfast and Liu[1] correctly state that the hearing aid adoption rate is approximately 33%. The authors attribute this "poor" adoption rate primarily to cost, which can exceed $2000 per unit. We believe that cost is not the primary barrier to adoption and provide the reader with data to support this belief.

First, data reveal that the number of hearing aids dispensed in the United States from 2007 to 2016 has steadily increased.[2] Second, the Figure, adapted from MarkeTrak 9, a hearing-aid industry marketing survey, illustrates global demand for hearing aids.[3] In the Figure, countries with the highest adoption rate are Norway (42.5%), the United Kingdom (41.1%), and Switzerland (38.8%).[3] The highest adoption rate in these countries is not surprising because hearing aids are fully (in Norway and Switzerland) or primarily (ie, in the United Kingdom) government subsidized. Looking at Norway, 42.5% of citizens needing hearing aids take advantage of the subsidy by adopting this technology. However, these data also reveal that 57.5% are unwilling to adopt hearing aids despite the fact that no cost is expected from the patient. In the unlikely event the United States subsidized hearing aids, market penetration is estimated to increase by no more than 10%, or that the United States would have an adoption rate similar to that of Norway.[4] Finally, a recent study[5] reported on 651 veterans screened to have hearing loss. Of those, only 28% complied with the recommendation to seek hearing aids. Furthermore, only 42% of the 28% actually adopted hearing aids, despite the fact that hearing aids are provided at no cost. Likewise, Australian researchers revealed that 39% of adults 50 years or older with hearing loss did not seek assistance for hearing loss[6] and 58% failed to adopt hearing aids.[7] Hearing health care in these latter examples is provided at minimal or no cost, yet noncompliance and nonintervention remains high. Simply stated, price—private and subsidized—is not the primary requirement to increase clinician compliance and adoption of hearing aids. This is not to suggest that price is not a consideration during the purchasing process, it is just not a primary factor. Other factors impeding hearing aid adoption include heightened social stigma, denial of hearing loss, and reduced self-efficacy.[8]

Grundfast and Liu[1] provided recent policy recommendations by the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM). Two recommendations—personal sound amplification products (PSAPs) and increased access—deserve a brief comment. First, the authors[1] note the US Food and Drug Administration (FDA) classifies PSAPs as augmentative amplifying products for listeners exhibiting normal hearing, whereas hearing aids are classified as an amplifying product for listeners exhibiting impaired hearing. Recently, PCAST recommended (and NASEM concurred) that PSAP manufacturers be permitted to advertise products to listeners with impaired hearing. While we advocate PSAPs as entry-level devices, emerging research suggests that some consumer-based devices can optimally reduce (1) the effect of reduced audibility caused by hearing loss, (2) cognitive decline because hearing sensitization is restored, and (3) social isolation. As such, it is essential that PSAPs meet a minimum standard for sound quality, functionality, and benefit. Grundfast and Liu[1] do not mention that hearing aid manufacturers must be registered with the FDA and hearing aids must be appropriately labeled (ie, model, serial number) and provide a User Instructional Brochure.[9] In addition, hearing aids must meet strict specifications (ie, tolerances) based on American National Standards Institute protocol S.33-2009. That is, minimal differences are present between the same model produced by a hearing aid manufacturer. When hearing aids arrive, the audiologist measures its performance using a hearing aid analyzer. On the one hand, if the hearing aids do not match the hearing aid tolerances, they are returned for replacement. On the other hand, PSAPs are exempt from FDA requirements. That is, tolerances for PSAPs are absent. In addition, hearing aids undergo strenuous in-house and third-party testing related to electroacoustic and behavioral performance to ensure consumer protection against a faulty product.

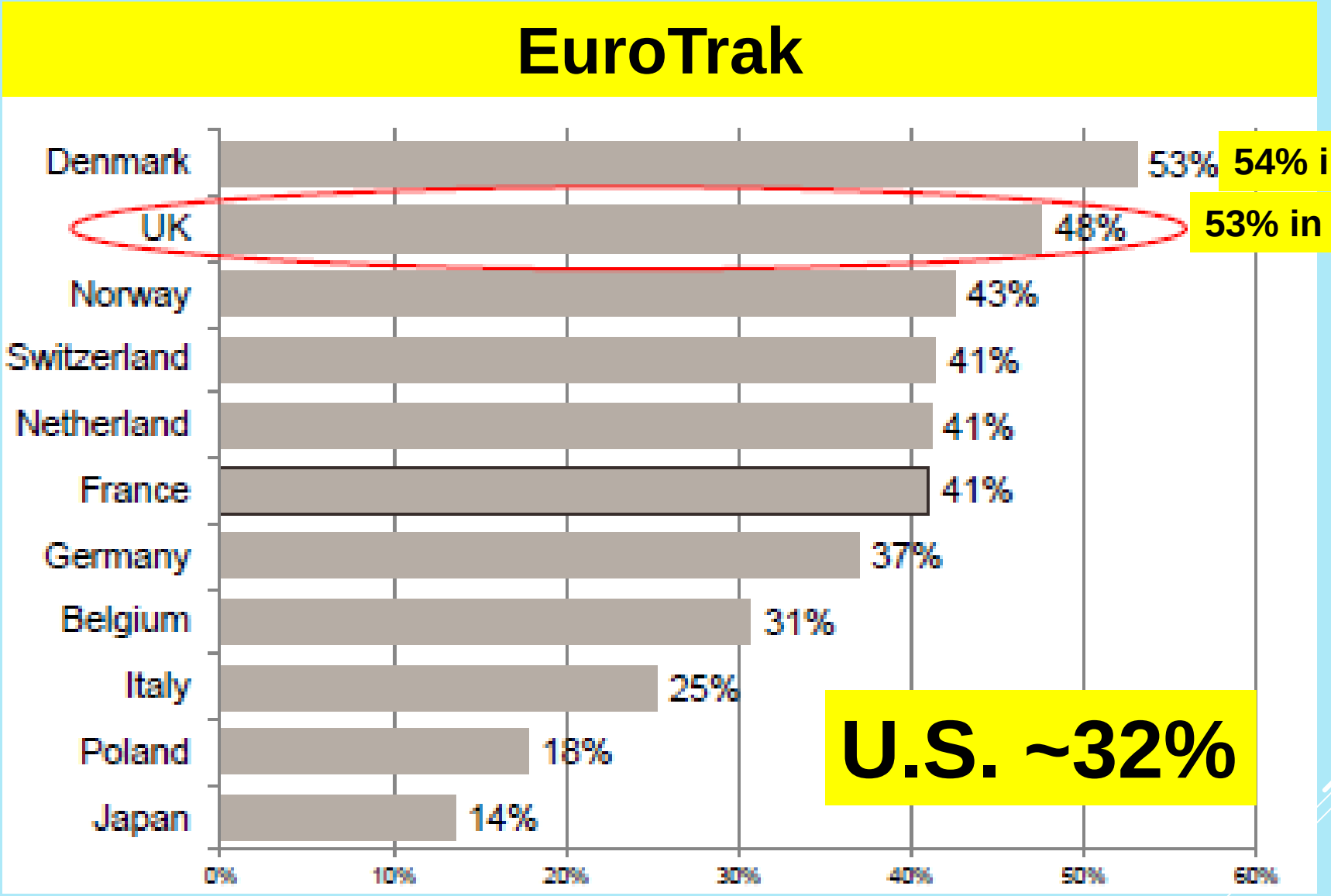
Second, when PSAPs are purchased, no guaranteed audiologic service is included; it is simply "out of the box" and "into the ear." With hearing aids, audiological follow-up is necessary to ensure the device provides maximum performance to the patient. Examples include (1) measuring the hearing aids in an analyzer to verify adherence to manufacturer specification, (2) programming by using real ear measures (REM) to a prescriptive target assuring maximum speech understanding, (3) providing a 4- to 6-week trial to determine if the patient wants to retain the hearing aids, (4) scheduling appointments during the trial period to fine-tune the hearing aids, and (5) scheduling service appointments (repairs, reprogramming, counseling) for maintenance and performance. All these services, and others, represent a considerable difference between the cost of the hearing aids dispensed via an audiologist vs purchasing a PSAP, where no such follow-up care exists. Thus, if cost were the only factor, audiologists could order several hearing aids at a cost equal or less than

Corresponding Author: Michael Valente, PhD, School of Medicine, Washington University in St Louis, Campus Box 8115, St Louis, MO 63110 (valentem@wustl.edu).

Other barriers:

a. Convenience and transportation
b. Accessibility
c. Denial re: degree of HL
d. "Yes, I have some HL, but not to point to get hearing aids"
e. Stigma
f. Cosmetics
g. Performance in noise doesn't meet expectations
h. Poor prior experience with amplification of family or friend.

EuroTrak



The British-Irish Hearing Instrument Manufacturers Association (2018)

Would providing hearing aids “free” significantly increase the US adoption rate?

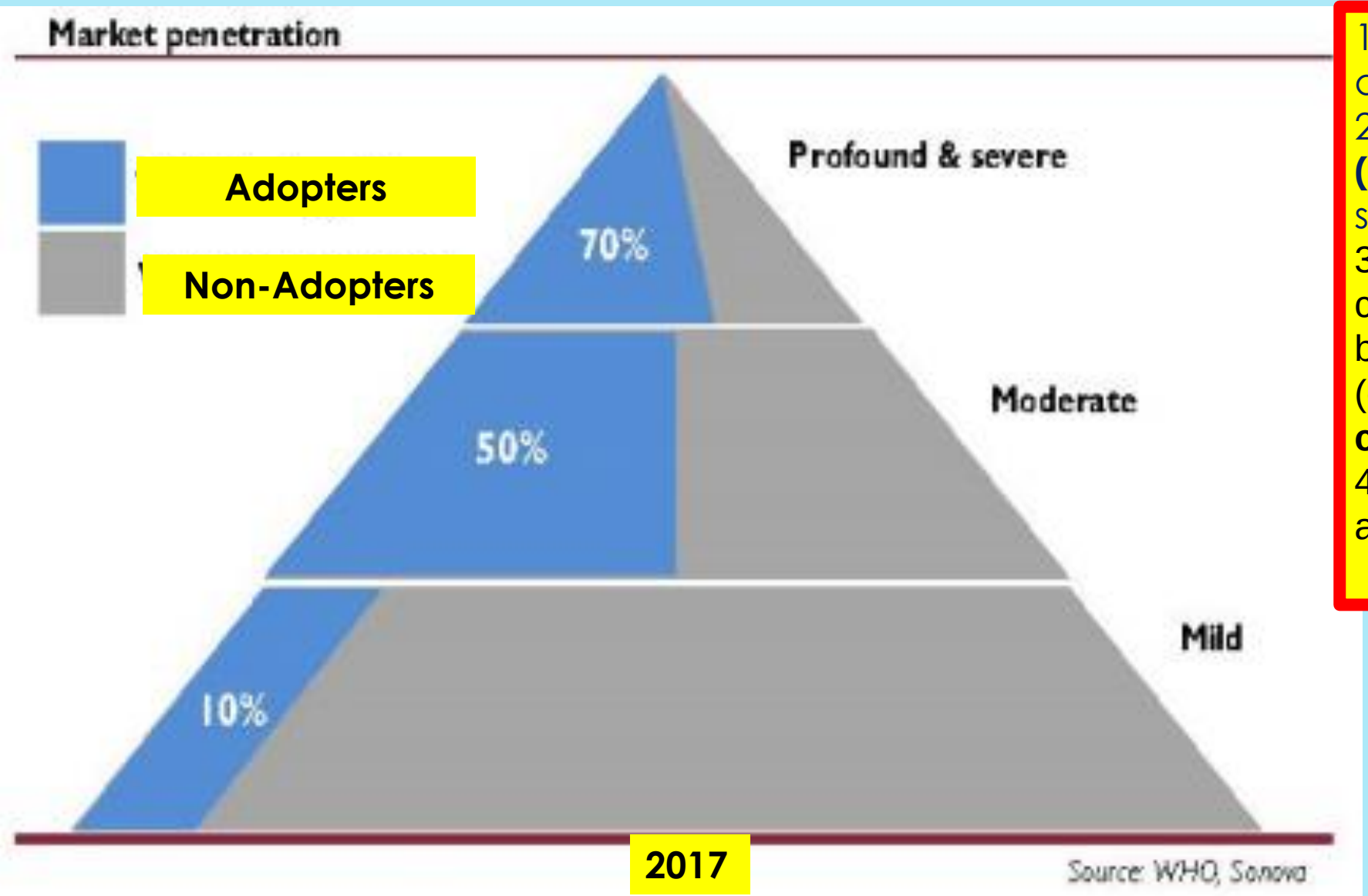
- **No.** Numerous countries provide hearing aids at no cost or at a very significant discount. The highest adoption rate is **54%** (**Denmark**) with the lowest at **14%** (**Japan**).
- The U.S. adoption rate is **~32%.** I’d predict adoption rate *might increase* to **45-50%** if offered “free.”
- “Free hearing aids” is already occurring via ***Medicare Advantage (>36% of enrollees)*** and **other third party payer (TPP) plans.** Congress continues to discuss including hearing aids in Medicare B.

Three factors patients felt the current dispensing model does not provide that led to OTCs

Key Factors	Solution
Excessive cost: which is a by-product of **bundled** model	***Intelligently*** implement **unbundled** model with a entry level hearing aid fit using REM and QC 2cc measures
Limitations re: accessibility: travel/traffic; distance; weather; parking; etc	Offer and charge for **remote care** AND **remote fine-tuning** to reduce # clinic follow-up visits
Inconvenient: appt adhering to provider schedule not patient; provided a timely appt; transferred to voice mail; cancel; re-schedule; multiple visits to obtain aids, etc.,	Offer and charge for **remote care** AND **remote fine-tuning** to reduce # clinic follow-up visits; aids in-stock
Our strategy to address these factors:	a. Dispense **high quality entry-level** device (in-stock) as an **alternative to OTC** using a **unbundled model *AND*** maintain **bundled** model with traditional aids (93%). b. Create **counseling tools** to provide patients a greater and honest understanding of differences between **unbundled and bundled models** and differences between **traditional** and **OTC/DTC** devices. c. Offer **remote care** and **remote fine-tuning** to address **accessibility** and **convenience**

The following slide led me to believe OTCs were **not a threat**, but rather an **opportunity**.

To take advantage of this opportunity the dispensing model of the clinic operation had to change.



1. As HL decreases: adoption rate decreases
2. I believe OTC **will not** have a **(-) impact** because we're not seeing these patients
3. This **lower rung** are the consumers **OTC/DTC** manufacturers believe will select them instead of us (**convenience**, **accessibility** and **cost)**.
4. These can be **program builders** and **not a threat**

OTC/DTCs present a significant opportunity

1. You can't reach all **non-adopters**, but you can reach **new** and **current** patients considering OTC. These can build your practice and increase revenue. Placing information on your **website** will attract those who are considering OTC/DTC**.** Also, consider offering **remote care** and **remote fine-tuning** to improve **accessibility** and **convenience**. Allow your clinic to stand-out from your "competition." Finally, these patients may migrate to a higher level of technology and **refer** patients to your clinic.

2. **New** and **current** patients **will** inquire about OTC/DTC aids when recommending hearing aids. You NEED to be prepared to address with excellent counseling tools. We created a **tri-fold** explaining adv/disadv of OTC/DTC and traditional aids AND offer both. Follows the business mantra of "they entered your house, keep them in your house."

3 Didn't adopt attitude that dispensing these "is below us." There are many high quality OTC/DTC devices available that can be programmed to hearing loss with REM (next slide).

https://www-nytimes-com.cdn.ampproject.org/c/s/www.nytimes.com/wirecutter/reviews/best-over-the-counter-hearing-aids/amp/

August 2022

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T | Wirecutter

The Best Over-the-Counter Hearing Aids and Other Hearing Solutions

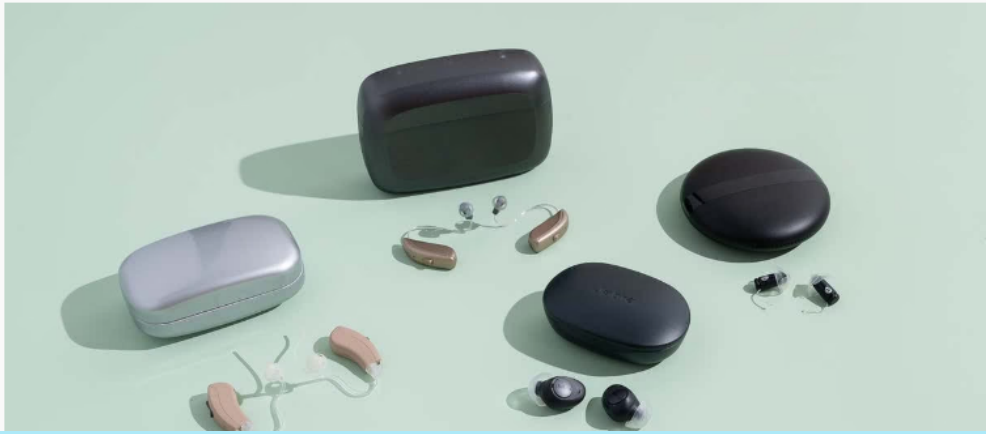
By Lauren Dragan

Updated August 26, 2022

Many "high quality" OTC aids that can be programmed could be added as products offered by a clinic.

New OTC aids are introduced almost daily.

Subscribe to *Hearing Tracker



Full List of OTC Hearing Aids

All OTC hearing aids currently (**Dec 2022**) approved by the FDA.

By Abram Bailey, AuD

AcoSound Celesto-W-BTE-M	Hangzhou AcoSound Technology Co.,Ltd.	874.3305	QUG
Hearing Assist CONNECT	Hearing Assist II, Inc.	874.3305	QUG
Hearing Assist CONTROL	Hearing Assist II, Inc.	874.3305	QUG
Hearing Assist STREAM	Hearing Assist II, Inc.	874.3305	QUG
otoTune™ app*	Soundwave Hearing, LLC	874.3305	QUG
Soundwave Hearing*	Soundwave Hearing, LLC	874.3305	QUG
Sontro™ Hearing Aids*	Soundwave Hearing, LLC	874.3305	QUG

Product	Company	FDA Class	Product Code
Bose SoundControl Hearing Aids	Bose Corporation	874.3325	QDD
BHA100 Series Braun Clear Hearing Aid	Kaz USA Inc. a Helen of Troy Company	874.3325	QDD
Jabra Enhance Plus	GN Hearing A/S	874.3325	QDD
MDHearingAid app MDHearingAid Smart hearing aids	MDHearingAid	874.3325	QDD
Vibe SF Self-Fitting Hearing Aid	WSAUD A/S	874.3325	QDD
Nuheara IQbuds 2 PRO Hearing Aid	Nuheara Limited	874.3325	QUH
Lucid® 7495*	HEARING LAB TECHNOLOGY, LLC	874.3305	QUG
NuvoMed HNB-4/0143	NUVOMED, INC.	874.3305	QUG
AcoSound Leya-W-RIC-S*	Hangzhou AcoSound Technology Co.,Ltd.	874.3305	QUG
AcoSound Celesto-W-BTE-M	Hangzhou AcoSound Technology Co.,Ltd.	874.3305	QUG
Hearing Assist CONNECT	Hearing Assist II, Inc.	874.3305	QUG
Hearing Assist CONTROL	Hearing Assist II, Inc.	874.3305	QUG
Hearing Assist STREAM	Hearing Assist II, Inc.	874.3305	QUG
otoTune™ app*	Soundwave Hearing, LLC	874.3305	QUG
Soundwave Hearing*	Soundwave Hearing, LLC	874.3305	QUG
Sontro™ Hearing Aids*	Soundwave Hearing, LLC	874.3305	QUG

Device	FDA Registered Device
Lexie B1 and B2	Bose SoundControl Hearing Aids
Sony CRE-C10	Vibe SF Self-Fitting Hearing Aid
HP Hearing PRO	Nuheara IQbuds 2 PRO Hearing Aid

First, let's address how to create an **unbundled** model to reduce charge to tackle "**cost**," but maintain **bundled** model.

Again, I think for reasons that hopefully will become clearer, it's important to offer both options.

https://hearinghealthmatters.org/thisweek/2022/valente-audiology-practice-management-fundamentals/

Running a Successful Audiology Clinic: Is a Bundled or Unbundled Approach Best?

512 views • 2 months ago

This Week in Hearing

Michael Valente, PhD, joins Dave Kemp to discuss the essential elements every practice owner or clinic manager should know to ...

0:45 **Michael Valente**: Thank you, Dave, for the invitation. It's always nice to talk about this particular topic, because I was involved wit...

CC

How to calculate ***cost/hour*** **+** ***% profit*** ***to create*** ***charge/hour*** **and** ***time analysis*** using an Excel spreadsheet I created to offer ***bundled*** ***and*** ***unbundled*** models. Felt it is important for patients to have choice. When provided counseling on the differences between the two, **93%** selected the bundled option fitted with traditional hearing aids.

Reducing the initial charge is crucial to address "*cost*" as one reason patients pursue OTC and not audiologist care.

Our model

First, maintained our **bundled** model for **current** and **new** patients who preferred this model because, in their words, did not want to be “nickeled and dimed to death” when counseled on new unbundled model.

Second, created an **unbundled** model to reduce charge to compete with OTC/DTC. In this model, the charge for REM and 2cc analysis are included.

It’s about **retention.** Patients select your clinic because they feel “you are the best.” Why provide a reason for them to pursue help elsewhere? I believe clinics should offer as many options as possible.

Creating an Excel spreadsheet to create an unbundled model

1. Gather **profit/loss (P/L) statement** to capture:
    a. **Direct** and **indirect** costs
    b. Separate out **costs of goods to be dispensed**

2. *Estimate* **billable hours:** the time staff are in the clinic generating income

3. **Calculate cost/hour = direct and indirect costs (–) cost of goods dispensed (/) billable hours**.

4. Select **desired profit** (**%**) and **add to cost/hour.** This is **charge/hour.**

5. Complete **time analysis (not just face-to-face time)** for all visit types associated with your dispensing practice to create "**menu of services**" in 30 min increments using **charge/hour (**e.g., $240/hour = $120/30 min; $60/15 min).

Final P/L 2017-2018

AUDIOLOGY - June 2018 YTD
Fiscal Year 18
(by location)

	CAM 11th Fl Audio June, 2018	CAM 3rd Fl Audio June, 2018	CID Audio June, 2018	West County Audio June, 2018	Audio Non Clinical June, 2018	TOTAL June, 2018
REVENUE						
Gross FFS Charges	1,762,490	8,095	425,095	1,409,812	-	3,605,492
Discounts	(3,801)	11	(219)	(819)	-	
Provision for Contr Adj	(458,852)	(5,896)	(36,022)	(204,093)	-	(704,863)
Net Collectable FFS	1,299,837	2,210	388,854	1,204,900	-	
less FFS Coll pst'd to A/R	1,289,111	4,030	397,812	1,220,405	-	2,911,358
Net Change to A/R	10,726	(1,820)	(8,958)	(15,505)	-	(15,557)
Sales and Service	-	89,629	7,027	100	-	96,756
Total Revenue	1,299,837	91,839	395,881	1,205,000	-	2,992,557
Expense/Alloc Credits	-	-	43,568	-		43,568
Total Sources	-	-	43,568	-		43,568
Total Revenue and Sources	1,299,837	91,839	439,449	1,205,000	-	3,036,125
EXPENSES						
Faculty Salary						
Staff Salary						
Fringes	139,186	5,133	47,369	78,745	10,633	281,066
Incentives	2,147	-	-	-	-	2,147
Consum Supplies, Other	35,676	225	14,674	33,172	-	83,747
Prov for Doubtful Accts	39,571	182	9,560	31,702	-	81,015
Rental Expense	-	-	-	34,725	-	
Resale	258,518	-	102,676	302,121	-	663,315
Total Direct Expense	925,947	27,429	319,877	713,235	56,913	2,043,401
ALLOCATIONS						
ACC Allocation	77,079	-	-	-	-	77,079
Overhead	147,896	4,939	45,222	85,435	-	283,492
Clinical Space Charge to the Dept	-	-	15,000	-	-	15,000
Total Other Alloc	224,975	4,939	60,222	85,435	-	375,571
Business Unit Allocations						
Admin / JU / O&M	21,533	193	2,889	12,176	-	36,791
Front End Billing	32,023	321	5,332	24,573	-	62,249
School Space	1,405	13	188	794	-	2,400
WUPN Alloc	296	3	40	168	-	507
WUPBS Alloc	26,165	104	7,055	22,551	-	55,875
JOSP Alloc	38	-	5	21	-	64
FPP Alloc	961	9	129	544	-	1,643
Registration Svc Alloc	807	7	108	457	-	1,379
Other Clin Prac Alloc	116,584	1,159	19,417	89,479	-	226,639
Total	199,812	1,809	35,163	150,763	-	387,547
Encumbrance Adjustments	(7,170)			(42,630)		
Total Business Unit Alloc	199,812	1,809	35,163	150,763	-	387,547
Total Dir. Exp. & Alloc	1,350,734	34,177	415,262	949,433	56,913	2,806,519
Accrued Profit / (Loss)	(58,067)	57,662	24,187	212,937	(56,913)	229,606
Cash Profit / (Loss)	(29,222)	59,664	42,705	260,144	(56,913)	326,178

CAM 11 | CAM -2 | CID | West County | Research

Income

Expenses

Profit/loss

CAM = $30,442
CID = $42,705
WC = $260.144
Res = -($56,913)

Cash P/L = $326,178

84.2% CR

Gross charges

Contractual adj

Net income

Total costs – resale

Total direct

Overhead

Total business unit expenses

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FPP Alloc	961	9	129	544	-	1,643
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	Available Hours/FTE	# FTE	Total Available	
	2080	9	18,720	40 *52 = 2080 * 9 = 18,720. Don't include 4 PSR because they don't bill
Total Direct Expense			$2,043,401	Total Direct Expense
Total Oth Allocations			$375,571	Total Other Expenses
al Business Allocations			$387,547	Additional Business Expenses
Sub-Total			$2,806,519	Total Direct + Indirect Expenses
Resale			$663,315	Expenses for Hearing Aids
Sub-Total			$2,143,204	Total Expenses – Hearing Aid Expenses
Contractual Adj			$704,863	Expense due to loss income
Total Expense			$2,848,067	Total Expenses
Non-Billable Hours				

	Hrs/day	# days		# Staff	Total	
Vacation	8	22	176	9	1,584	
Holidays	8	8	64	9	576	
Sick	8	12	96	9	864	
Unrecorded	12			9	108	* Non-billable hours
Meetings	8	5	40	9	360	
Personal days	8	2	16	9	144	
Total					3,636	
Sub-Total Billable					15,084	20%
Cost/hour Non-Correected					$188.81	Cost/hour 2017-2018

$2,848,067/15,084

Other Non-Billable	
No-Show	645
Cancellations	6,419
Staff Meetings	0
CEU Meetings	0
OSHA training	0
Xmas parties	0
Staff lunches	0
Maternity Leave	0
Jury Duty	0
Teaching	0
Patient Seminars	0

Additional non-billable hours

Points to need to calculate cost/hour customized for your facility and not what is being charged "down the road".

Each clinic site has different expenses and billable hours due to differences in benefits (vacation, sick, holidays, research, meetings, etc)

	Available Hours/FTE	# FTE	Total Available	
2	2080	9	18,720	40 *52 = 2080 * 9 = 18,720. Don't include 4 PSR because they don't bill
3	Total Direct Expense		$2,080,344	
4	Total Oth Allocations		$340,249	
5	al Business Allocations		$383,908	
6	Sub-Total		$2,804,501	
7	Resale		$660,733	
8	Sub-Total		$2,143,768	
9	Contractual Adj		$804,729	
10	Total Expense		$2,948,497	

Example for another year

11	Non-Billable Hours					
12		Hrs/day	# days		# Staff	Total
13	Vacation	8	22	176	9	1,584
14	Holidays	8	8	64	9	576
15	Sick	8	12	96	9	864
16	Unrecorded	12			9	108
17	Meetings	8	5	40	9	360
18	Personal days	8	2	16	9	144
19						
20	Total					3,636
21	Sub-Total Billable					15,084
22						
23	Cost/hour Non-Correected					$195.47

*12 hrs/year/staff

24		
25	Other Non-Billable	
26	No-Show	645
27	Cancellations	6,419
28	Staff Meetings	0
29	CEU Meetings	0
30	OSHA training	0
31	Xmas parties	0
32	Staff lunches	0
33	Maternity Leave	0
34	Jury Duty	0
35	Teaching	0
36	Patient Seminars	0
37	Research	0
38	Other	0
39	Other	0
40	Other	0
41	Other	0
42	Other	0
43	Other	0
44	Other	0
45	Other	0
46	Other	0
47	Total	7,064
48		
49	Total	8,020
50		
51	Cost/hour	$367.64
52	Corrected	
53		

54		Cost/hour based on Percent Profit									
55	Cost/hour	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
56	Non-corrected	$215.02	$234.57	$254.11	$273.66	$293.21	$312.75	$332.30	$351.85	$371.40	$390.94
57	Corrected	$404.41	$441.17	$477.94	$514.70	$551.46	$588.23	$624.99	$661.76	$698.52	$735.29
58											
59											
60		Cost/hour Based on Desired Profit in Dollars									
61	$ Profit	$50,000	$100,000	$150,000	$200,000	$250,000	$300,000	$350,000	$400,000	$450,000	$500,000
62	Non-corrected	$198.79	$202.10	$205.42	$208.73	$212.05	$215.36	$218.68	$221.99	$225.30	$228.62
63	Corrected	$373.88	$380.11	$386.35	$392.58	$398.82	$405.05	$411.28	$417.52	$423.75	$429.99

Next, how a **low-cost entry level aid** using an **unbundled** model was adopted along with **counseling** as an **alternative to OTC** and provide customized **high-quality care**

https://hearinghealthmatters.org/thisweek/2022/otc-part-audiology-practice-valente/

Successfully Integrating OTC Hearing Aids into an Audiology Practice

730 views • 2 months ago

This Week in Hearing

After last week's discussion on the essential elements of running a successful practice, such as calculating cost/hour and how this ...

0:10 So here we have **Mike Valente**, ready to present part two of his presentation here. So Mike, take it away. **Michael Valente**: David

CC

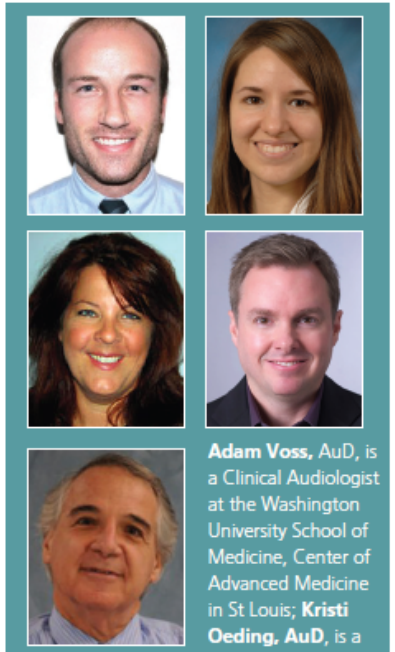
How to integrate a **entry level** hearing aid as an **alternative to OTC** using an **unbundled** model along with a ***tri-fold brochure*** on adv/disadv between OTC and traditional aids using **bundled** model. In our case, >90% elected the **traditional bundled** aids.

Coupler and Real-Ear Performance between PSAPs and Hearing Aids

How do today's PSAPs stack up in comparison with traditional hearing aids?

By ADAM VOSS, AuD, KRISTI OEDING, AuD, A.U. BANKAITIS, PhD, JOHN PUMFORD, AuD, and MICHAEL VALENTE, PhD

Before jumping to the conclusion that any PSAP and/or OTC hearing device would be suitable for the many different types of hearing losses, we need to look at their coupler and real-ear performance data. This study suggests PSAPs are suitable for mild losses only.



Adam Voss, AuD, is a Clinical Audiologist at the Washington University School of Medicine, Center of Advanced Medicine in St Louis; **Kristi Oeding, AuD**, is a PhD candidate at the University of Minnesota-Twin Cities in Minneapolis; **A.U. Bankaitis**, PhD, is Vice President of Oaktree Products Inc in Chesterfield, Mo; **John Pumford, AuD**, is

Hearing aids currently remain the "gold standard" for treating hearing loss. Other amplification options, however, such as Personal Sound Amplification Products (PSAPs) and Over-The-Counter (OTC) devices have gained consumer and audiologist interest. This interest has increased due to recommendations from the President's Council of Advisors on Science and Technology (PCAST),[1] National Academies of Sciences Engineering Medicine (NASEM),[2] Consumer Technology Association (CTA)[3] and the media.[4-7] The new law passed by Congress and signed by the President suggests that these PSAPs and OTCs would be appropriate for patients with "mild" to "moderate" hearing loss. The results of the current study do not agree with this suggestion, which will be explained in more detail later in this text.

One finding of the PCAST[1] report is the US adoption rate of hearing aids is approximately 15-30% for persons with hearing loss.[1] The adoption rate, however, is anywhere from 6-14% for patients with "mild" hearing loss, and as great as 55-73% for patients with more severe hearing loss.[8-9] While the report[1] recognizes many barriers exist to obtain hearing aids (denial of hearing loss, stigma, access, limited knowledge concerning amplification options, etc), one prominently cited barrier is cost. Cost to the consumer is a significant driving force behind the increased interest in PSAPs and OTCs, as the cost of these devices can range from less than $20 to hundreds of dollars, compared to hearing aids that can cost several hundred to several thousand dollars. It is important, however, to remember that the PSAP or OTC costs to the consumer is exclusively related to the invoice cost of the device. Hearing aids, on the other hand, include the cost of the device hearing loss. Only a few studies have examined characteristics of PSAP and OTC devices.[10-17] Results from these studies are mixed, but overall there is a suggestion that PSAP and OTC devices can have a high maximum peak output, high *equivalent internal noise* (EIN), and not adequately match a valid prescriptive target. Some studies reported PSAP and OTC devices were appropriate for a low-frequency hearing loss,[12] "mild to moderate" gently sloping or flat hearing loss,[12] and some devices performed similarly to a hearing aid in a speech recognition task.[11]

The primary goal of the current study is to provide additional information that can be used by hearing care professionals to counsel patients on which PSAP/OTC device might best fit their hearing loss. The current study does *not* endorse PSAPs/OTCs replacing hearing aids because the authors believe hearing aids, correctly fit by a dispensing professional, are the gold standard to achieve optimal hearing. Instead, the current study is intended to help clinicians better counsel patients who cannot afford a hearing aid on an appropriate PSAP/OTC for his/her hearing loss.

In the current study, two "premium" hearing aids, two "basic" hearing aids, three "advanced" PSAPs, five "intermediate" PSAPs, and five "basic" PSAPs were examined (Tables 1 and 2). PSAPs were arbitrarily separated into categories based on user control/programmability and available options. Electroacoustic (ANSI S3.22-200918) and *real-ear measures* (REM) were measured using eight "typical" audiometric configurations shown in Table 3. REM examined differences between the hearing aids and PSAPS using manufacturer first-fit versus programmed to match (ie, ±5 dB at 250-6000

2018 - Hear Rev 25(11):10-18

1. **8** typical **audiometric configurations (next slide)**.
2. **Independent variables**:
   1. **First-fit** and **programmed** REAR to NAL-NL2
   2. **50** and **65** dB SPL input levels
   3. **4** hearing aids from **two** manufacturers (**premium** and **basic**)
   4. **21** PSAPS **($48 - $499**)
3. **Dependent variable**: "closeness" (%) to NAL-NL2 (**+/- 5 dB** @ **9** freq between **250-6000 Hz**)

Audiograms used in Voss et.al. (2018)

Audiogram	250 Hz	500 Hz	750 Hz	1000 Hz	1500 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz
1	10	10	10	10	10	15	20	30	40
2	20	20	25	25	30	35	40	45	50
3	35	35	35	40	45	50	55	60	65
4	55	55	55	55	60	65	70	75	80
5	65	70	75	75	80	80	80	80	80
6	10	10	10	10	10	15	30	55	70
7	20	20	25	25	35	55	75	95	95
8	30	35	50	60	70	75	80	80	85

Key points from Voss et. al., (2018)

- **Programming** improved the ability to match NAL-NL2 re: **first-fit** for the **4 hearing aids**, **21 PSAPs** @ both input levels (**50 and 65 dB SPL**)
- Most PSAPs could not match NAL-NL2 at either input level for first-fit or programmed when HL @ 1000-6000 Hz **≥ 40 dB**
- For **all 8** audiometric configurations, the **2 premium and 2 entry level** hearing aids were able to adequately match NAL-NL2 when programmed at either input level
- For the 4 hearing aids, there was **little difference** between **premium** and **basic** in ability to match NAL-NL2
- Bear in mind that most PSAPs **first-fit** performance was poor. Performance improved when programmed, but even then performance was still poor re: hearing aids. This is especially true when HL @ 1000-6000 Hz ≥40 dB HL.

Voss et al (2018) was the catalyst to pursue an **entry level** aid dispensed using an **unbundled** model as our initial strategy as an **alternative** to **OTC**.

Practices might decide to select other devices. This may include OTCs or other devices which seem to change daily.

Recall, this began in 2018-2019. Today, there are many new options for devices to offer. **If I have time, remind me to tell you my experience with Mimi, AirPod2 Pro and a Aluratek ABC53F BT transmitter.**

Developed new **counseling tools to take home.** Felt this was a key for the success of offering the new fitting option.

Also, this new option as well as information on OTC's had to be placed in our website.

Steps taken to integrate an entry level aid using an unbundled model

- Needed a inexpensive device allowing effective programming to match NAL-NL2 as best as possible for a wide variety of audiograms
- Sought HA with invoice cost ≤ $200 and purchased 100 to keep in stock to reduce # of visits
- Contacted our four manufacturers to pursue interest in providing an entry level aid at ~$200/aid with a 1 year warranty that could be returned
- REM and 2cc had to be part of dispensed device and this was added to invoice cost of aid using a unbundled model.
- Created a “menu” of services with charge/service based on time required for visit type. Patients counseled that all visits following the fitting would entail a charge. Signed a form acknowledging this.
- Charge to the patient had to be competitive with OTC/DTC or this new model would not be successful.
- Up to this point the clinic, like most in the US, exclusively used a bundled model.
- Essential to maintain traditional using bundled model
- Created counseling tools to help direct patients to best option based on numerous factors
- Tracked % of patients pursuing traditional versus entry level aids

First, negotiated invoice cost for entry level aid. Selected the Phonak V30. This was replaced with their updated entry level aid when the V30 was discontinued

Purchased 100 aids in two colors and divided among our clinical sites.

	Widex		ReSound		Phonak
	Unique		Enya 3		V-30
Cost	$215		$225		$200
Warranty	1		1		1
Channels	4		8		8
Bands	4		8		8
Programs	3		4		automatic: 2
Tinnitus	Yes		Yes		Yes
Return?	No		Yes		Yes
Change color	Yes		Yes		Yes
Extend Warranty	Yes		Yes		?
Battery	312		312		10/312/312T/13
Frequency Shifting	Yes		No		Yes
OSPL90	114		116		114
HF F/O Gain	55		57		46
EIN	21		23		19
Battery drain	1		1.23		1.2
Phone Rating	M4/T4		T2-T4		M2/T2

*** These services built into charge for aid(s)**

Basic Aid

1. ***HAE**
2. ***2cc measure (QC)**
3. ***Programmed to NAL-NL2**
4. Aids “in stock”
5. 1-year warranty
6. 4-week trial; can return
7. We’re not going anywhere
8. Purchase extended warranty
9. We repair or send for repair
10. Provide remote care/remote fine-tuning
11. *Far greater level of service than many OTC/DTC*

				Mon	Bin	
Basic Hearing Aid				$640	$1,000	
Menu						Charge
Change color of case						$55/aid
REM after initial fit						$120
Counsel on use of aids						$120
Download App and pair						$120
Counsel on App						$60
Coupler measure						$60
Earmold/ear						$100
1/2 hour visit						$120
1 hour visit						$240
Unaided and aided speech in noise (QuickSIN)						$120
Unaided and aided questionnaire						$60
Additional programming (fine-tuning)/1/2 hour						$120
Return aid(s) for repair						$60
Replace receiver(s)						$60 + cost of receiver
Troubleshooting (dead, weak, excessive drain, Fb, etc)						$60/15 min
Routine maintenance (replace dome/wax guard)						$60 + cost of supplies
Loudness judgments						$120
Address questions via email/text/phone						$60/15 min
Domes, waxguard, retention pieces ,etc						$5/pack
Supplies - see menu of charges for supplies						

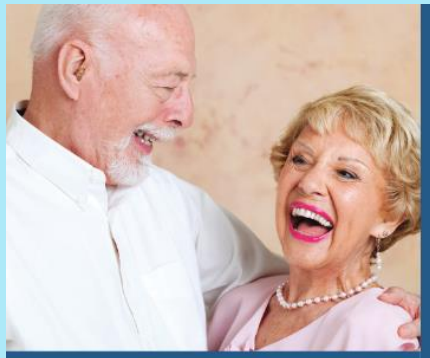
Unbundled charge for these services

Example of menu based on charge/hour of $240

OTC/DTC

1. No HAE
2. No 2cc measures
3. Not programmed to NL-NL2
4. Will take time to obtain
5. May not have 1 year warranty
6. May not have 4 week trial or ability to return
7. May be out of business
8. Perhaps can’t purchase extended warranty
9. Care for repairs yourself
10. May not offer remote care/remote fine-tuning
11. *Far lower level of service than our entry level aid*

Patient brochure on options for hearing aids



Barnes-Jewish West County Hospital
1044 N. Mason Road, Suite L20
St. Louis, MO 63141
Appointments: 314-362-7509

Center for Advanced Medicine
4921 Parkview Place, Suite 11A
St. Louis, MO 63110
Appointments: 314-362-7489

Central Institute for the Deaf
4560 Clayton Avenue
St. Louis, MO 63110
Appointments: 314-747-7100

Toll free, all locations: 800-437-5430

WHEN SHOULD MY HEARING BE CHECKED?

Your hearing should be checked by a clinical audiologist if you:

- Hear a buzzing, ringing, chirping or roaring in your ear(s).
- Receive complaints that you have the radio or television volume turned up too loud.
- Have difficulty understanding children's voices.
- Find that people often seem to mumble or speak unclearly.
- Have difficulty understanding people in noisy environments.
- Often ask others to repeat themselves or misunderstand conversations.
- Find it a strain to understand a conversation.
- Notice environmental sounds seem too loud.

Symptoms of HL

For more information, call 800-437-5430

ADULT AUDIOLOGY

Your Options for Hearing Devices

Washington University in St. Louis Physicians

HEARING.WUSTL.EDU

WASHINGTON UNIVERSITY PHYSICIANS

THE WORLD OF HEARING AIDS AND AMPLIFICATION IS CHANGING.

According to the National Institutes of Health, about 28.8 million people in the U.S. could benefit from using hearing aids. However, only 15-30% of those with hearing loss opt for hearing aids. One reason for this is thought to be the cost.

With today's technology, there is no reason to be left out of the conversation. Hearing aids and personal sound amplifiers can now be purchased online, in retail stores and in pharmacies at several different price points.

Options available for sound amplification include personal sound amplifiers (PSAPs), over-the-counter (OTC) devices and hearing aids. So how do you decide on the best instrument for your hearing loss?

WHAT ARE MY OPTIONS FOR HEARING DEVICES?

Hearing Aids are a regulated medical device that must be prescribed by a licensed hearing professional. Washington University offers the full array of hearing aids, along with testing, real-ear measures and fittings customized specifically to each person's type and degree of loss. Sophisticated hearing aids can be expensive, and our recommendations come without any bias for a manufacturer or device type – Washington University audiologists don't get commissions on sales. With this bundled package, patients get free after-fit care, adjustments and replacement parts during the warranty of the device.

Basic, or Entry-Level Hearing Aids are offered by Washington University, but at a lower cost. Basic hearing aids offer less sophisticated options than some of the more advanced alternatives. Even with fewer options, Washington University audiologists can make basic hearing aids accommodate most patients' hearing loss, but there is a charge for each fitting and service visit.

One in eight people in the U.S. over age 12 has hearing loss in both ears, based on standard hearing examinations.

Source: National Institutes of Health

Personal Sound Amplification Products (PSAPs) are marketed for hearing enhancement and are not intended to be used for hearing loss. Washington University does not offer these devices. They can be purchased online or over-the-counter without a hearing evaluation or doctor's prescription.

Over-the-Counter (OTC) hearing devices are a new category created by the FDA, and will be available in the year 2020. This new class of self-programmable devices will be marketed for individuals with mild to moderately-severe hearing loss. They will be available at retailers without a prescription. While these devices may improve access to hearing devices for some people, because they can be purchased without the assistance of a licensed audiologist, they also carry the risk of being used improperly.

WHY CHOOSE WASHINGTON UNIVERSITY?

Service quality is a priority with our staff of professionals and is exhibited in everything from scheduling to follow-up care.

We offer:

- Recommendations for hearing aids based on your custom needs. All types and levels of technology will be addressed. If you choose a PSAP or OTC device, verification of these devices and follow-up care will be offered with a fee for the services applied.
- Selection of many manufacturers' hearing aids in a variety of price ranges (our staff does not receive commissions).
- Free follow-up visits for the duration of a non-basic hearing aid warranty (2-3 years) for the best possible hearing aid performance.
- Free hearing aid reprogramming and cleaning for the duration of the warranty (2-3 years) of a non-basic device.
- Free orientation class on the care, use and expectations of hearing aids.

For more information, call 800-437-5430

Why select our clinic

Factors	Premium and Advanced HA	Basic HA	PSAP	OTC
Hearing Test	√	√	X	X
Hearing Aid Evaluation	√	√	X	X
Quality Control	√	√	X	X
Real Ear Measures	√	√	X	X
After Fit Care	NC During Warranty	√*	X	X
Extended Warranty	√	√	X	X
Loaner	NC During Warranty	√*	X	X
Counseling	NC During Warranty	√*	X	X
Warranty	2-3 years	1 year	?	?
4 Week Trial	√	√	X	X
Return for Credit	√	√	?	?
Adjustments	NC During Warranty	√*	X	X
Solvency	√	√	?	?
Replacement parts	NC During Warranty	√	X	X
* Additional fee	NC = no charge			

Number entry level aids dispensed (July 1, 2019 – January 31, 2020)

Then the pandemic hit

	CAM		CID		WC	
	HA	Entry	HA	Entry	HA	Entry
July	24	2	4	1	23	2
Aug	22	2	11	0	34	2
Sept	28	1	7	1	39	2
Oct	22	4	8	0	21	4
Nov	20	3	9	0	23	4
Dec	25	2	19	0	36	0
Jan	36	0	9	0	30	0
Feb						
Total	177	14	67	2	206	14
	CAM		CID		CAM	
Sum HA	177		67		206	
Sum Basic	14		2		14	
%	0.08		0.03		0.07	
Sum HA	450					
Sum Basic	30					
%	0.07					

Although this wasn’t completed before I retired I would meet with our **website** staff to expand the information in our brochure and place on our website.

We need to educate potential patients on OTC, DTC, traditional hearing aids, unbundling, bundling, etc. We need to educate on the provided services to address these different technologies.

Also include information on offering **remote care** and **remote fine-tuning**.

Finally, let's address how r**emote care** and **remote fine-tuning** was created and introduced to address **accessibility** and **convenience**. This component was still a "work in progress" when I retired in 2020.

Be sure to check your state licensure law

Note: several **OTC/DTC** companies and insurance plans provide this service.

https://hearinghealthmatters.org/thisweek/2022/remote-care-audiology-practice-management/

Successfully Integrating Remote Care into an Audiology Practice with Dr. Michael Valente

215 views • 1 month ago

This Week in Hearing

Dr. **Michael Valente** returns to discuss how remote care and remote fine tuning can help address issues of accessibility and ...

CC

Discuss how to integrate ***remote care*** and ***remote fine-tuning*** using an ***unbundled*** model to address ***accessibility and convenience***.

Survey Reveals 90% of Americans Used Telehealth in The Past Year

NEWS PROVIDED BY
Independa
Jan 10, 2023, 13:00 E

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Differentiating remote care and remote fine-tuning

Remote care: Resolve problems remotely (e.g., secure zoom), but does not use manufacturer software or require a clinic visit. This addresses **accessibility and convenience**. Audiologists have been engaging in this form of “remote care” for years (i.e., telephone; e-mail), but “seeing” the patient along with his/her hearing aids significantly improves the ability to resolve problems without the need for an office visit.

Remote fine-tuning (synchronous and asynchronous): resolves problems remotely via smartphone using a strong WIFI or smartphone with unlimited data and does not require an office visit. This uses manufacturer software to reprogram hearing aids as well as provide additional services provided within the software. This also addresses **accessibility and convenience**.

Examples of remote care

1.How many times have you seen patients and thought this problem could have been resolved remotely without the need for an office visit? Would open space in the clinic for other patients and visit types and improve convenience and accessibility for patients.

2. Counsel: correct insertion of earmolds/domes/batteries; reconnect aids, phone and other devices; download updated app and check pairing, connect TV device and other devices to stream to aids; R/L dome or mold; change wax guards; receiver problems; etc.,

3. Troubleshoot TV device, remote mic and/or streamer, charger, moisture in tubing or cracked tubing, battery, corrosion. **Is an appointment required as follow-up to resolve the problem?**

4. Can be charged using “menu of services” (unbundled) or NC (bundled for duration of warranty).

5. Can be provided by a **audiology assistant** depending upon licensure laws.

I contacted our manufacturer reps at **Widex, Phonak, ReSound and Starkey** to learn how often **remote fine-tuning** is utilized by their accounts.

All were surprised that **remote fine-tuning** was used **<10%.** This was surprising given its' potential to **improve** patient care/satisfaction, accessibility and convenience and increase # appointments and revenue.

Their assessment why **remote fine-tuning** was not used:

a. Hesitant to **adopt and learn new technology**
b. Hesitant to counsel on **availability** and **advantages** of remote fine-tuning
c. Lacking knowledge of **how** to integrate remote fine-tuning into their practice
d. Lacking knowledge of how/what to **charge**
e. Concerned re: **Scope of Practice** and **state/federal laws**
f. Fear of **losing patients** if **they** didn't see their patients **in the clinic**
g. Confident patients couldn't handle or have access to this technology

Fear of losing patients

Audiologists fear **“losing”** patients if remote care and remote fine-tuning were offered in spite of improving **accessibility and convenience**.

Is this concern legitimate when so many **other** healthcare professionals routinely schedule remote care and don’t report their patients haven’t returned for in-office visits when face-to-face is necessary?

Remote care and remote fine-tuning are **marketing tools** used by many DTC/OTC manufacturers and insurance plans to attract consumers to purchase their products and abandon “brick and mortar” clinics

Fear of violating Scope of Practice or state/federal laws

Fear of **violating** federal and/or state **licensing laws or scope of practice** is legitimate, but can be answered by viewing AAA and ASHA links, state licensing boards or obtain legal advice.

This could be an issue with **asynchronous** remote-fine tuning.

For example, we contacted the **Missouri licensing board** for advice on the providing **RC and RFT**. We **never** received a response. To circumvent this obstacle we sought the advice of **General Counsel** before moving forward.

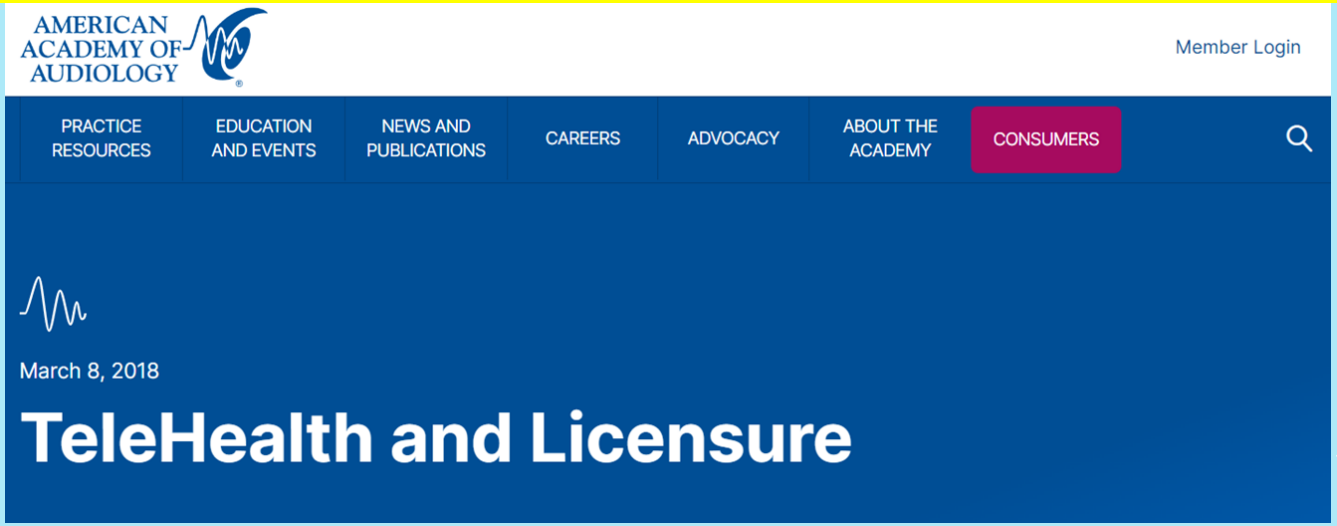
ASHA Resources

COVID-19: Tracking of State Laws and Regulations for Telepractice and Licensure Policy

Payment and Coverage Considerations for Telepractice Services During Coronavirus/COVID-19

AAA Resource

https://www.audiology.org/telehealth-and-licensure/



ASLP-IC

Audiology & Speech Pathology – **Interstate compact**

https://www.asha.org/advocacy/state/audiology-and-speech-language-pathology-interstate-compact/

https://aslpcompact.com/

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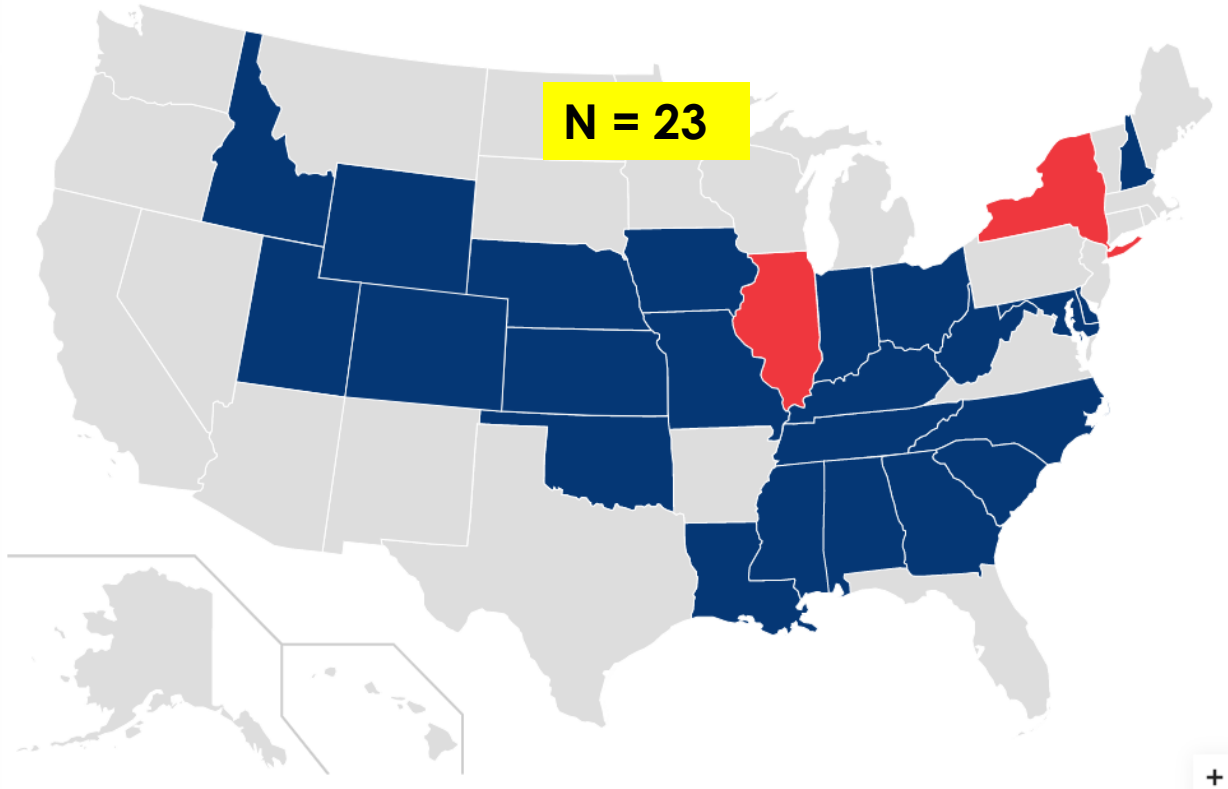


Patients can’t “handle” remote care or remote fine-tuning

A. **Zoom, Microsoft Team and face-time** are widely used by our patients for a variety of social and professional communication.

B. Yes, there are patients who do not want to use or are unable to use this service, but **audiologists** or **HIS** of several **manufacturers of OTC/DTC products and apps** provide this service. Surely, the audiologists/HIS providing remote care and remote fine-tuning and the patients using these services can’t be different or smarter from the patients seen in Audiology clinics

C. The patients of other **healthcare professionals** routinely use remote care. Almost all of the ENT staff (nurses, nurse practitioners and physicians) use remote care. Our **physician and dentist** offer this option when we schedule appointments

D. Data from the **government accountability office** on use of telemedicine by **Medicare** recipients

Fear of how to fit into schedule – several suggestions

- Need to think “out of the box” and collaborate with colleagues within and outside of your organization. I contacted **four** colleagues in **private practice**. Excellent presentations on **Audiology Online**. There are several **Facebook** groups. For example, I belong to **Audiology Antics and Anecdotes for All Hearing Professionals** and **Audiology Best Practices**
- Change the schedule of one or more audiologists:
  - Schedule ½ hr visits one day/week/audiologist. This is what our physician does.
  - Schedule ½ hr visits in the AM or PM/audiologist. This is what ENT staff did
  - Perhaps **audiology assistant**
- Offering **remote care and remote fine-tuning** would help **promote** the clinic as providing a service probably not offered by other clinics. Separate yourself from your competition.
- Place fact that you offer these services on your website

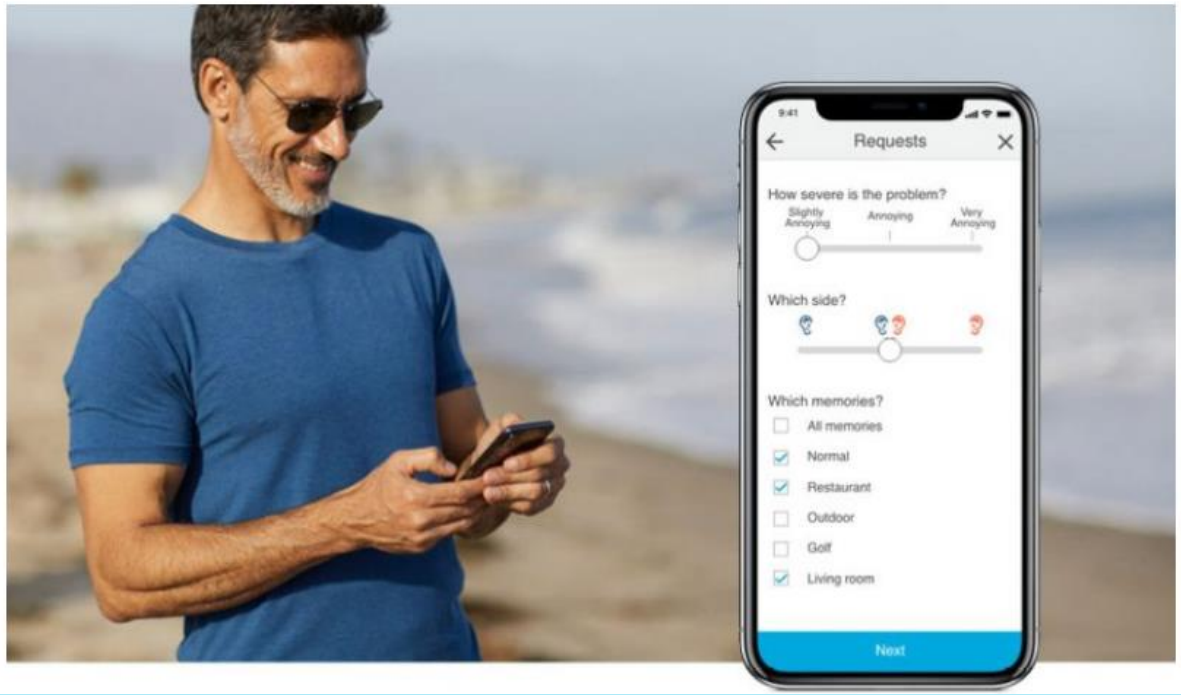
To promote remote fine-tuning we created **manufacturer-specific** handouts

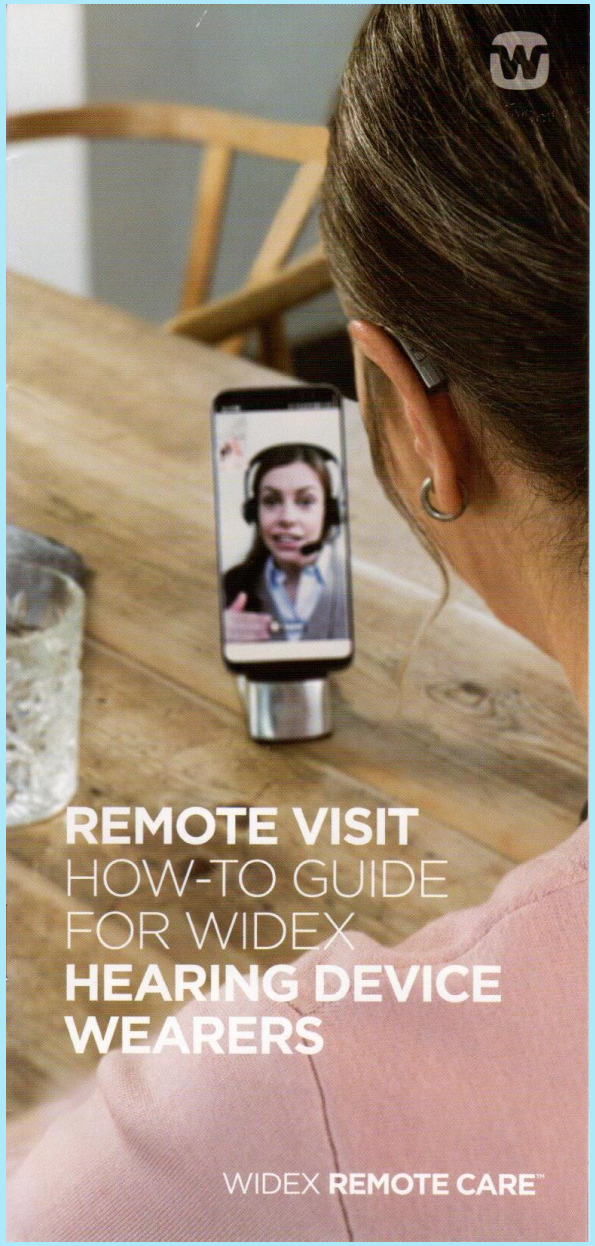
- What is **remote care** and **remote fine-tuning**?
- How can **remote care** and **remote fine-tuning** benefit me?
- Advantages of **remote care** and **remote fine-tuning**
- Limitations of **remote care** and **remote fine-tuning** (***manufacturer - specific***)
- What are the next steps?
- How do I schedule a session?
- What requirements are necessary for a **remote care** or **remote fine-tuning** session? (***manufacturer - specific***)
- What is cost (**patient specific**)?
  - **No charge**
  - **Annual package** of three appointments **=** using the charge/hour
  - "**Pay as you use"** = using the charge/hour
- **Provide manufacturer brochures on remote fine-tuning**

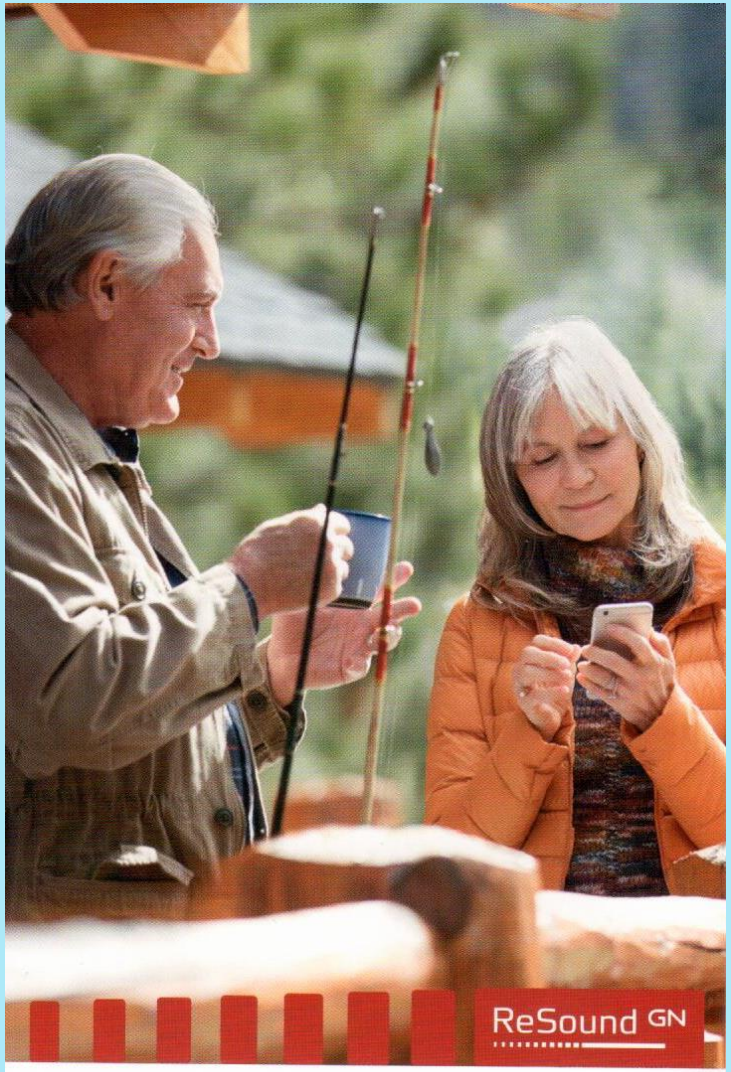
Starkey

[redacted]

HEARING CARE ANYWHERE




REMOTE VISIT
HOW-TO GUIDE
FOR WIDEX
HEARING DEVICE
WEARERS
WIDEX REMOTE CARE™



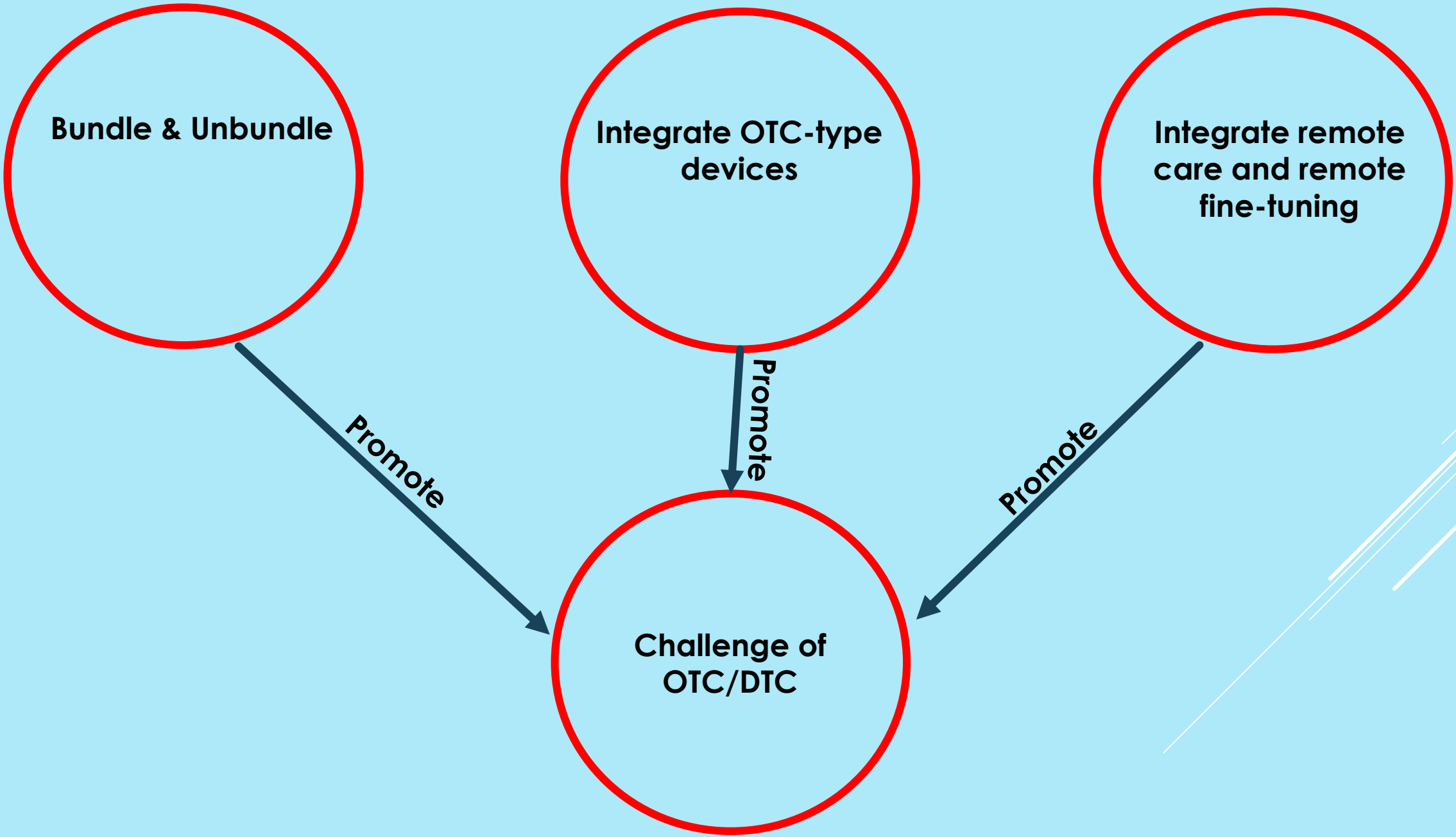
ReSound Assist

Hearing care wherever you are

Finally, created **step-by-step instructions** along with screenshots for each manufacturer on how to perform remote-fine-tuning.

These were “tested” before forwarding to each audiologist to be used by the staff as guides (“cookbook”) until became comfortable with its’ use.

Three-Prong Approach to Address Challenge of OTC/DTC



Thank you for your interest.

If you have any questions please contact me @

valentem@wustl.edu