Learner Objectives

• 1. Identify the differences between Personal Sound Amplification Product (PSAP), Over The Counter (OTC) and professionally dispensed amplification.

• 2. List at least 3 benefits dispensing professionals can provide hearing impaired individuals versus self selected devices.

• 3. Discuss pricing structures that can be applied to professionally dispensed, self selected OTCs and PSAPs devices.

• 4. Identify unique audiological services that are not duplicated by other professions.

Hearing aids, OTCs, PSAPs

1974 Audiologists can dispense hearing aids
1993 Costco begins to offer hearing aids
1996 Widex introduced Senso, first commercially successful digital hearing aid
2009 Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs)
2011, October UHC offers hearing aids via hi HealthInnovations mailed to consumer *March 28, 2012: hi HealthInnovations receives a cease and desist letter from the U.S. Food and Drug Administration (FDA) re: on-line hearing test
2012 Audicus web-based retailer on the scene
2014 FDA loosens restrictions on PSAPs approved by FDA for “non-hearing impaired” consumers
2015 Big Box captured 10% of the market
2016, December FDA issued Guidance Document: medical clearance requirement will not be enforced (deemed “potential barrier to availability and accessibility of hearing aids”)
2017, August: FDA Passes Over the counter hearing aid act
2017 pressure for FDA to create an OTC hearing aid category
Hearing Aid (per FDA)

2009

• Any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

• Must comply with required conditions for sale in 21 CFR 801.421
  - Re: patient and professional labeling, (e.g., device model, serial number, date of manufacture)
  - User Instructional Brochure be provided to hearing aid recipients
  - Medical clearance waiver requirement (which is no longer enforced Dec 2016)

Personal Sound Amplification Product (PSAP)

2009

• Intended to amplify environmental sound for non-hearing impaired consumers. Not intended to compensate for hearing impairment.

• There is no regulatory classification, product code, or definition for these products. No requirements for registration of manufacturers and listing of these products with FDA.

• Manufacturers must report defects and adverse events


Hearing Aid v PSAP (per FDA)

2013

• Hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing. Hearing aids are usually programmed to address an individual’s degree of hearing loss across sound frequencies to improve speech intelligibility.

• PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss.

• To clearly distinguish between PSAPs and hearing aids, FDA relies on the intended use of each product to determine whether it is a medical device or an electronic product. The intended use may be established by labeling or promotional materials.
OTC (over the counter) Hearing aids

• There is no such classification (Per FDA)

• BUT:
  • OTC typically refers to a hearing aid (as defined by FDA) that is NOT obtained (or fit) by a dispensing professional, but sold directly to the consumer. Or sold "over-the-counter"
  • Many on-line sites are selling products from the same manufacturer dispensers user (Eg, buyHeal.com)

• Industry requests FDA category for over-the-counter hearing aids with the following regulations:
  • provide reasonable assurances of safety and efficacy;
  • establish output limits and labeling requirements; and
  • describe requirements for the sale of hearing aids in-person, by mail, or online, without a prescription. The FDA must determine whether premarket notification is required for over-the-counter hearing aids to provide reasonable assurance of safety and effectiveness.

PSAPs and OTC hearing aids

Why are we seeing these new options?

Technology
Consumer access to information
Consumers report on hearing aids (doesn’t look good for us) 2009
Poor Market penetration for amplification (hearing aid adoption)
President’s Council of Advisors on Science and Technology, October 2015
Our traditional model now scrutinized by regulatory agencies and consumers.

What has this done for our profession?
Created market for OTC, PSAPs.
Hearing aid penetration

Low Penetration

1 in 3 Americans between 65 and 74 has hearing loss.
Nearly 1/2 of those over 75 have difficulty hearing.
40% of the over 60 population experiences hearing loss, only 20% use hearing aids.

An estimated 30 million to 48 million Americans have hearing loss that diminishes the quality of their lives.

Only 20 percent of those who might benefit from treatment actually seek help.

But is this the whole picture?

PSAPs & OTCs

Disadvantages
- Patient selecting their own device without benefit of hearing healthcare professional
- Untreated hearing loss is not a benign condition, potential missed medical condition
- HA gain and output may not be appropriate
- Poor quality product, patient “gives up” on amplification
- We are out of a job!

Advantages
- Possibly encourage consumers to take action
- Increase consumer awareness (more access to information)
- Penetrate the untapped 75% of the market
- Audiology change to provide service (not product)
- We still have a job and its not being a “salesperson”

Sources: Niels Granholm Leth, Carnegie Bank, WHO, Sonova

Figure 1: Niels Granholm Leth, Sharing Healthcare: Market Conditions Better Than Perceived, Carnegie Sector Report (Jun. 27, 2007).
PSAPs & OTCs & hearing impaired

Facts

We assume barriers to adopting amplification are price...

Fact: European/Scandinavian countries with free hearing aid have 40% adoption (US is 33%) (Amlani & Valente)

They found more significant factors may include social stigma, denial of hearing loss, and reduced self-efficacy.

Another possible barrier could be the process of working with a hearing healthcare provider. People want “do it yourself”

Fact: Hearing aid Adoption and Satisfaction increases with audiologist involvement

National survey conducted by Healthy Hearing - 809 participants. Only about 2.3% said they would be willing to give up any of the services of a hearing care professional

Preliminary study results on 60 patients with self-fitting hearing aids

- Some subjects could successfully fit themselves, with good instruction materials
- Some correctly identified problems, but needed help with the fitting
- Some could not successfully fit themselves

Source: www.healthyhearing.com

Implications of OTC Approach to Hearing HealthCare

- Results indicated 83% were satisfied with the provider-driven fit, compared to 48% who were satisfied with the OTC fitting.
John Hopkins and Towson University study 2017:

42 adults with mild-moderate hearing loss different compared 5 PSAPs to a traditional hearing aid

• Ran EAA, REM and sentences in noise in various conditions

Results:

• suggest some PSAPs may be comparable to HAs in a controlled environment when fit by an audiologist.

• some PSAPs may pose a danger to consumers and result in fittings so poor that they are detrimental to hearing ability

Poorer performing PSAPs evaluated by Consumers Reports 2017

• Inexpensive models:
  • The Bell & Howell Silver Sonic XL $20
  • The MSA 30X $30
  • Showed very little benefit in any of their tests
  • Sometimes actually blocked incoming sounds (like earplugs)
  • Consumer Reports “hearing expert” notes the devices have the potential to cause additional hearing damage by over-amplifying sharp noises, such as the wail of a fire engine.
  • expert recommends avoiding very inexpensive models, which generally cost less than $50.
    • They don’t seem to help much—if at all
    • Could actually further diminish ability to hear

PSAPs v Hearing Aids

11 high end and low-end (PSAPs) and hearing aids

• Ran EAA
• Ran EEM on KEMAR
  Attempted to match NAL-NL2 target for variety of losses and 2 configurations
Results

- High-end hearing aids were able to meet NAL-NL2 targets for the most audiometric configurations. Two high-end PSAPs and one app were able to meet NAL-NL2 targets up to a moderate high frequency hearing loss.
- Most low-end hearing aids and PSAPs had inappropriately high amounts of low frequency gain.
- Directional benefit was present in only the two high-end hearing aids and one of the high-end PSAPs.
- Overall, most devices included in this study had a high degree of internal noise, with only devices in the hearing aid category achieving ANSI standards.
- High-end PSAPs provided appropriate levels of amplification and directional benefit for users with high-frequency hearing losses ranging from mild to moderate in severity.
- Some low-end PSAPs and low-end hearing aids are inappropriate for any configuration and severity of high-frequency hearing losses.

### Comparison Table

<table>
<thead>
<tr>
<th>Source: SoundWorld website</th>
<th>Companion</th>
<th>Soundsoft Hearing N-700</th>
<th>Ematic Connect</th>
<th>NAL hearing Aid</th>
<th>MD hearing Aid</th>
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<tbody>
<tr>
<td>Noise Reduction/BT suppression</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Directional/aid</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>X</td>
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<td>Rechargeable batteries</td>
<td>YES</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Smartphone programmable</td>
<td>YES</td>
<td>X</td>
<td>X</td>
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<td>Voice prompts</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Bluetooth streaming (phone/music)</td>
<td>YES</td>
<td>With remote ($199)</td>
<td>With Remote ($199)</td>
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<td>x</td>
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<tr>
<td>Price</td>
<td>$449</td>
<td>$898</td>
<td>$699</td>
<td>$1980/for 2</td>
<td>$350</td>
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<tr>
<td>Price with Bluetooth</td>
<td>$449</td>
<td>$1188</td>
<td>$980</td>
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Personal Sound Amplification Products (PSAPs)

https://youtu.be/2TMS5pqXtLc

Bean Technical Specs
Price: $214 ($399 pair)

<table>
<thead>
<tr>
<th>Feature</th>
<th>The BEAN</th>
<th>The BEAN T-coil</th>
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<tbody>
<tr>
<td>Input Modes</td>
<td>Microphone</td>
<td>Microphone and Telecoil</td>
</tr>
<tr>
<td>Gain</td>
<td>LO (15 dB) - HI (23 dB)</td>
<td>LO (15 dB)</td>
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<tr>
<td>Signal Processing</td>
<td>Analog</td>
<td>Analog</td>
</tr>
<tr>
<td>Compression Type</td>
<td>Wide Dynamic Range Adaptive</td>
<td>Wide Dynamic Range Adaptive</td>
</tr>
<tr>
<td>Maximum Output [LO]</td>
<td>112.5 dB SPL</td>
<td>112.5 dB SPL</td>
</tr>
<tr>
<td>Maximum Output [HI]</td>
<td>115 dB SPL</td>
<td>NA</td>
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<tr>
<td>Telecoil 1 kHz Sensitivity (nom.)</td>
<td>NA</td>
<td>-49.5 dB @ 100mA/m</td>
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<tr>
<td>Tap</td>
<td>3%</td>
<td>3%</td>
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<tr>
<td>Battery Type</td>
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<td>10A zinc-air</td>
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<tr>
<td>Battery Life</td>
<td>10-12 days</td>
<td>10-12 days</td>
</tr>
<tr>
<td>Battery Current (typ)</td>
<td>435 uAh</td>
<td>425 uAh</td>
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</tbody>
</table>

Bean Insertion Gain response in "H" position (more gain)
Sound World Solution “Companion”
Price $449 ($735 pair)

- Companion Hearing Aid TECHNICAL SPECIFICATIONS
- Product Type Hearing Aid
- Form Factor BTE/RIE - Behind-the-Ear/Receiver-in-Ear
- Battery Rechargeable, lithium ion
- Battery Life 18 Hours
- Programmability Via Bluetooth connection to Smartphone, tablet, PC or Mac; or via controls on device
- Gain/Output 62 dB of gain and 126 dB SPL of maximum output
- Dimensions 9.6 mm wide x 48 mm high x 28 mm deep

Sound World Solution “Companion”

OTC, PSAPs, Big Box   Where do we fit in?
Commodity: a good or service whose wide availability typically leads to smaller profit margins and diminishes the importance of factors (such as brand name) other than price

Patient access to more information
This has commoditized hearing aids
Patient are now consumers of a product
Audiologist has become salesperson

We need a NEW MODEL
What is wrong with the current model:
As many as one third of fittings completed by audiologists and hearing instrument specialists were inappropriate and did not provide the proper gain for the patient. (Kasewurm)
Difficult to differentiate based on innovation when we all offer comparable products Brian Taylor
By offering FU at “no cost” build expectation that the service isn’t’ worth much its all the device (Van Vliet)
Product is the focus

What do we like about our current model?
You receive payment up front (with promise of FU at “no cost”) Consumers like things bundled (otherwise feel “nickel and dimed”) Are we comfortable asking to be paid for our service?

So what is our FUTURE?
Let’s take a look at our history, again

1974 Audiologists can dispense hearing aids
Before 1974 Audiology was rehabilitation profession

The Future - ?
Audiologists can and do recommend/offer:
• Communication assessments, beyond hearing eval... speech in noise testing, COAT, pre/post assessments
• Hearing aids
• Implantable devices
• Assistive listening devise
• Aural Rehab
• Counsel re: communication strategies
BUT wait there’s more...
What does this look like
Identify unique audiological services that are not duplicated by other professions.
Audiology must position itself as the professional who offers hearing health care. And the service has a value (and a price).

• Unbundle hearing aid service from device cost
• Charge for ALL of your services
• Counsel patients on all the hearing health care options (including PSAPs, AR, communication strategies, hearing aids, implantable, ALDs) – and CHARGE for the counseling/recommendations
• Offer PSAPs & Hearables in your clinic
• Service/fit OTC or "big box" fit aids

• Best practices:
  * Scientifically-based protocols (including detailed testing, real ear measurements, verification), aided discrimination (recorded speech materials), conducting speech-in-noise testing
  * Evidence-based outcomes which clearly demonstrate the value of our evaluation, management and treatments. (verification and validation)

Discuss ALL hearing treatment options

Add Value with your fee structure

Fee structure: separates cost of device from services (evaluation, fitting, orientation, delivery, counseling, and long-term care and management of the devices)
Fee for services will highlight importance of professional services in the success of the hearing aid fitting.

• It's not just about price, it's about expertise, personal service, quality, and perceived value (Robert M. Traynor)
• Patients don't care about the price, they care about the benefit. Don't sell features, focus on benefit
### Bundling vs Unbundling

<table>
<thead>
<tr>
<th>Bundled</th>
<th>Partially Unbundled</th>
<th>Completely Unbundled</th>
</tr>
</thead>
<tbody>
<tr>
<td>One fee:</td>
<td>Device, Dispense, Service</td>
<td>Device Fee</td>
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<tr>
<td></td>
<td></td>
<td>Dispense Fee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Service Fee (patient choice)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Programming Fee</td>
</tr>
</tbody>
</table>

**Bundled**
- Charge 1 fee that includes:
  - Device
  - Fitting
  - Orientation
  - Programming
  - Verification
  - Validation
  - Counseling
  - Follow up
  - Services for set time (1, 2, 3 years)

**Partially Unbundled**
- Charge a fee for each service:
  - Device
  - Fitting
  - Orientation
  - Programming
  - Verification
  - Counseling
  - Follow up
  - Fee for all future services as incurred

**Completely Unbundled**
- Charge a fee for each service:
  - Device
  - Fitting
  - Orientation
  - Programming
  - Verification
  - Counseling
  - Follow up
  - Fee for all future services as incurred

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**Too Little?**

**Completely Bundled:**

Charge 1 fee that includes:
- Device
- Fitting
- Orientation
- Programming
- Verification
- Validation
- Counseling
- Follow up
- Services for set time (1, 2, 3 years)

**Too Much?**

**Completely Unbundled:**

Charge a fee for each service:
- Device
- Fitting
- Orientation
- Programming
- Verification
- Counseling
- Follow up
- Fee for all future services as incurred
Receive HA from Manufacturer
- Visual inspection and listening check (92592/3)
- Quality Assurance (92594/5, V5011)
  LAA, HAC

Day of Fitting
- Office Visit (V5299)
- Conformity Evaluation (V5020)
- Probe Microphone Measures
- Functional Gain Validation
- Hearing Aid Programming (V5014)
- Orientation (V5011)
- Care, maintenance, use
- Dispensing Fee binaural (V5160)
  Hearing Aid – Ex. digital BTE binaural (V5261)

Hearing aid fitting follow-up
- Quality Assurance (92592/3, 92594/5, V5011)
- Recommended: 2 week and 4 week (as needed)

See also AAA, "A Guide to itemizing Your Professional Services"
More Resources

Communication/Needs Assessments
• COAT (Characteristics of Amplification Tool)
• HHIE (Hearing Handicap Inventory Elderly/Adult)

Outcomes measures
• Verification (REM)
• Validation
  • APHAB
  • SADL
  • HHIE (pre and post)
  • QuickSin pre and post fitting
  • SSQ12 – gauge effectiveness of any treatment option

More Resources

ALDs
• Phone
• Alerting devices
• TV
• Connectivity to devices (streamers, smartphone apps, TV streamers)
• PockeTalker

Devices
• Traditional hearing aids
• PSAPs
• Hearables
• Hearing aid “Apps”

Hearables

http://hearable.world/ HearablePrism2017.png
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REGULATORY AGENCIES:


https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127086.htm


S.670 - Over-the-Counter Hearing Aid Act of 2017 H.R. 1652


H.R. 2430 FDA Reauthorization Act of 2017. Became Public Law No: 115-52. (Sec. 709)

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HEARING AIDS/PSAPs:

Denis Van Vliet, Serving your Patients and OTC Devices. The Hearing Review Vol 24 no 6 June 2017


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