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Clinical Implementation of Non-Custom Amplification

Lori Zitelli, AuD

Moderated by:
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Clinical Implementation of Non-Custom Amplification

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UPMC Department of Otolaryngology
University of Pittsburgh
Wednesday, August 30, 2017
Today’s Learner Outcomes

As a result of this course, participants will be able to...

• 1) Describe the differences between hearing aids, PSAPs, and non-custom amplification

• 2) Explain the negative effects that untreated hearing loss can have on healthcare outcomes

• 3) Describe one way that non-custom amplification can be used in either an inpatient or outpatient setting

Disclosure

Lori Zitelli is employed by UPMC and the University of Pittsburgh.

She will receive an honorarium from AudiologyOnline for this lecture.

She has no additional relevant disclosures to divulge.
What does the term “non-custom amplification” mean to you?

**PSAP**

Headset amplifier

Hearing aid

<table>
<thead>
<tr>
<th>HA</th>
<th>PSAP</th>
<th>Non-Custom Amplification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wearable sound-amplifying device</td>
<td>Wearable electronic product</td>
<td>Could be non-custom hearing aid</td>
</tr>
<tr>
<td>Intended to compensate for impaired hearing</td>
<td>Intended for non-hearing impaired consumers to amplify sounds in certain environments</td>
<td>Could also be PSAP</td>
</tr>
<tr>
<td>Regulated by the FDA</td>
<td>Not subject to medical device regulations</td>
<td>“Non-custom” means not fit to an evidence-based output target and no custom coupling</td>
</tr>
</tbody>
</table>

[www.fda.gov/RegulatoryInformation/Guidances/ucm373461.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm373461.htm)
FDA language makes clear what PSAPs cannot advertise.
www.fda.gov/RegulatoryInformation/Guidances/ucm373461.htm

- **Labeling or promotional materials** cannot:
  - Suggest the use of a PSAP for hearing impaired consumers
  - Establish an intended use for the electronic product as a medical device, which would therefore be subject to the regulatory requirements for a hearing aid

This applies to what the manufacturers can claim or advertise about the product...
...not who chooses to buy it
or whom audiologists can use it with!

The FDA says that assistive listening devices can be used with patients who have hearing loss.

- ALDs include a large variety of devices designed to help you hear sounds in everyday activities.

- They may be used by both normal hearing and hearing impaired people to improve listening in these settings.

- ALDs can be used to overcome the negative effects of distance, poor room acoustics, and background noise.

- ALDs can be used with or without hearing aids.

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm181482.htm#1
Non-custom amplification can be used...

...for people who have no hearing loss.

- “...perfect for watching television or getting the most from the theater, meetings, lectures, worship services, or simple conversations.”

...for people who have hearing loss.

- Enhances communication
  - Of special interest in healthcare settings, where we know untreated hearing loss can negatively impact healthcare outcomes
  - Immediate solutions are often needed

We use non-custom amplification in our clinics all the time!

- We use a non-custom headset amplifier device for patients who have untreated hearing loss in healthcare settings.
  - This can be considered an “off label” use of this device, as it is a PSAP and not intended for use with hearing-impaired people

- We also sell a non-custom ear-level device
  - This device is a hearing aid which is not programmed to meet evidence-based output targets (i.e. it is programmed to first fit) or used with a custom coupling
What is ear-level non-custom amplification & why use it?

- Entry-level technology hearing aid
- Programmed to first fit based on patient’s audiogram
- Can be customized (fit to evidence-based output targets or fitted with custom coupling) for an additional fee if patient chooses to pursue that level of service
- Allows us to “capture” patients who otherwise may have purchased PSAPs or non-custom amplification elsewhere
  - Hopefully, will come back to us for a solution when they choose to pursue the next level of service (customization)

We use non-custom amplification in the following clinical settings:

1. Inpatient
   - While hospitalized (headset)
   - After discharge

2. Outpatient
   - Day of clinic (headset)
   - After appointment

- Ear-level
- Headset
Successful communication is necessary in order for patients to understand care providers, participate in shared decision-making, and to stay connected to friends and family throughout the course of treatment.

Untreated hearing loss can negatively affect healthcare outcomes.

- Communication disabilities can lead to poor adherence to treatment recommendations and clinical outcomes that may include accidental injury or further medical difficulties (Lawthers et al., 2003)
- Patients with communication problems are 3 times more likely to experience a preventable adverse event than patients without such problems (Bartlett et al., 2008)
- Older adults with a communication disability reported dissatisfaction with overall quality, accessibility, and receipt of information related to their healthcare (Hoffman et al., 2005)
- In older adults, hearing loss is independently associated with increased health care use and burden of disease (Genthier et al., 2017)
- Self-reported hearing loss is independently associated with higher total medical expenditures (Foley, Frick, & Lin, 2014)
- Self-reported hearing loss is independently associated with lower ratings of patient-physician communication and overall healthcare (Mick, Foley, & Lin, 2014)
- Hearing loss is associated with billions of dollars of excess costs in the United States, but significant variance is seen between studies (Huddle et al., 2017)

Interventional audiology focuses on preventing and treating hearing loss before it becomes a barrier to other treatments or leads to other comorbidities.

Taylor & Tysoe (2015)

**Interventional Medicine**

- Increased costs of healthcare
- Focus on *preventing illnesses*

**Interventional Audiology**

- Goal: Minimize impairment
- Goal: Maximize Function
Interventional Audiology can be implemented in an interdisciplinary team setting or through other clinical interactions (inpatient AND outpatient).

 Currently, UPMC is using interventional audiology in the following settings:

- Interdisciplinary post-trauma clinic
- Interdisciplinary Survivorship clinic
- Outpatient geriatric care center
- Outpatient audiology clinic
- Inpatient audiology services
- Residential care facilities

The impact of your services can extend beyond what you do on the day that you see the patient in clinic.
Patients are seen in UPMC’s Post-Trauma Clinic approximately 2 weeks after they’re discharged from the inpatient trauma service.

The Post-Trauma Clinic’s goals are to consolidate rehabilitative resources and facilitate optimal recovery.
Patients are screened for hearing loss by the audiology provider in the Post-Trauma Clinic and put into 1 of 4 categories:

- **Green = go!**
  - Normal Hearing - no communication adaptations necessary.

- **Yellow = be careful!**
  - Pt with hearing loss.
    - Remember: clear speech, face-to-face, good lighting, reduce noise.

- **Red = potential danger zone!**
  - Pt with significant hearing loss.
    - Please use amplifier for appt.
    - Remember: clear speech, face-to-face, good lighting, reduce noise.

- **Post-Trauma Clinic patients who can’t pass a 25 dB hearing screening (as of 7/12/17)**
  - 40%

Perhaps due to the nature of these patients’ injuries, many of them have at least some degree of measurable hearing loss.
When intervening on the day of clinic, we found...

When you look specifically at the 65+ group, it’s a very different picture.
Can we promote better adherence to audiology follow-up recommendations in Post-Trauma Clinic?

Post-Trauma Clinic Patients Requiring Audiology or ENT Follow-up who Reported that a UPMC Clinic was Convenient

Follow-up recommendations include:
- Audiogram
- Medical f/u
- Cerumen removal
- HA Discussion

- Patients who followed up in Pgh (12%)
- Patients who reported a clinic in Pgh was convenient and did NOT follow-up (83%)
- Patients who are deceased (3%)

Head & Neck Cancer Survivorship Clinic

“...we view survivorship as the period after treatment has ended, and when a person is seen as free of disease.”

http://www.otolaryngology.pitt.edu/upmc-head-neck-cancer-survivorship-clinic
The primary goal of our Survivorship Clinic is to identify and treat unmet needs among our survivors.

- Once the cancer is gone, these patients’ lives don’t go back to “normal.”
- Some of the most prevalent treatment-related issues reported include: swallowing, pain, skin changes, dry mouth, dental health, opening mouth/trismus, taste, excess/thick mucous/saliva, shoulder disability/motion, voice/hoarseness (Chera et al, 2014)
- Team members include providers from:

  - “The idea of the survivor’s clinic is wonderful. I felt abandoned after my surgery, and there were side effects that I didn’t know who to go to, to deal with. I came away from the appointment with a lot of information and a better sense that I can care for myself better.” — Survivorship Patient

I am learning to come to peace with the fact that hearing is not these patients’ primary concern...

- (...even though we all know how much hearing can impact healthcare!)
- My challenges in this clinic?
  - First, assuring the patient that they are in the right exam room
    - (“I’m not here for a hearing test...where’s Dr. Johnson?”)
  - QUICKLY convincing the patient that their ability to hear for all of these appointments MATTERS because it can affect their outcomes for the problems that ARE impacting their lives
  - Dealing with their rejection (with a smile!)
  - Educating patients about the effects of ototoxic medication and convincing patients who have been treated with an ototoxic chemotherapy who pass the hearing screening that they should have their hearing checked
    - They may be treated with the same drug in the future, if needed
A little more than 3/4 of the patients seen in Survivorship Clinic did not pass the 30 dB HL hearing screening...and only ~half of those think they have a hearing loss.

Approximately 1/4 of the patients seen in the ENT Survivorship Clinic passed the 30 dB HL hearing screening bilaterally.
The majority of patients who had an amplifier recommended to them used it, but 40% declined.

Pts with known significant HL or failing 30 dB HL screening bilaterally at all frequencies who had amplifier recommended to them

- 40% Used amplifier during appts
- 60% Declined amplifier use

Again, the challenge of promoting better adherence...

Survivorship Patient Follow-Ups:
Of those who needed audiology follow-ups and said a UPMC location was convenient...

- 82% Survivorship Pts who DID follow-up
- 17% Survivorship Pts who did NOT follow-up
- 1% Survivorship Pts who are deceased
In the Shadyside Senior Care Center, outpatient primary care services are provided to older adults.

- “Our goal is to help older patients stay independent, optimize self-care ability, and maintain quality of life.”
- Team members include:

http://www.upmc.com/Services/seniors/geriatrics/services/Pages/outpatient-care.aspx

They very kindly gave us space in their busy office to set up our equipment.
As of 7/24/17, 169 unique patients have been seen in the Shadyside Senior Care Office by audiology providers.

- Services include:
  - Hearing screenings prior to appointment with provider
  - Intervention during appointment, if needed
  - Comprehensive audiometry
  - Immittance testing, if indicated
  - Ear irrigation (only if non-occluding)
  - Comprehensive hearing aid services
    - Discussions
    - Programming
    - Verification
    - Troubleshooting/repairs/cleaning
  - Referrals to appropriate providers for medical treatment

Almost 200 patients have been seen in this office by an audiologist from January-August, 2017.

**Hearing Screenings in Geriatric Clinic**  
(n = 194, includes some repeat patients), average age = 83

- Passed the Hearing Screening (7%)
- Failed Some Frequencies (17%)
- Failed All Frequencies & Used Amplifier (3%)
- Failed All Frequencies & Declined Amplifier (6%)
- Declined Hearing Screening (3%)
- Did Not Have Hearing Screening (due to known HL, time constraints, pt seen for audiogram, not part of clinic protocol yet, etc) (64%)
Of the patients who were screened (or at least, we attempted to screen them!) prior to their appointment in the outpatient geriatric clinic, only 19% passed.

### Geriatric patients who were screened

- **Passed the Hearing Screening (19%)**
- **Failed Some Frequencies (47%)**
- **Failed All Frequencies & Used Amplifier (9%)**
- **Failed All Frequencies & Declined Amplifier (17%)**
- **Declined Hearing Screening (9%)**

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A broad range of inpatient audiology services are offered in many UPMC hospitals.

- **Diagnostic Testing**
  - Audiometry
  - Tympanometry
  - Acoustic Reflex Testing
  - Auditory Evoked Potentials

- **Hearing Aid Services**
  - Electroacoustic Check / Cleaning
  - Hearing Aid Batteries
  - Earmolds
  - Tubing Change

- **Personal Amplifiers**
  - Headset for patient to wear
  - Wheel for on/off and volume adjustment
  - Battery compartment for AAA battery (included)
  - Microphone to pick up sound of family and MIs, nurses, PCTs, TV, etc.

[Listener or SuperEar](https://www.sonictecnologyproducts.com/superear-se9000)
Even though we’re delivering more non-custom amplifiers than ever...

Non-Custom Amplifiers Dispensed to PUH/MUH Inpatients as of 8/16/17

<table>
<thead>
<tr>
<th>Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017 (YTD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>36</td>
<td>39</td>
<td>59</td>
<td>110</td>
<td>197</td>
<td>255</td>
<td>233</td>
</tr>
</tbody>
</table>

Interventional Audiology Initiative Starts

Armed with our hospital census data, we can estimate how many patients age 65+ were admitted and have significant untreated HL.

- **2014-2015 Fiscal Year** 12,188 admits
  - 46% No significant Untreated HL (6,628)
  - 54% Significant Untreated HL (5,560)

- **2015-2016 Fiscal Year** 12,098 admits
  - 46% No significant Untreated HL (6,382)
  - 54% Significant Untreated HL (5,716)

- **2016-2017 Fiscal Year** 12,251 admits
  - 46% No significant Untreated HL (6,670)
  - 54% Significant Untreated HL (5,581)
We can also estimate the percentage of patients aged 65 and older with probable untreated hearing loss who were not identified at any point during their inpatient stay as someone who might benefit from an amplification device and as a result were at risk for less than optimal communication with their healthcare providers and visitors.

<table>
<thead>
<tr>
<th>Year</th>
<th>Admits</th>
<th>Percentage of Pts with HL who received amplifiers</th>
<th>Percentage of Pts with probable HL who DIDN'T receive amplifiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-2015</td>
<td>12,188</td>
<td>3%</td>
<td>97%</td>
</tr>
<tr>
<td>2015-2016</td>
<td>12,098</td>
<td>4%</td>
<td>96%</td>
</tr>
<tr>
<td>2016-2017</td>
<td>12,251</td>
<td>6%</td>
<td>94%</td>
</tr>
</tbody>
</table>

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**Do you know how to use the device?**

(2016 data)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>37%</td>
<td>16%</td>
<td>48%</td>
</tr>
<tr>
<td>Nurse</td>
<td>49%</td>
<td>7%</td>
<td>45%</td>
</tr>
<tr>
<td>Family</td>
<td>16%</td>
<td>7%</td>
<td>78%</td>
</tr>
</tbody>
</table>

**Is the device helping you to communicate?**

(2016 data)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>36%</td>
<td>18%</td>
<td>46%</td>
</tr>
<tr>
<td>Nurse</td>
<td>38%</td>
<td>16%</td>
<td>46%</td>
</tr>
<tr>
<td>Family</td>
<td>15%</td>
<td>8%</td>
<td>77%</td>
</tr>
</tbody>
</table>
### Future Areas of Expansion?

<table>
<thead>
<tr>
<th>Emergency Room</th>
<th>Palliative Care</th>
<th>Radiology / Imaging</th>
<th>Inpatient Rehabilitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pts needing help probably also being missed in ED</td>
<td>• Hearing allows pts to access treatment plans, goals-of-care discussions, and social/spiritual support (Smith, Jain, &amp; Wallhagen, 2015)</td>
<td>• Patient motion is a frequent cause of degradation of MR images, which added to substantial costs to the radiology department (Andre et al, 2015)</td>
<td>• Assistive technology</td>
</tr>
<tr>
<td>• 36% of elderly patients seen in ED reported HL (Ballaggio et al, 2008)</td>
<td>• Hospice and palliative medicine providers believe age-related HL impacts care, but only 15% screen for HL (Smith, Ritchie, &amp; Wallhagen, 2016)</td>
<td>• Information and communication together can reduce anxiety that patients experience related to imaging procedures (Tasegal et al, 2015)</td>
<td>• Bowel/bladder training</td>
</tr>
<tr>
<td>• May need to alter consult system to accommodate timing needs</td>
<td></td>
<td></td>
<td>• Neuropsychology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Occupational therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Physical medicine and rehabilitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Physical therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Rehabilitation engineering</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Rehabilitation nursing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Robotics and gaming</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Speech and language therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Transitional rehabilitation units</td>
</tr>
</tbody>
</table>

The sky is the limit!

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References: