

# Could Your Practice Benefit from More Acronyms?

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Speaker Financial Disclosure Statement  
Nathan Williams is employed by Boys Town National Research Hospital.  
Speaker Non-Financial Disclosure Statement  
Nathan Williams has no non-financial relationships to disclose.

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A new challenge...

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## Learner Objectives

- Attendees should be able to categorize hearing aids, PSAPs, and OTCs.
- Formulate better direction moving forward for how your clinic will include/exclude PSAP and OTC devices.
- Develop protocols for the assessment and recommendations of PSAPs and OTCs for their practice.

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Recent History

- Regulatory requirements for hearing aids and PSAPs
- Hearing Aids
  - Any wearable instrument or device designed for, offered for the purpose of, or represented as aiding person with or compensating for, impaired hearing (includes air conduction, bone conduction, body worn, etc).<sup>1</sup>

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Recent History

- Regulatory requirements for hearing aids and PSAPs
- PSAP
  - Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the Food, Drug, and Cosmetic Act. Therefore, there is no regulatory classification, product code, or definition for these products.<sup>1</sup>

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Recent History

- Regulatory requirements for.....OTCs....TBD
- OTC
  - \_\_\_\_\_
- August 18, 2017 – FDA Reauthorization Act of 2017 (H.R. 2430). Required development of regulations for OTC hearing aids within the next 3 years.<sup>2</sup>
- Goal: make amplification more accessible and affordable.

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Recent History – Audiology Advocacy<sup>3</sup>

- ADA, AAA, ASHA, and IHS recommendations for regulations of OTCs:
  - Establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment.
  - Define concise, outside-of-the-box labeling appropriate for OTC devices, with strong recommendations to consult with a hearing health care professional.
  - Define comprehensive, inside-the-box labeling appropriate for OTC medical devices

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Recent History – Audiology Advocacy<sup>3</sup>

- ADA, AAA, ASHA, and IHS recommendations for regulations of OTCs (continued):
  - Define the new OTC category so that it is easily understood by consumers and aligns with risk-class requirements for safety and effectiveness.
  - Ensure adequate provisions for consumer protection, in coordination with the Federal Trade Commission.

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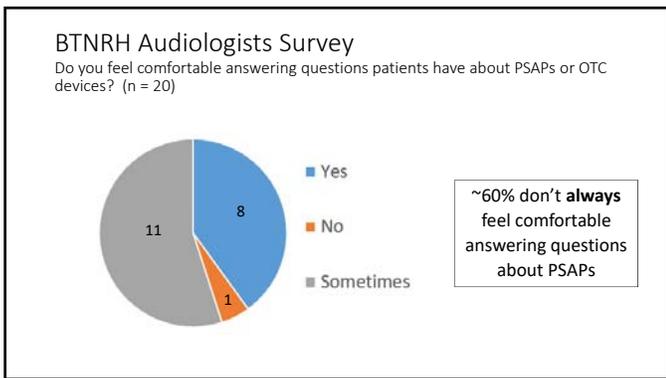
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### BTNRH Audiologists Survey

**What do we need in order to feel more comfortable?**

**MORE INFORMATION!**

- Need basic/general information on PSAPs
- Need specifics on PSAPs available such as: features, cost, candidacy
- HA vs. PSAP comparison
- Would like objective info about higher quality devices that we can recommend

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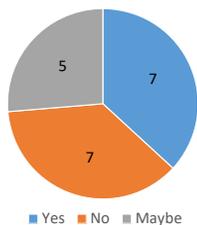
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### BTNRH Audiologists Survey

As an audiology clinic, do you think we should provide PSAPs for patient's to purchase? (n = 19)




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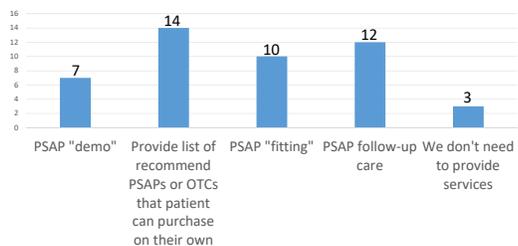
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### BTNRH Audiologists Survey

Regarding PSAPs or OTCs, what services do you think we should provide to patients? (n: 20)




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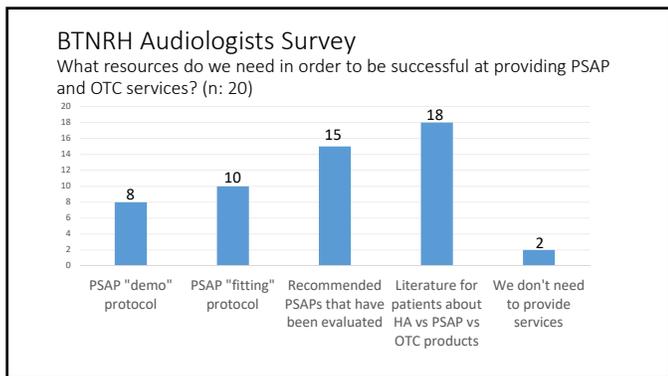
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### BTNRH Audiologists Survey

**In summary...**

- **QUALITY and appropriateness of devices**
- **Management of patient expectations**
- **Understanding of differences between HA vs OTC vs PSAP and expectations between the devices**
- **Cost and time investment to train staff**
- **Cost/time investment if we keep a stock of devices in house**

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### Research on PSAPs...EAA of DTCD<sup>4</sup>

- 9 devices (A) marketed to improve situational hearing, (B) readily available to the public, (C) cost \$30 - \$400
- EAA performed using a Verifit and SpeechMap at 55-, 65-, and 75-dB SPL
- EAA included:
  - Frequency range with goal to amplify speech 250 – 6000 Hz
  - THD not to exceed 3% at 500-, 800-, and 1600 Hz
  - Assessment of equivalent internal noise not to exceed 28 EIN
  - Max OSPL 90 not to exceed 120 dB SPL
- Scored based on each device's ability to provide appropriate levels of amplification within 5 or 10 dB SPL at nine frequencies (250 – 6000 Hz) based on NAL-NL2 and NAL-R prescriptive targets based and a mild to moderate hearing loss.

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Research on PSAPs...EAA of DTCD<sup>4</sup>

Results

- 5 / 9 devices met all four of the EAA criteria
- 8 devices were able to approximate at least half (5/9) targets within 10 dB SPL
- 3 devices were able to approximate at least half (5/9) targets within 5 dB SPL

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Research on PSAPs...Clinic Performance of PSAP vs HAs<sup>5</sup>

- 56 participants with varying degrees of mild, moderate, and moderately severe hearing loss based on 4 frequency average (500-, 1000-, 2000-, and 4000-Hz).
- Variety of speech intelligibility in noise, listening effort, and self-rating in 4 conditions (unaided, use of PSAP, use of basic HA, and use of premium HA).
- Pupilometry was performed to objectively measure listening effort.

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Research on PSAPs...Clinic Performance of PSAP vs HAs<sup>5</sup>

Results

- In the **mild** and **moderate** groups, there was no meaningful difference between PSAP, basic HA, and premium HA for speech perception, sound quality, listening effort, and user preference.
- For the **moderately severe** hearing loss group, the premium HA had better performance across most tests with 70% of participants preferring the use of the premium HA.

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Research on PSAPs...PSAP vs HA for SPIN<sup>6</sup>

- 42 participants with mild to moderate hearing loss, no prior amplification use; no cognitive impairment
- AZ Bio sentences in noise; 20 sentences per condition
- Participants repeated sentences in noise under 7 conditions
  - Unaided
  - With a hearing aid
  - With 5 different PSAPs
- Sentences presented at 0 degrees azimuth at 35 dB HL; speech babble presented directly behind at 30 dB HL

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Research on PSAPs...PSAP vs HA for SPIN<sup>6</sup>

Results

- Unaided average performance: 76.5%
- The hearing aid and 4 / 5 PSAPs improved speech understanding.
- Although the hearing aid improved the mean accuracy the most, 3 / 5 PSAPs demonstrated an improvement that was within 5 percentage points of the hearing aid.
  - HA – 88.4%
  - PSAP 1 – 87.4%
  - PSAP 2 – 86.7%
  - PSAP 3 – 84.1%
  - PSAP 4 – 81.4%
  - PSAP 5 – 65.3%

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What about in the clinic?

SUBSTANCE	Begin	End
Phone (handset)		
Phone (cordless)		
Suppression		
Diffuse Sound		
Diffuse Stereo Sound		
TV (on)		
Television (off)		

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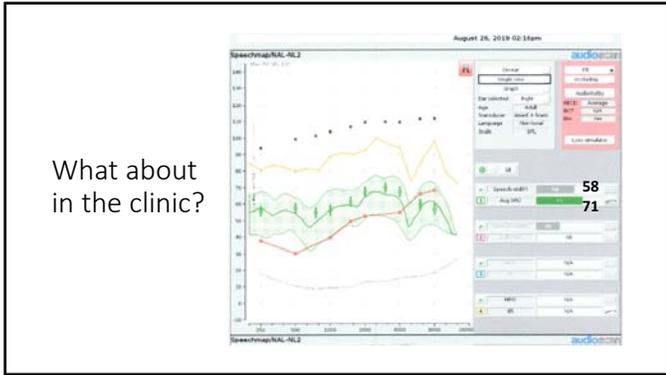
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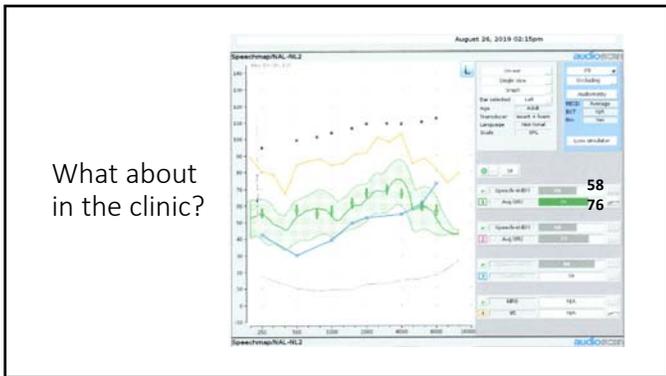
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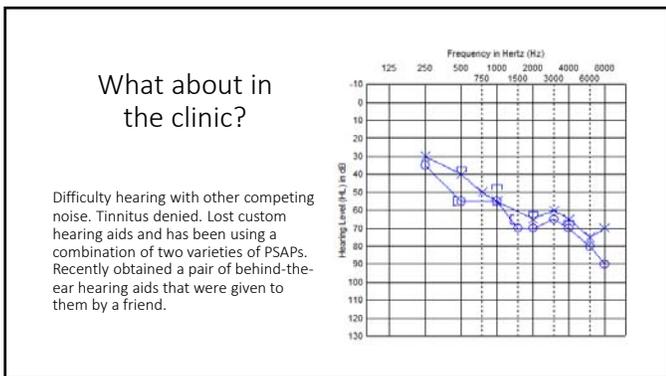
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What about in the clinic?

- PSAP 1
- PSAP 2
- Hearing Aid




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Conclusions from research studies and the clinic...

- “As the variety of amplification options increases, otolaryngologists and other hearing care professionals have an opportunity to provide support and recommendations to consumers who wish to pursue DTCDs as a communication solution. While some adults will be able to explore products independently and find benefit, others may require more professional guidance from an audiologist for professional fitting of hearing aids and rehabilitative education.”<sup>7</sup>
- Some PSAPs were associated with improvements in speech understanding for individuals with hearing loss that were similar to results obtained with a hearing aid.

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Are we going to lose patients?

- Hearing aid sales up 3.8% in the first half in 2019.<sup>8</sup>
- Given the distribution shift toward older adults, it is estimated that the number of adults 20 years or older with hearing loss (PTA > 25 dB) is expected to gradually increase from 15% in 2020 to 22.6% in 2060.<sup>9</sup>

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Are we going to lose patients?

2017 Vision Market statistics.<sup>10</sup>

- During 2017
  - Lasik surgery 9.2%
  - Contact lens 7.5%
  - Prescription eyeglass usage 2.2%
  - OTC readers 3.4%

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Vision Care Products & Services—Total U.S. Market



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Dealing with competition...<sup>11</sup>

- Do not get emotional with patients.
- Do not negotiate with yourself to keep business.
- Do not attack the competition.
- Outline both you and your competitors STRENGTHS/WEAKNESSES/OPPORTUNITIES/THREATS
- Use patient-centered success tools.

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Protocol considerations...

- Determine the type(s) of PSAP and OTCs you recommend.
- Candidacy Evaluation
  - Comprehensive hearing test.
- Inclusion criteria
  - Mild to moderate sensorineural hearing loss
  - Medical clearance needed?
- Fitting Process
  - Real ear measurement to assess improvement in audibility and ensure appropriate MPO.
  - Fitting and orientation – determine if this is a one time charge, includes follow-up appointments and care, if there is a warranty, and establish a repair process.
- Validation Measure

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Protocol considerations...

- Determine the type(s) of PSAP and OTCs you recommend.
- Candidacy Evaluation
  - Comprehensive hearing test.
- Inclusion criteria
  - Mild to moderate sensorineural hearing loss
  - Medical clearance needed?
- Advise patient to proceed with purchase and selection online.

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Protocol considerations...

- Candidacy Evaluation
  - Comprehensive hearing test.
- Determine the type(s) of PSAP and OTCs you recommend.
- Advise patient to proceed with purchase and selection online.

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Protocol considerations...

What to charge the patient?

- Electroacoustic analysis?
- Fitting and Orientation fee?
- Something else determined by your practice.
- What if someone comes in with a PSAP/OTC?

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Next Steps...

- Have a conversation with people in your clinic on how to proceed.
- Keep an eye out for good products from established, reputable manufacturers. Some PSAPs and OTCs can actually provide sufficient benefit for some people.
- If feeling led, get involved with AAA, ADA, ASHA, and IHS to assist with developing standards for OTCs.
- Educate the public on the strong need for an appropriate hearing assessment to avoid overlooking co-morbidities of hearing loss (ear infections, dizziness, tinnitus, asymmetric HL of unknown etiology, etc).

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Future research:

- Electroacoustic and speech intelligibility research on the to-be-released OTC products.
- Results of long-term PSAP, OTC, and HA use in real life environments.

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