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PSAPs: Our Role in the Disruptive Environment



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Vice President
Oaktree Products, Inc.

Learning Outcomes

After this course learners will be able to:

- List two specific regulatory differences between PSAP and hearing aid.
- Discuss real-ear probe mic differences between PSAP and hearing aid performance based on current research.
- Explain one current limitation of PSAPs described as appropriate for adults with mild to moderate hearing loss.

Objectives

- Legislative landscape
- Recent comparison studies

FDA

- **February 2009**

- Guidance document
- Hearing aid vs PSAP
- Not applicable for hearing loss
- Amplify environmental sounds

- **November 2013**

- Intended Use

#1 COST of HA Technology

sonova HEAR THE WORLD

Sivantos the hearing company

GN

William Demant

Starkey

WIDEX®

BUNDLE

83%

RESTRICTED Access
to shop for Best Value

ACCESS

Remarkable
Very Good
Good
Average
Poor

VERTICAL
INTEGRATION

Clinical Expertise

Best Research Evidence

EBP

Patient Values & Preferences

Valente 2000; Johnson & Ricketts 2015

Poor DISTRIBUTION

models of hearing aids



Rx Example ¹			
(single vision no astigmatism)			
Eye	SPH	CYL	AXIS
OD	+1.25		
OS	+1.00		
ADD		Note: NVO	



FOUR KEY RECOMMENDATIONS

OTC
Over the Counter



Rx Example ¹			
(single vision no astigmatism)			
Eye	SPH	CYL	AXIS
OD	+1.25		
OS	+1.00		
ADD		Note: NVO	



STATUS

- **MEDICAL CLEARANCE**

- **Dec 7, 2016:** FDA Eliminates Hearing Aid Medical Clearance Regulation – Effective Immediately



- **OTC Hearing Aid Act**

- **July 12, 2017:** passed by US House
- **August 4, 2017:** bill approved by US Senate
- **August 23, 2017:** signed into law by President

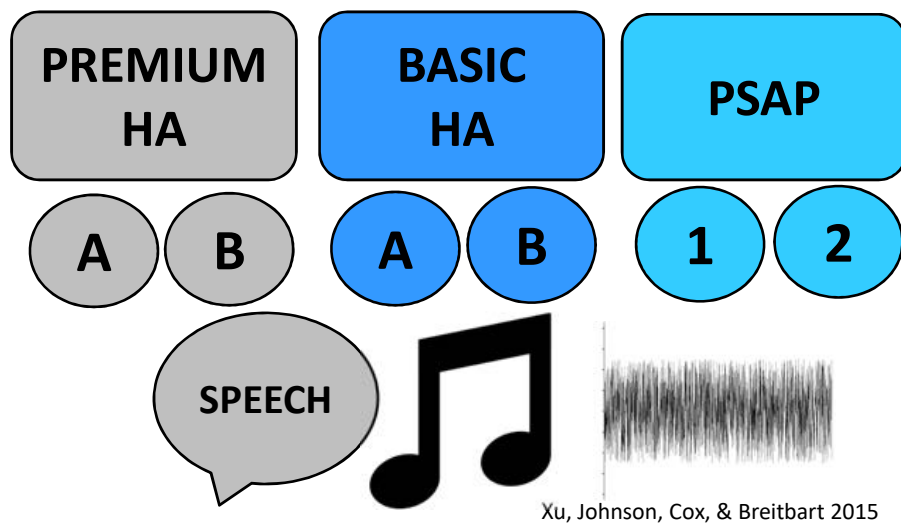
Objectives

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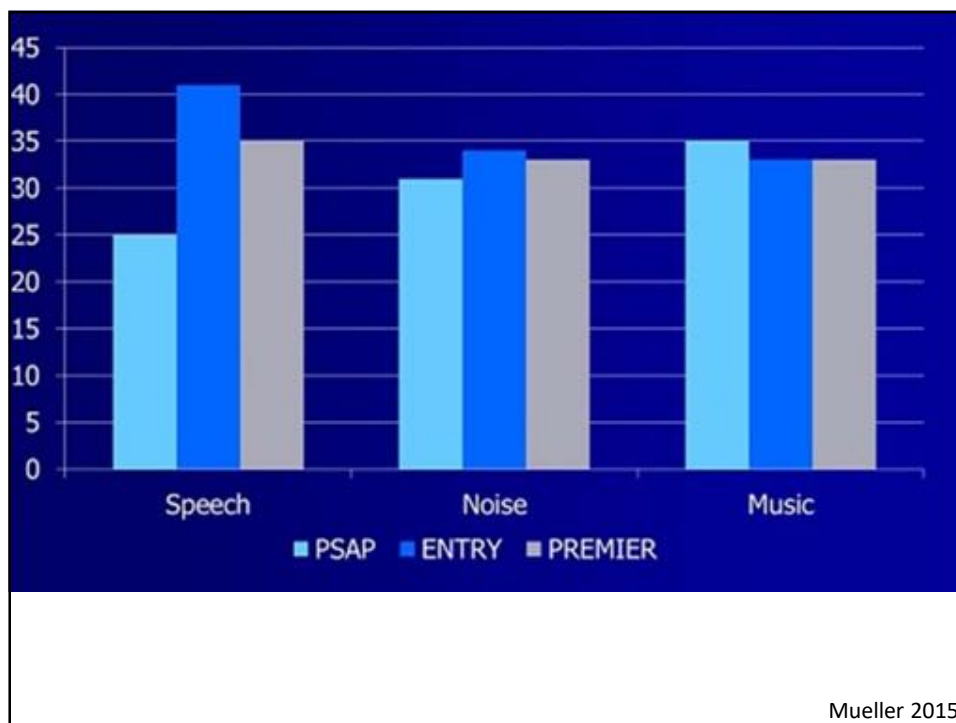


Laboratory Comparison of PSAPs & Hearing Aids

Hearing Aid Research Laboratory, University of Memphis



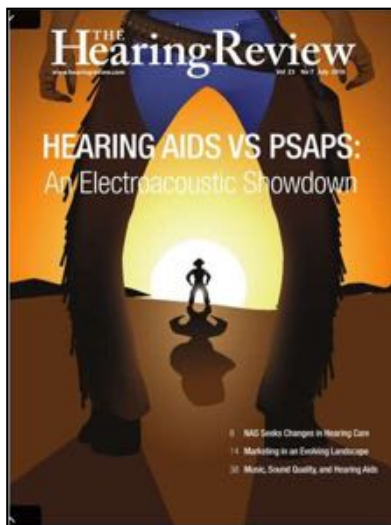
Xu, Johnson, Cox, & Breitbart 2015



Mueller 2015

PSAPs vs Hearing Aids:

An Electroacoustical Analysis of Performance & Fitting Capabilities



- Low-end vs High-end
- Electroacoustic Analysis
- On-ear fitting capabilities

Smith, Wilber, & Cavitt 2016

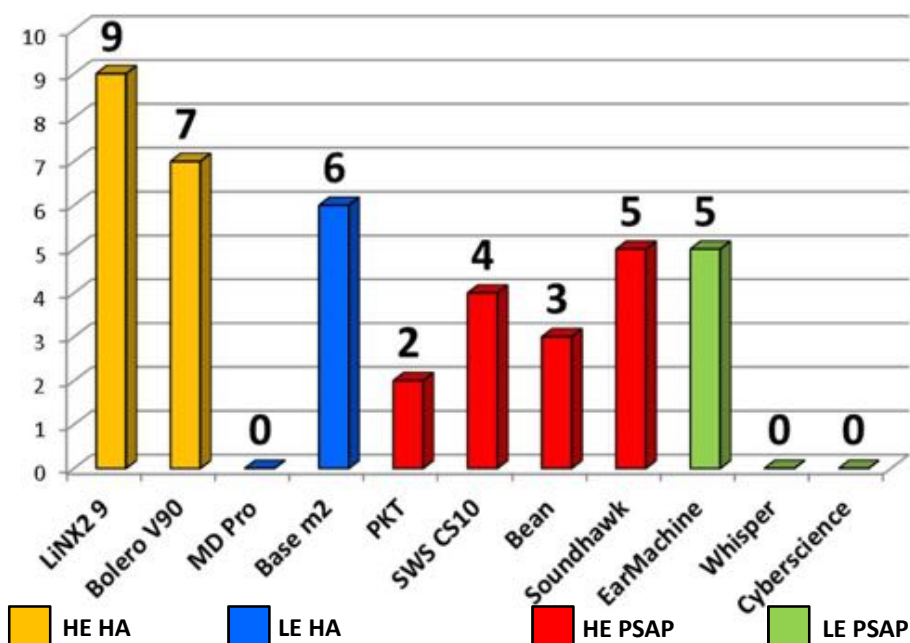
PSAP		Hearing Aid	
H I G H E N D	<p>WS PockeTalker</p> <p>Soundhawk</p> <p>Etymotic Beam</p> <p>SWS CS-10</p> <p>\$150-\$349</p>	H I G H E N D	<p>Resound LiNX9</p> <p>Phonak Bolero V90-SP</p> <p>\$3200</p>
L O W E N D	<p>Cyberscience</p> <p>Earmachine App</p> <p>Woodland Whisper</p> <p>\$1-\$49</p>	L O W E N D	<p>Hansaton Base M2</p> <p>MD Hearing Aid Pro</p> <p>\$199-\$399</p>

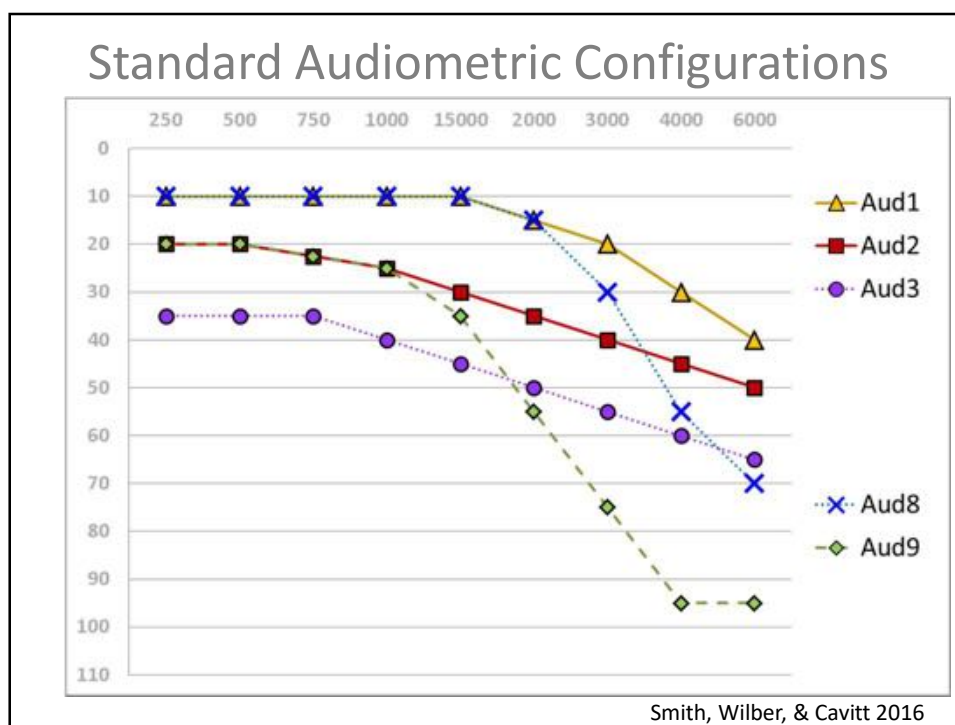
Smith, Wilber, & Cavitt 2016

Device	Category	Flat & Gently-Sloping						
		Very Mild	Mild	Moderate	Moderate-Severe	Severe I	Severe II	Profound
LINX2 9	HE HA	99%	100%	100%	100%	97%	90%	66%
Bolero V90	HE HA	98%	100%	99%	97%	79%	61%	36%
Base m2	LE HA	93%	98%	95%	92%	40%	8%	1%
Soundhawk	HE PSAP	99%	98%	96%	65%	13%	0%	0%
EarMachine	LE PSAP	93%	97%	88%	57%	27%	12%	0%
SWS CS10	HE PSAP	98%	96%	91%	84%	23%	0%	0%
Bean	HE PSAP	99%	94%	69%	14%	0%	0%	0%
Pocketalker	HE PSAP	90%	88%	75%	72%	47%	21%	3%
MD HA Pro	LE HA	80%	78%	71%	65%	36%	14%	0%
Cyberscience	LE PSAP	52%	46%	37%	35%	39%	21%	2%
Whisper	LE PSAP	38%	37%	31%	30%	21%	14%	0%

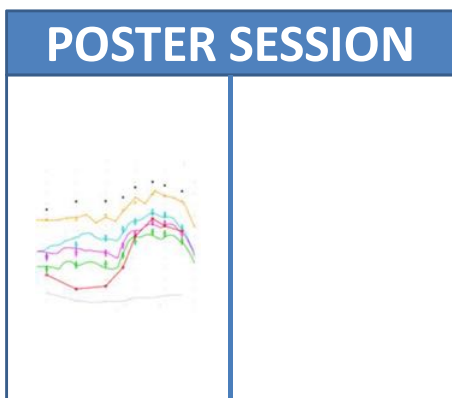
Device	Category	Steeply-Sloping		
		Very Mild	Mild	Moderate-Severe
LINX2 9	HE HA	98%	98%	99%
Bolero V90	HE HA	97%	96%	91%
Base m2	LE HA	90%	93%	72%
Soundhawk	HE PSAP	99%	98%	68%
EarMachine	LE PSAP	91%	88%	48%
SWS CS10	HE PSAP	96%	86%	69%
Bean	HE PSAP	94%	67%	23%
Pocketalker	HE PSAP	87%	82%	63%
MD HA Pro	LE HA	77%	82%	60%
Cyberscience	LE PSAP	47%	36%	31%
Whisper	LE PSAP	44%	38%	31%

Number of Audiograms Matched NAL-NL2 Target





Objective Analyses & Comparison of PSAPs



- 10 PSAPs/OTC
- REM (NAL targets)

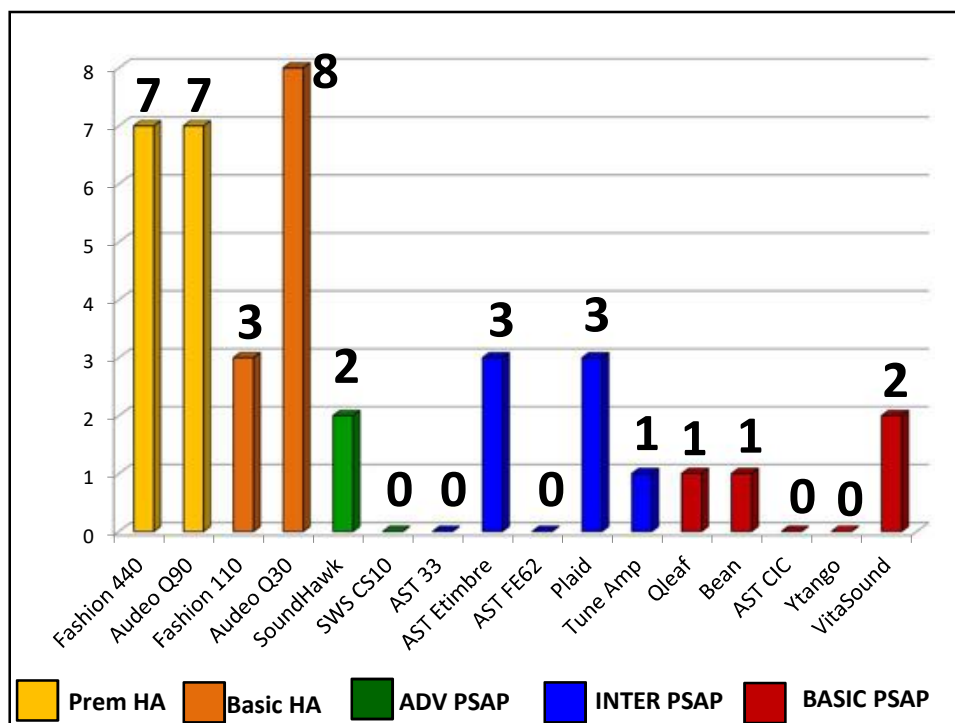
Reed, Betz, Grabowski, Korczak, Lin, & Mamo 2015

Pilot Electroacoustic Analysis of a Sample of Direct-to-Consumer Amplification Products

BEAN	BEAN-T	CS-50+	LifeEar	MD Hearing Aid Air
SOUND HAWK	TWEAK BASIC	TWEAK FOCUS	SONG BIRD ULTRA	MSA30X

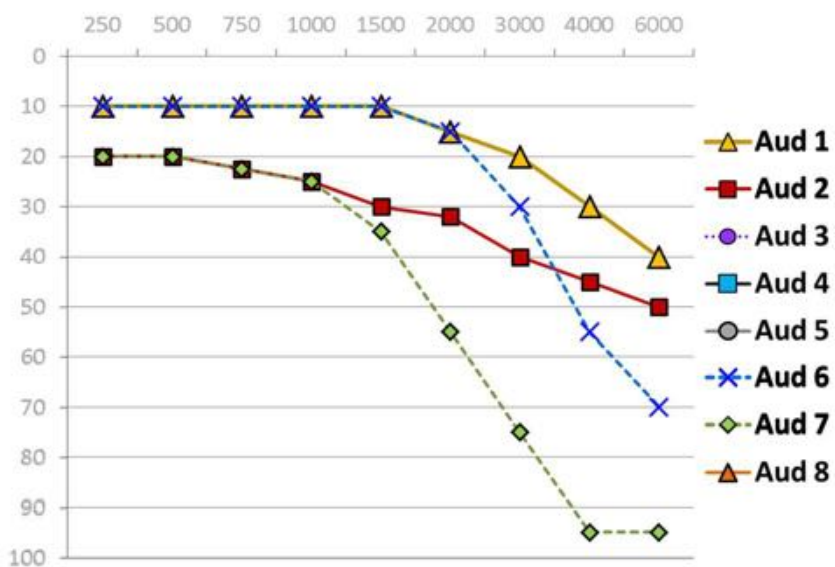
- **MOST MATCHED TARGET +/-10 dB SPL (5 of 9)**
- **THREE +/-5 dB SPL (at least 5 of 9)**

Reed, Betz, Lin, & Mamo 2017

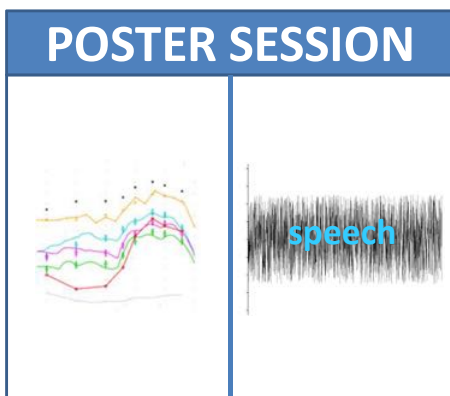




Standard Audiometric Configurations



Objective Analyses & Comparison of PSAPs



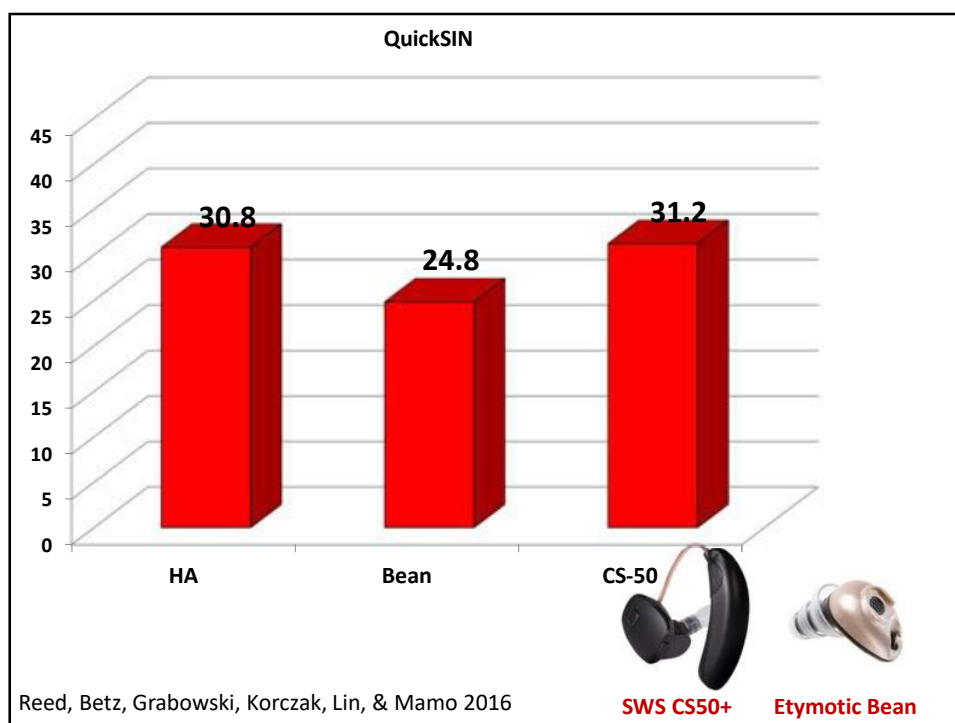
- Pilot data
- 5 subjects
- Speech-in-noise
 - QuickSIN
 - Word-in-Noise



SWS CS50+

Etymotic Bean

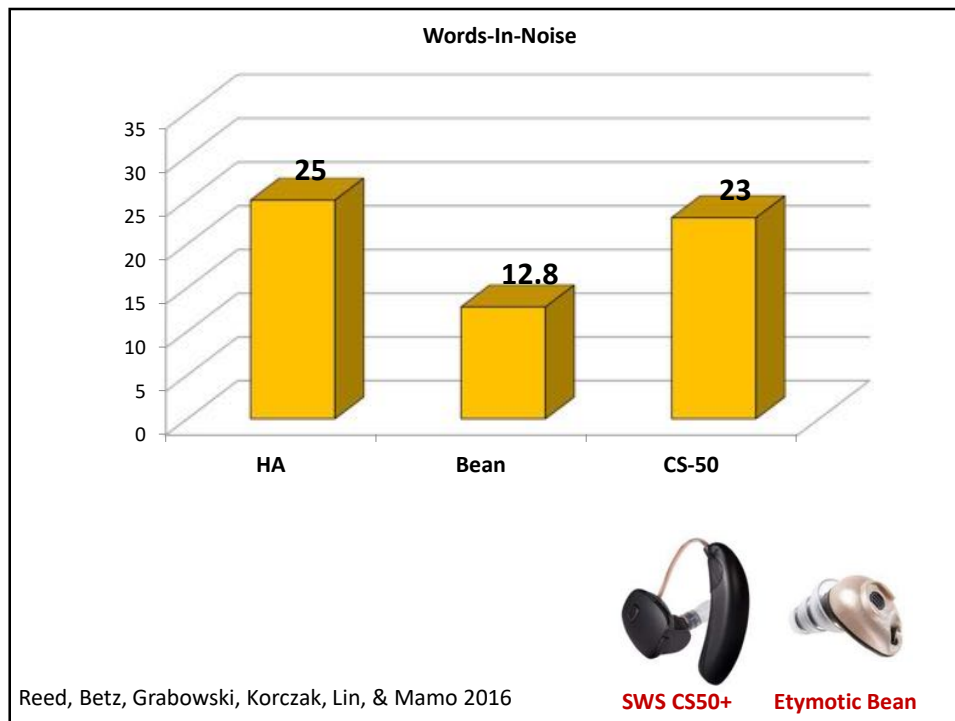
Reed, Betz, Grabowski, Korczak, Lin, & Mamo 2015



Reed, Betz, Grabowski, Korczak, Lin, & Mamo 2016


SWS CS50+







Etymotic Bean



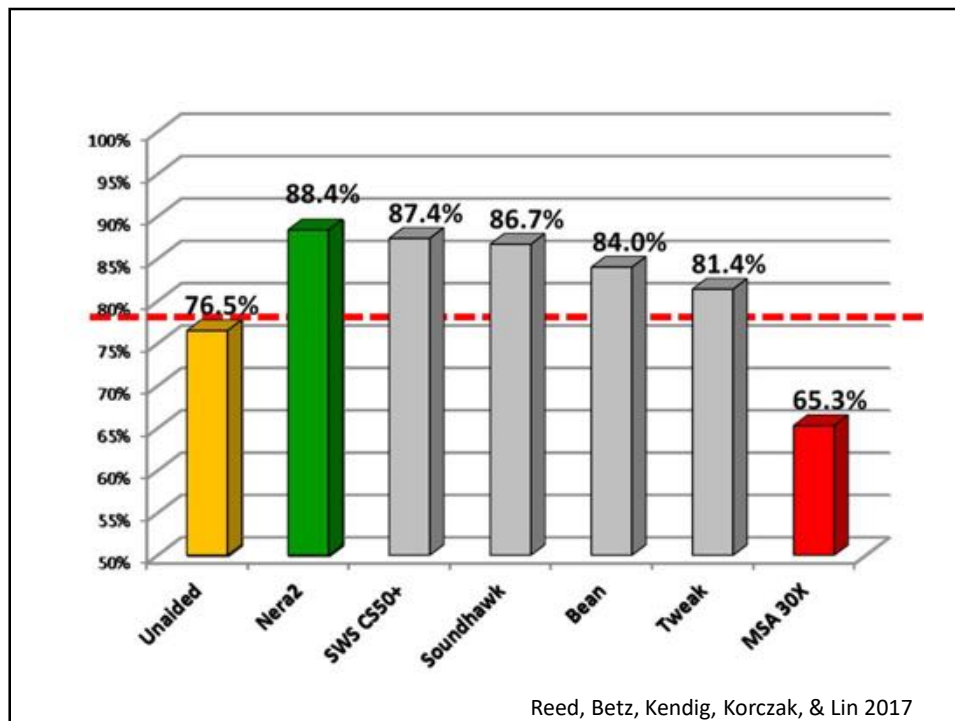
PSAP vs Conventional Hearing Aid

JAMA



\$1910	\$300	\$30
		
Oticon Nera2	Etymotic Bean	MSA 30X
		
SWS CS50+	Tweak Focus	Soundhawk
\$350	\$270	\$350

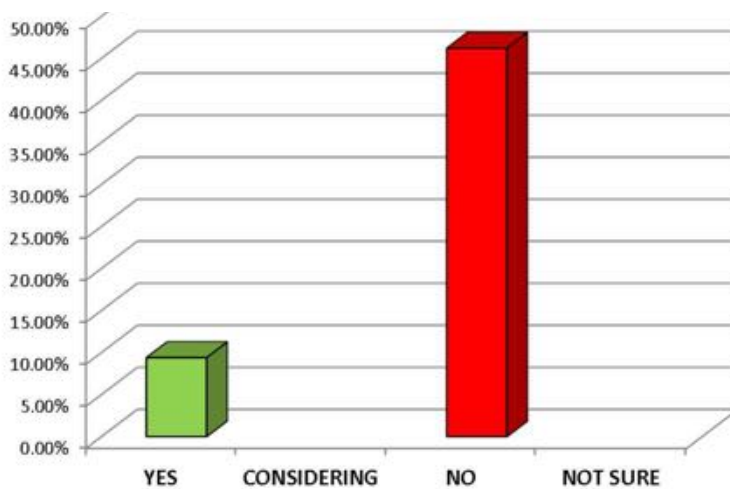
Reed, Betz, Kendig, Korczak, & Lin 2017



GENERAL CONCLUSIONS

- Hearing aids perform better than PSAPs in meeting NAL-NL2 targets
- Some PSAPs show comparable scores on speech in noise tests to hearing aids
- Some PSAPs may be appropriate up to a mild hearing loss

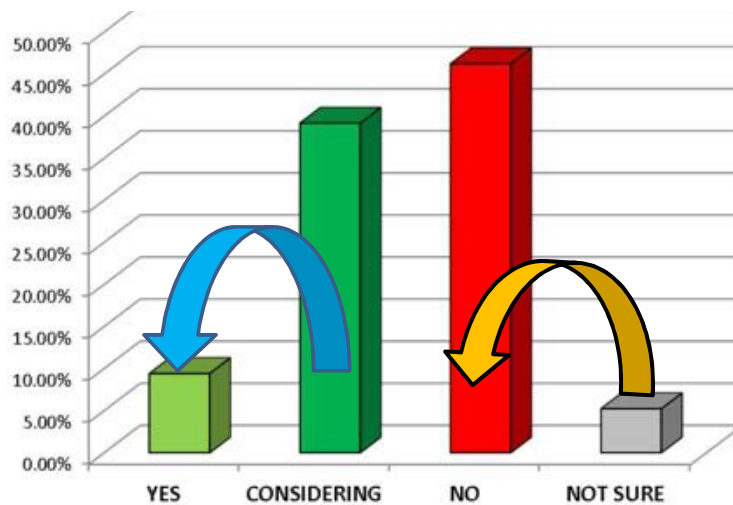
Potentially Offer PSPAs?



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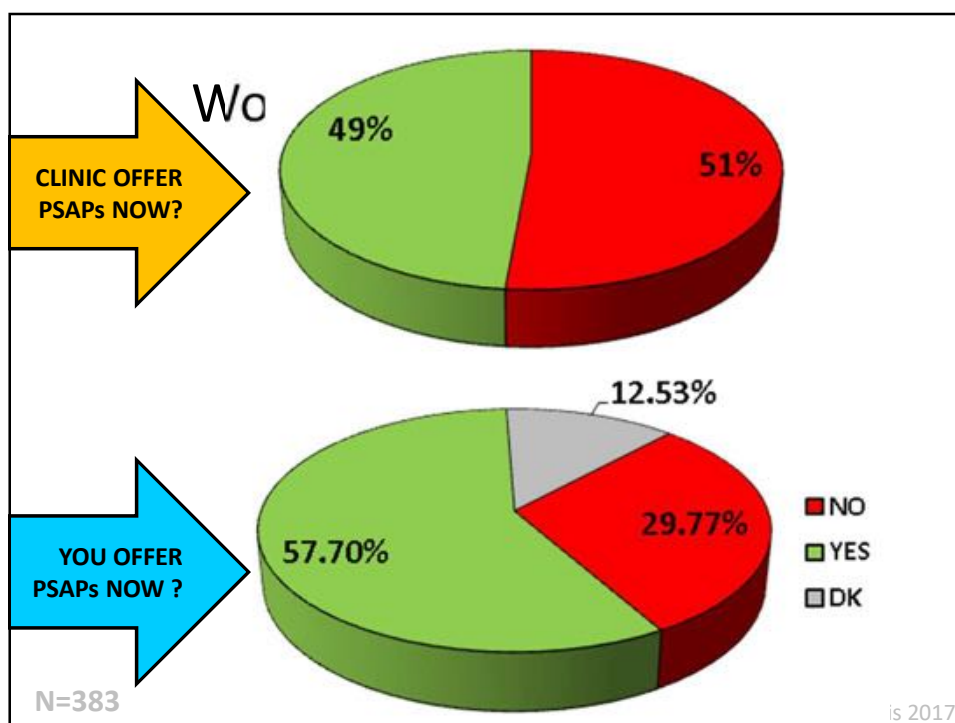
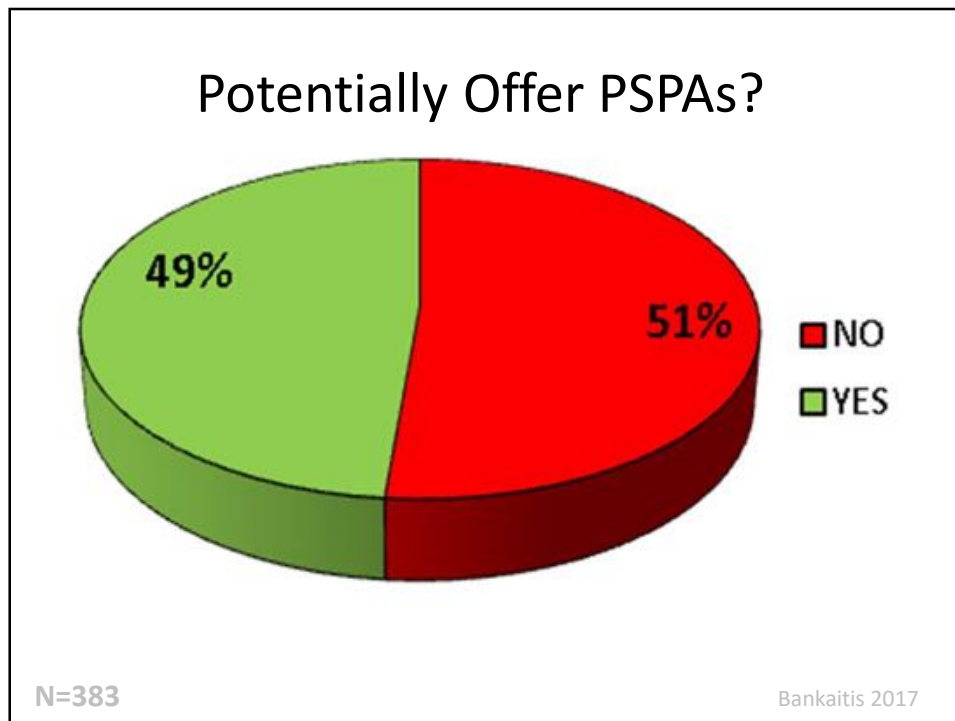
Bankaitis 2017

Potentially Offer PSPAs?

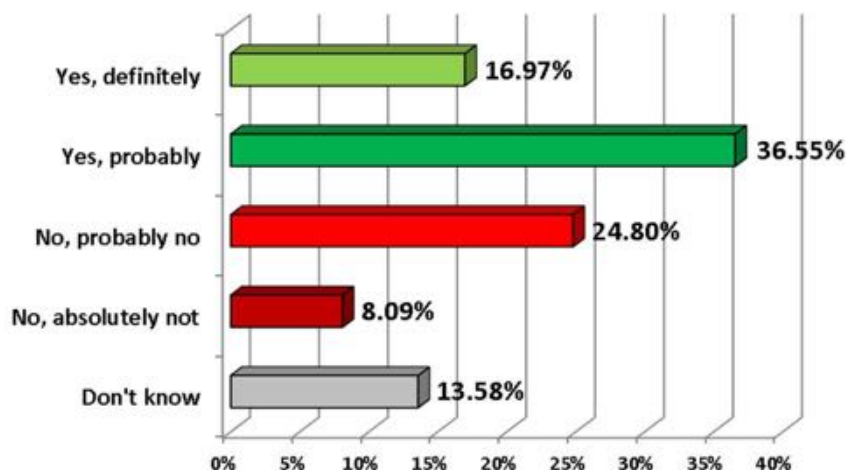


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Bankaitis 2017



Change in Business Practices?



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Bankaitis 2017

GENERAL CONCLUSIONS

- Hearing aids perform better than PSAPs in meeting NAL-NL2 targets
- Some PSAPs show comparable scores on speech in noise tests to hearing aids
- Some PSAPs may be appropriate up to a mild hearing loss
- Huge variability in price, features, quality & performance
- DO YOUR DUE DILLIGENCE



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