

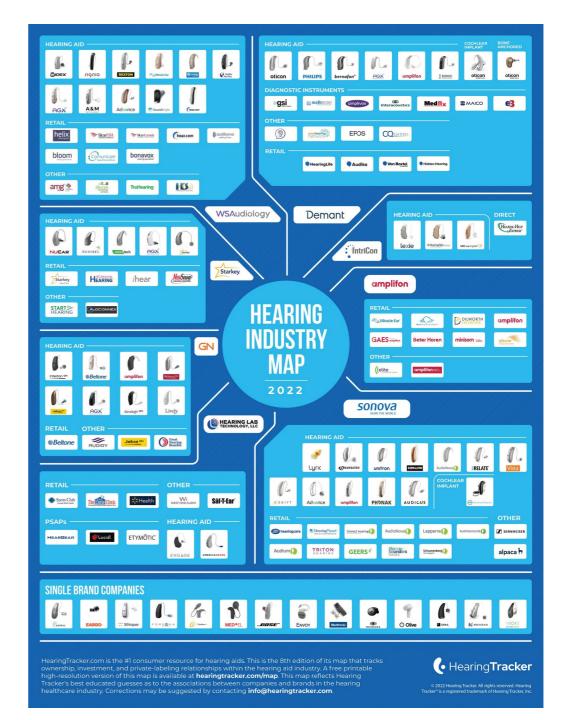
Where are we in 2022? Hearing Industry Landscape and Emerging Technologies

Laurel A. Christensen, Ph.D.

Chief Audiology Officer, GN Hearing

Hearing Industry

What are you hoping to hear about today?





A Very Dynamic Marketplace.

1

115TH CONGRESS 1ST SESSION

S. 670

To provide for the regulation of over-the-counter hearing aids.

IN THE SENATE OF THE UNITED STATES

March 21, 2017

Ms. Warren (for herself, Mr. Grassley, Ms. Hassan, and Mr. Isakson) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the regulation of over-the-counter hearing

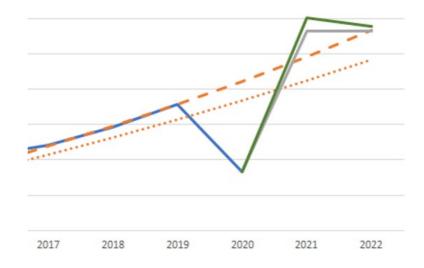
- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

OTC

Covid - 19



Market Rebound







Omni-Channel



Market Growth Drivers – US Commercial Market

- Aging Population: Baby Boomers will continue to grow the market
- Patient Satisfaction: Remains at record levels.
- Repeat Purchases: Increases in existing wearers, will increase re-purchases over time.
- Healthcare Benefits: Delivering new patients to market.
- Omni-channel: Driving additional demand through telehealth and self-fitting capability, which is expected to attract a younger end user.

	2014	2018	2025
US Population (millions)	318.6	327.2	347.3
Hearing Loss Incidence	10.6%	10.8%	10.8%
Adoption Rate	30.2%	34.1%	38.8%
Active Wearer Population (millions)	10.2	12.1	14.6

Data synthesis utilizing MT2019 and MT2022 data Excludes OTC, which could ultimately account for an additional 3.0 to 5.0 million wearers within 3-5 Years

4.7M units from repeat purchases alone



Topics



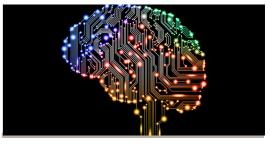




2 Convergence of CE and Hearing Aids



Connectivity



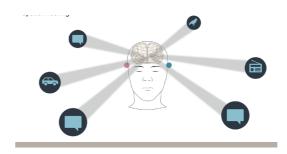
Al Al



Environmental Classification



Hearing in Noise



Spatial Perception



R Health



OTC





The starting point...

The OTC Act?

п

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OTC Draft Overall Summary

The OTC draft defined the new **OTC category** as expected, but it also re-defined all today's classic HI's into a **Prescription** category:

OTC	Prescription	
For mild-to-moderate HL & adults only	For all HL & ages	
OTC (Direct-to-Consumer) or Self-Fitting with HCP – State Laws are pre-empted	As today: State laws apply, e.g. some states require a state licensed HCP	
New & specific technical requirements such as max 120 dB SPL, no gain limitation, insertion depth limitations, etc.	As today	
New labeling requirements unique for OTC	New labeling requirements (from 20??)	
Required for market claims like "Intended to treat Hearing Loss"		
Medical grade quality system (CAPA, NPD R&D process, manufacturing)		

Note:

• FDA has stated they will enforce new regulation

OTC Regulation

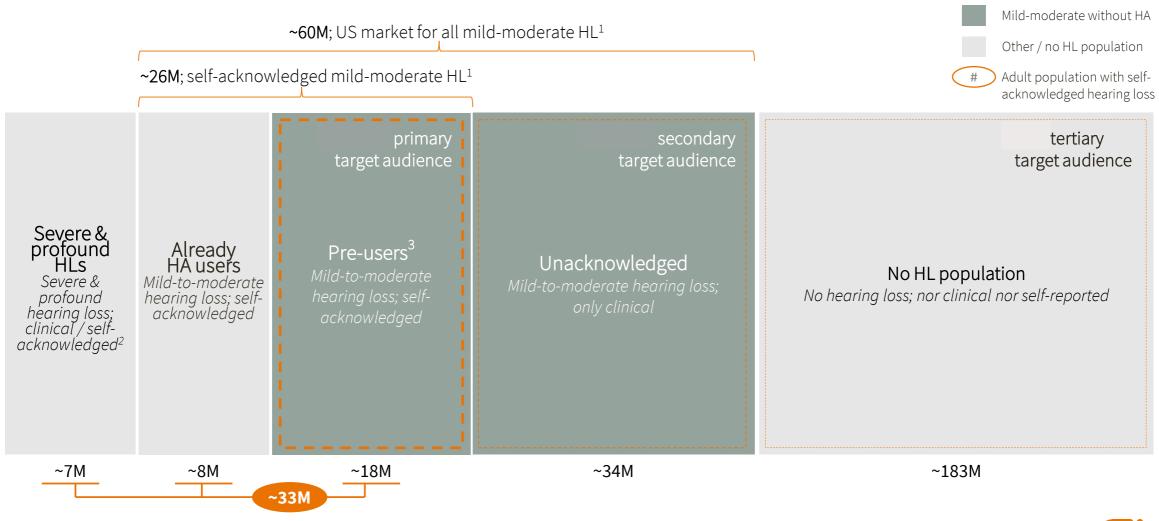
- Comments to the OTC Rule from HIA
 - Limit the Maximum Output for OTCs to 110 dB SPL instead of the 115/120 dB SPL that is proposed
 - Apply a gain limitation of 25 dB
 - Require 510Ks for all OTC devices
 - Require Class II Quality Practices





The opportunity...

18M with acknowledged mild-to-moderate hearing loss and no solution





The research...

What did we learn from these pre-users?



Over 10 studies completed



Simplified hearing aid

Cheap and accessible alternative to hearing instruments with hearing as main / only use case

Key consumer driver: PRICE





Lifestyle hearing

Hearing assistance as part of a CE experience, e.g., consumerized form factor and features

Key consumer driver: STIGMA





They mentioned three occasions to be the most problematic

At work

Both in open plan offices, meetings, and informal chat



In noisy locations



At restaurants, cafés and bars



Recipients perceives hearing issues to be a moderate to serious problem

44%-37%¹

55%

37%

Across all recipients

19-16% ¹

26%

15%



Lifestyle Hearing

6 key drivers:

 Acknowledge loss but looking for support in certain situations only

Want a "miniature" discreet but visible product in non-traditional form factor

 Don't want a traditional hearing aid but do want comfort of medical technology & back-up support

Want a multi-functional easy to use device

Tend to be younger than today's first-time user.

Plan to research purchase on-line



Ideal scene for individuals with hearing loss

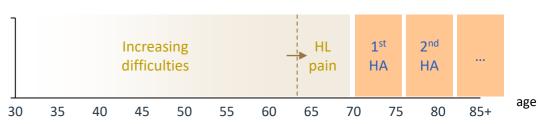


Because of the situation we have discussed today...

- Large population with untreated hearing difficulties
- Long wait time before embarking on hearing journey
- High(er) purchase intent for this product with younger segments

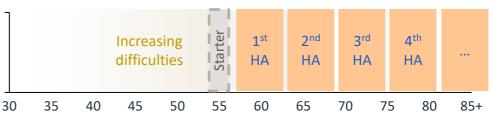
We can together move towards the ideal scene...





Age of individual. 1st HA ~ 70, aware of difficulties due to loss since ~64





age



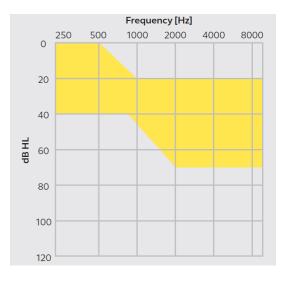
How to serve your patients

Evaluate patients to determine the best solution for their hearing loss.

As hearing care professionals, our mission is to evaluate patients' hearing challenges and abilities in order to apply those findings to the most appropriate hearing care recommendation.

- Share with each patient that you strive to fit based on his/her hearing loss, lifestyle and budget.
- Utilize comparative tools to share the differences between technology options and the impact on his/her hearing solution. This may include items like audiogram overlays representing product fitting range and technology features/benefits handouts.
- Recommend OTCs when appropriate and serve you patients' with a customized offering package to meet their needs.

Jabra Enhance Plus fitting range





Care/Support packages

Create 2 to 3 customized offering packages to meet a variety of patients' needs.

Assess and Go

Office Visit + Testing + Devices

- Diagnostic and assessment services are billed to the patient and/or insurance.
- Device cost
- Any additional EarGels or visits would be charged.

Assess and Fit

Office Visit + Testing + Devices + Fitting/Orientation Fee

- Diagnostic and assessment services are billed to the patient and/or insurance.
- Device cost
- Personalize the devices (set up app, pair, instruct them through set up process and answer any questions)
- Any additional EarGels or visits would be charged.

Assess, Fit and Follow

Office Visit + Testing + Devices + Care/Support package

- Diagnostic and assessment services are billed to the patient and/or insurance.
- Device cost
- Care/Support package:
 - Personalize the devices (set up app, pair, instruct them through set up process and answer any questions) if needed
 - Clean & check visits (quarterly)
 - Replacement EarGels
 - Loaner if devices go in for repair

Disclaimer: These packages are suggested guidelines to consider as you think about what solution best meets your practice needs.

Who is playing in this segment?







Lexie Lumen







Etymotic Research













Convergence of CE and Hearing Aids





In-The-Ear Convergence

'Medical' Customs today



Modern Custom Products



Self-fitting Lifestyle Hearing



Advanced Hearing Amplification



Design is moving away from the tradition "medical" in-the-ear product to modern, ear bud styles due to the convergence of consumer electronics products for hearing loss.



Custom Hearing Aids taking on a non-medical look

Starkey Livio



Insio Charge and Go AX





Earbuds with Hearing Enhancement

AirPod Pro



Olive



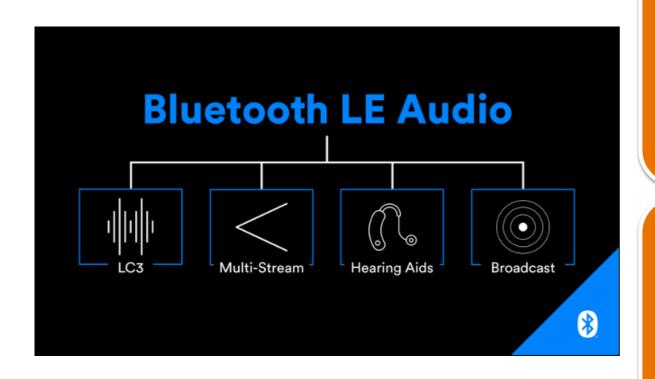


Connectivity





Bluetooth



Bluetooth Classic

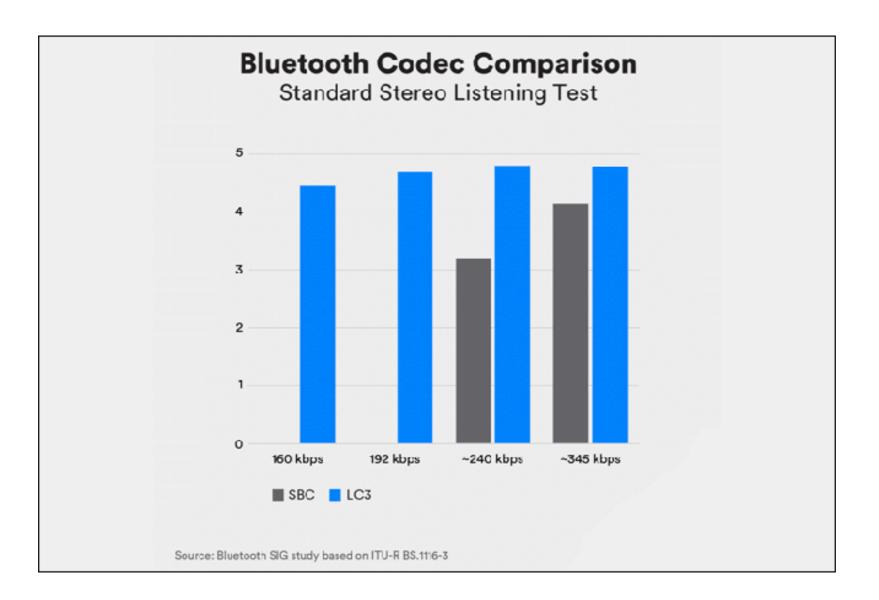
- Streams to One Device
- High Power Consumption
- Compression of the signal causes distortion

Low Energy
Audio (LC3) –
Low Complexity
Communication
Codec

- Steams to Multiple Devices
- Lower Power Consumption
- Broadcast Audio
- From Single Device to Multiple Devices
- Public Venues
- Replacing the Loop and TC Eventually



Sound Quality of Bluetooth Classic vs. LC3 Bluetooth





Seniors and Smartphones



Pandemic was especially isolating for seniors

Smartphones played a role in mitigating some of this isolation

HCPs should be promoting Smartphones to patients

Only 10.4% of the 65+ population had a landline alone without cellphone service

According to AARP, 77% of those aged 70+ own a smartphone, but from those aged 85+ this decreases to 65 – 70%

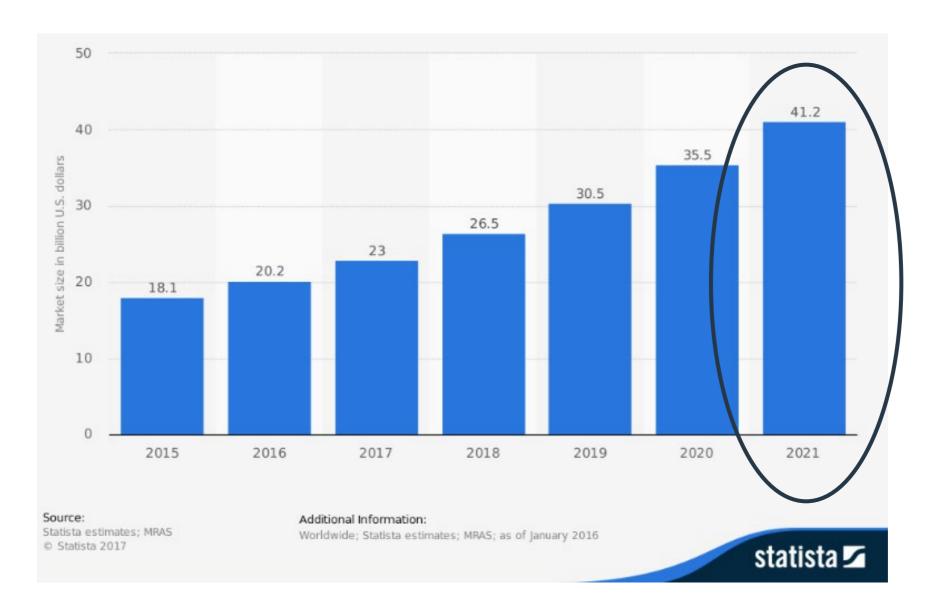


Why telehealth?





Global telemedicine market size from 2015 to 2021 (in billion U.S. dollars)*





Apps to Control Hearing Aids

program control

volume control, including a mute option

sound enhancer adjustments personalized settings and programs

battery life monitoring

tinnitus management saving settings for specific locations

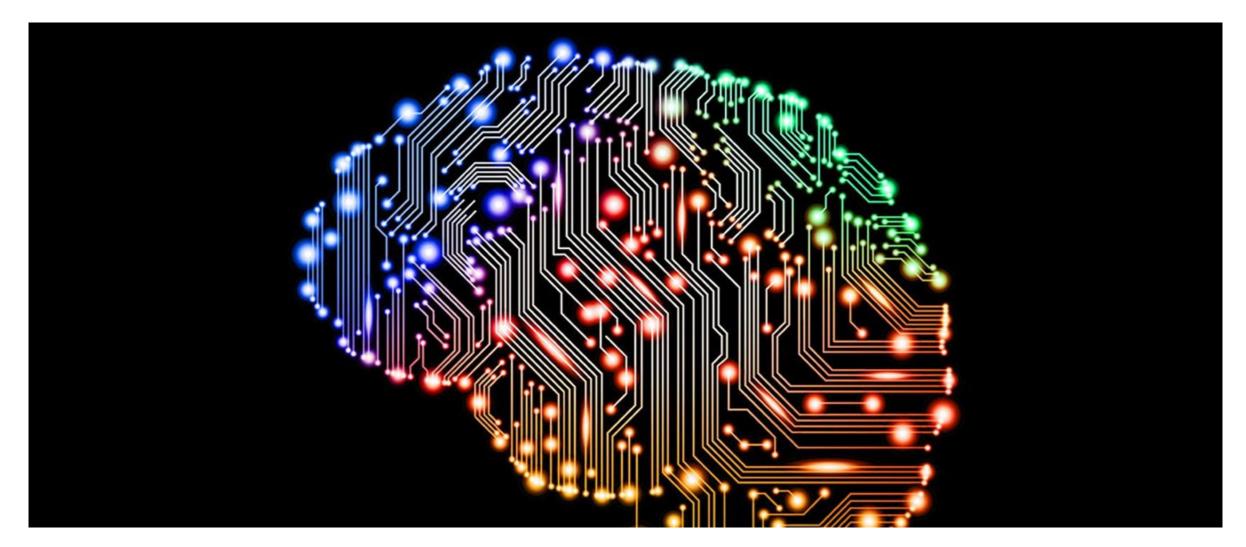
find my hearing aids feature

audio streaming

support from hearing care professionals And more will come....



Artificial Intelligence





Artificial Intelligence



Artificial intelligence (AI)
describes the development and
use of a computer system with
the ability to perform some of
the functions that are
normally associated with human
intelligence and discernment,
such as learning, problemsolving, decision-making, and
pattern recognition.



Machine Learning

Machine learning is
a type of artificial intelligence
that enables (trains) an
algorithm to build a predictive
model from input data
and then applies that learning
without the need for
human intervention – to
make useful predictions
from new data.



Deep learning is a Machine
Learning method based on
artificial neural networks that
mimics the workings of the
human brain in processing data.
Deep learning can even happen
without human supervision and
draw from unstructured and
unlabeled data.



Like sense organs in the human body, electronic sensors can play a vital role in Al. Sensor solutions are mostly responsible for data acquisition that is then transmitted and computed by a more capable network device.

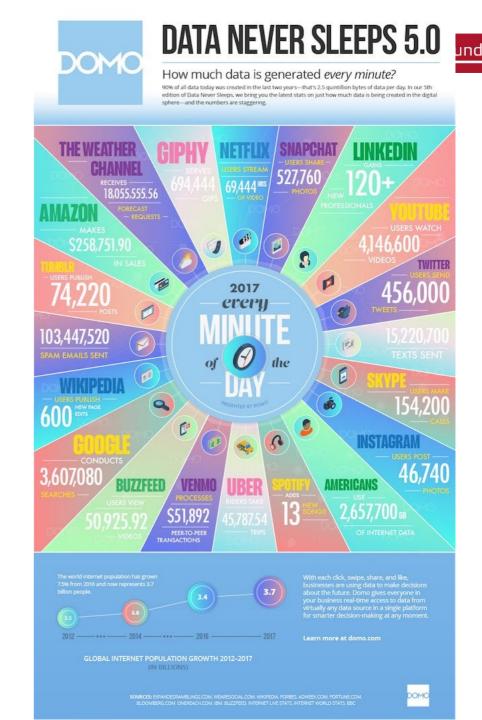


Data Analytics

We live in a world where there is more information captured on a minute-by-minute basis about our daily lives than ever before.

Practically everything we do leaves a trail.

BIG DATA - term for data sets that are so large or complex that traditional data processing application software is inadequate to deal with them. Since the data sets are so huge, the challenges include capture, storage, analysis, data curation, search, sharing, transfer, visualization, querying, updating and information privacy.



Where is Big Data being used?

- Retail what is selling, where is it positioned, what time of day does it sell – all used to organize stores
- Feeding the hungry –data can be used to maximize crop yields, minimize the amount of pollutants released into the ecosystem and optimize the use of machines and equipment
- Fitness data used to track fitness, reward behavior, recommend fitness routines
- Prevent crime data-driven strategies based on intelligence and public data sets help deploy resources more efficiently











Precision Medicine

A medical model that proposes the customization of healthcare, with medical decisions, treatments, practices, or products being tailored to the individual patient. In this model, diagnostic testing is often employed for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis.



Precision Medicine





Individual user needs & preferences

- Hearing aid users wear their hearing aids in a variety of acoustic environments.
- The resulting individual preferences and needs are variable.

 The industry faces the challenge of providing users with appropriate solutions.





Where is Al Being Used in Hearing Aids Today?

Widex Evoke – Real-Time Machine Learning

- Learns your preferences in any listening environment through A/B comparison
- Learns from other users who send data to the Cloud

Starkey Livio

Uses integrated sensors and artificial intelligence which can detect if you've fallen

Oticon More

Used offline DNN to develop an environmental classifier to steer hearing aid features



Environmental Classification











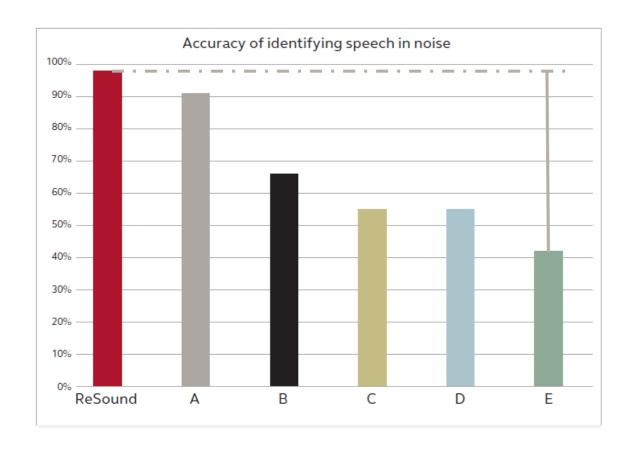
Classifier – Yelamsetty et al., 2021 This study has a lot of people talking!

Repeated Groth and Cui – but only for classifiers that classified Music

- The top concern they identify is classifying music, especially music in the presence of any other environmental sound.
- They point out that the signal processing strategies to enhance music and the signal processing to enhance speech and/or reduce background noise are most often opposed so the hearing aids will struggle in environments with both music and other sounds.
- People know when they want to listen to music. It is an intentional activity. You don't really need
 the hearing aid to decide that for you. If the hearing aid does decide it is very likely that hearing in
 noisy environments will suffer.



ReSound ONE – Environmental Classification



ReSound and premium hearing aids from 5 other manufacturers were exposed to a conversation between a male and a female speaker in different kinds of noisy environments (party, train station, grocery store, hand mixer etc.)

The hearing aids were connected to their respective fitting software and the data logging was read from the hearing aids

All manufacturers have classification environments that include speech-in-noise

ReSound showed the greatest accuracy at 98%. The least accurate hearing aid classified only 42% of hours as speech-in-noise.

Source: Groth (2015)



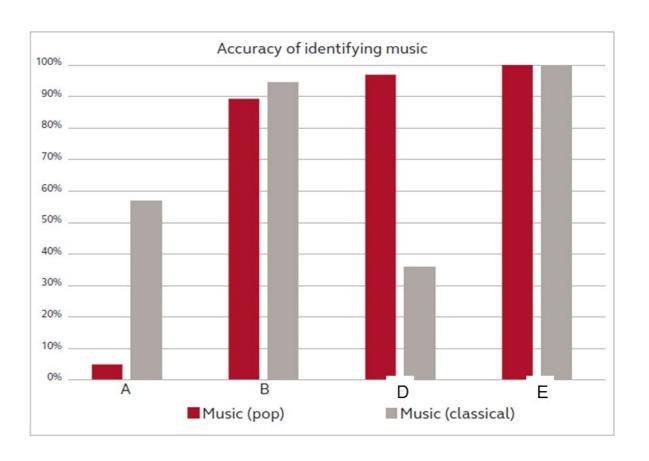
Music Classification: Limited accuracy

Tested music classifier from four manufacturers

Evaluated in a test box with looped sound files and read data logging

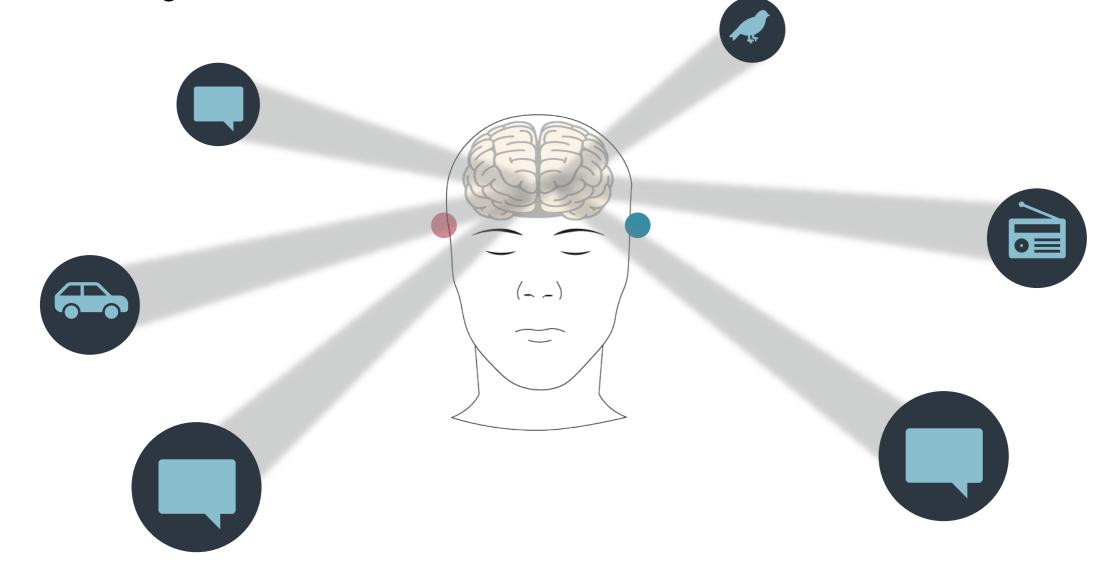
Two different genres of music

Note: Brand E was least accurate for speech-in-noise





Spatial Hearing



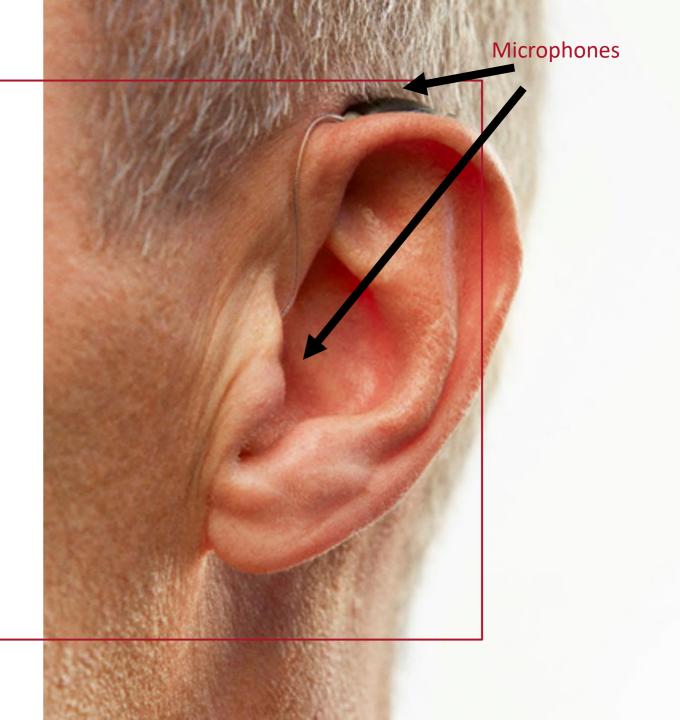


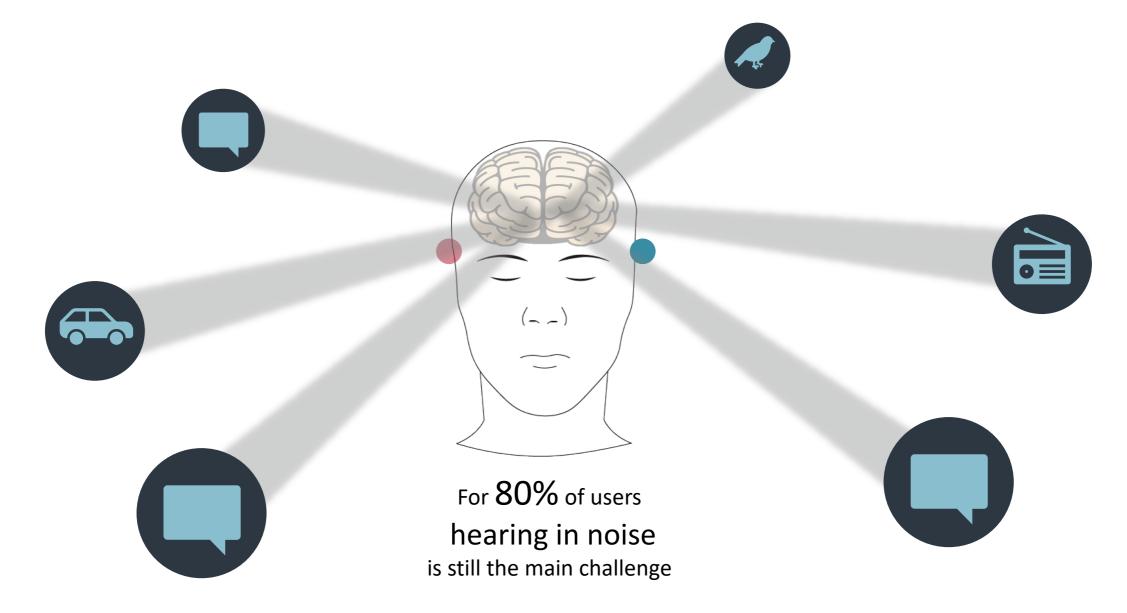
M&RIE

M&RIE MAKES SENSE

Our individual ear provides

- Our own unique acoustics
- Localization
- Spatialization





(source: MarkeTrak 10, 2019)





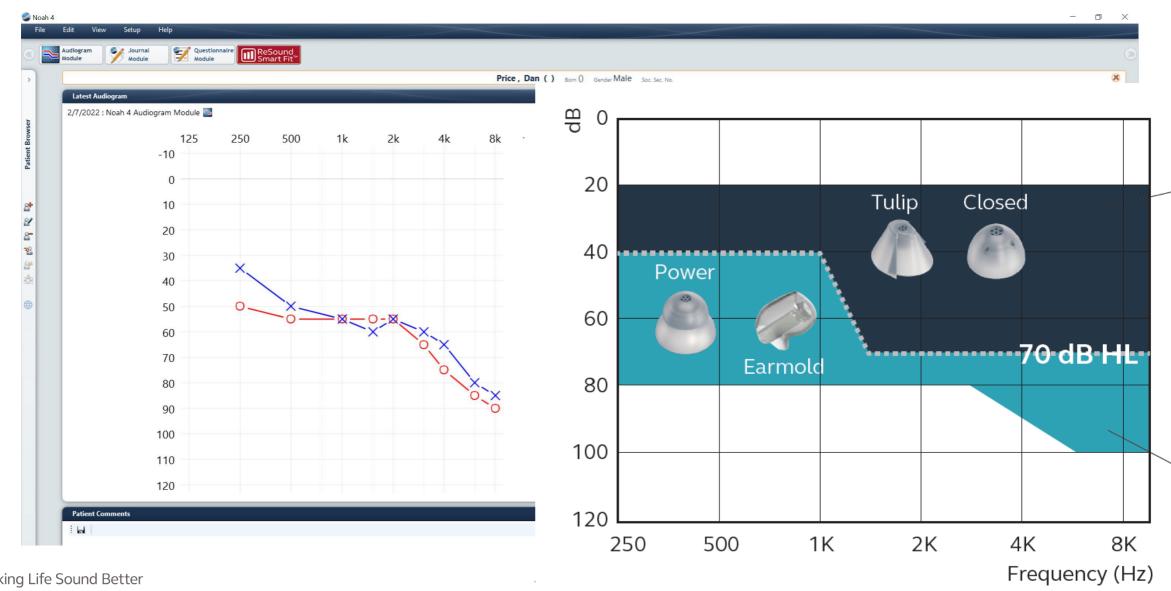
For 80% of users hearing in noise is still the main challenge

(source: MarkeTrak 10, 2019)

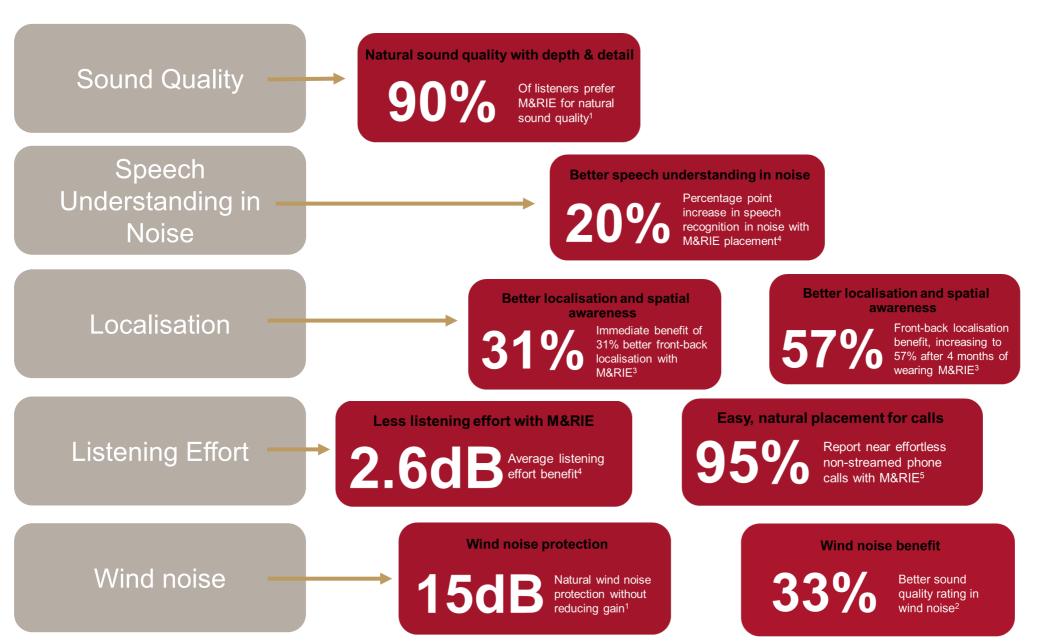




Hearing Loss



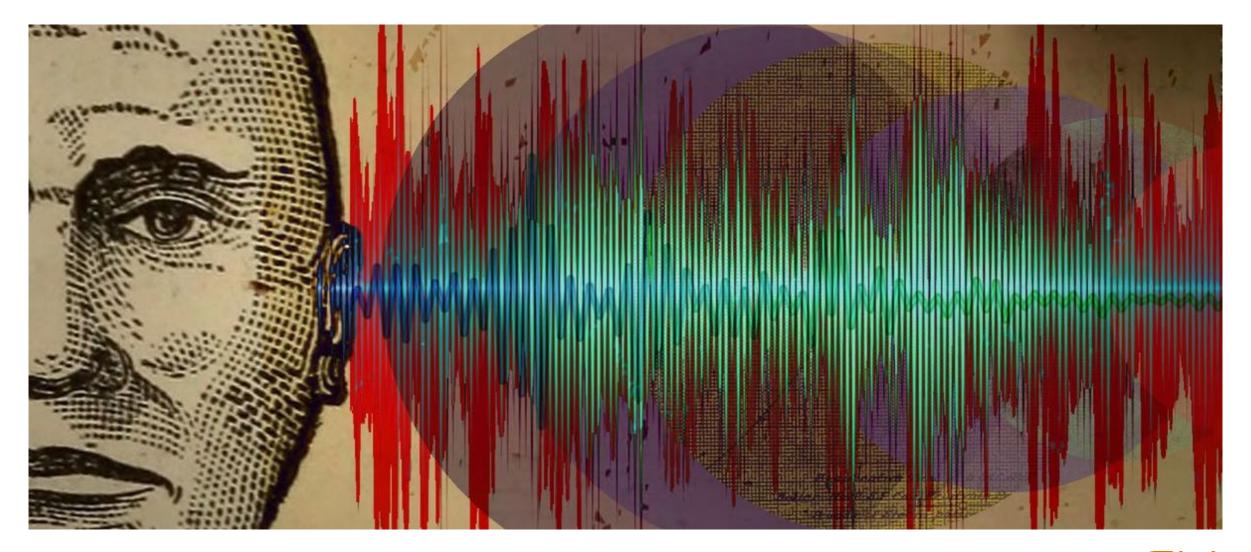
GN Making Life Sound Better



- Groth J. An innovative RIE with microphone in the ear lets users "hear with their own ears". ReSound white paper, 2020.
 - Andersen P, Schindwolf I, Jespersen C. Less wind noise with M&RIE leads to better sound quality. ReSound white paper, 2021.
 - Jespersen C, Schindwolf I, Groth J. Benefits of M&RIE with long-term use. ReSound white paper, 2021. Write up in progress, title subject to change
 - Quilter M, Groth J, Krueger M. Reduced listening effort and improved speech intelligibility with M&RIE. ReSound white paper, 2021. Write up in progress, title subject to change
- Quilter M, Hartenstein R, and Groth J. Percentage of users who report regular calls without effort or very little effort, 2021 Jespersen C, Kirkwood B, Schindwolf I, M&RIE receiver preferred for sound quality and localisation, ReSound white paper, 2020,



Hearing in Noise





OMNI HEARING

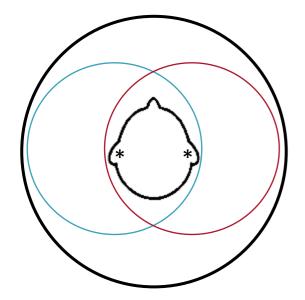


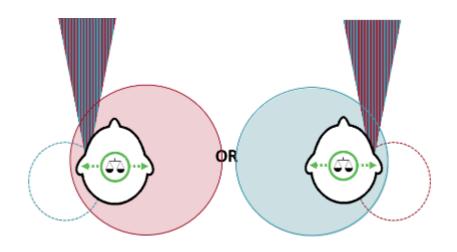
BEAMFORMERS + OMNI

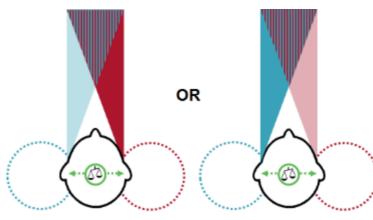


BEAMFORMERS











Accessories















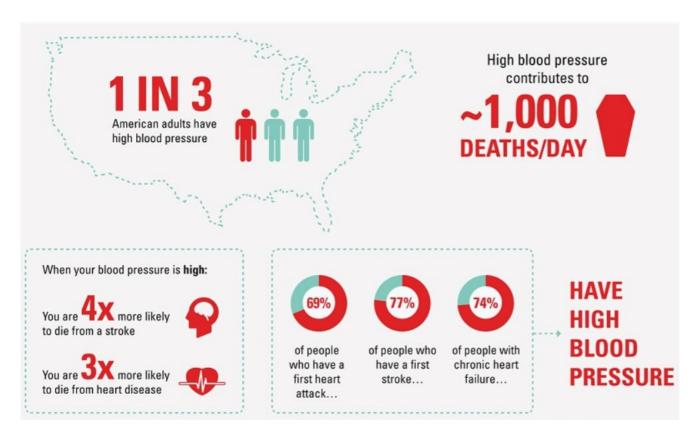


Health





High Blood Pressure



Connection between Hypertension and Hearing loss

- Patients with hypertension have greater increase in hearing loss compared to those without
- Hearing system susceptible to vascular changes





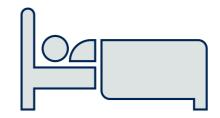
Sleep apnea is linked to:

- High blood pressure
- Atrial fibrillation
- Sudden cardiac death
- **Meart** failure

More than

18 MILLION

Americans have it.



Connection between Sleep Apnea and Hearing loss

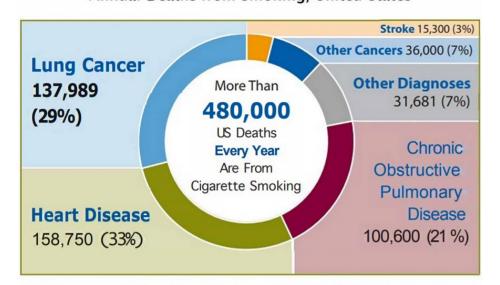
- 31% increased risk of HF HL
- 38% increased risk of any HL
- 90% increased risk of LF HL

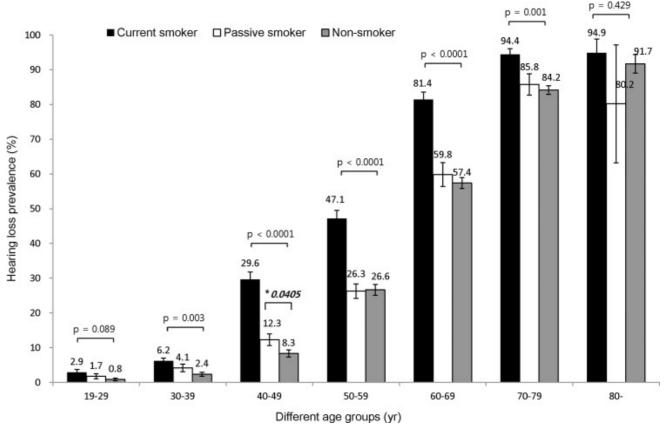




Smoking





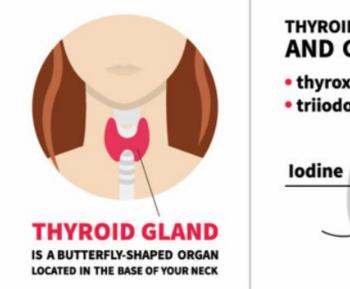


Prevalence of bilateral HF HL

Source: CDC, Chang et al, (2016)

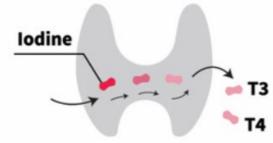


Thyroid Disease



THYROID GLAND TAKES IODINE. AND CONVERT IT INTO:

- thyroxine (T4)
- triiodothyronine (T3)



WHAT CAN GO WRONG WITH THYROID?









Hyperthyroidism

Cancer

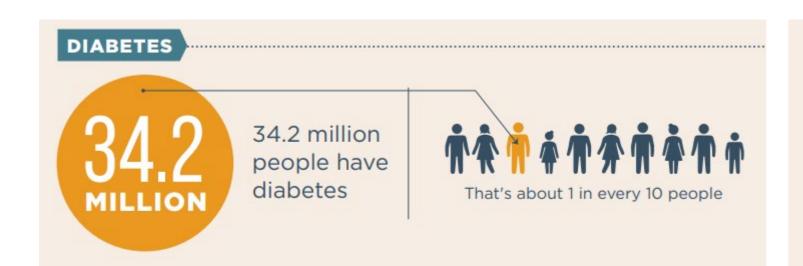
Hypothyroidism

- lodine is essential for thyroid function
 - Thyroid hormone needed for auditory system maturation
- HL is more than twice as high for those with low iodine levels (ped)

Hyperthyroidism

- Propylthiouracil (Rx)
 - Cytoplasmic antibodyassociated small-vessel vasculitis





Hearing loss is twice as common in adults with diabetes compared to those who do not have the disease





Source: NIH (2008), Bainbridge et al., 2008

Ototoxicity

>200

OTC and Rx Meds

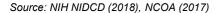
Common examples:

- Salicylates Aspirin
- Antibiotics Aminoglycosides,
- Loop Diuretics Lasix, Edecrin, Bumex
- Chemotherapeutic Agents Cisplatin, Nitrogen Mustard, Vincristine
- Nonsteroidal Anti-inflammatory Drugs (NSAIDS) - Advil, Aleve, Motrin



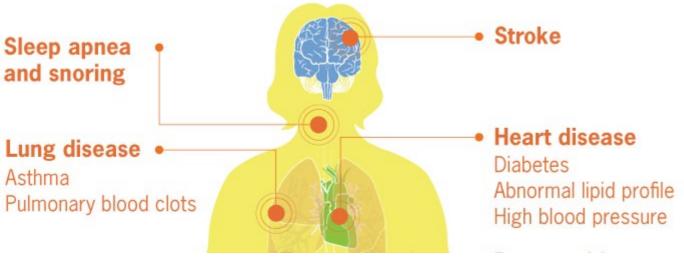






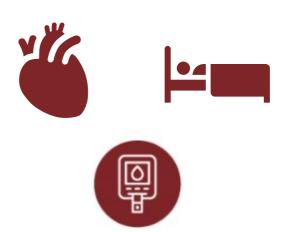
Obesity

Increased incidence of



Connection with Hearing loss

- 21.5% rate of SNHL
 - 13.44% in non-obese
- 1.73-fold increase in odds of SNHL

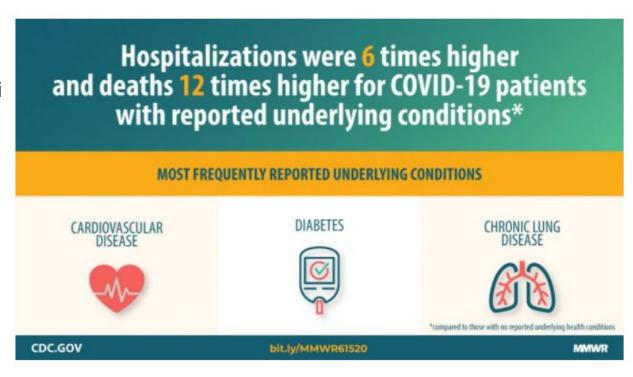


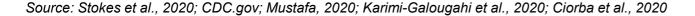


Covid-19 (Coronavirus)



- Reduced TEOAE and HF hearing (Mustafa, 2020; Karimi-Galougahi et al., 2020)
- Some balance symptoms noted (Karimi-Galougahi et al., 2020)
- Possible impact
 - Viral infection impact on hair cell function
 - Hypoxia respiratory illness
 - Ototoxic medication (Ciorba et al., 2020)
 - azithromycin, favipiravir, remdesivir, lopinavir, and hydroxychloroquine







Hearing loss impact on health





Irritability, negativism and anger



Fatigue, tension, stress, and depression



Avoidance or withdrawal from social situations



Social rejection and loneliness



Reduced alertness and increased risk to personal safety



Reduced job performance and earning power



Diminished psychological and overall health





MarkeTrak 10 (Harvey, 2020)

62

Those with hearing difficulty are 3.5+ times more likely to have each of the conditions below.

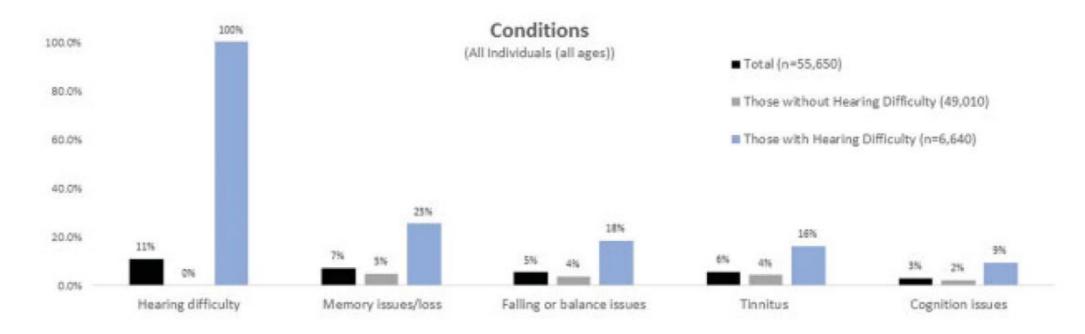


Figure 4 Those with hearing difficulty are 3.5+ times more likely to have each of the conditions listed within the graph.

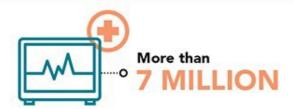


Falls

OLDER ADULT FALLS A Common Concern

IN 2014:





of those falls required medical treatment or restricted activity for at least a day.



older adults died as a result of falls that's 74 older adults every day.

- People with a 25-decibel hearing loss, classified as mild, were nearly 3X more likely to have a history of falling
- Every additional 10-decibels of hearing loss increased the chances of falling by 1.4-fold





Source: CDC, Lin et al., 2012

Health care burden and Hospitalizations

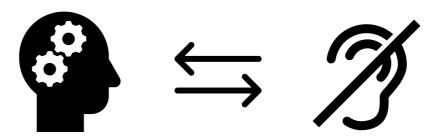
Uncorrected hearing loss may raise the risk of mental and physical health problems and leads to higher hospitalization rates and health care costs.

- Analysis of health data from more than 150,000 people 50 and older reporting age-related hearing loss and no evidence of hearing aid use
- Untreated hearing loss is associated with a greater risk of
 - Depression (41% greater risk over 10 years)
 - Dementia (52% greater risk over 10 years)
 - Heart attack
 - Falls (30% greater risk over 10 years).
- 50% more hospital stays, and a 44% higher risk of being readmitted to the hospital within 30 days (over a 10-year period)

JAMA (Reed et al., 2018)



Cognition and hearing loss





Dementia Epidemiology – Worldwide*

- 35.6 million estimated 2010 (24.2M 2001; 4.6M new cases/yr)
 - > 46% Asia
 - > 30% Europe
 - 12% North America
- Doubling ~ every 20 years
 - > 65.7M 2030; 115.4M 2050
- Majority (57.7%) live in low- and middle-income countries
 - 40% increase Europe over next 20 yrs
 - ▶ 63% ↑ North America
 - 77% ↑ southern Latin America; 134-146% rest of Latin America
 - > 89% ↑ Asia Pacific; 117% East Asia; 107% South Asia
 - ▶ 125% ↑ North Africa and Middle East
- \$315 B (2005 US \$) costs for dementia care/yr worldwide
 * Alzheimer's Disease International World Report, 2009 www.alz.co.uk/worldreport; Ferri et al.,
 2005; Wimo et al., 2003



All-Cause Dementia – NIA and AA (McKhann et al., 2011)

➤ Revised version of NINCDS-ADRDA (McKhann, et al. 1984; Sensitivity 81%, Specificity 70%)

Cognitive or behavioural (neuropsychiatric) symptoms that:

- 1. Interfere with ability to function at work or usual activities
- 2. Represent a decline from previous levels of functioning and performing
- 3. Are not explained by delirium or major psychiatric disorder
- 4. Cognitive impairment detected and diagnosed through:
 - a. History from client and knowledgeable informant
 - Objective cognitive assessment (mental status or neuropsychological testing)



All-Cause Dementia – NIA and AA (McKhann et al., 2011)

 Cognitive or behavioural impairment involves a <u>minimum of two</u> of the following.

≻Impaired:

- a. ability to acquire and to remember new information (e.g., repetitive questions or conversations, misplacing personal items, forgetting events or appointments, etc.)
- b. reasoning and handling of complex tasks (e.g., poor understanding of safety risks, poor-decision making, inability to manage finances, etc.)
- c. visuospatial abilities (i.e., agnosia and apraxia) (e.g., inability to recognize faces, common objects, or environment; inability to operate simple implements or orient clothing to body

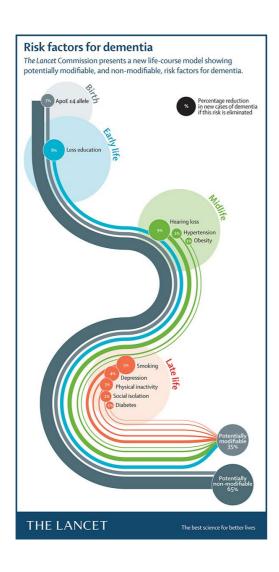


All-Cause Dementia – NIA and AA (McKhann et al., 2011)

- d. Impaired language functions (e.g., speaking, reading, writing difficulty thinking of common words while speaking, hesitations; speech, spelling and writing errors)
- e. Changes in personality, behaviour or comportment (e.g., uncharacteristic mood fluctuations agitation, impaired motivation and initiative, apathy, loss of drive, social withdrawal, decreased interest in previous activities, loss of empathy, compulsive or obsessive behaviours, socially unacceptable behaviours)



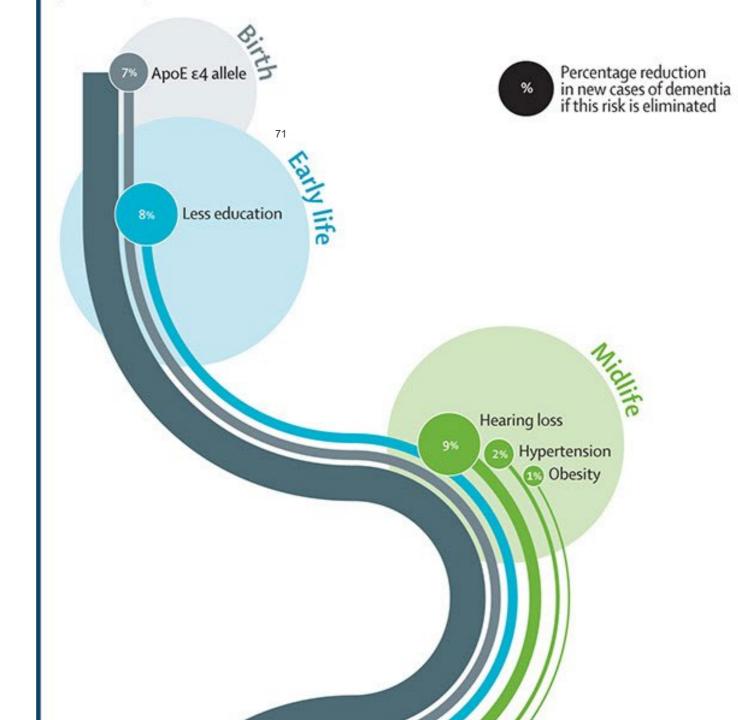
35% of Risk Factors for Dementia are Modifiable



Source: Lancet, 2017



Birth, Early life, Midlife

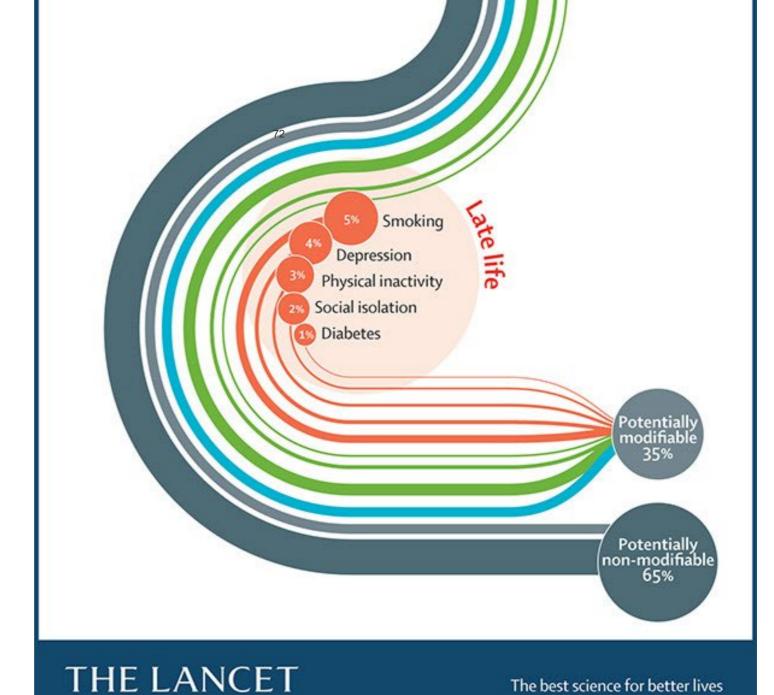


Source: Lancet, 2017

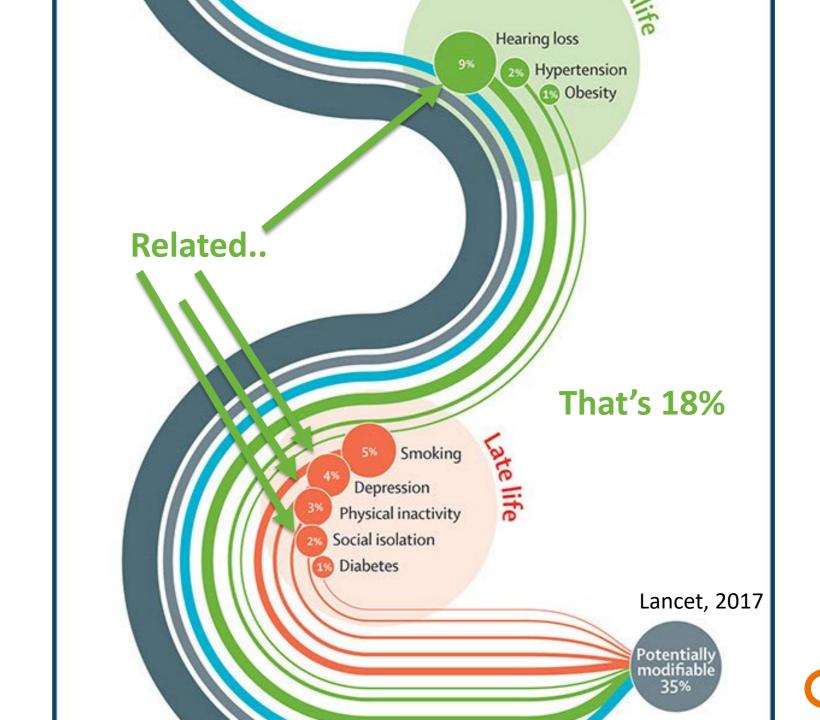
GN Making Life Sound Better



Later in life









Relationship between Hearing Loss and Cognitive Decline

Greater cognitive decline in individuals with Alzheimer's who had HI at baseline compared with individuals with AD and NH (Uhlmann et al., 1986)

Correlation between the amount of hearing loss and the severity of cognitive impairment

Every additional 10 dB of hearing loss over a 25 dB hearing loss, 20% increase in risk of developing dementia (Lin et al., 2011)

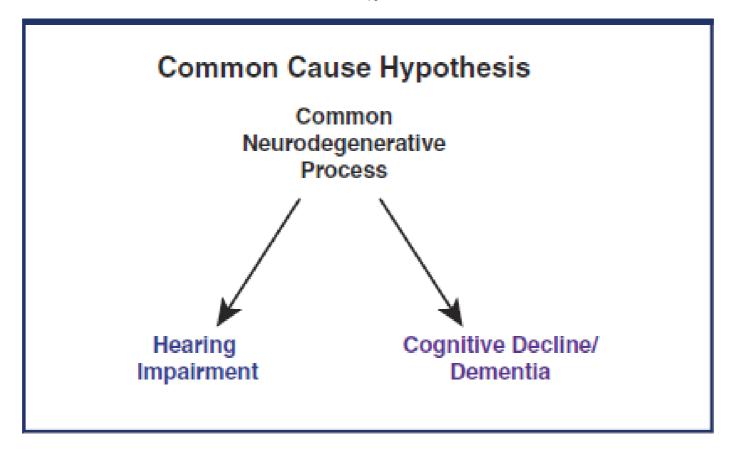


How are hearing and cognition decline related?

75

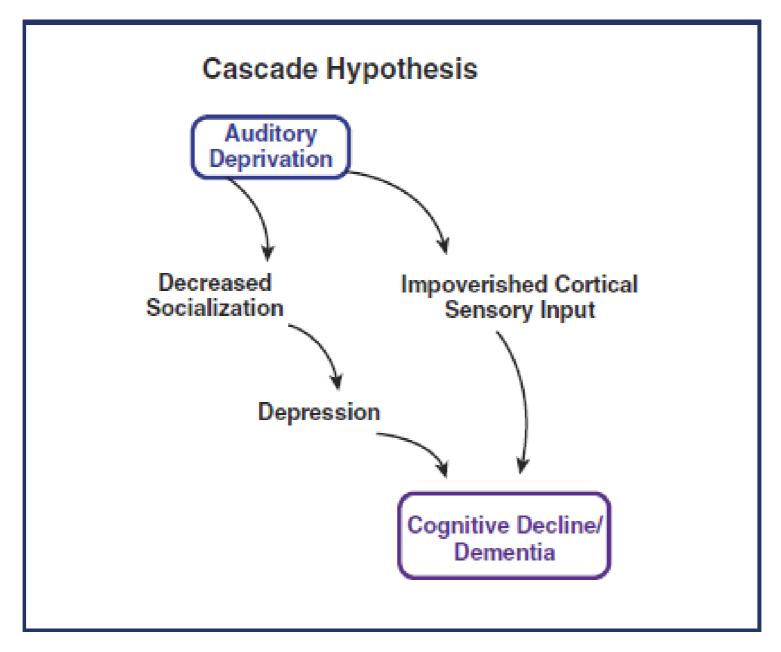
No definitive answers yet, but possible theories are...



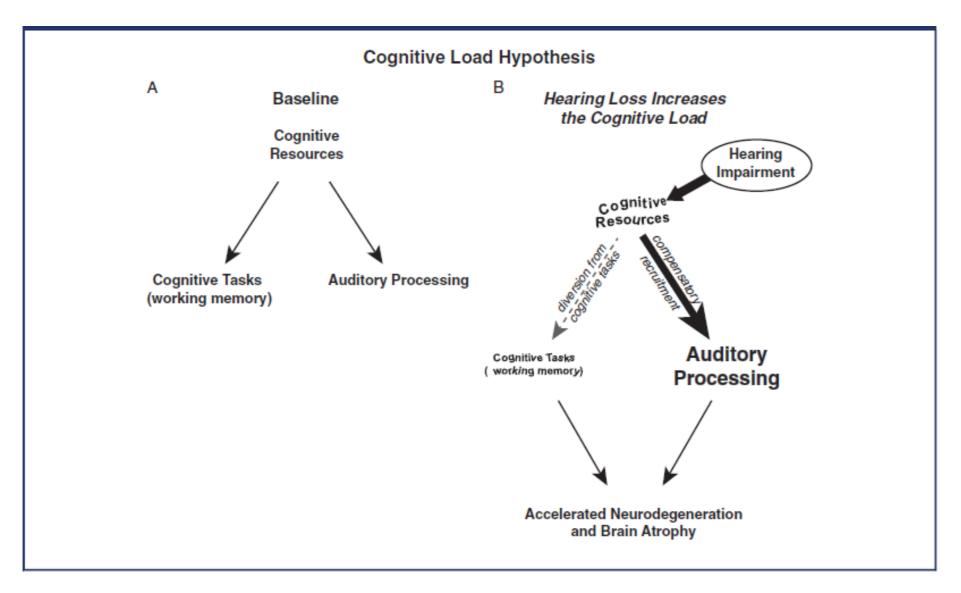


Stahl, 2017



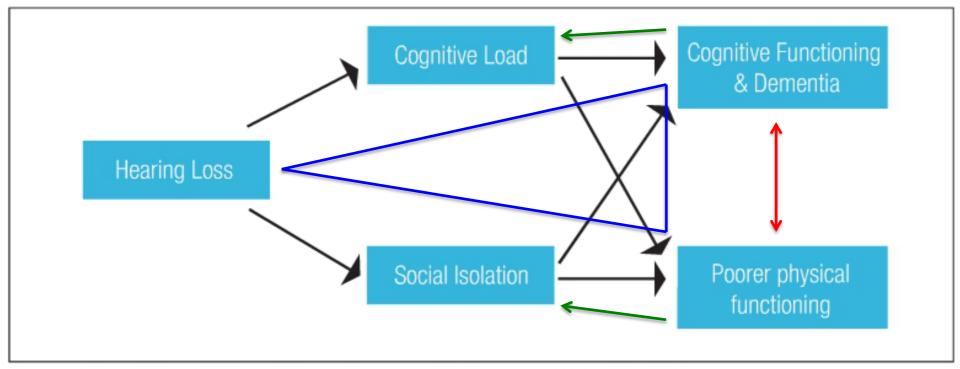








Listening effort, hearing loss, and cognitive decline



Conceptual model of hearing loss with cognitive and physical functioning in older adults.

Adapted: The Hearing Review International, Spring 2013

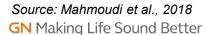


Hospitalizations

Table 2. Unadjusted Data of Nationally Representative Health Care Costs and Use Outcomes Among Older People With Self-reported Hearing Loss^a

		Hearing Aids		_
Patient Characteristic	Total	Without	With	Difference (95% CI)
No. of patients	1336	734	602	
Total cost, mean (SD), \$				
Health care	12 839 (20 478)	12 254 (20 254)	13 435 (20 082)	1181 (-1247 to 3609)
Out of pocket	1727 (4448)	1463 (4792)	1997 (4098)	534 (94 to 973) ^b
Medicare	8293 (169 50)	8269 (17 000)	8317 (16793)	48 (-1928 to 2024)
Any hospitalization, % (95% CI)	21 (19 to 24)	21 (17 to 24)	22 (18 to 26)	1 (-4 to 6)
Any ED visits, % (95% CI)	26 (23 to 29)	26 (22 to 31)	25 (21 to 30)	-1 (-7 to 4)
Any office visits, % (95% CI)	95 (93 to 96)	93 (90 to 95)	98 (95 to 99)	5 (2 to 7) ^b
Health care intervention, No. (SD)				
Hospitalization	1.60 (7.00)	1.80 (8.85)	1.39 (4.82)	-0.41 (-1.16 to 0.34)
ED visits	0.45 (1.21)	0.47 (1.35)	0.42 (1.07)	-0.05 (-0.18 to 0.08)
Office visits	14 (17.61)	13 (19.20)	15 (15.86)	2.71 (0.86 to 4.57) ^b

Abbreviation: ED, emergency department.



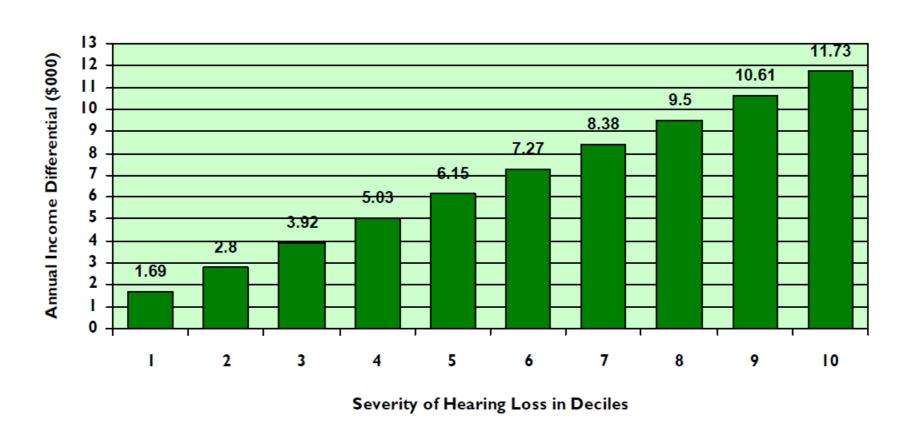


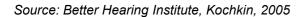
^a Source: The 2013-2014 Medical Expenditure Panel Survey, Household Component Files.²²

^bSignificant at $\alpha = .05$.

Income

Figure 3. Household income differential - aided versus unaided by severity of hearing loss (linear model)







MarkeTrak 10 (Harvey, 2020)

Observed Changes Attributed to Hearing Aids

(Current Owners who got HA(s) in last 5 years (n=702))

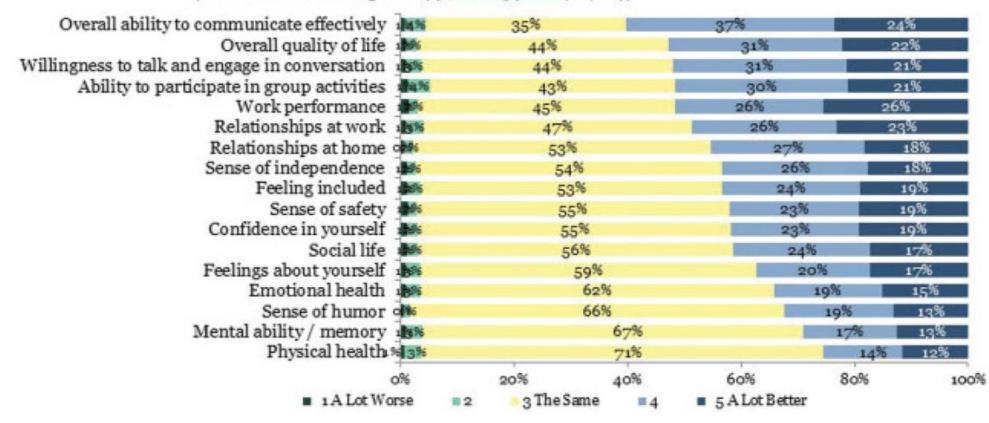


Figure 6 Observed changes attributed to hearing aids.



Frequency of Experiences

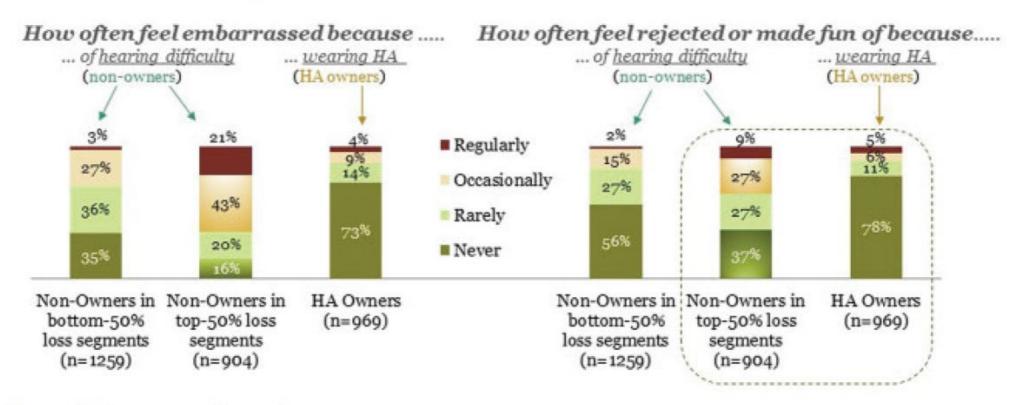


Figure 3 Frequency of experiences.



Topics







2 Convergence of CE and Hearing Aids



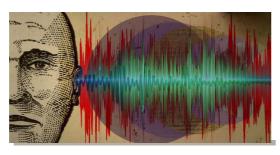
Connectivity



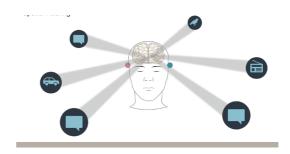
AI AI



Environmental Classification



Hearing in Noise



Spatial Perception



R Health



