CMS 2025
Quality Conference
Make America Healthy: Improving Health Outcomes Through Prevention, Quality, and Safety

Empowering Ageing: Tech-driven Tools to Support Function and Well-being

Moderator:

Tanya Pagan Raggio-Ashley, MD
Regional Medical Officer,
Center for Clinical Standards and Quality,
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Speakers

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Associate Professor,

University of Chicago

Ryan Roemmich, PhD

Associate Professor,

Kennedy Krieger Institute

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Regional Medical Officer,

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CMS

CMS 2025 Quality Conference

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Using Technology to Address Gaps in Aging

How Wearables and Voice AI Could Modernize

Screening, Monitoring and Management

CMS Quality Conference 7/2/2025

Megan Huisingh-Scheetz, MD MPH AGSF FGSA Associate Professor
Associate Director, Aging Research Program
Co-Director of the Successful Aging and Frailty Evaluation Clinic Section of Geriatrics and Palliative Medicine
University of Chicago

THE UNIVERSITY OF CHICAGO | Biological Sciences Division

Disclosures

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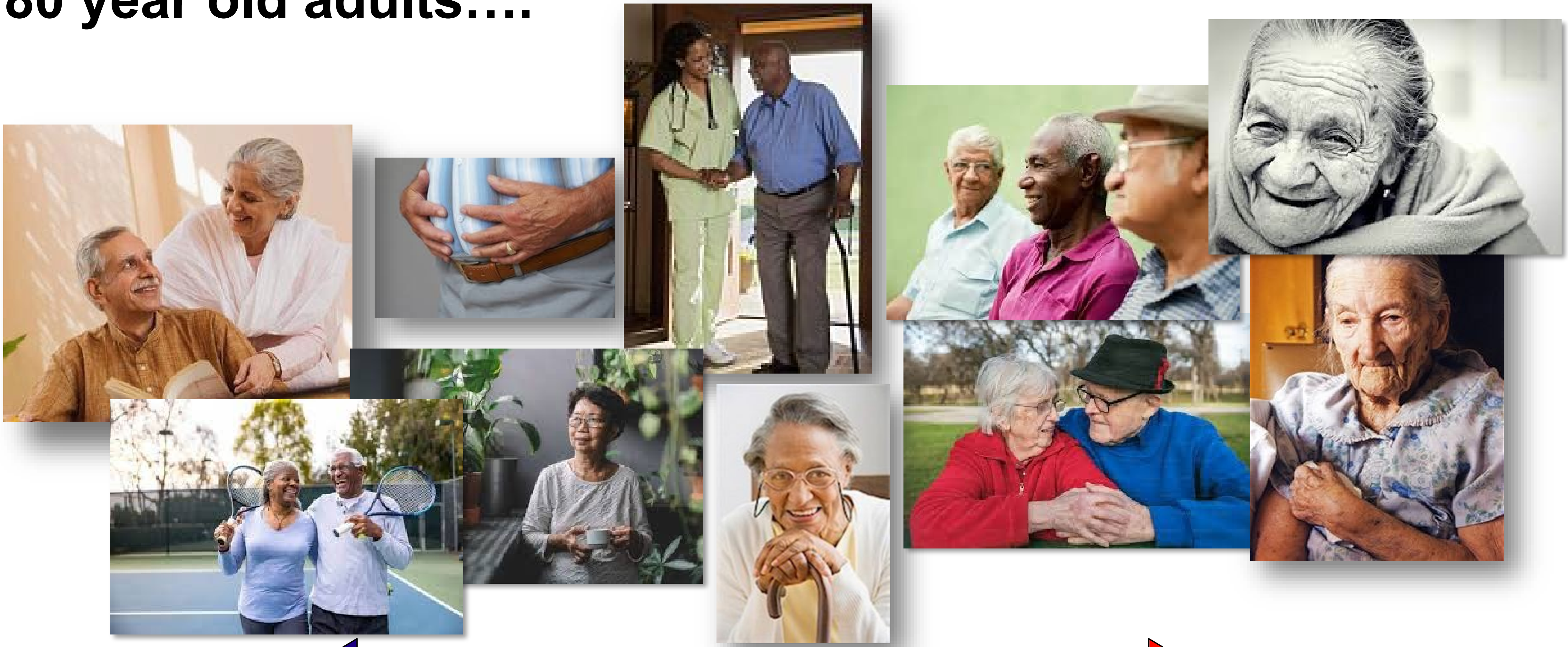
NIA R01AG04353	Waite(PI)
NORC	

The University of Chicago and NORC hold Intellectual Property Rights to EngAGE, a technology program which will be discussed today. To date, EngAGE has not been licensed.

80 year old adults….



Physiologically Robust ⟷ **Frailty** ⟷ **Physiologically Fragile**

Engelman et al. Development Review. 36(3):511-539 (September 2010).
Huisingh-Scheetz and Walston. J of Geriatric Oncology. 2017; 8(1):8-15.
Morley J et al. 2013; JAMDA, *14*(6), 392-397
Huisingh-Scheetz M,, et al. Gerontol B Psychol Sci Soc Sci, 2021, Vol. 76, No. S3, S299–S312

Frailty Science

External Triggers

Jeremy Walston, MD
Raymond and Anna Lublin Professor of Geriatric Medicine & Gerontology
Deputy Director, Division of Geriatric Medicine and Gerontology
Co-Director, Biology of Healthy Aging Program
Johns Hopkins University

Molecular & Genetic

- Mitochondrial dysfunction
- Epigenetic alterations
- Senescence
- Autophagy
- Altered intercellular communication
- Genomic instability
- Telomere attrition
- Stem cell exhaustion
- Deregulated nutrient sensing
- Loss of proteostasis

→

Physiology

- Impaired Stress Response System
- Sarcopenia
- ↑IL-6, CRP, WBC, Cortisol
- Altered Energy Metabolism
- Altered Bone Metabolism
- RAS
- ↑Clotting markers
- Glucose intolerance
- ↓IGF-1, DHEA-S, androgens, estrogens
- ↓Micronutrients (total carotenoids, retinol, Vit D, Vit B6, folate)
- ↓Immune function
- ↓Hemoglobin
- ↓Diurnal cortisol variation
- ↓Heart rate variability

→

Clinical Phenotype

- Weakness / grip strength
- Unintentional weight loss
- Slowness / gait speed
- Exhaustion
- Low physical activity

→

Outcomes

- Falls / Fracture
- Dependency
- Social isolation
- High Health Care Utilization
- Procedural Morbidity & Mortality
- Death

Disease

Walston 2017, figure adapted with permission

1) Hubbard 2009 J Cell Mol Med; 2) Travison 2011 J Clin Endocrinol Metab.; 3) Michelon 2006 J Gerontol A Biol Sci Med Sci.; Frisoli 2011 Bone.; 4) Shlipak 2004 Amer J Kidney Dis; 5) Collerton 2012 Mech Aging Dev, 6) Mitnisky 2015 BMC, 7) Johar 2014 J Clin Endocrinol Metab, 8) Parvaneh 2015 Gerontology; 9) Varadhan ,et al, J Gerontology, 2014; 10) Kalyani R, et al Lancet 2014; 11) Leng, et al., Aging 2004; 12) Walston, J et al Archives IM 2002; 13) Lopez-Otin et al, Cell 2013; 14) Gonzalez A et al, BMC Geriatrics 2023. 15) Huisingh-Scheetz and Walston. Journal of Geriatric Oncology. 2017; 8(1):8-15. 16) Morley J et al. 2013; JAMDA, 14(6), 392-397

Indications for frailty and physical function evaluation

4Ms Age-Friendly Health Systems Guide

– Mobility assessment at all encounters

Frailty Screening Expert Recommendations

– ≥ 70 years
– ≥ 5% weight loss in prior year

Condition and Event Triggers

– Falls evaluation
– Prior to elective procedures
– Diabetes treatment decision making
– Cancer treatment decision making
– Valvular disease treatment decision making
– Medicare Annual Wellness Visit

https://www.johnahartford.org/dissemination-center/view/book-age-friendly-health-systems-a-guide-to-using-the-4ms-while-caring-for-older-adults
Morley JE, Vellas B, van Kan GA, et al. Frailty consensus: a call to action. J Am Med Dir Assoc 2013;14:392-7.
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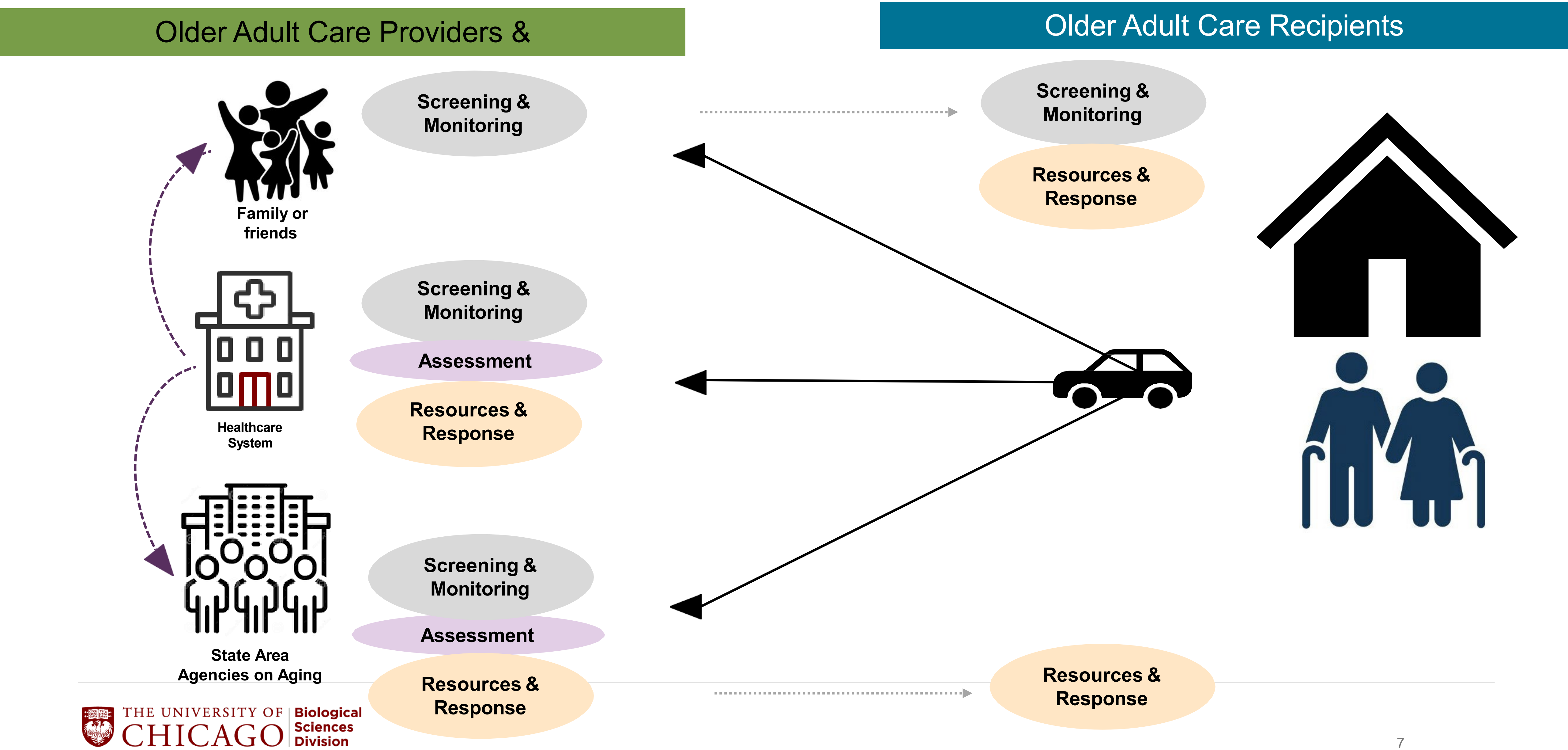
The Successful Aging & Frailty Evaluation (SAFE) ™ Clinic

PRIMARY CARE TRANSPLANT UROLOGY ONCOLOGY THORACIC SURGERY

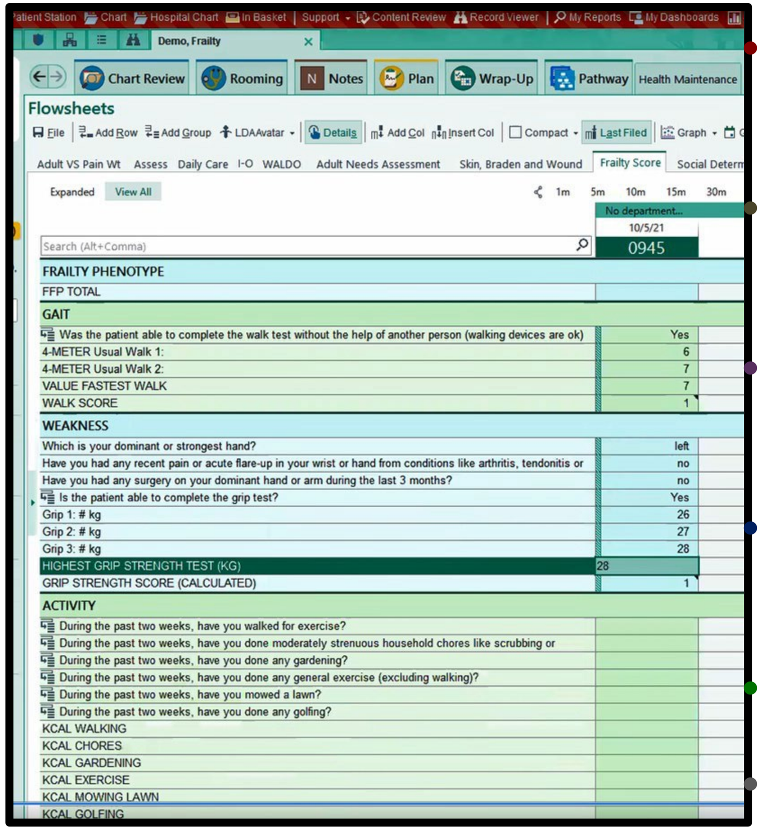
Geriatricians, Geriatrics APP, Social Workers, Physical Therapist, Pharmacist

SOCARE SOCARE TOP

Community-dwelling older adult care & research now…



Frailty and Physical Function Assessment & Management Gaps

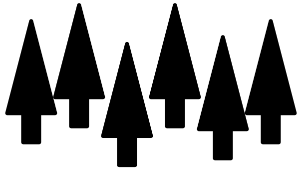


- Lack of consistent, routine, universally-shared screening of all older adults that trigger early referral to care resources
- Time consuming evaluations which prohibits broad adoption despite guidelines
- Requires in-person assessments which places an extra burden on people who struggle to reach health services
- No mechanism to monitor or incorporate trajectories in risk assessment
- Insufficient long-term programming to management frailty
- Inefficient coordination of care providers

Bandeen-Roche K, Gross AL, Varadhan R, Buta B, Carlson MC, Huisingh-Scheetz M, et al. J Gerontol A Biol Sci Med Sci. 2019.
Huisingh-Scheetz M, Martinchek M, Becker Y, et al. JAMDA. 2019. PubMed PMID: 30737166.
Huisingh-Scheetz M, Buta B, Bandeen-Roche K, et al. *J Gerontol B Psychol Sci Soc Sci.* 2021;76(Supplement_3):S299-s312.
White DK, Neogi T, Nevitt MC, et al. *J Gerontol A Biol Sci Med Sci.* 2013;68(4):456-464
Huisingh-Scheetz M, Buta B, Abaoud A, Bandeen-Roche K, Danilovich M, Hall J, Harrell E, Hawkley L, Lach H, Martinchek M, Mathur A, Mir N, Nieman C, Toto P, Boot W. 2021. Gerontological Society of America Virtual Functional and Frailty Measurement Tip Sheets. The Gerontological Society of America. Available at https://www.geron.org/images/documents/VirtualFunctionalandFrailtyMeasureBestPractices.docx
Huisingh-Scheetz M, Buta B, Abaoud A, Bandeen-Roche K, Danilovich M, Hall J, Harrell E, Hawkley L, Lach HL, Martinchek M, Mathur A, Mir N, Nieman C, Toto P, Boot W. 2021. Tip Sheets for the Synchronous, Remote Administration of Objective Functional and Frailty Measures Among Community-Dwelling Older Adults Using Video Conferencing. The Gerontological Society of America. Available at https://www.geron.org/images/documents/TechSIGtipsheet.pdf.

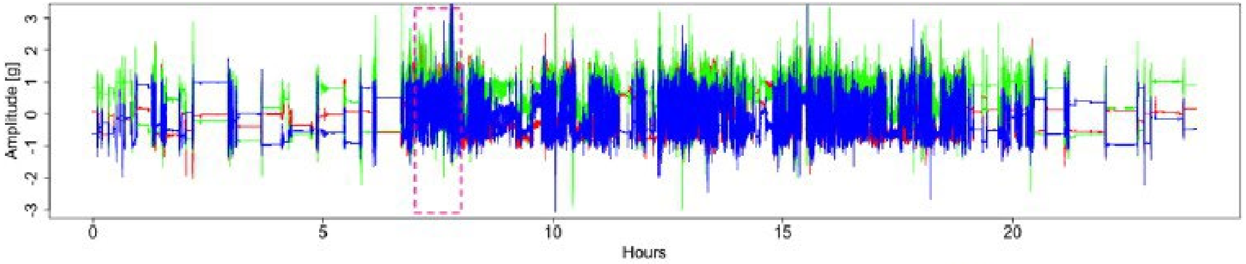
Screening for and Monitoring Frailty with Technology?

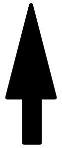
Accelerometers



Forest View

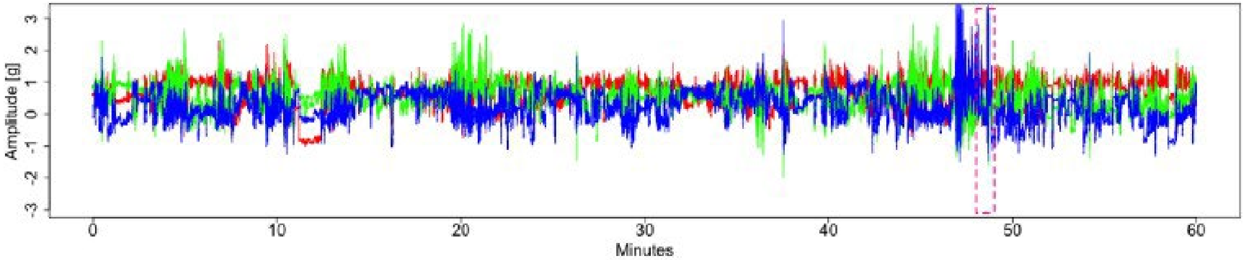
24 hours of data



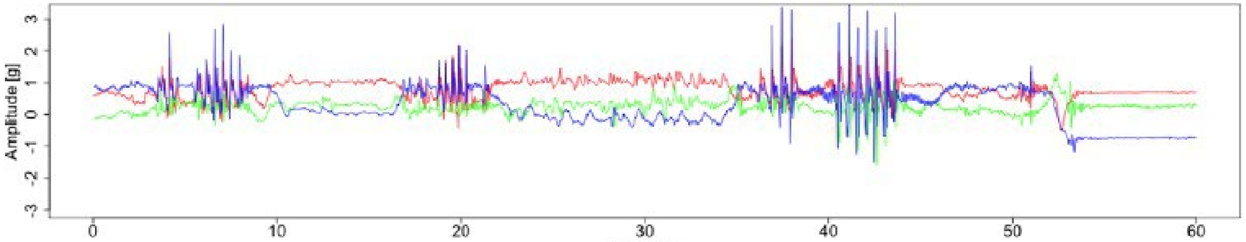


Tree View

1 hour of data

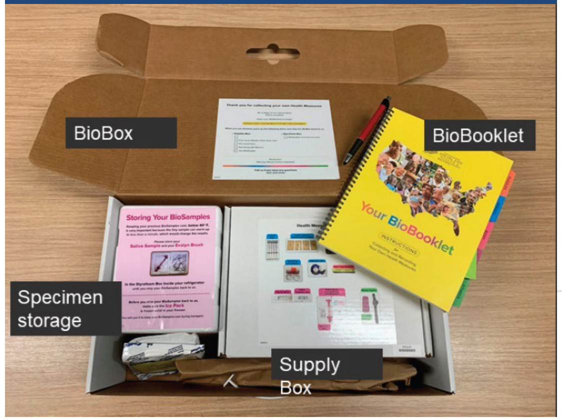


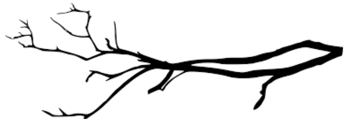
1-mintue of data



Karas M, Bai J, Straczkiewicz M, et al. Accelerometry data in health research: challenges and opportunities. *Stat Biosci.* 2019;11(2):210-237.

NSHAP BioBox & BioBooklet

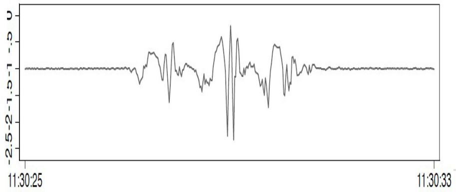




Branch View

A few seconds

3-Meter Usual Walk	Timed Up and Go	5-Repeated chair stands



Accelerometry activity patterns are complex.

Huisingh-Scheetz M, et al, J of Gerontology: Series B Psychological Sciences and Social Sciences, 2014. Palmerini L, Bagalà F, et al. *Sensors (Basel).* 2015;15(5):11575-11586.

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Schrack J, et al, J of Gerontology: Series A Biological Sciences and Sciences, 2018 Urbanek JK, Zipunnikov V, Harris T, et al. *J Gerontol A Biol Sci Med Sci*. 2018;**73**: 676-681. Urbanek JK, Zipunnikov V, Harris T*, et al. Physiol Meas*. 2018;**39**: 02NT02.

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Strain T, Wijndaele K, Dempsey PC*, et al. Nat Med*. 2020.

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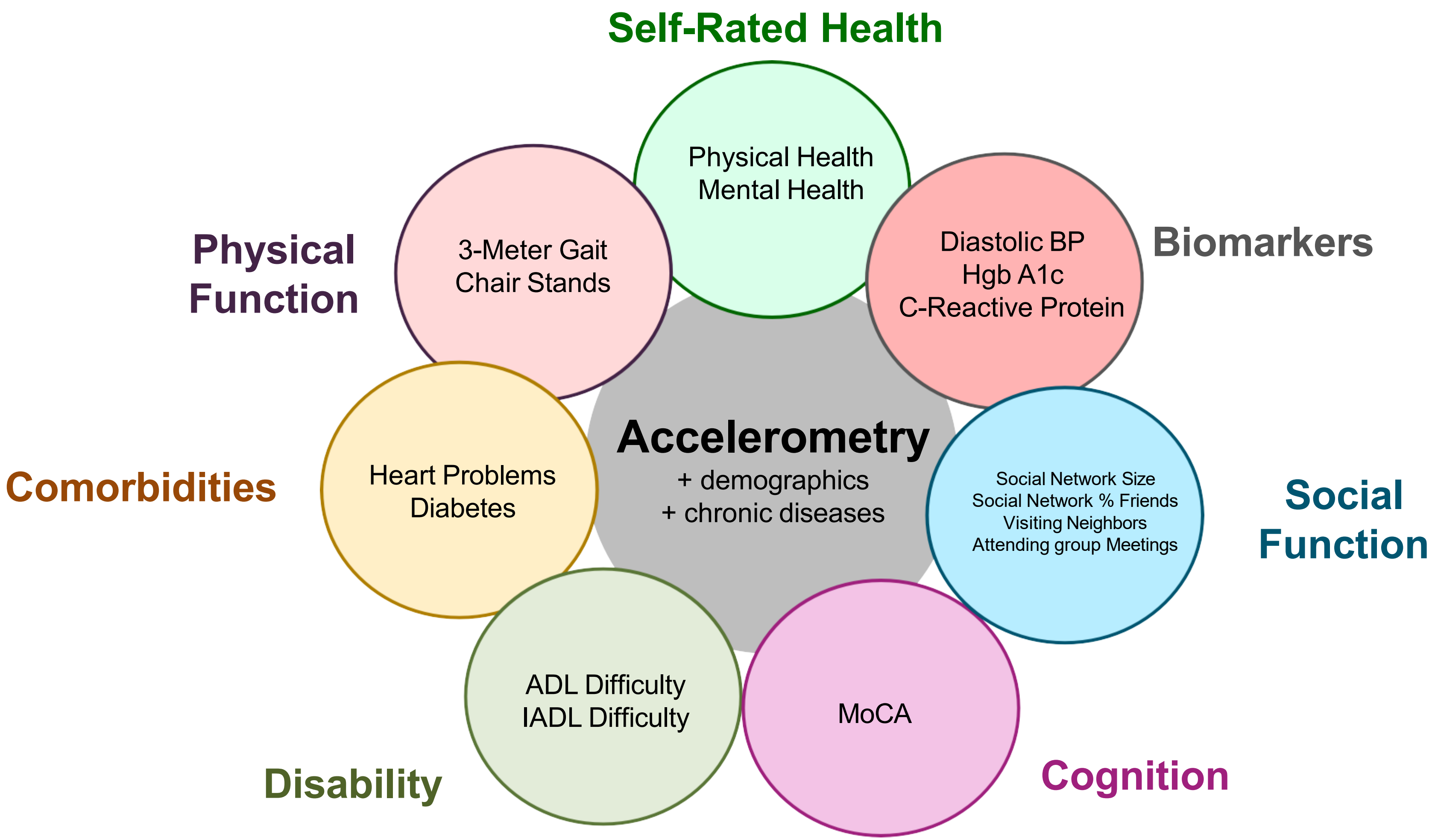
Shi C et al, npj Aging, 2022

Wanigatunga AA, Chiu V, Cai Y, et al. Med Sci Sports Exerc. 2023;55(2):281-8.

Wanigatunga AA, Liu F, Urbanek JK, et al. J Aging Phys Act. 2023;31(3):408-16. Epub 20221013. Wanigatunga AA, Cai Y, Urbanek JK, et al. J Gerontol A Biol Sci Med Sci. 2022;77(9):1882-9.

Wanigatunga AA, Liu F, Wang H, et al. A. J Alzheimers Dis. 2022;88(2):459-69.

Higher activity volume = better physical, cognitive and social health



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Huisingh-Scheetz M, et al, J of the Amer Geriatrics Society, 2016
Kocherginsky M, Huisingh-Scheetz M (co-first author), PloS One, 2017
Ho E, et al, BMC Public Heatlh, 2018
Huisingh-Scheetz M, et al, J of Gerontology: Series A Biological Sciences and Sciences, 2018. *Editor's Choice.*
Huisingh-Scheetz M, et al, J of Gerontology: Series A Biological Sciences and Sciences, 2021.
Rubin D et al, Digital Biomarkers, 2022
Shi C et al, npj Aging, 2022

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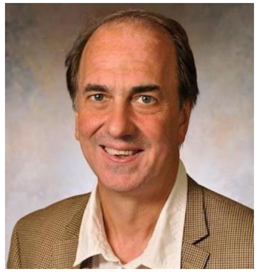

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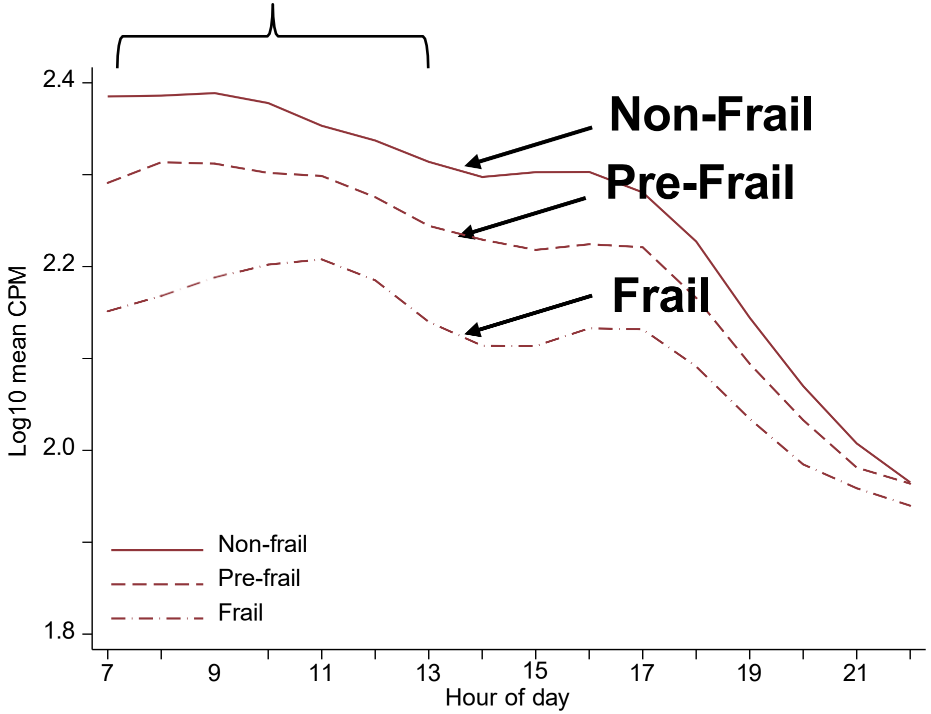
Director, Biostatistics & Statistical Computing
Center for Translational Data Science
UChicago

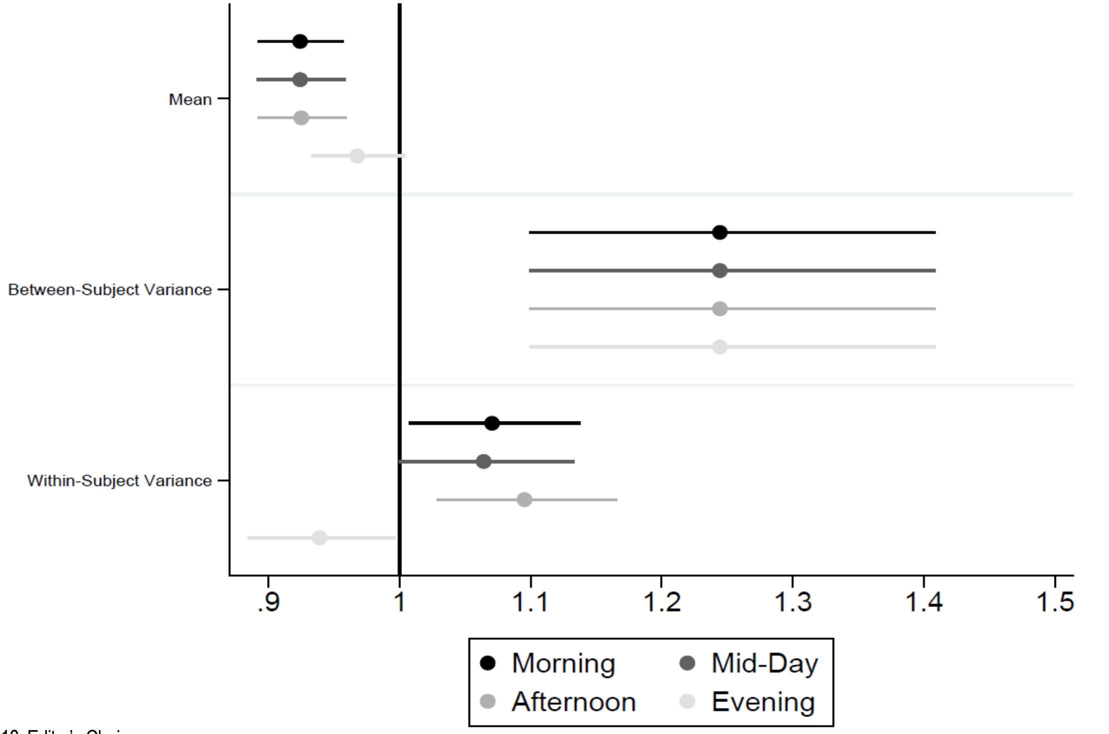
Higher activity volume = better physical function

Linear Regression Outcomes	β (p-value)	N
3-meter walk (seconds)	**−0.02 (<0.001)**	610
Chair stands (seconds)	**−0.02 (0.002)**	554

Frailty-related morning delay



Combining morning activity levels & pattern variance are independently associated with frailty



Proportion change for each frailty point across day

Huisingh-Scheetz M, et al, J of the Amer Geriatrics Society, 2016
Huisingh-Scheetz M, et al, J of Gerontology: Series A Biological Sciences and Sciences, 2018. Editor's Choice.
Huisingh-Scheetz M, et al, J of Gerontology: Series A Biological Sciences and Sciences, 2021.

Combined accelerometry features from just 2-3 mornings predicts frailty decline and death, increasing feasibility and scalability.

Survey-Weighted 2-Stage Multivariate Regression Model Predicting 5-Year Mortality & Frailty

N=584 (n=104 died, n=480 alive at 5 years)

	Partially Adjusted Model		Fully Adjusted Model*	
	Logistic	Ordinal	Logistic	Ordinal
	5-Year Mortality*	5-Year Frailty*	5-Year Mortality*	5-Year Frailty*
	OR (p-value)		OR (p-value)	
Mean Morning Hourly Activity (z-score)$^{\Delta}$	0.51 (**0.004**)	0.81 (0.12)	0.64 (**0.04**)	0.82 (0.16)
Within-Subject Morning Hourly Activity (z-score)$^{\Delta}$	0.65 (**0.04**)	0.68 (**0.01**)	0.64 (0.10)	0.67 (**0.01**)
Baseline frailty score (0-4)	1.54 (**0.002**)	2.25 (**<0.001**)	1.43 (**0.04**)	1.99 (**<0.001**)

$^{\Delta}$For each 1 standard deviation

*Adjusted for demographics, Charlsons, BMI, MoCA

Accelerometry variable correlation: -0.13

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Huisingh-Scheetz M, Brown S, Pagan M, Cabrera C, Rubin D, Mir N, Madariaga ML, Schumm LP, Wroblewski K, Hedeker D. Mean and Variability of Morning Hour Activity Predict Risk of 5-Year Mortality and Frailty Decline in a National Sample. *Submitted.*

Machine learning models can use of many accelerometry pattern features to maximize prediction of aging outcomes.

Accelerometry Measures
75th Percentile VMC
75th Percentile of CPM
Harmonic features (98)
Correlation = 0.01 to 0.91

XGBoost machine learning model predicting any decline vs none/improvement on cognitive test using >100 accelerometry pattern features

Sample 1. Local, n=115, 65+, 82% African-American, 7-day hip accelerometry, 1-year follow-up

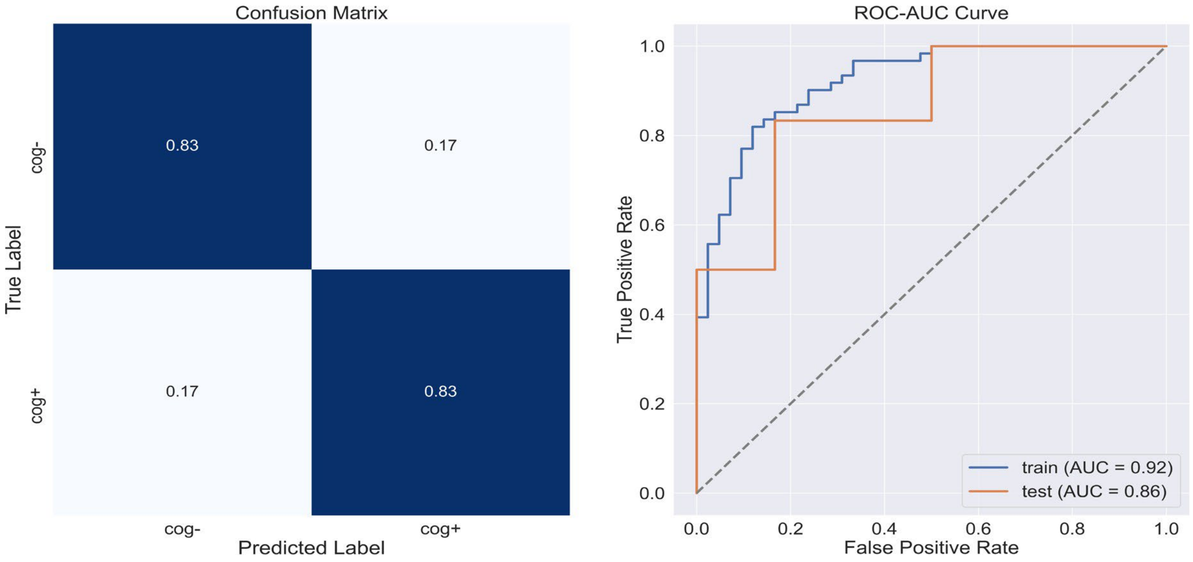

Figure 1. Confusion matrix and ROC-AUC curve summarizing experiments relating 7-day hip accelerometry to 1-year MoCA decline in local sample.

Sample 2. Nationally representative, n=575, 65+, 74% White, 3-day wrist accelerometry, 5-year follow-up.

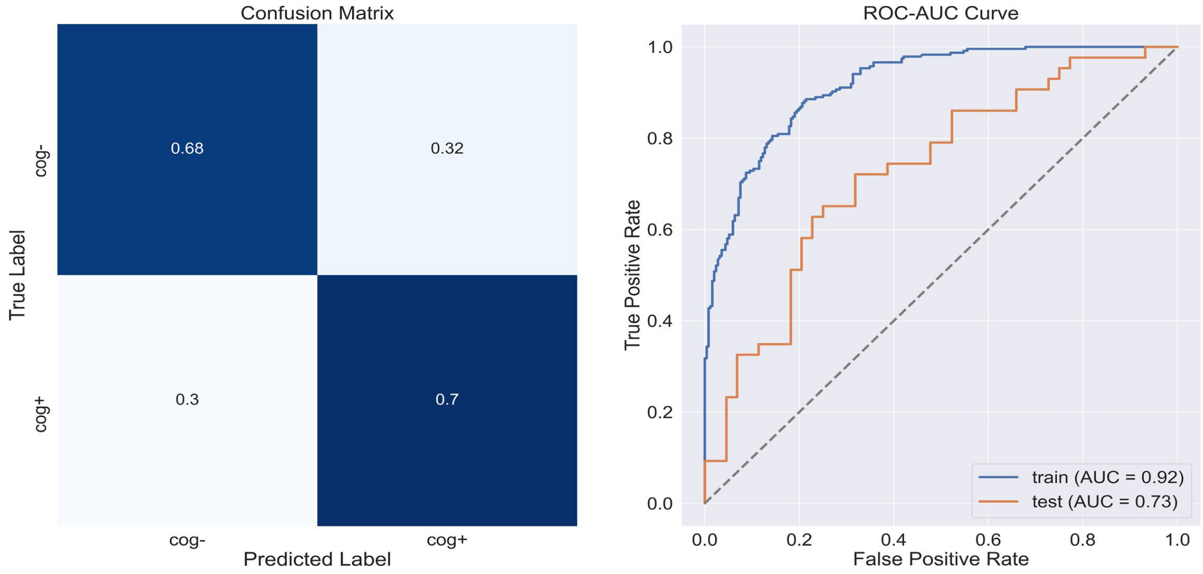

Figure 2. Confusion matrix and ROC-AUC curve summarizing experiments relating 72-hour wrist accelerometry to 5-year MoCA-SA decline.

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Shi C et al, npj Aging, 2022

<u>Detecting and Monitoring Frailty</u>: Combining accelerometry measures to improve detection AND prediction of frailty (prelim results).

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Case Western

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Professor
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Yanan Long, PhD
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Michelangelo Pagan, BS
University of Chicago

Free-Living wrist and hip accelerometry forecast frailty decline among older adult over 1 and 5 years in two distinct observational cohorts. *In progress.*

Accelerometry Measures
Sleep
Total sleep time
Wake Time
Wake after sleep onset
Sleep fragmentation
% Sleep
Sleep variance
Activity
Activity timing
Total activity volume
Peak activity
Average activity level
Mean daily active-to-sedentary transition probability
Time in activity by intensity
Average number of sustained moderate-to-vigorous activity bouts
Activity variance
Gait
Stride amplitude
Cadence
Stride-to-stride variability
Cyclical Patterns
Harmonic features (98)

Detection: frailty phenotype = 0 vs ≥1 points

Method	F_1 (↑)	Precision (↑)	Recall (↑)	Accuracy (↑)	AUROC (↑)
Tabular					
CatBoost	0.624	0.690	0.570	0.657	0.657
LightGBM	0.898	0.815	1.000	0.887	0.887
XGBoost	0.804	0.673	1.000	0.757	0.757
DART	0.761	0.697	0.837	0.736	0.736
MLP	0.570	0.933	0.410	0.690	0.690
ResNet	0.840	0.842	0.838	0.840	0.840
Time Series					
MiniRocket-Ridge	0.637	0.614	0.661	0.622	0.622
MiniRocket-Logistic	0.606	0.626	0.586	0.618	0.618

1-Year Prediction: frailty phenotype = worse vs same/better

Method	F_1 (↑)	Precision (↑)	Recall (↑)	Accuracy (↑)	AUROC (↑)
Tabular					
CatBoost	0.807	0.964	0.694	0.834	0.834
LightGBM	0.704	0.891	0.582	0.756	0.756
XGBoost	0.796	0.856	0.743	0.809	0.809
DART	0.752	0.645	0.902	0.703	0.703
MLP	0.812	0.891	0.746	0.828	0.828
ResNet	0.589	0.857	0.448	0.687	0.687
Time Series					
MiniRocket-Ridge	0.680	0.803	0.590	0.722	0.722
MiniRocket-Logistic	0.538	0.658	0.455	0.609	0.609

*Hip accelerometry data; local cohort; adjusted for age, educ, race, income, comorbidities, baseline frailty

Discussion

How do we leverage all non-invasive sensor information to universally screen for aging decline in the free-living environment?

How do we scale scientific findings?

How do we implement data into caregiver, clinical and community workflows?

How can we use the data to trigger and monitor interventions?

Managing Frailty with Technology?

Evidence-Based, In-Home Frailty Treatment

	Short Term Medicare Coverage	Long Term Medicare Coverage
Exercise	Physical & Occupational Therapy	None
Protein	Dietician (few indications)	None
Multidisciplinary Care	Geriatrics	Geriatrics
	Social worker	None
	Pharmacy (few indications)	Pharmacy (few indications)

Older Adults Health Technology Industry Landscape

Image by: Keren Etkin
https://www.thegerontechnologist.com/

Engage

Empowering and connecting for a happier, healthier you

Website

Voice Activated Device

Louise Hawkely, PhD
Senior Research Scientist
NORC

In partnership with NORC at the UChicago and Orbita, Inc

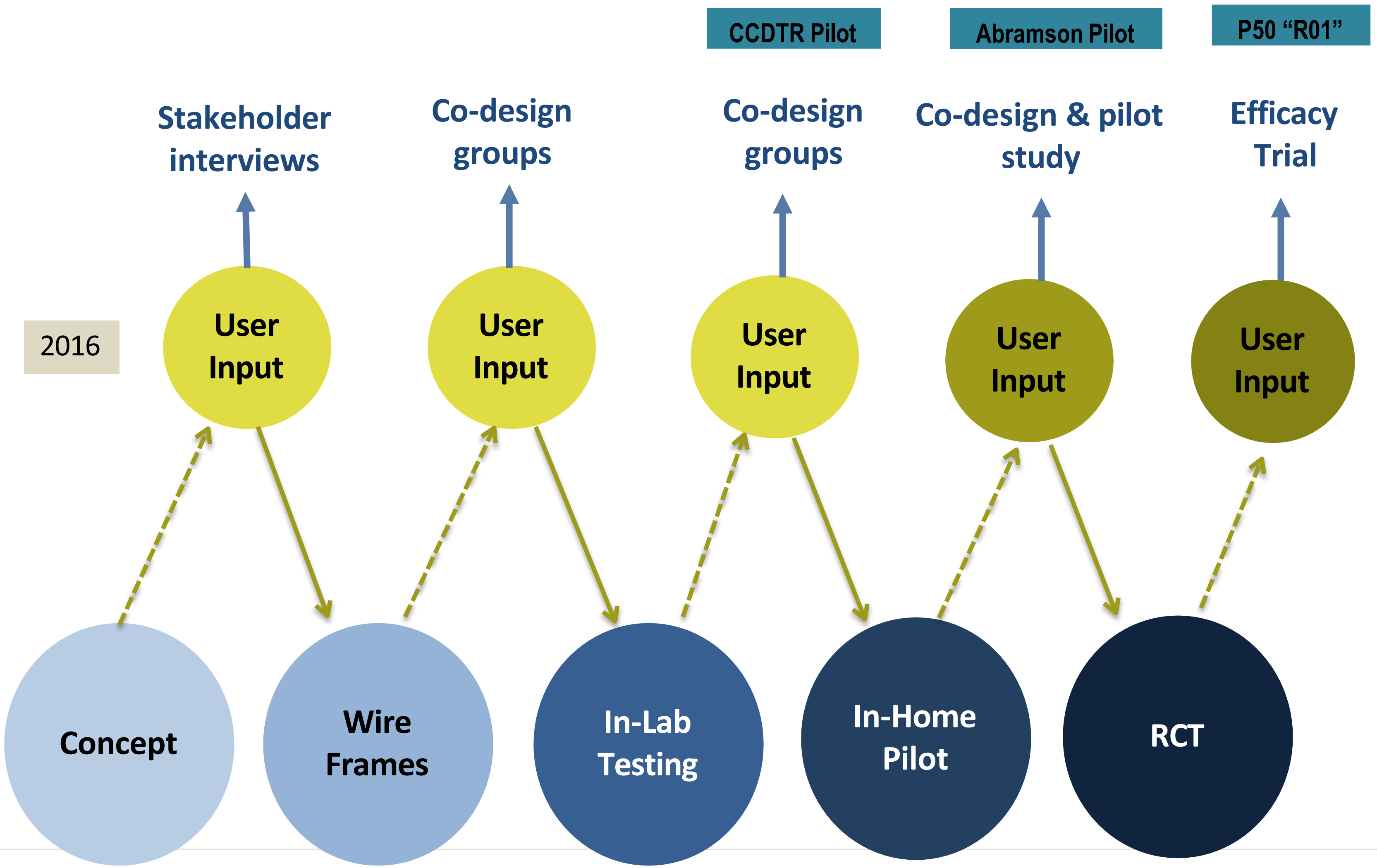
Older adult user

- Custom Alexa skill
- NIA Go4Life Program Exercises
- Audio & visual instructions
- Pictures
- Music
- Reads encouraging family messages
- Auto adjusts intensity

Care partner user

- Daily exercise tracking
- Notices of (in)activity
- Send and receive messages
- Data from website are stored on HIPPA-approved server.

Participatory design means Co-CREATION



Hussain S, et al. International Journal of Design; 6 (2), 2012: 91-109.
Hoffman AS, et al. The Gerontologist. 2020;60(5):935-946.
Laura Finch, PhD[1]; Unique Opportunity and Motivational Targets for Exercise Behavior Change Among Non-Frail, Pre-Frail and Frail Older Adults. Under review.

EngAGE 6-month, Double-Blinded, Randomized Controlled Trial

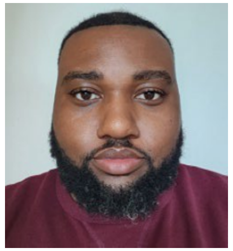
Aim: To test the efficacy of EngAGE on physical & social function versus paper-based exercises.

Intervention arm: EngAGE: Custom voice-activated device application for in-home exercise

Comparison arm: Paper-based in-home exercises

Target group:

- 124 Multimorbid, frail, homebound older adult + care partner dyads.
- 70 dyads randomized to date.



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Research Staff

Ellen Bloss, MS
Research Staff

Wen Wan, PhD
Biostatistician

Trial registration: ClinicalTrials.gov NCT05337514
Funding: NIMHD P50MD017349-01, 8199

Prelim blinded outcomes (merged trial arms)

at least 1 chair stand at baseline

	Visit Baseline (N = 61)	Month 3 (N = 45)	Month 6 (N = 41)
Time to complete 5 chair stands			
Mean (SD)	21.66 (6.74)	20.31 (7.61)	19.82 (6.18)
Median (Range)	20.0 (11.7 – 46.0)	19.3 (9.3 – 45.1)	19.0 (8.0 – 34.4)
N (N Missing)	61 (0)	37 (8)	38 (3)
Unable to do or >60 seconds.	0 (0.00%)	1 (2.63%)	1 (2.56%)
>=16.70 seconds.	48 (78.69%)	22 (57.89%)	25 (64.10%)
13.70-16.69 seconds.	11 (18.03%)	9 (23.68%)	9 (23.08%)
11.20 -13.69 seconds.	2 (3.28%)	5 (13.16%)	2 (5.13%)
< =11.19 seconds.	0 (0.00%)	1 (2.63%)	2 (5.13%)
Missing	0	7	2

Unable to do at least 1 chair stand at baseline

	Visit Baseline (N = 9)	Month 3 (N = 8)	Month 6 (N = 8)
SPPB Chair Score:			
Unable to do or >60 seconds.	9 (100.00%)	4 (50.00%)	2 (25.00%)
>=16.70 seconds.	0 (0.00%)	3 (37.50%)	4 (50.00%)
13.70-16.69 seconds.	0 (0.00%)	1 (12.50%)	0 (0.00%)
11.20 -13.69 seconds.	0 (0.00%)	0 (0.00%)	1 (12.50%)
< =11.19 seconds.	0 (0.00%)	0 (0.00%)	1 (12.50%)

Discussion…

What is the best strategy to promote tech interventions that are broadly usable and easily adoptable across a range of tech literacy?

How do we use team science to evaluate new and existing tech-based, long-term care programs for healthy aging?

How do we pair monitoring tools with interventions?

Thank you.

megan.huisingh-Scheetz@bsd.uchicago.edu

Precision rehabilitation and emerging technologies

Ryan T. Roemmich, PhD

Director, Center for Movement Studies, Kennedy Krieger Institute

Associate Professor, Department of Physical Medicine and Rehabilitation, Johns Hopkins University School of Medicine

Director, Rehabilitation Precision Medicine Center of Excellence, Johns Hopkins Medicine

CMS Quality Conference

July 2, 2025

What is precision rehabilitation?

Focus on **function**

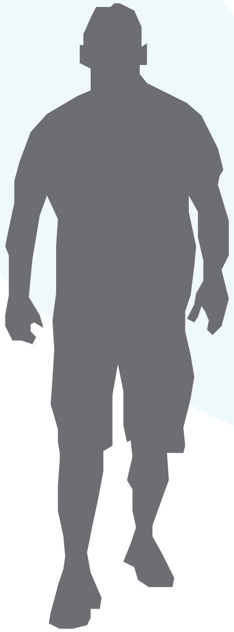
What is the patient's physical status?

Does the patient have a support system?

Where was the patient discharged after their inpatient stay?

Is there relevant genetic information available?

What is the patient's socioeconomic background?



What is the patient's emotional status?

What is the patient's cognitive status?

Does the patient have reliable transportation?

Does the patient live in proximity to necessary services?

How can we provide the right patient with the right care at the right time?

What is the Rehabilitation Precision Medicine Center of Excellence?

Precision at three levels

Healthcare system/operations

- How should rehabilitation be structured and delivered?
- How can we make informed decisions about resource allocation?

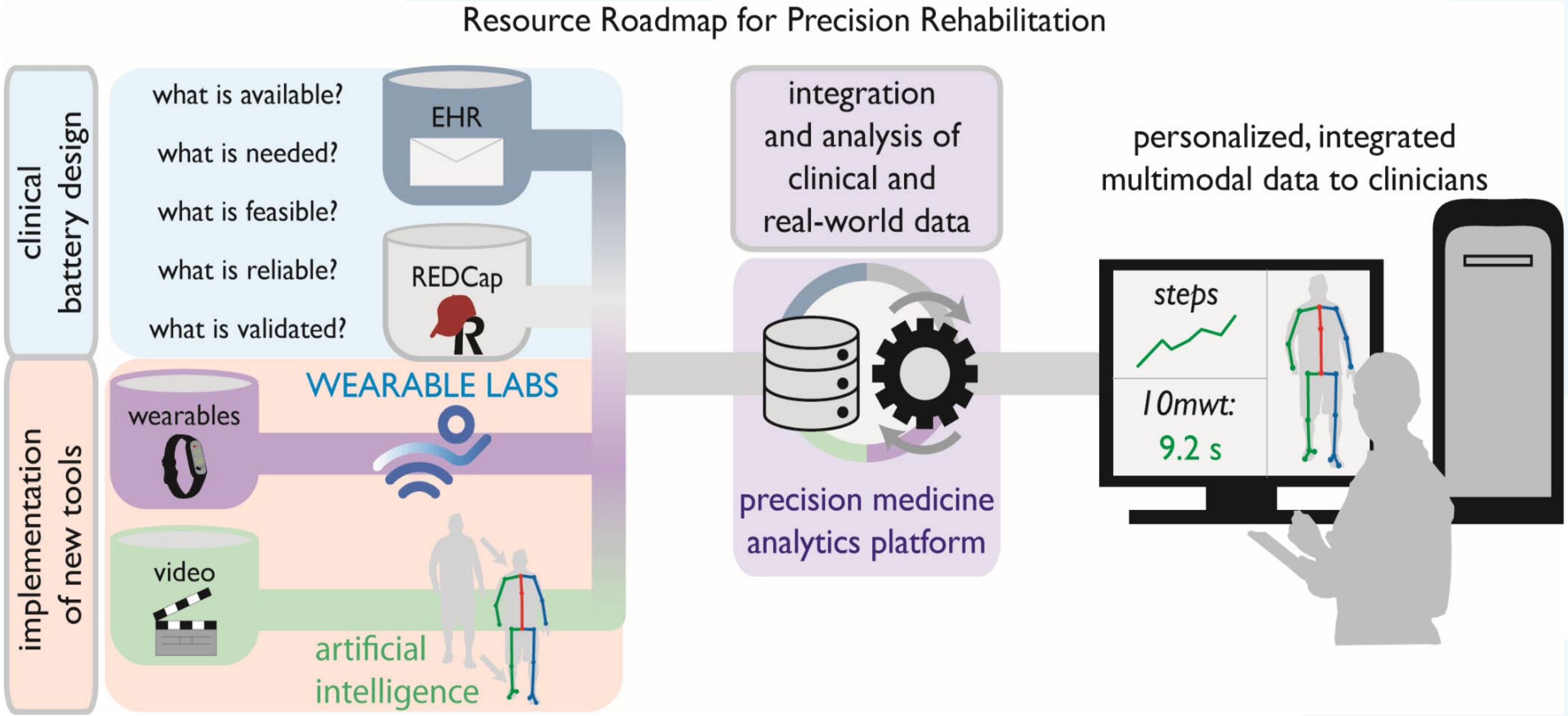
Measurement

- How can we develop tools for measurement outside of the clinic?
- How can we develop tools for more granular assessment?

Personalized interventions

- How can we develop interventions to target patient-specific deficits?

Roadmap for precision rehabilitation



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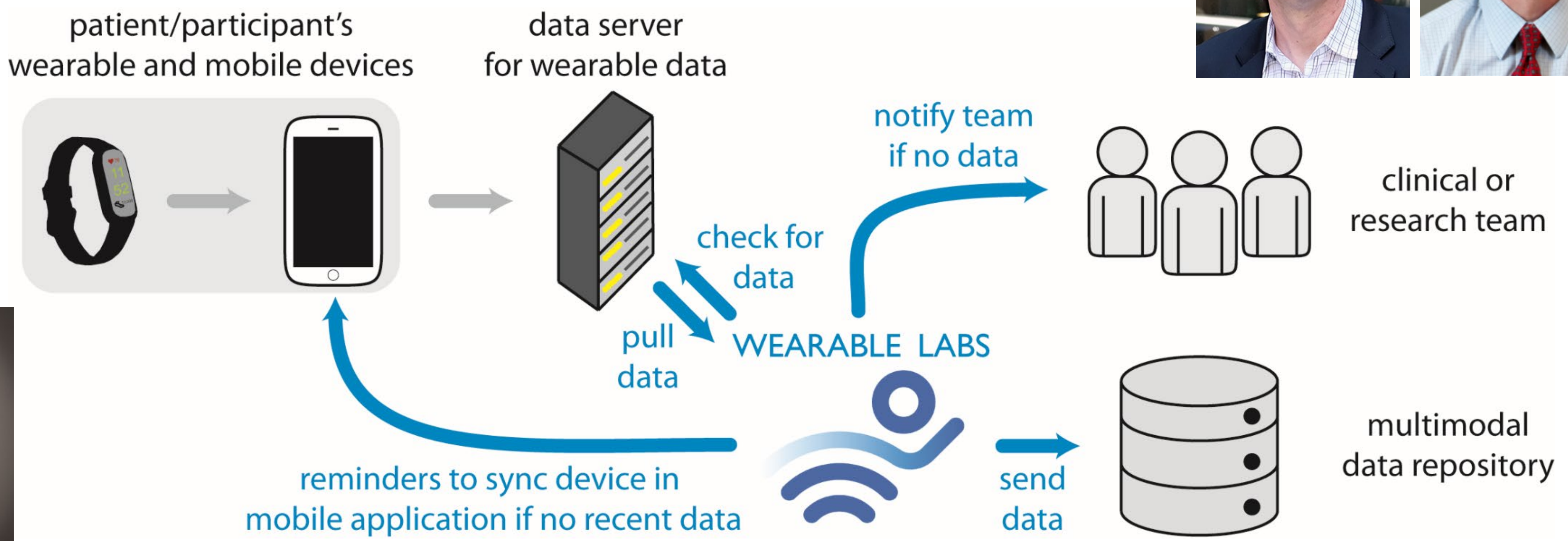
Wearable Labs



Impact of automated data flow and reminders on adherence and resource utilization for remotely monitoring physical activity in individuals with stroke or chronic obstructive pulmonary disease

Margaret A. French, Aparna Balasubramanian, Nadia N. Hansel, Sharon K. Penttinen, Robert Wise, Preeti Raghavan, Stephen T Wegener, Ryan T. Roemmich, Pablo A. Celnik

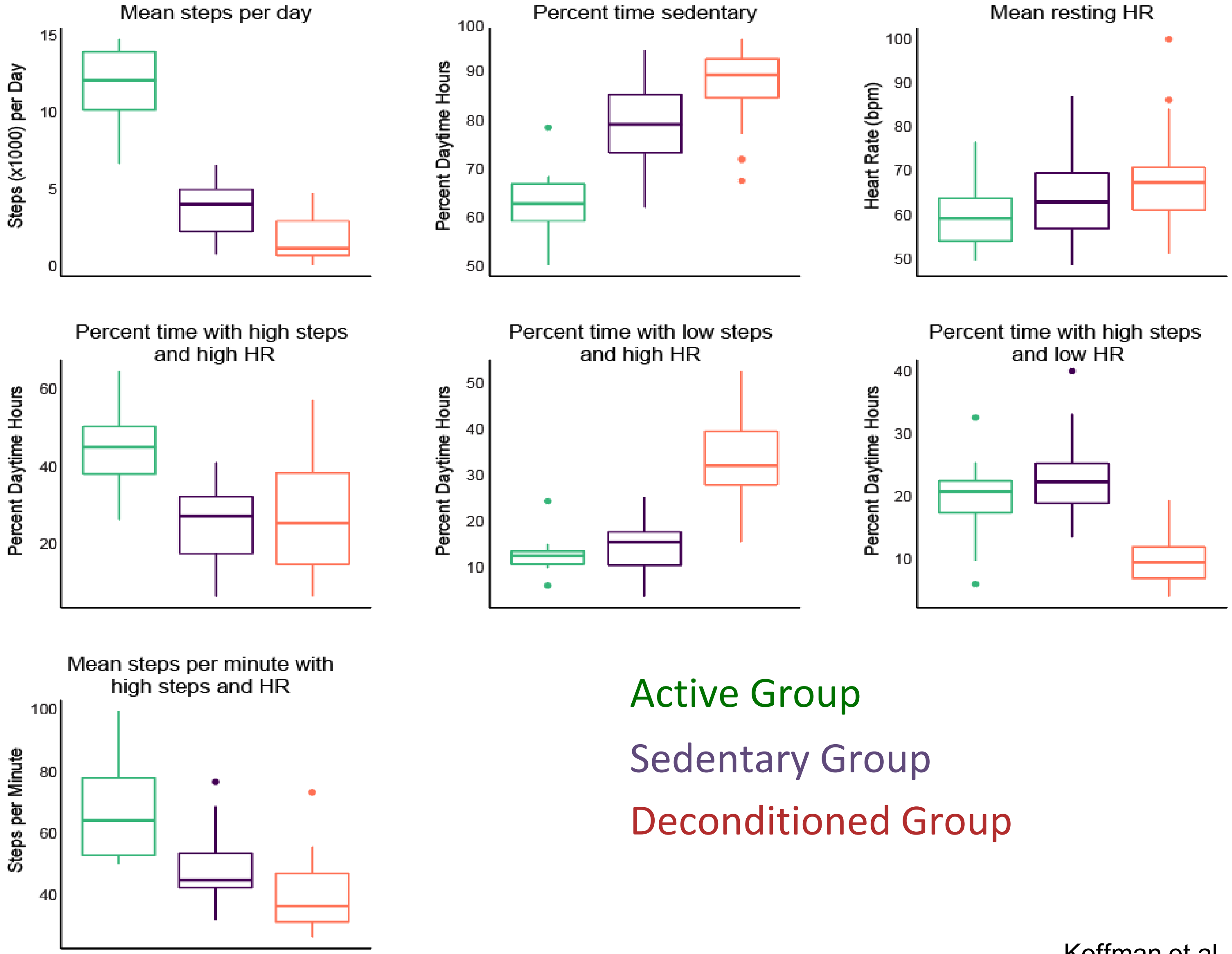
doi: https://doi.org/10.1101/2024.04.15.24305852

Original Research

The feasibility of remotely monitoring physical, cognitive, and psychosocial function in individuals with stroke or chronic obstructive pulmonary disease

Margaret A French [1], Eva Keatley [1], Junyao Li[1], Aparna Balasubramanian[2], Nadia N Hansel[2], Robert Wise[2], Peter Searson[1,3], Anil Singh[4], Preeti Raghavan[1], Stephen Wegener[1], Ryan T Roemmich [1,5], and Pablo Celnik[1]

Leveraging wearables in rehabilitation research



Active Group

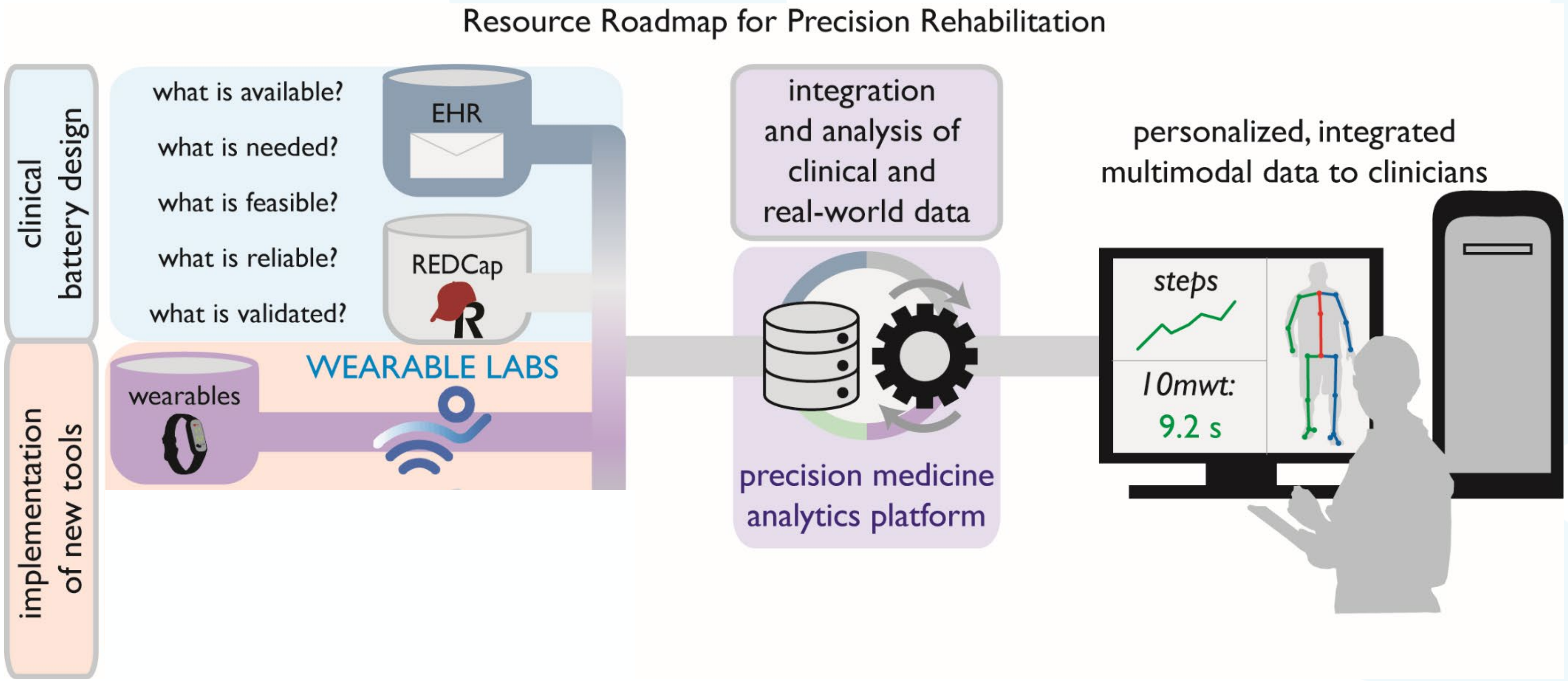
Sedentary Group

Deconditioned Group

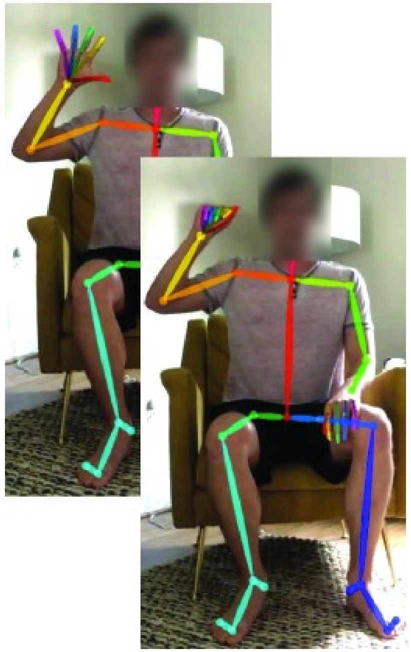
Emily Akrong
Elizabeth Rosenthal

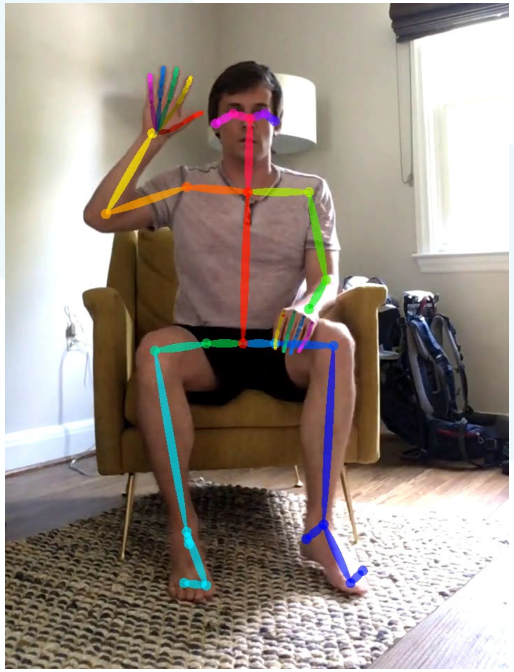
Koffman et al., Journal of the American Heart Association, 2023.

Roadmap for precision rehabilitation…



Measurement of human movement





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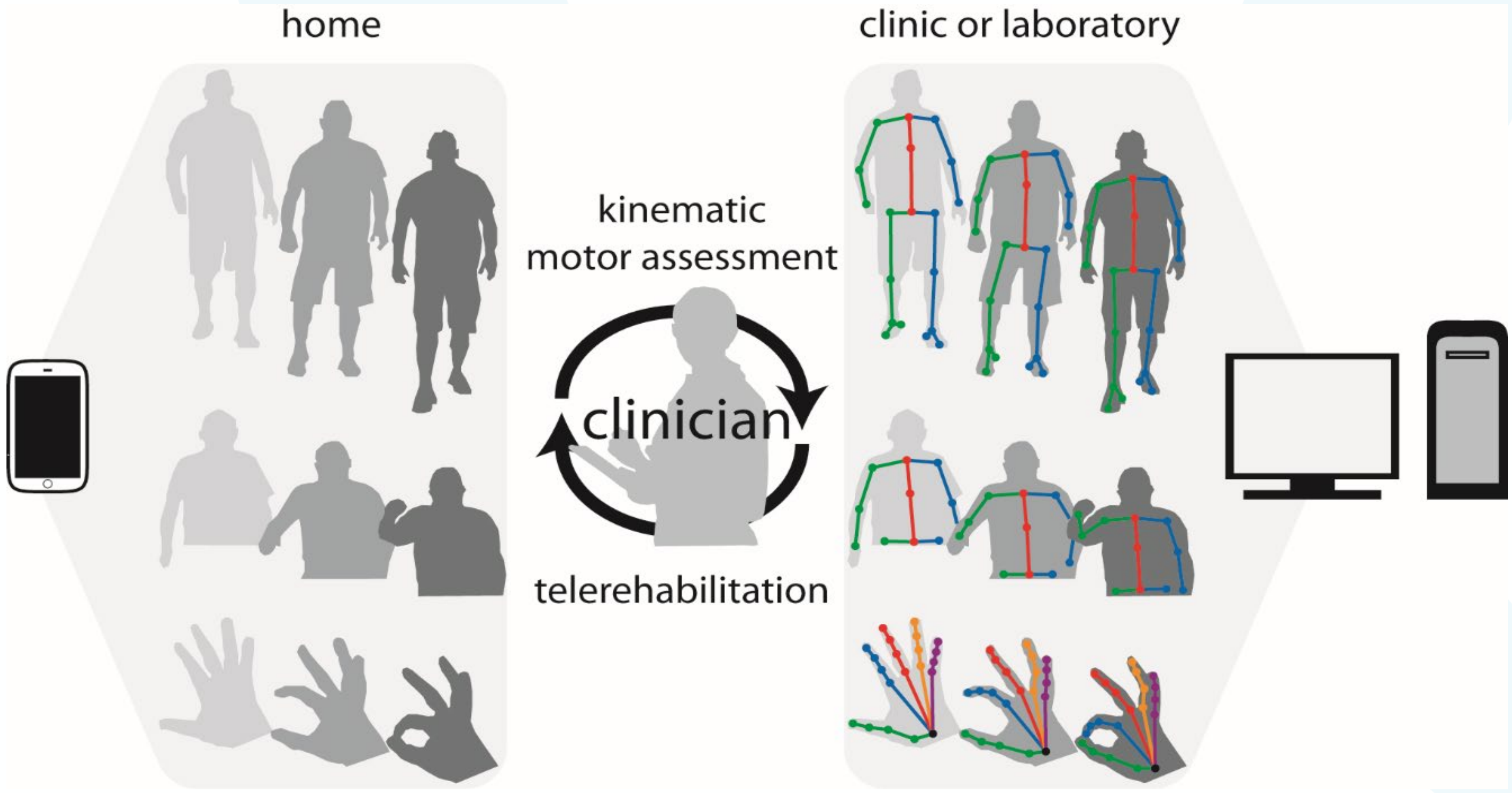
We see considerable potential for use of this technology to address rapidly expanding needs for remote measurement and delivery of telerehabilitation.

The Big Picture Goal:

Clinician-centered use of pose estimation for facilitating remote assessment and telerehabilitation



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Interest around KKI/Hopkins (and elsewhere)

Validation of markerless video-based gait analysis using pose estimation in toddlers with and without neurodevelopmental disorders

Jeffrey T. Anderson[1], Jan Stenum[2], Ryan T. Roemmich[2,3] and Rujuta B. Wilson[1,4]*

RESEARCH ARTICLE

Video-based quantification of human movement frequency using pose estimation: A pilot study

Hannah L. Cornman[1,2,3], Jan Stenum[1,2], Ryan T. Roemmich[1,2]*

JOURNAL ARTICLE

Accuracy of Video-Based Gait Analysis Using Pose Estimation During Treadmill Walking Versus Overground Walking in Persons After Stroke FREE

Kristen John, BS, Jan Stenum, PhD, Cheng-Chuan Chiang, DO, Margaret A French, PT, DPT, PhD, Christopher Kim, MS, John Manor, DO, ATC, Matthew A Statton, MD, Kendra M Cherry-Allen, PT, DPT, PhD, Ryan T Roemmich, PhD

RESEARCH ARTICLE

Clinical gait analysis using video-based pose estimation: Multiple perspectives, clinical populations, and measuring change

Jan Stenum[1,2], Melody M. Hsu[1,3], Alexander Y. Pantelyat[4], Ryan T. Roemmich[1,2]*

ANALYSIS & PERSPECTIVE

Opportunities for Improving Motor Assessment and Rehabilitation After Stroke by Leveraging Video-Based Pose Estimation

Cherry-Allen, Kendra M. PT, DPT, PhD; French, Margaret A. PT, DPT, PhD; Stenum, Jan PhD; Xu, Jing PhD; Roemmich, Ryan T. PhD

RESEARCH ARTICLE

Two-dimensional video-based analysis of human gait using pose estimation

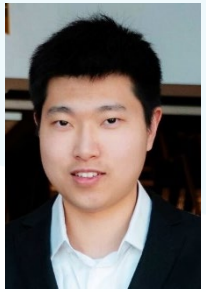
Jan Stenum, Cristina Rossi, Ryan T. Roemmich

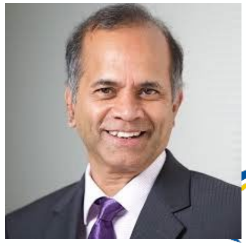
Applications of Pose Estimation in Human Health and Performance across the Lifespan

by Jan Stenum [1,2], Kendra M. Cherry-Allen [2], Connor O. Pyles [3], Rachel D. Reetzke [4,5], Michael F. Vignos [3] and Ryan T. Roemmich [1,2,*]

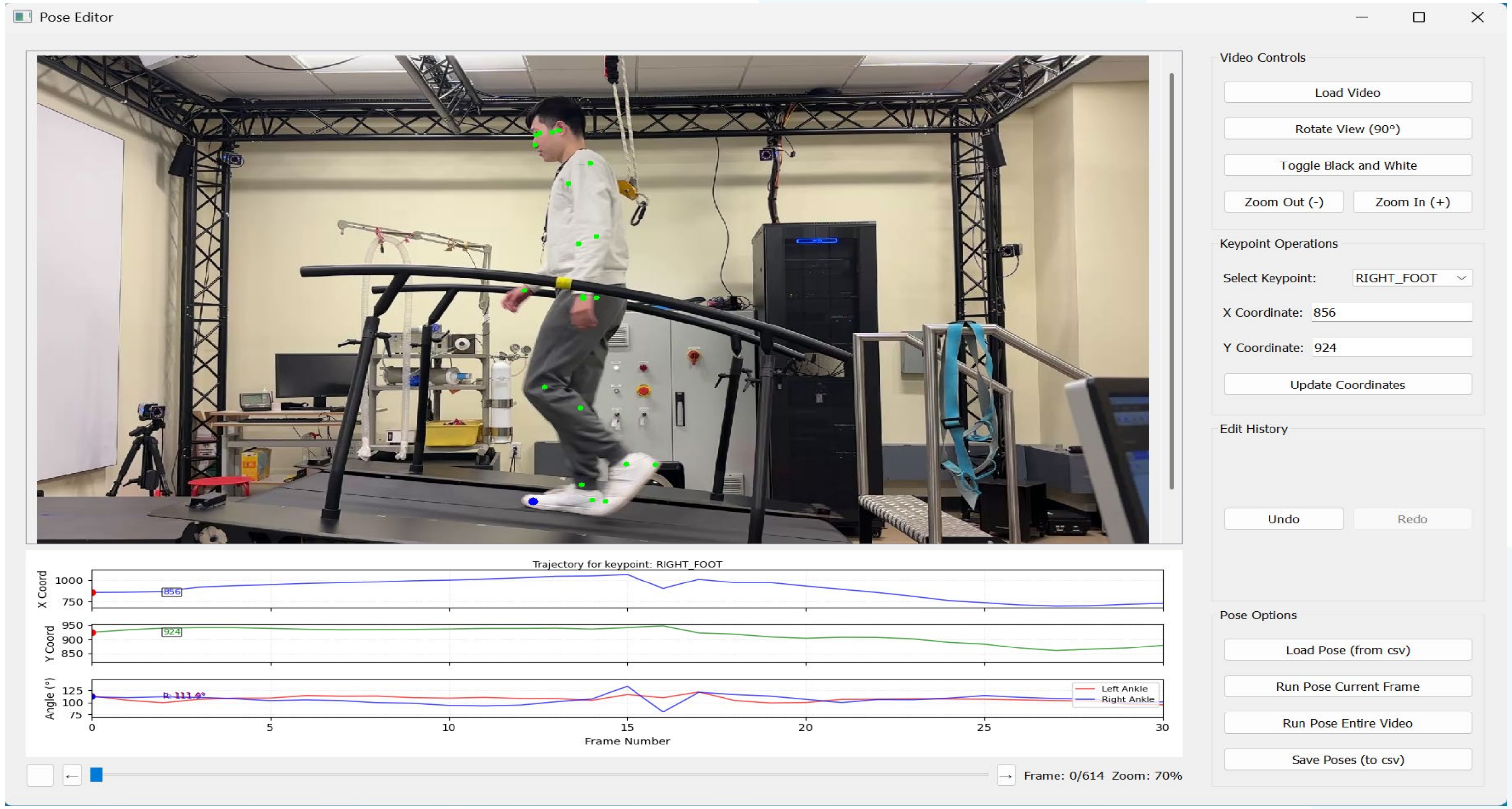






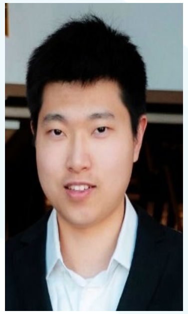




Improving accessibility



https://github.com/JeffZC/pose-editor/tree/mediapipe-rr21






CurveAssure

JOHNS HOPKINS TECHNOLOGY VENTURES

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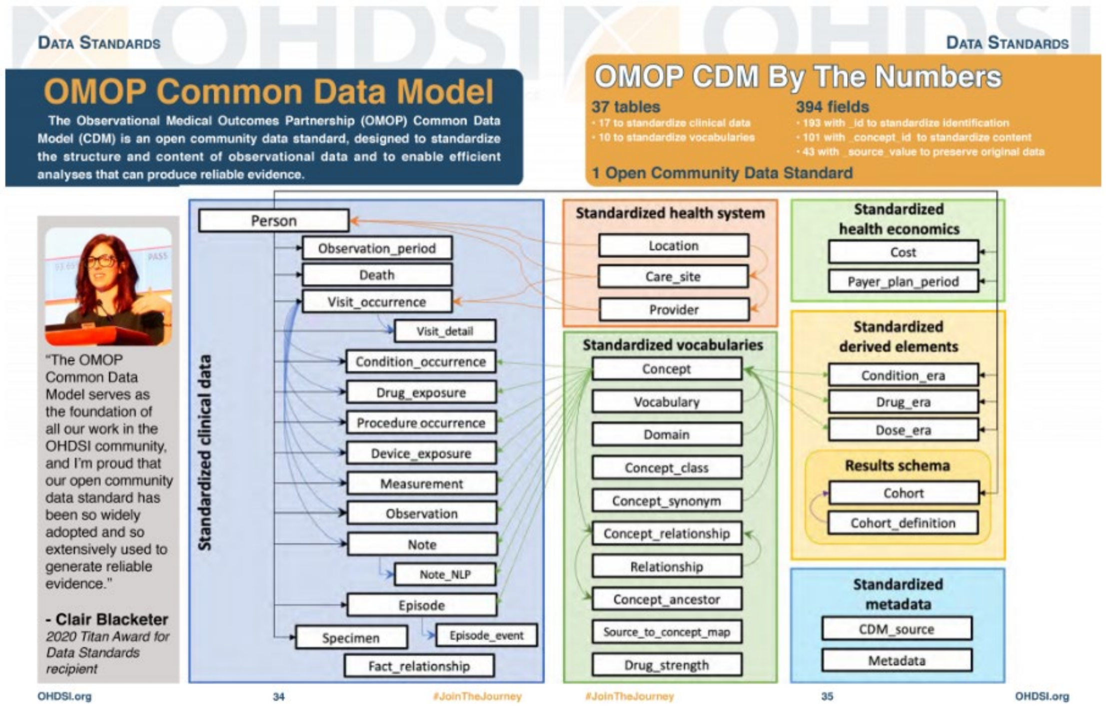
Where are we headed?

Expanding inter-institutional collaboration

- Rehabilitation Common Data Model group

Incorporating useful technology

- Beiwe (MGH collaboration)
- NLP (collaborations with Depts of Medicine and Radiology)



Rehabilitation Precision Medicine Center of Excellence

Our team 2019-now

Thank you!

Email: Roemmich@kennedykrieger.org

Funding:
JH AITC (NIH P30AG073104)
NICHD, NIA
American Parkinson Disease Association
Stanford RESTORE Center (NIH P2CHD101913)
Sheikh Khalifa Stroke Institute (JHM)
Association of Academic Physiatrists
American Heart Association

JOHNS HOPKINS
BLOOMBERG SCHOOL *of* PUBLIC HEALTH

Cochlear Center for Hearing and Public Health

Transforming Hearing Through Evidence, Policy & Awareness

Frank Lin, MD PhD
Professor of Otolaryngology & Epidemiology
Johns Hopkins University

Disclosures:

Independent contractor to Apple since 2022 (currently on sabbatical with Apple from 2024-2025)

My presentation today is in my role as a Professor at Johns Hopkins University. I do not represent or speak on behalf of Apple Inc.

Foundational Principles

Everyone’s hearing declines with age

Hearing allows us to engage with others & the environment and is foundational to health

Transformative approaches are needed to address hearing loss globally

Hearing Health Transformation Over the Past Decade

Evidence
Demonstrating the impact of hearing & hearing interventions on health

Regulatory policy
Allowing for innovation & accessibility in the hearing technology market

Awareness
of hearing as a life course aspect of health – JHU Hearing Number campaign

Hearing Health Transformation Over the Past Decade-

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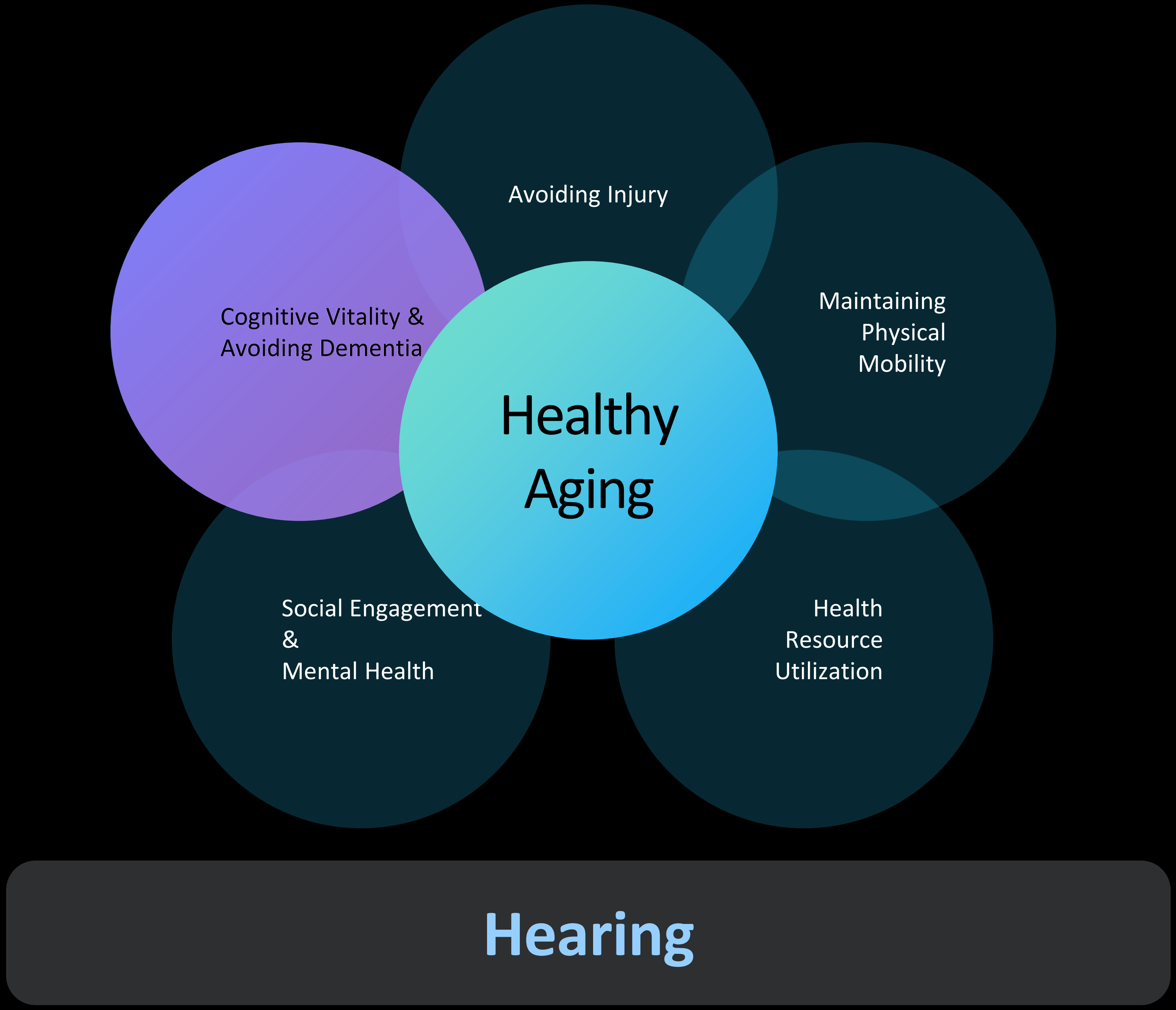
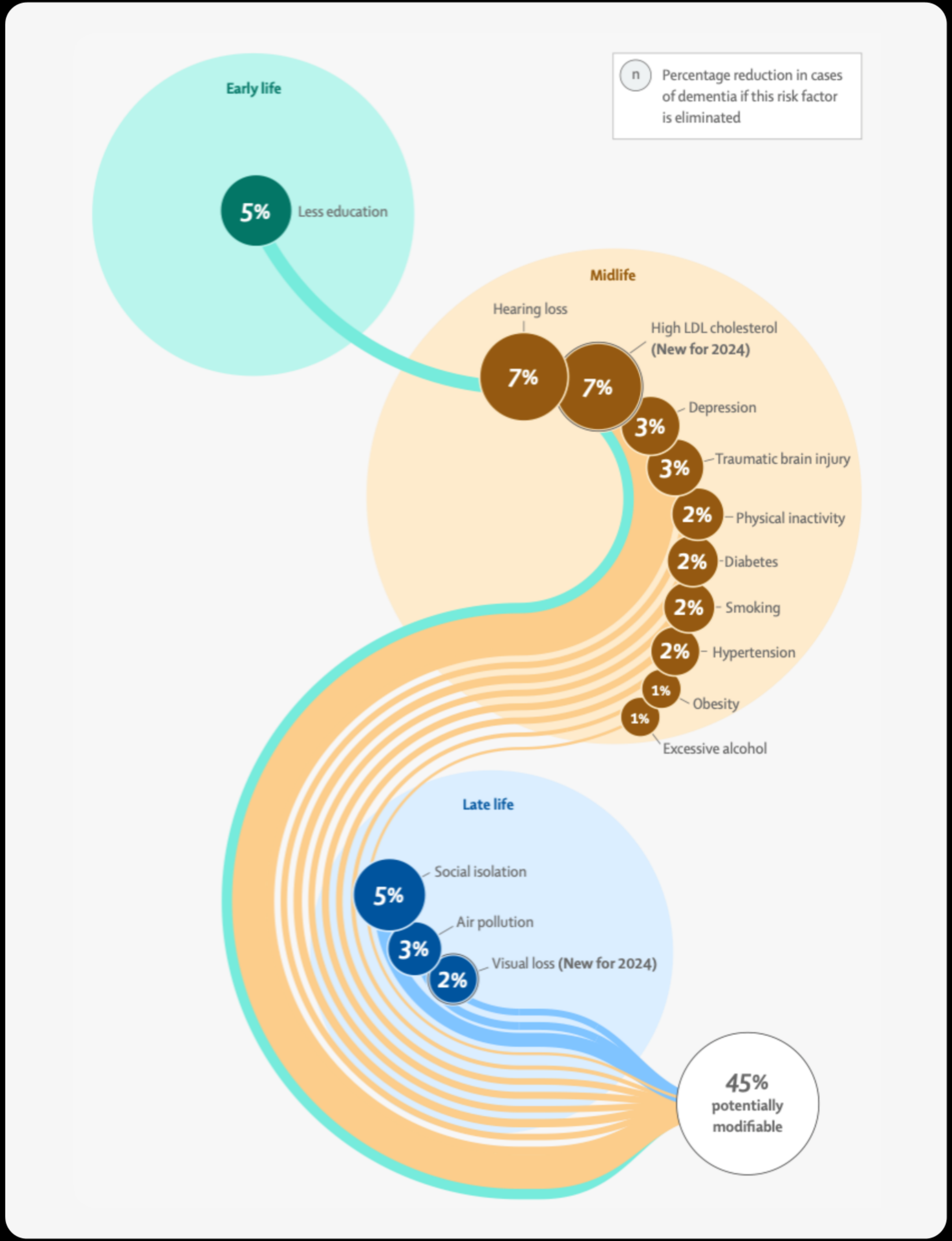

Avoiding Injury
Cognitive Vitality & Avoiding Dementia
Maintaining Physical Mobility
Healthy Aging
Social Engagement & Mental Health
Health Resource Utilization
Hearing



Potentially Modifiable Risk Factors for Dementia

2024 Lancet Commission on Dementia Prevention, Intervention & Care

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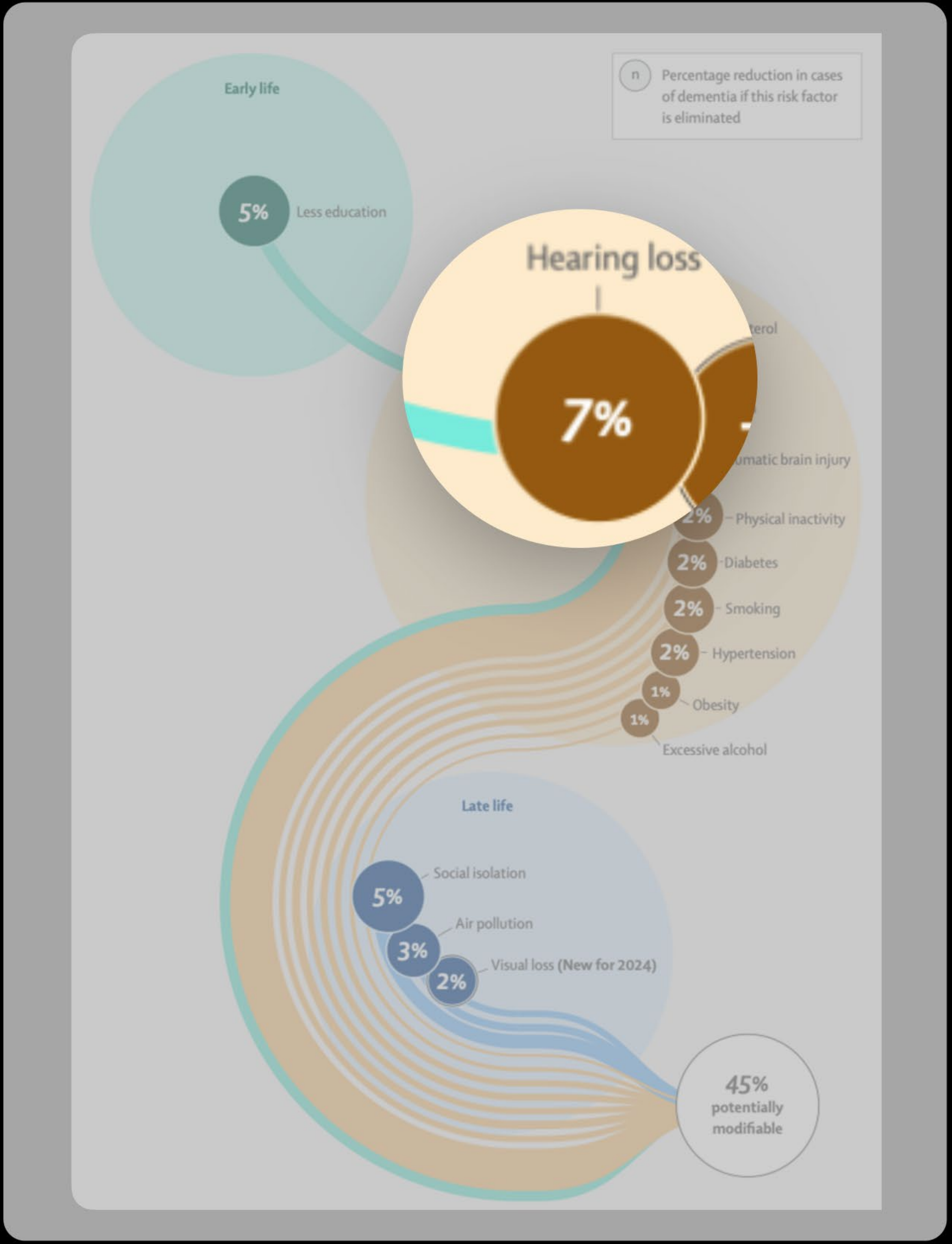
Hearing loss in mid & late life identified as one of the single largest potentially modifiable risk factors for dementia



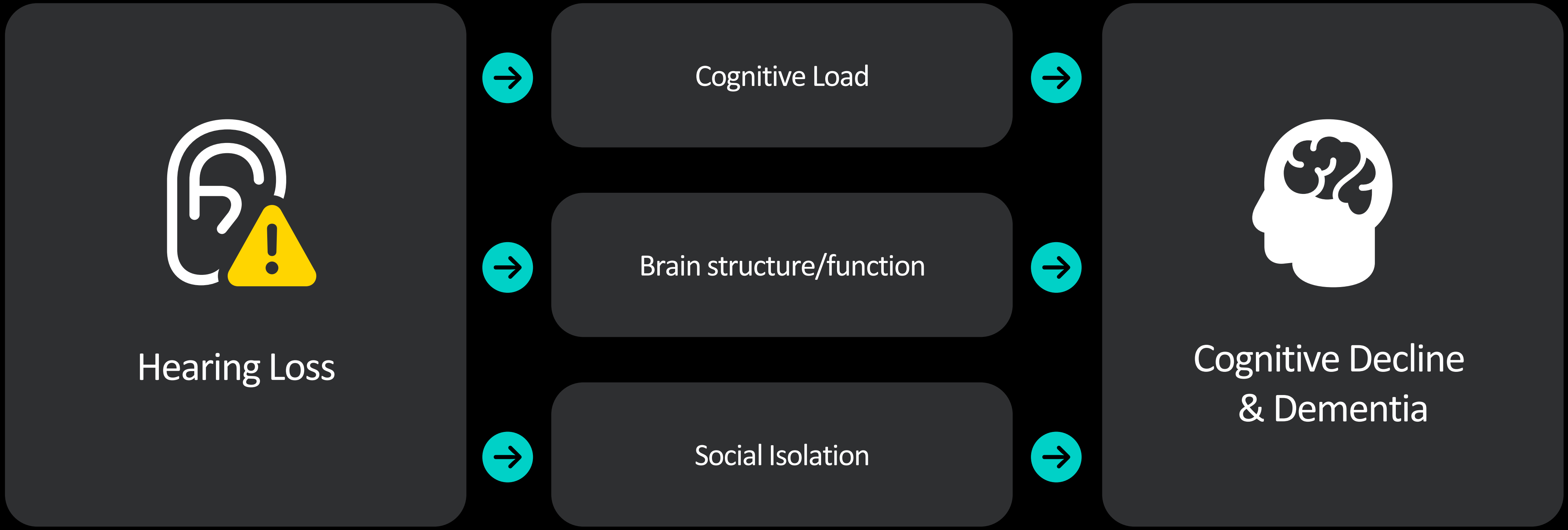
Potentially Modifiable Risk Factors for Dementia

2024 Lancet Commission on Dementia Prevention, Intervention & Care

Hearing loss in mid & late life identified as one of the single largest potentially modifiable risk factors for dementia

Hearing Loss & Dementia

Mechanistic Pathways



F. Lin & M. Albert, Aging & Mental Health, 2014

Potential role for hearing intervention in reducing risk of cognitive decline & dementia

Cognitive Load	Reduce the cognitive load of processing degraded sound
Brain structure/function	Provide increased brain stimulation
Social Isolation	Improve social engagement

F. Lin & M. Albert, Aging & Mental Health, 2014

ACHIEVE Collaborative Research Group (2014 - present)

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Data coordinating center

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Study governance unit & Washington County field site

UMMC The MIND Center

Jackson field site

WAKE FOREST UNIVERSITY

Forsyth County field site

SCHOOL OF PUBLIC HEALTH UNIVERSITY OF MINNESOTA

Minneapolis field site

MAYO CLINIC

MRI reading center

ACHIEVE study

USF UNIVERSITY OF SOUTH FLORIDA

Hearing intervention design

UNIVERSITY OF PITTSBURGH

Health education control intervention design

NIH/NIA R34AG046548, R01AG055426, R01AG060502, R01AG076518


THE LANCET

Volume 402 · Number 10404 · Pages 747–824 · September 2–8, 2023 www.thelancet.com

"Based on evidence from the ACHIEVE study, hearing loss might be a particularly important global public health target for dementia prevention efforts."

See Articles page 786

September 2023

Hearing intervention confers a 48% reduction in cognitive loss over 3 years in adults at increased risk of cognitive decline in the ACHIEVE (n = 977) randomized controlled trial

Hearing Health Transformation Over the Past Decade..

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Demonstrating the impact of hearing & hearing interventions on health

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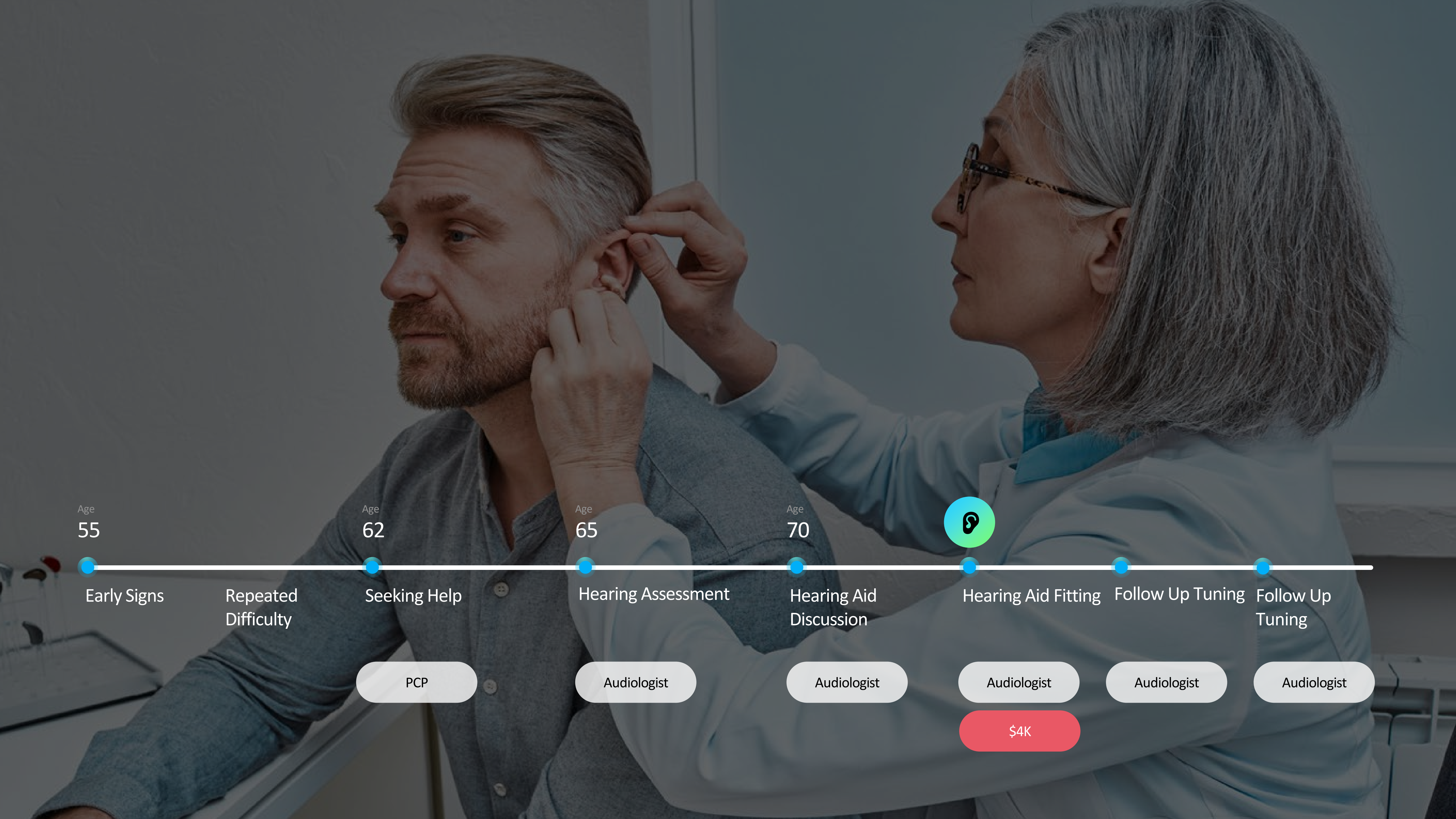
Awareness
of hearing as a life course aspect of health – JHU Hearing Number campaign


Age
55
Early Signs
Repeated Difficulty
Age
62
Seeking Help
PCP
Age
65
Hearing Assessment
Audiologist
Age
70
Hearing Aid Discussion
Audiologist
Hearing Aid Fitting
Audiologist
$4K
Follow Up Tuning
Audiologist
Follow Up Tuning
Audiologist

Historical Regulatory Policy for Hearing Aids Contributed to this Care Model

Original 1977 FDA regulations for hearing aids (based on technology of that era) precluded hearing aids from being sold OTC directly to consumers

Gatekeeper model – Providers control access to HAs

Barriers to entry for any new hearing aid manufacturer given need to sell through clinical providers

Extensive ‘friction’ & high costs for consumers to access hearing care

Correcting the Hearing Market Required Changing Outdated Regulatory Policy

Bipartisan efforts in Congress & the White House resulted in passage of the OTC Hearing Act of 2017 and enactment of regulations in 2022


U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / News & Events / FDA Newsroom / Press Announcements / FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

FDA NEWS RELEASE

FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

More Affordable Hearing Aids Could Be in Stores as Soon as Mid-October

Share | Post | Linkedin | Email | Print

More Press Announcements

For Immediate Release: August 16, 2022

Español

Today, the U.S. Food and Drug Administration issued a final rule to improve access to hearing aids which may in turn lower costs for millions of Americans. This action establishes a new category of over-the-counter (OTC) hearing aids, enabling consumers with perceived mild to moderate hearing impairment to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription or a fitting adjustment by an audiologist.

The rule is expected to lower the cost of hearings aids, furthering the Biden-Harris Administration's goal of expanding access to high-quality health care and lowering health care costs for the American public. It is designed to assure the safety and effectiveness of OTC hearing aids, while fostering innovation and competition in the hearing aid technology marketplace.

Today's action follows President Biden's Executive Order on Promoting Competition in the American Economy, which called for the FDA to take steps to allow hearing aids to be sold over the counter and set a swift 120-day deadline for action, which the FDA met. In 2017, Congress passed bipartisan legislation requiring the FDA to create a category of OTC hearing aids, but it was not fully implemented until now. Consumers could see OTC

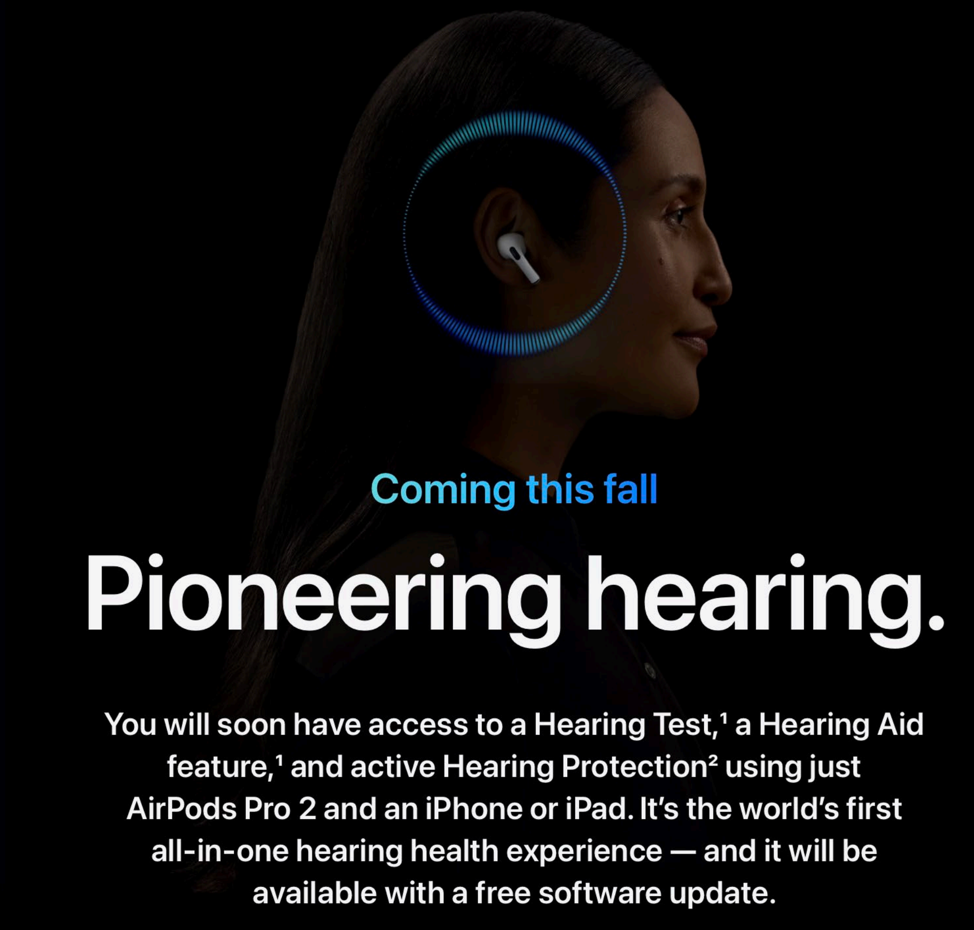
Content current as of:
08/16/2022

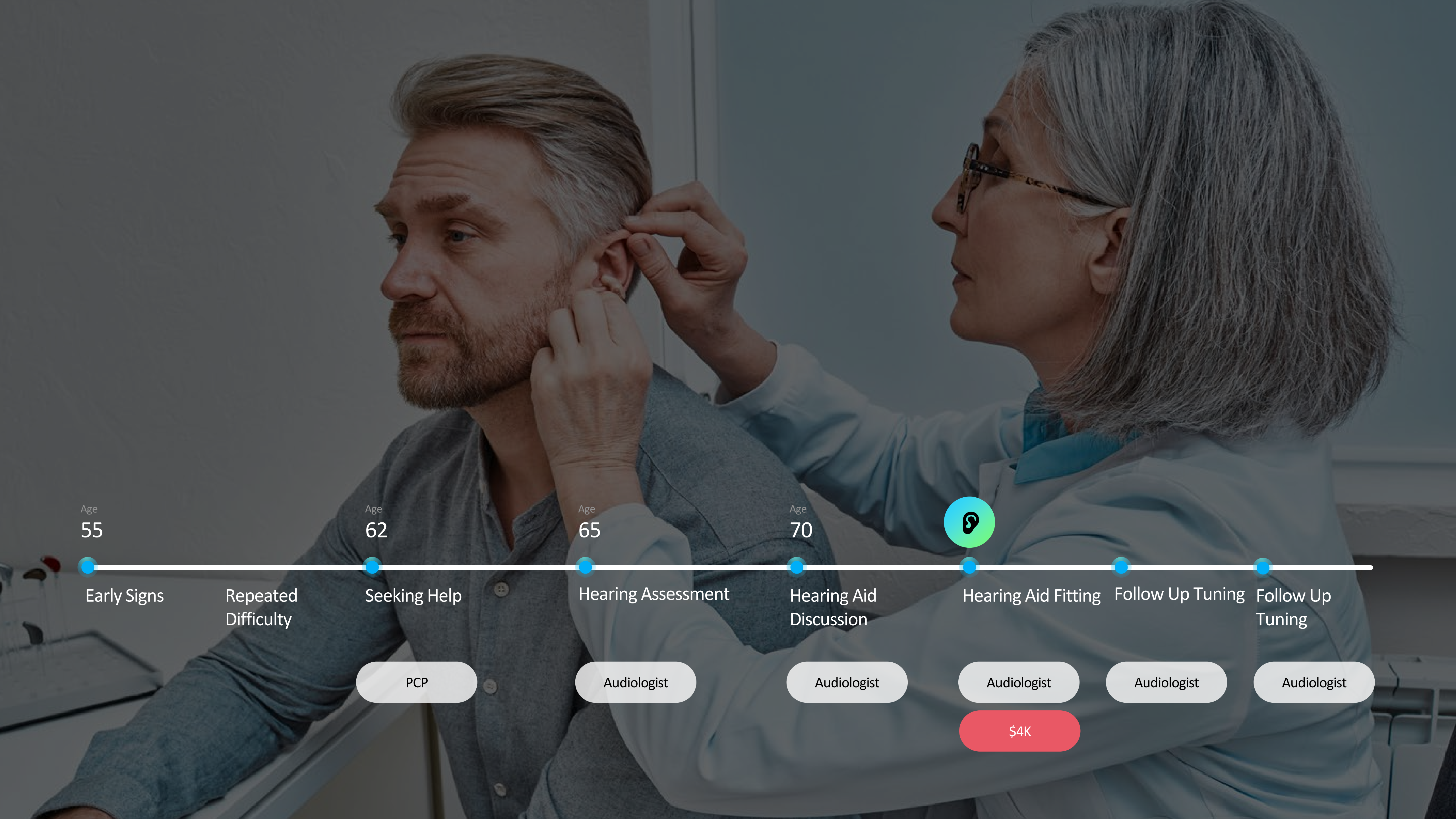
Regulated Product(s)
Medical Devices

Follow FDA
Follow @US_FDA
Follow FDA
Follow @FDAMedia

Market Entrants since 2022

September 2024

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SONY
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EssilorLuxottica
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Jabra GN
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Early Signs
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$250

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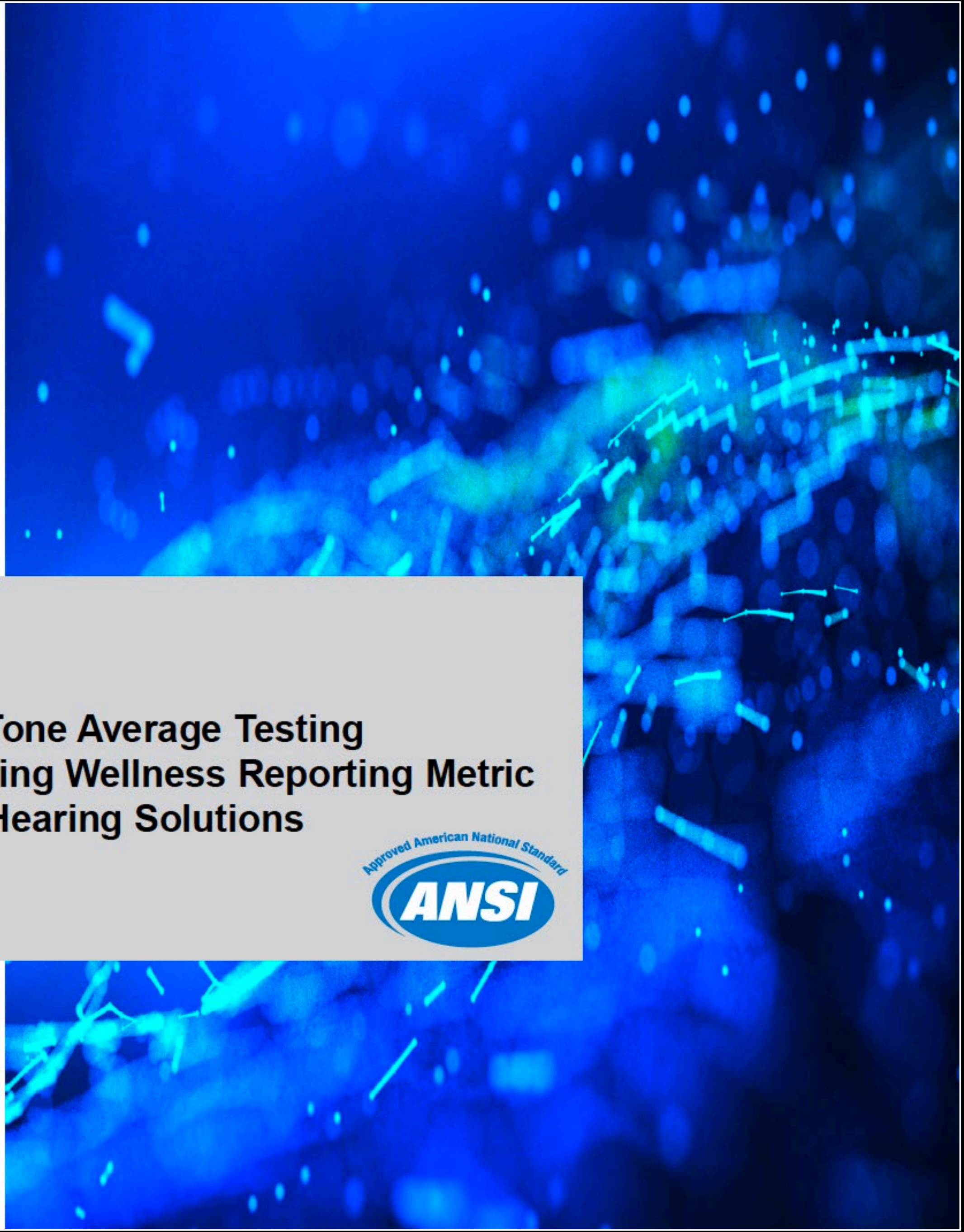
Consumer Technology Association™



ANSI/CTA Standard

Four Frequency Pure Tone Average Testing Methodology and Hearing Wellness Reporting Metric for Consumer-Facing Hearing Solutions

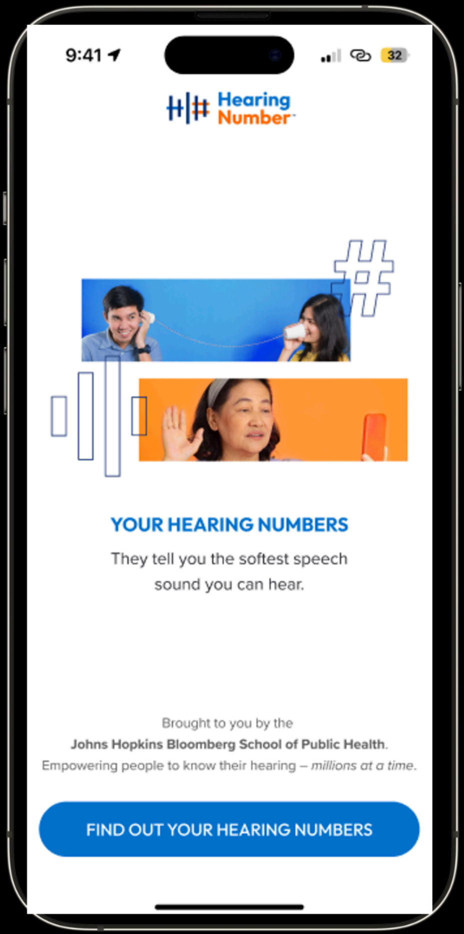
ANSI/CTA-2118

Approved American National Standard ANSI

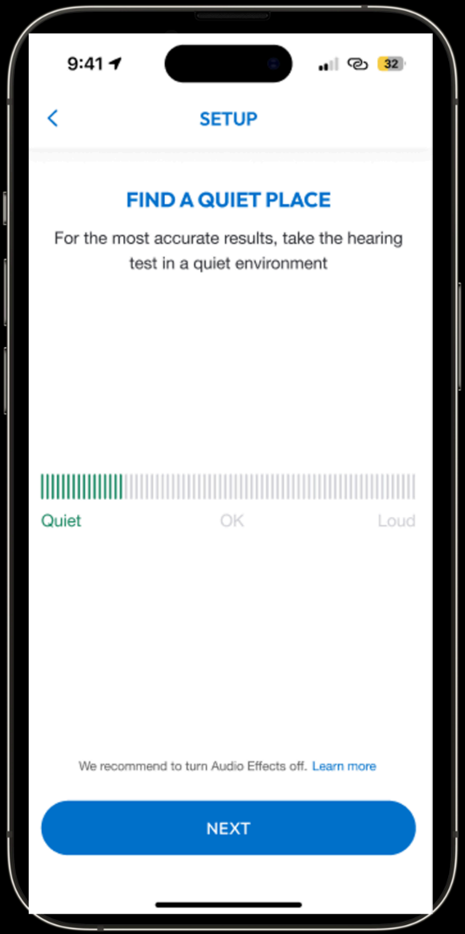
October 2023

January 2025

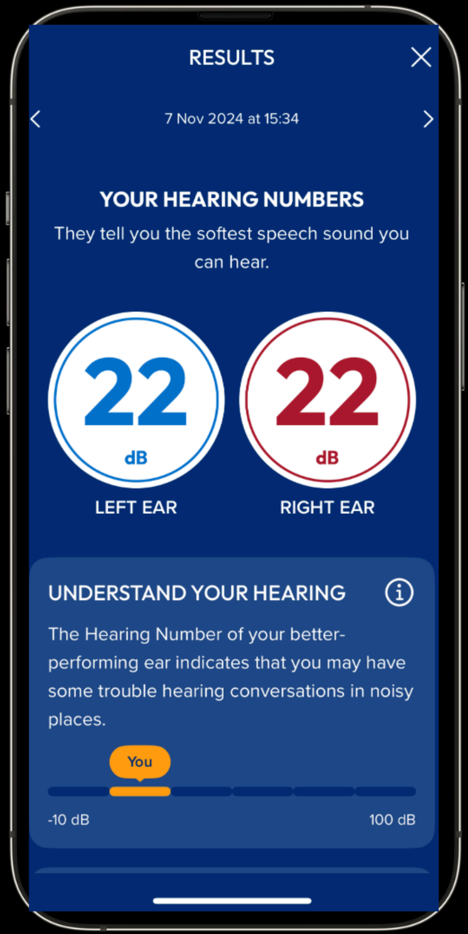
Official Launch of JHU Hearing Number App & Campaign



Test on iOS or Android in multiple languages

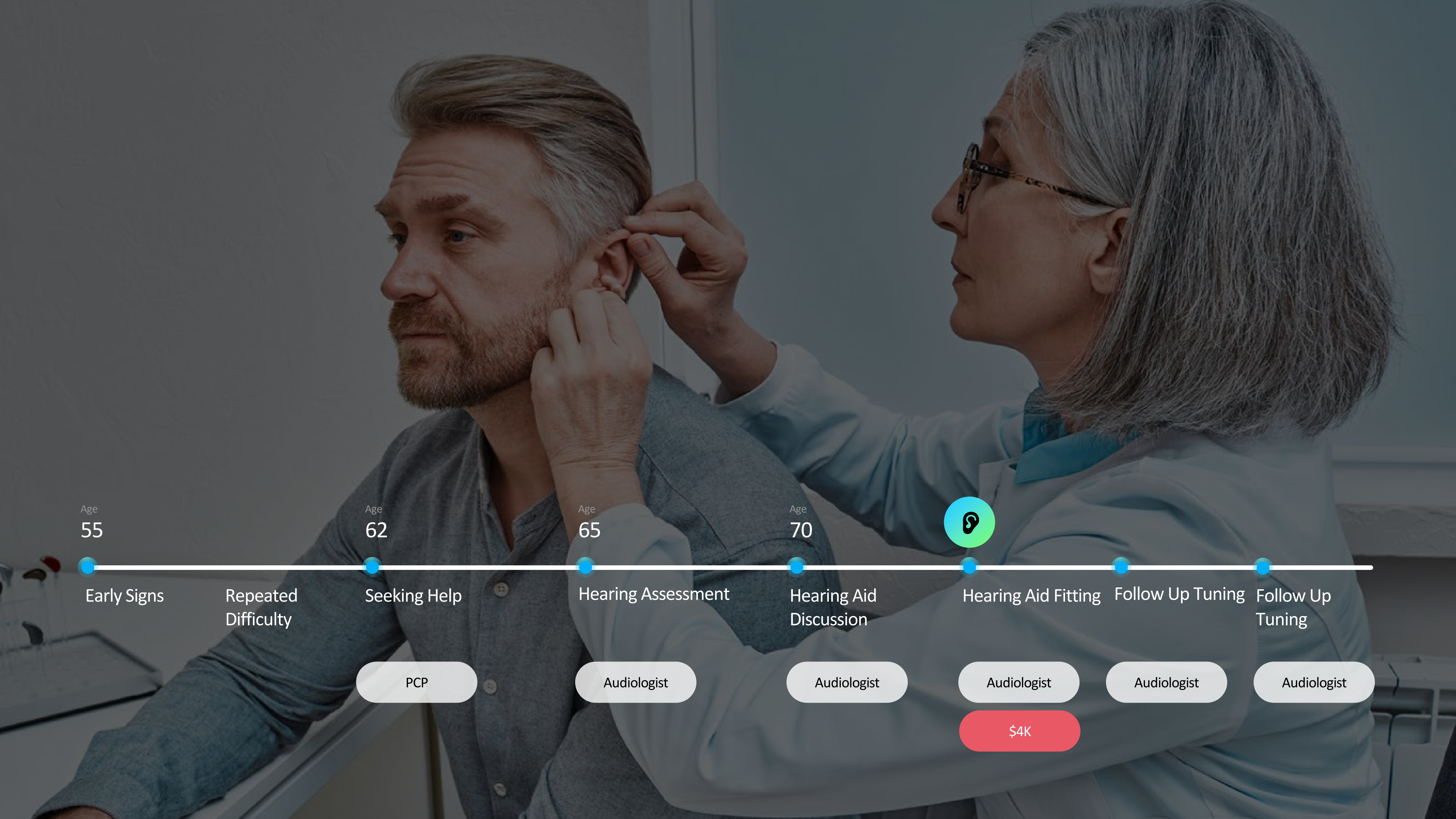


Meets CTA/ANSI PTA4 Standard



Actionable & Shareable Results

Available in 6 Languages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$4K


SONY
EssilorLuxottica
lexie
Jabra GN
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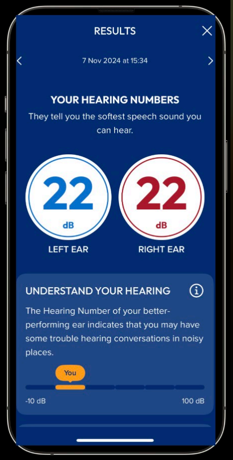
Early Signs
Hearing Aid
$250

From Late-Life Hearing to Life-Course Hearing



Hearing Awareness

Hearing Protection

SONY
hp
EssilorLuxottica
lexie
Jabra GN

Hearing Augmentation

Age 20	Age 30	Age 40	Age 55
4 dB / 5 dB	9 dB / 8 dB	12 dB / 12 dB	19 dB / 17 dB

Hearing Health Transformation Over the Past Decade....

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Improving public health through empowering individuals to act on their hearing health over their life course

Frank Lin, MD PhD

Professor of Otolaryngology & Epidemiology

Johns Hopkins University

flin1@jh.edu

AchieveStudy.org

HearingNumber.org

JHUCochlearCenter.org

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH | Cochlear Center for Hearing and Public Health