



**Including Older Adults in
Research-
Educating Research Teams to
meet the NIH Lifespan
Inclusion Policy
Elizabeth Eckstrom, MD, MPH*
Oregon Health & Science University**

Lifespan Enterprise Committee Older
Adult Working Group, CTSA network

*I have no conflicts of interest

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What does this toolkit include?

- **Overview:** “If there is only time for one presentation” module, as well as the framework on which others hang
- **Motivation: What are the benefits of inclusion?**
- **Overcoming challenges / recognizing opportunities in complexity:**
 - Design and data analysis strategies
 - Frailty/Multimorbidity
 - Cognitive impairment/ consenting older adults
 - Polypharmacy
 - Study adaptability- for sensory deficits, extra time needed to complete study measures, etc.
- **Enriching participation and findings when including older adults**
- Focusing protocols on geriatric outcomes
- Community engagement / cultural considerations / diverse inclusion
- **Institutional Socialization** – creating infrastructure to value and facilitate older adult inclusion

Language matters- Let's make research Age Friendly

Instead of these words:	Try:
“Seniors,” “elderly,” and similar “other-ing” terms that stoke stereotypes	Using more-neutral (older people, Americans) and inclusive (“we” and “us”) terms
“Struggle,” “battle,” “fight,” and similar conflict-oriented words to describe aging experiences	The Building Momentum metaphor: “Aging is a dynamic process that leads to new abilities and knowledge we can share with our communities ...”
“Tidal wave,” “tsunami,” and similarly catastrophic terms for the growing population of older adults	Talking affirmatively about changing demographics: “As Americans live longer and healthier lives ...”

Lundebjerg, N.E., Trucil, D.E., Hammond, E.C. and Applegate, W.B. (2017), When It Comes to Older Adults, Language Matters: Journal of the American Geriatrics Society Adopts Modified American Medical Association Style. J Am Geriatr Soc, 65: 1386-1388. <https://doi.org/10.1111/jgs.14941>

A patient story



Why have this conversation?

Lockett, et al, JAGS 2019

	Total studies with upper age limits	Trials that exclude people ≥65 y	Trials that exclude people ≥75 y
Congestive heart failure	11	2 (18%)	7 (64%)
Cardiac dysrhythmias	12	1 (8%)	11 (92%)
Coronary atherosclerosis	68	14 (21%)	49 (72%)
Heart attack	33	5 (15%)	23 (70%)
Stroke	60	20 (33%)	24 (40%)
COPD	7	1 (14%)	5 (71%)
Pneumonia	16	6 (38%)	6 (38%)
Lung cancer	33	12 (12%)	23 (70%)
Prostate cancer	25	0	4 (16%)
Osteoarthritis	8	4 (50%)	4 (50%)

Why have this conversation?

- Many diseases are distinctly different in older adults, yet haven't been studied in these age groups
 - Poor renal clearance
 - Lower muscle mass
 - Effects of multiple comorbidities
 - Phenotype of disease may be different (e.g., atherosclerotic heart disease)

Why have this conversation?

- Older under-resourced populations have lower participation in research- we need to reduce structural racism and ensure equity in research inclusion for older adults
- Clinicians caring for older adults, particularly those from diverse populations, have little evidence to guide their care
- People at the highest risk of disease often have the greatest chance to benefit from research!

Inclusion Across the Lifespan: guidance for applying the policy

The Inclusion Across the Lifespan policy (IAL) applies to *all exempt and non-exempt human subjects research* (see [NOT-OD-18-116](#)), beginning with competing grant applications due *on/after January 25, 2019*, and R&D contract solicitations issued on/after this date.

Prior to this date, the [Inclusion of Children in Research Policy](#) continues to be in effect.



Remember: Scientific Review Groups (SRGs) will assess each application/proposal as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project.

*Exclusion based on age must be due to ethical or scientific reasons. Acceptable justifications may include:

- The disease to be studied does not occur in the excluded age group
- The research topic is not relevant to the excluded age group
- Knowledge sought is already available for the excluded group
- Separate study for the excluded age group is warranted or preferable
- Research involves data from pre-enrolled participants
- Laws/regulations bar inclusion of individuals in a specific age group in research.
- The study poses unacceptable risk to the excluded age group

**“Arbitrary upper age limits
for trial entry are almost
never justified”**

FDA

Considerations

- Recruitment, Enrollment, Retention
- Study exclusions
- Consenting older adults who might have limited ability to consent
- Poly-pharmacy, drug-drug interactions, adverse events
- Budget challenges
- Need for study adaptability
- Need to measure outcomes important to older adults (e.g., function, mobility, cognition)
- Sensory deficits
 - Measurement tools may need to be adapted (e.g., font size of surveys)

Mr. Scott



- New diagnosis prostate cancer
- Lives with wife in senior low income housing
- Neither drive; daughter takes them to church
- Korean war veteran

Strategies for Recruitment

- Overcome transportation issues
 - home visits, mobile units and study center
- Use multiple recruitment methods
 - Phone, social media, telemedicine
 - EHR, waiting rooms
 - Local gyms, community centers, meal sites, places of worship, DMV records, rotary, long term care communities
 - Be visible in the community- older adults want to know the PI and how their contributions matter. Local festivals, give talks
 - Allow plenty of time- recruiting older adults can take longer
 - Partner with community agencies like Area Agencies on Aging

Exclusions

- Describe the epidemiology of disease or condition across age, comorbidity, and racial/ethnic characteristics
 - Review the epidemiology and then develop strategies for inclusion based on the results
- Any restrictions based on age, comorbidity, or gender/sex should be well-justified
- Engage aging experts to assist in study adaptations- thoughtful vs. thoughtless exclusions
- Add age to application enrollment tables
 - Creates a place for the data to be collected to facilitate reporting

Mr. Scott



- Your study team pulls his name from the EHR, you call him
- Daughter drives them to a group enrollment visit
- He enrolls in the study with home visits, motivated by desire to help others with cancer and by the people he met at the enrollment visit

Mr. Scott



- Baseline data collection includes risk identification
 - Decreased renal function
 - Hard of hearing
 - Trouble swallowing

Mr. Scott

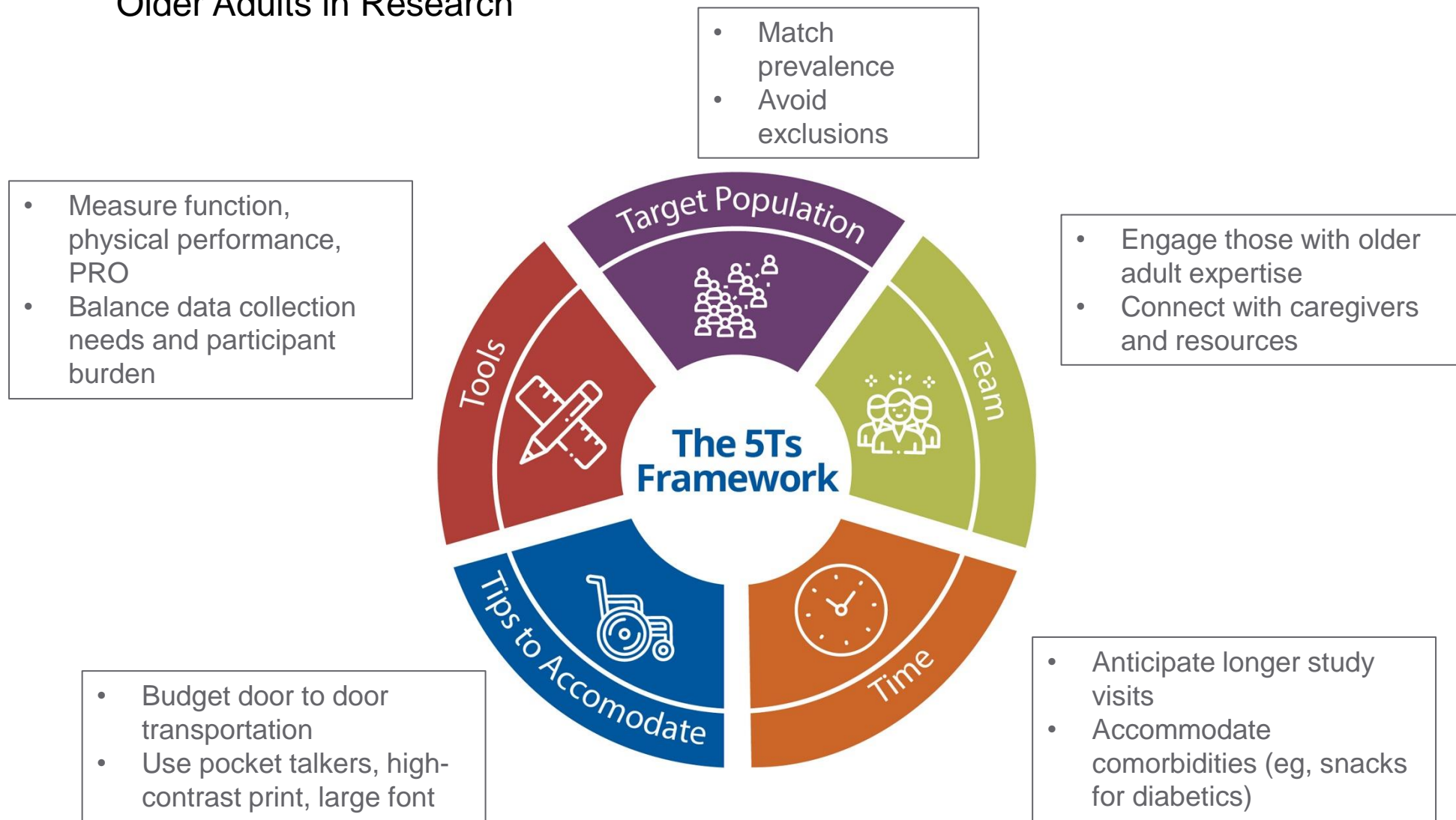


- Study adaptations include
 - Liquid formulation
 - Slower uptitration with mobile lab checks
 - Mailed reminders of upcoming study visits
 - Consent signed with daughter so reminder calls can go to her

Measuring Outcomes Important to Older Adults

- Cure/longevity often not a priority for older adults
- Quality of life and maintaining function much more important
- Include measures of mobility (e.g., Timed Up and Go or gait speed), cognition (e.g. Mini-COG, MOCA), function (Activities of Daily Living), what matters (goals)

The 5Ts: Preliminary Development of a Framework to Support Inclusion of Older Adults in Research



Bowling, et al, *Journal of the American Geriatrics Society*, Volume: 67, Issue: 2, Pages: 342-346, First published: 29 January 2019, DOI: (10.1111/jgs.15785)

Summary:

- Recruitment, Enrollment, Retention
 - Creative recruitment sites, think about transportation, flexible data collection, keep subjects informed
- Study exclusions
 - Must have good rationale for age/comorbidity exclusions
- Consenting older adults who might have limited ability to consent
 - Decision making capacity, include a proxy
- Budget
 - Budget for extra study needs
- Measurement tools need to be adapted (e.g., font size of surveys)

A patient story



What we hope this group will do...

- Use/adapt these slide sets to make them your own
- Add your own stories!
- Reach out to non-aging researchers to share these slide sets/ give talks
- Help us improve these resources
- We will have materials ready for use in the coming months

Questions?

Elizabeth Eckstrom, MD, MPH

Eckstrom@ohsu.edu

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