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From Access to Inclusion

The Experience of People Living with Dementia and Care Partners

Andrea Gilmore-Bykovskyi, PhD, RN
Assistant Professor
University of Wisconsin-Madison School of Nursing
School of Medicine & Public Health – Geriatrics Division

Investigator, Care Research Core
Wisconsin Alzheimer’s Disease Research Center Care

Affiliate Scientist, GRECC
William S. Middleton Memorial Veterans Affairs Hospital

School of Nursing
UNIVERSITY OF WISCONSIN–MADISON

Wisconsin Alzheimer’s Disease Research Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

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Contact Information

Andrea Gilmore-Bykovskyi: algilmore@wisc.edu

Overview

1 – Introduce foundational ethical, scientific, and practical considerations for inclusion of people living with dementia and their care partners in clinical research

2 – Summarize the current state of science and priorities advanced by advocacy organizations established through collaboration with people with dementia and care partners

3 – Outline major gaps and priorities for future research

Conceptualizing Inclusion: *What is the Goal?*

“Who ought to receive the risks and benefits of research? This is a question of Justice”
—The Belmont Report

“Achieving health equity requires valuing all individuals and populations equally”
—Dr. Camara Jones

“Just, rigorous research compels optimal participation from all without undue burden or exclusion”
-Gilmore-Bykovskyi, Jackson & Wilkins

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Source: www.nextavenue.org

Taylor et al, *JAGS,* 60:413–419, 2012; Gilmore-Bykovskyi et al, *TMM,* 27(2), 97-100;

Conceptualizing Inclusion: *Disease-Specific Challenges*

Impaired Decision Making

- Fluctuating cognitive and functional abilities
- Inconsistent approaches to assess capacity to consent to research (and assent/dissent)
- Evaluating cognitive capacities vs specific to consent situation
- Unintended consequences of over-protectionist frameworks (i.e. case of guardianship)

Capacity* ♦ Understanding ♦ Expression of choice ♦ Appreciation ♦ Reasoning

Statutes and Processes for Alternate Decision Maker

- Even with 2017 changes to the Common Rule (requires LAR), state and institutional policies for proxy consent in research are inconsistent
- Not all people with dementia have a LAR or proxy decision-maker
- Adequacy and appropriateness of proxy decision-makers for research decisions is unclear
- Emphasizes singular vs shared or distributed decision-making, which may not be culturally appropriate or consistent with decision-making preferences
- Several studies demonstrate that proxy decision making often involves the PLWD

Black et al, *AJGP, 2013;* Chamberlain et al., *Can J Aging,* 2018; Fetherstonhaugh et al., *JME*, 2017; Louie, *WLR*, 2019; Trachsel et al., *Am J Alzhimer's Dis*, 2014

Conceptualizing Exclusion
Who is Left Out

The Disappearing Subject: Exclusion of People with Cognitive Impairment and Dementia from Geriatrics Research

Janelle S. Taylor, PhD,[*] *Shaune M. DeMers, MD,*[†] *Elizabeth K. Vig, MD, MPH,*[‡§] *and*
Soo Borson, MD[†]

Currently less than 4% of people with a diagnosis of dementia are involved in a clinical research study (Alzheimer's Society, 2014)

Review of 434 articles

- 16% apply recruitment methods likely to reduce participation
- 29% explicit exclusion criteria
- 19% excluding individuals for having dementia
- 6% provided justification for exclusion criteria

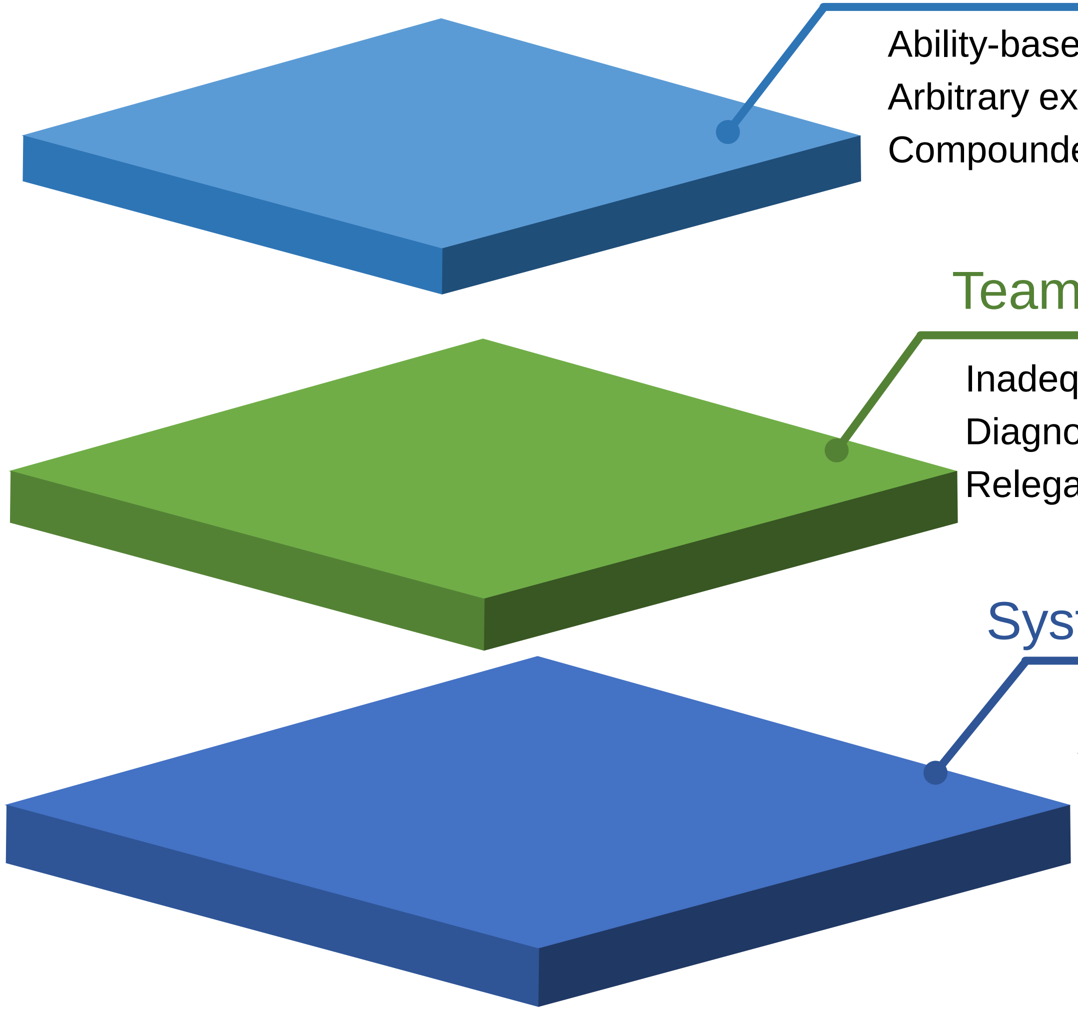
Review ISRCTN Clinical Trial Registry

- Review of UK-based clinical trials found only 18% included adults who lacked capacity consent

Taylor et al, *JAGS,* 60:413–419, 2012; Sherpard et al, *TRIALS,* 20: 474, *2019*

Conceptualizing Exclusion

How are individuals left out?



Individual/Interpersonal

Ability-based discrimination
Arbitrary exclusion/inclusion criteria
Compounded accessibility barriers

Teams and Institutions

Inadequate training to include PLWD
Diagnosis as determinant for capacity
Relegated inclusion – on the margins

Systems and Structural Norms

Accountability structures
Inconsistent regulatory and statutory guidance
Inflexible policies/norms (dyad vs network)
Minimal structures for integration of end-user voice
Study partner requirements

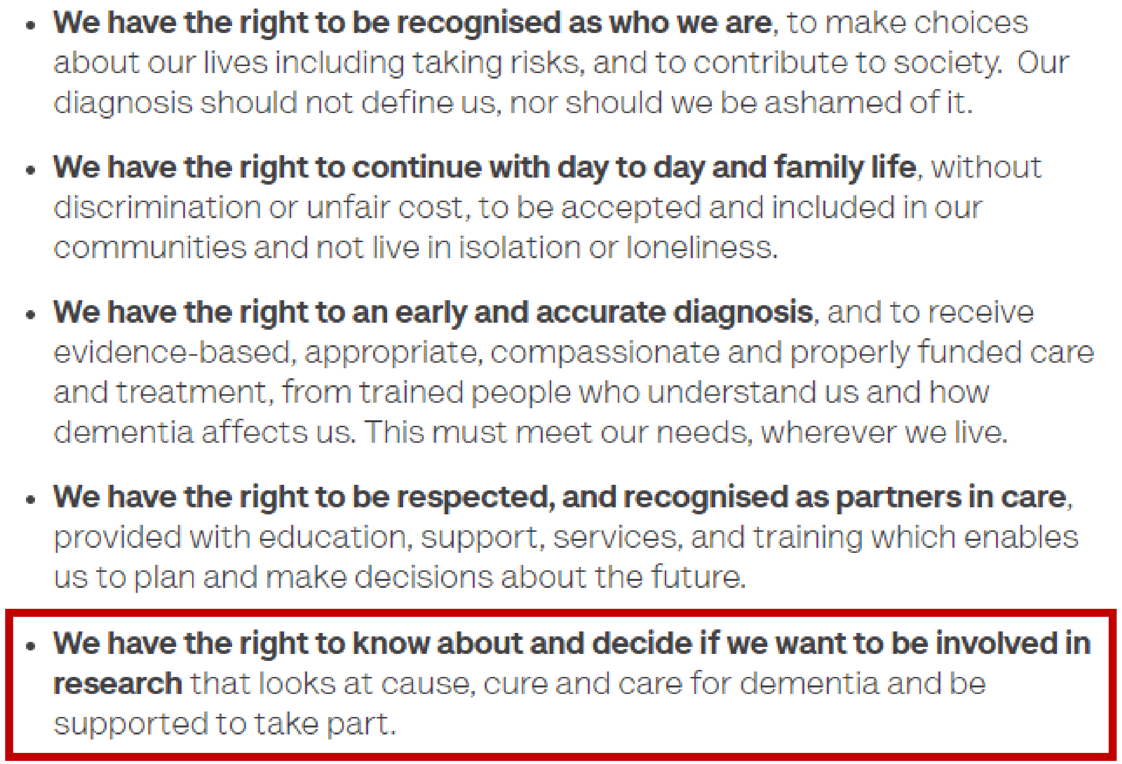
Brooks et al., *Soc Res Prac,* 3-14, 2017; Taylor et al, *JAGS,* 60:413–419, 2012; Thorogood et al., Lancet, 18(2):135-136, 2019

Priorities from People Living with Dementia

- Generally endorse use of proxy decision makers, future planning preferential
- Incongruent preferences how decisions should be made
- Robust evidence that consistent involvement in research design process and priority setting is feasible and can shape research priorities (Alzheimer's society, Alzheimer Europe)

- ♦ **Canadian Dementia Priority Setting Partnership**
- ♦ **Position on Patient and Public Involvement** developed by Alzheimer Europe collaboration with INTERDEM and European Working Group of People with Dementia

The Dementia Statements



- **We have the right to be recognised as who we are**, to make choices about our lives including taking risks, and to contribute to society. Our diagnosis should not define us, nor should we be ashamed of it.
- **We have the right to continue with day to day and family life**, without discrimination or unfair cost, to be accepted and included in our communities and not live in isolation or loneliness.
- **We have the right to an early and accurate diagnosis**, and to receive evidence-based, appropriate, compassionate and properly funded care and treatment, from trained people who understand us and how dementia affects us. This must meet our needs, wherever we live.
- **We have the right to be respected, and recognised as partners in care**, provided with education, support, services, and training which enables us to plan and make decisions about the future.
- **We have the right to know about and decide if we want to be involved in research** that looks at cause, cure and care for dementia and be supported to take part.

Gove et al. *Aging & Mental Health*, 2017; Alzheimer Europe; Black et al, *AJGP, 2013;* Karlawish et al. *AJGP,* 2008

Emergent Paradigms for Decision Making and Determining Preferences

Supported Decision Making

- Individual with dynamic impairment enters freely into agreement with closely trusted person or network of supporters to assist in making informed choices
- Approaches to developing and testing alternative consent models not well established

Obtaining Perspectives on Research

- *Motivational misconceptions* – reasons for participation decisions not aligned with study risk/benefit ratio despite evidence of understanding
- *Divergent decision-making preferences* – inclusion person with dementia, dynamic
- Difficulty engaging with abstract nature of ‘research participation’ and varying ideas of what research is

Peterson, Karlawish, Largent, *American Journal of Bioethics*, 2020; Benson et al., 2020

What is Next?

Research Priorities and Opportunities

New models for decision-making

- Longitudinal planning
- Supported decision-making
- Beyond dyadic and singular decision making

Determine Preferences

- Approaches for collaborative prioritization preferred approaches for research inclusion

Clarify and Measure Sources of Exclusion

- Comparisons by institution and state policy
- Assess accountability measures

Training Needs

- Training programs, resources, guidance

Science of Engagement

- Applied recruitment science and intervention
- External measures of success

Thank you!

Contact:

algilmore@wisc.edu