STAKEHOLDER ENGAGEMENT IN ePCTs FOR PEOPLE LIVING WITH DEMENTIA

Ellen Tambor, MA
On Behalf of the Stakeholder Engagement Team
Housekeeping

• All participants will be muted

• Enter all questions in the Zoom chat box and send to everyone

• Moderator will review questions from chat box and ask them at the end

• Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.

• Visit impactcollaboratory.org

• Follow us on Twitter: @IMPACTcollab1
IMPACT Stakeholder Engagement Team (SET)

Leader
• Gary Epstein-Lubow, MD

Associate Team Leader
• Katie Maslow, MSW

Executive Committee Members
• Louise Phillips, MD
• Ellen Tambor, MA

Administrative Core Liaisons
• Susan Mitchell, MD, MPH
• Jill Harrison, PhD

Core Support
• Laurie Herndon, MSN
Agenda

• Definitions and Rationale for Stakeholder Engagement in Research

• Importance of Engagement in ePCTs

• Special Considerations for Engagement in ePCTs for AD/ADRD

• Role of Stakeholder Engagement in the IMPACT Collaboratory
Stakeholder Engagement

**Definitions***

**Stakeholder:** Responsible for or affected by health- and healthcare-related decisions

**Engagement:** Bi-directional relationship between the stakeholder and researcher

**Who to Engage**

**Patients**
- Includes advocates, family members, and family caregivers

**Clinicians**
- Clinical experts, clinician leaders, front-line clinicians (physicians, nurses and other direct care staff)

**Other Stakeholders**
- Administrators, payors, research funders, etc.

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Rationale for Engagement

**Moral/Ethical Arguments**
- Right of citizens to have a voice in the use of public funds
- Right of individuals to be involved in shaping research that pertains to them

**Pragmatic Arguments**
- Improving the quality, relevance, and usefulness of clinical research
- Increasing transparency, credibility, and trust in the clinical research enterprise

“Nothing about us, without us”
Importance of Engagement in ePCTs

• Pragmatic Clinical Trial (PCT)
  • “Designed for the primary purpose of informing decision-makers regarding the comparative balance of benefits, burdens and risks of a biomedical or behavioral health intervention at the individual or population level”*

• Embedded PCT (ePCT)
  • Pragmatic randomized clinical trials embedded in routine health care

Engagement Throughout the ePCT Life Cycle

**PLANNING the study**
- Choosing a research question
- Designing the intervention
- Selecting outcome measures
- Determining inclusion/exclusion criteria
- Determining study requirements
- Designing study protocol to minimize burden to patients and clinicians
- Promoting/supporting the study
- Drafting/reviewing study materials
- Providing resources

**CONDUCTING the study**
- Developing recruitment strategies
- Promoting and assessing compliance with study requirements
- Serving as study champions
- Assisting with retention strategies
- Solving problems/removing barriers
- Considering privacy and data sharing issues
- Advising on analyses
- Interpreting study results

**DISSEMINATING the results**
- Determining key messages for different stakeholder groups
- Identifying avenues for dissemination
- Assisting with development of manuscripts and other dissemination materials
- Sharing findings via professional networks and social media
- Supporting implementation or de-implementation of intervention
- Considering changes to policies and guidelines

Stakeholder Engagement in ePCTs for AD/ADRD

Special Considerations for Engaging:

- People living with dementia (PLWD) and their family caregivers
- Healthcare system stakeholders
Special Considerations for Engaging PLWD

**Matching Capacity**
- Cognitive symptoms
- Strengths and preferences
- Familiarity with research
- Symptom progression

**Accommodating Heterogeneity**
- Range in disease severity
- Race/ethnicity
- Socioeconomic status
- Geography

**Engagement Approaches**
- Flexibility
- Preparation and support
- Meeting logistics
- Timelines

**Engaging Caregivers**
- Caregiver burden
- Caregivers as proxy respondents
- Caregivers as independent stakeholders

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NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE
Diverse Care Settings
• Hospital
• Nursing Home
• Adult Day Center
• In-Home Care

Clinician and Other Care Provider Burden
• Complex care needs of PLWD
• Shortage of dementia-capable work force
• Staff turnover
• Nursing home crises (COVID-19)

Diverse Professional Roles
• Physician
• Nurse
• Medical/Nursing Assistant
• Physical Therapist
• Occupational Therapist
Stakeholder Engagement in the IMPACT Collaboratory

**Stakeholder Engagement Team**

- Stakeholder Advisory Committee
- Lived Experience Panel Alzheimer’s Association

**Pilot Study Process**

- Pre-Proposal
  - Priority topics
  - Engagement guidance and resources
- Proposal
  - Investigator assistance
  - Proposal review
- Funded Pilots
  - Tools
  - Consultation

**Why**

To ensure:
- Relevant topics & outcomes
- Appropriate study design
- Feasible study protocol
- Successful protocol implementation
- Widespread dissemination of effective interventions

**Who**

- People living with dementia (PLWD)
- Family members
- Caregivers
- Providers
- Direct Care Staff
- Administrators
- Payors
- Other

**How**

Using existing best practices for:
- Meaningful stakeholder engagement
- Engaging PLWD in research
- Stakeholder engagement in PCTs

Evaluation
### Stakeholder Advisory Committee

**Role:**
Advise the IMPACT Collaboratory about stakeholder engagement activities, strategies to assist investigators with stakeholder engagement, and priority topics for the development of guidance materials.

| **Membership:** |
|-----------------|-----------------|
| • People living with dementia (2) | • Leading Age |
| • Alzheimer’s Association | • AARP |
| • National Alliance for Caregiving | • AMDA: Society for Post-Acute and Long-Term Care Medicine |
| • LEAD Coalition | • American Geriatrics Society |
| • Association for Frontotemporal Degeneration | • Centers for Medicare and Medicaid Services |
| • Lewy Body Dementia Association | • Veterans Administration |
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Stakeholder Engagement in Pilot Studies

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Lived Experience Panel

Collaboration between IMPACT Collaboratory (PCRO and SET) and the Alzheimer’s Association (AA)

Role:

● Reflect on outcomes and relevance of pilot studies
● Identify high priority outcomes and gaps
● Review written documents

Panel Composition:

● 4 - Individuals living with a diagnosis of early stage Alzheimer’s, Mild Cognitive Impairment (MCI) or other dementia
● 4 - Care partners/caregivers of an individual living with dementia
● 4 - Caregivers/family members who can represent the perspective of one or more individuals living in the middle or late stage
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Other Cores
- Pilot Studies Core
- HCS Core
- PCRO Core
- Training Core
- Health Equity Team
Topic Prioritization

2017 National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers

• Persons Living with Dementia Stakeholder Group “Top 6 Outcomes that Matter”

1. Psychosocial care practices and behavioral strategies to address problematic symptoms
2. Person-centered approaches to assessment and care planning
3. Tailored resources and models of coordinated care
4. Implications for use of the term “cognitive impairment” or “cognitive disorder” instead of “dementia”
5. Implications on advocacy, stigma and reported prevalence rates as a result of consolidating disease names of all memory disorders
6. Implications of financial burden on diagnosis, treatment, and research participation

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RAPT Model

Readiness Assessment for Pragmatic Trials

Baier, Jutkowitz, Mitchell, McCready and Mor, 2019
RAPT Model
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Baier, Jutkowitz, Mitchell, McCreedy and Mor, 2019
RAPT Model
Readiness Assessment for Pragmatic Trials

Impact
How useful will the results be?

Evidence
To what extent does the evidence base support efficacy?

Alignment
To what extent does the intervention align with external stakeholders’ priorities?

Risk
Is it known how safe the intervention is?

Acceptability
How willing are providers likely to be to adopt the intervention?

Feasibility
To what extent can the intervention be implemented under existing conditions?

Cost
How likely is the intervention to be economically viable?

Measurement
To what extent can outcomes be captured?

Providers
Direct Care Staff
Administrators

Baier, Jutkowitz, Mitchell, McCreedy and Mor, 2019
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Questions?