Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum

Pre-Release Public Forum

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Purpose of today’s forum

• Present the background, framework, and study considerations of the Healthy Aging Targeted PCORI Funding Announcement (PFA)
• Answer questions about overall study considerations
  • If you have a general question about the PFA, please write it in the chat
  • If you have specific questions about your own application, please reach out to the PCORI HelpDesk (sciencequestions@pcori.org). Put “Healthy Aging” in the title
• Provide key dates for the PFA
Housekeeping items

- Today’s preannouncement forum provides preliminary insights into the PFA. However, the requirements for the study will be finalized in the PFA released Sept 7, 2021
- This forum is being recorded
- These slides and a recording of today’s webinar will be available on the PCORI website under the meetings and events tab for this Forum
- FAQs will be available at a later date
Background

• Current healthcare system not well-equipped to address the complex care needs of older adults and their caregivers

• PCORI’s Board of Governors has approved a funding announcement on Healthy Aging that would invite applications for comparative effectiveness research (CER) at different phases of the aging continuum

• This funding announcement was informed by extensive input from our stakeholders, e.g., clinicians, payors, patients/advocates, researchers, funders, healthcare systems
Framework for Healthy Aging Funding Announcement

Interventions Optimizing Physical and Mental Functioning Across the Aging Continuum

The Aging Continuum

Maintain Function & Independence
- Healthy/1 or 2 well-managed chronic conditions
- Goal: stay healthy, prevent progression of condition

Manage Chronic Conditions
- Chronic/multiple chronic conditions sub-optimally managed
- Goal: slow/reverse progression of conditions

Support for Significant Functional Impairment
- At higher risk of adverse events
- Goal: Stabilize condition and maintain quality of life

Caregiving Across the Continuum
Four primary research questions

• What are the most effective approaches to maintaining function and independence among older adults living in the community across different phases of the aging continuum?

• What are the most effective approaches to facilitating management of chronic/multiple chronic conditions among older adults living in the community?

• What are the most effective approaches to supporting older adults in the community with significant functional (physical and/or cognitive) impairment to maintain their quality of life?

• What are the most effective approaches to reducing caregiver stress and improving quality of life of caregivers caring for older adults across different phases of the aging continuum?
Study Considerations: Target Population

- Older adults (in the domains below) & their caregivers
  - Community-dwelling participants: regular housing, assisted living, senior housing
  - Younger, non-Medicare eligible, populations considered w/justification
  - Groups benefiting from health equity approach, e.g., rural-dwelling, low income, racial/ethnic groups, individuals with low health literacy, limited English proficiency, or living in unstable circumstances, etc.
  - **Note**: Strongly encouraging large studies targeting diverse study population with broadly applicable interventions powered for heterogeneity of treatment effects (HTE) analyses

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**Manage Chronic Conditions**
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**Support for Significant Functional Impairment**
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Study Considerations: Target Population (cont.)

- Older adults (in the domains below) & their caregivers
  - Caregivers: family members or close friends serving as the primary caregiver or caregivers to an older adult
  - Inclusion of caregivers is strongly recommended for the first two domains and required for the third domain

**Maintain Function & Independence**
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Caregiving Across the Continuum
Study Considerations: Study Design

- Individual or cluster randomized controlled trials
- Natural experiments
- Studies with implementation component will help with dissemination and widespread adoption of effective interventions
  - Hybrid Type 1 or 2 designs
  - Mixed methods
- **Note**: Proposals need to adhere to PCORI’s methodology [standards](#)
Study Considerations: Interventions/Comparators

• The comparison proposed must address a critical decisional dilemma and an evidence gap
  • Justify that the comparators are the critical ones in the current context of older adult/caregiver needs
  • Needs evidence of prior efficacy or have documentation of widespread use
  • One comparator can be usual care, but must be exceptionally well-justified and described
Research question domains and example interventions

- Physical activity
- Multicomponent interventions (physical activity, nutrition, occupational therapy, behavioral interventions, etc.)
- Social support
Research question domains and example interventions

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- Care coordination models
- Care models leveraging technology
- Polypharmacy
Research question domains and example interventions

- Care delivery models integrating clinical and community-based services
- Models of long-term services and supports

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The Aging Continuum

Support for Significant Functional Impairment

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Research question domains and example interventions

Interventions Optimizing Physical and Mental Functioning Across the Aging Continuum

Caregiving Across the Continuum

• Caregiver training and education interventions (dyadic shared-decision models, care coordination, practical hands-on skills training)
• Supportive Interventions (e.g., well-being and resilience, integrated family support, stress management)

• Note: Strongly encouraging studies that look at patient-caregiver family units or family-centered interventions and are powered for both individual- and family-level outcomes
• Note: Domains 2 and 3 can test interventions that include formal/paid caregivers, in addition to caregivers as defined
Study Considerations: Setting/Outcomes

• **Settings**
  - Primary and specialty care clinics, home, and community settings such as assisted living, senior housing, retirement facilities, adult day care centers
  - Multisite studies required in order to support widespread implementation of effective interventions
  - Should not be exclusively delivered in institutional settings

• **Example outcomes:**
  - Physical function measures (Activities of Daily Living, Mobility);
  - Mental health measures (Depression, Anxiety, Social isolation, Cognitive function);
  - Quality of life & Caregiver stress/burden;
  - Delay to institutionalization & Healthcare utilization;
  - Additional clinical measures (e.g., blood pressure control, antipsychotic use)
Study Considerations: Patient-Centeredness and Patient Engagement

**Patient-Centeredness**
- Addresses questions and outcomes that are important to patients
- The interventions proposed for comparison are currently available or can be made available if the study results are positive
- Study design is low-burden to participants

**Patient and Stakeholder Engagement**
- Patients and stakeholders are partners in research, not only “subjects”
- Incorporates the expertise of patients, clinicians and other stakeholders for the purpose of improving the study design, conduct and analysis
- Range of engagement approaches: Input, Consultation, Collaboration, Shared leadership
- Can occur by building upon existing relationships, or developing new ones
Funding/Budget

- Total PCORI commitment of $50M
- Maximum direct cost per study: $5M
- Study duration: up to 5 years dependent on study design
Summary of takeaway points

• Strong review of the evidence gap and justification for selected comparators
• Detailed explanation of the key decisional dilemma
• Stakeholder engagement in all aspects of study design and research question
• Multisite settings
Key Dates

• Online system opens
  • September 7, 2021

• Applicant Town Hall Session
  • September 13, 2021; 12 pm ET

• Letter of intent (LOI) deadline
  • October 5, 2021 by 5pm ET

• Application deadline
  • January 11, 2022 by 5pm ET

• Merit review
  • April 2022

• Awards announced
  • July 2022
Questions?

sciencequestions@pcori.org