

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

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Pre-Release Public Forum

Vivian Towe, Program Officer  
Tabassum Majid, Program Officer  
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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](mailto: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

Healthiest Older Adults

#### 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

End of Life Care

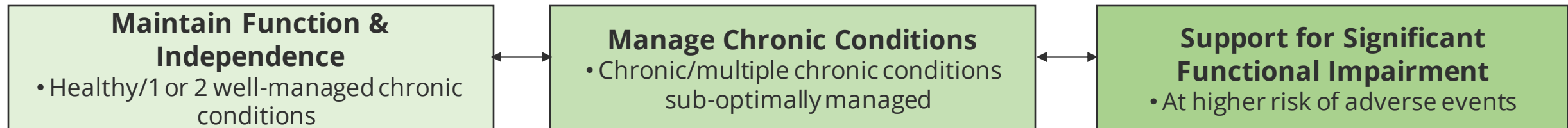
### Caregiving Across the Continuum

# 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

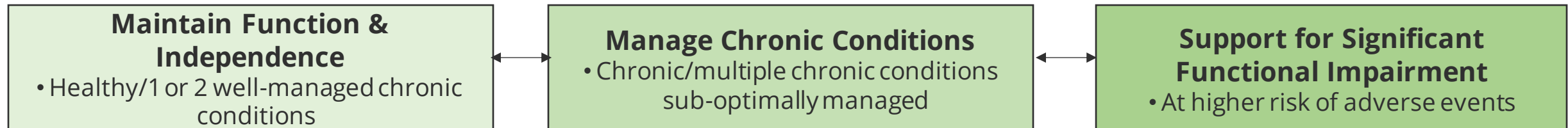
- Older adults (in the domains below) & their caregivers
  - Community-dwelling participants: regular housing, assisted living, senior housing
  - Younger, non-Medicare eligible, populations considered w/justification
  - Groups benefiting from health equity approach, e.g., rural-dwelling, low income, 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



# 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



**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

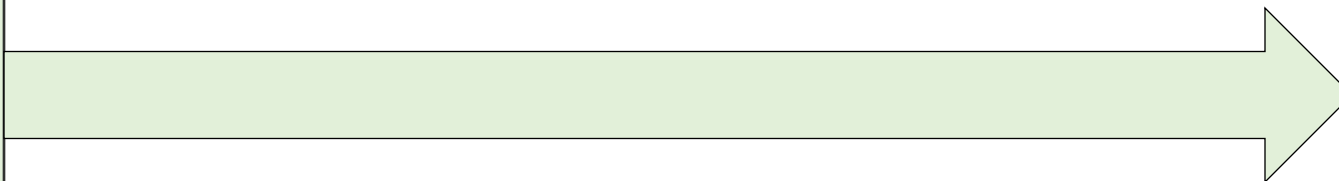
# Research question domains and example interventions

## 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



- Physical activity
- Multicomponent interventions (physical activity, nutrition, occupational therapy, behavioral interventions, etc.)
- Social support

# Research question domains and example interventions

## Interventions Optimizing Physical and Mental Functioning Across the Aging Continuum

### The Aging Continuum

#### Manage Chronic Conditions

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

- Care coordination models
- Care models leveraging technology
- Polypharmacy

# Research question domains and example interventions

## Interventions Optimizing Physical and Mental Functioning Across the Aging Continuum

### The Aging Continuum

#### Support for Significant Functional Impairment

- At higher risk of adverse events
- Goal: Stabilize condition and maintain quality of life

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

# 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?

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[sciencequestions@pcori.org](mailto:sciencequestions@pcori.org)

