

# A Patient-Centered Approach to Comparative Effectiveness Research Focused on Older Adults: Lessons From the Patient-Centered Outcomes Research Institute

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**ABSTRACT:** The mission of the Patient-Centered Outcomes Research Institute (PCORI) is to fund the production of high-quality evidence that will enable patients and clinicians to make informed, personalized healthcare decisions. Since 2012, the PCORI has invested \$177 million in patient-centered comparative effectiveness research (CER) that specifically targets the health needs of older adults, with additional relevant studies in its broader portfolio. Developing the PCORI's research portfolio has provided us with significant insights into what factors to consider when conducting CER in older adult populations. When comparing the net benefit of two or more interventions for older adults, investigators should consider the following: absolute risk difference, competing risks, life expectancy, the difference between chronologic and physiologic age, the importance of patient preferences, and other potential drivers of variable treatment effects. Investigators should also engage older adults and their caregivers as partners throughout the research process. Their input helps to identify key outcomes of interest and insights about the conduct of the research. As the PCORI continues to support research that addresses the healthcare decisions of the rapidly growing older adult population, it needs to partner with patients and researchers to identify the most important questions to address. *J Am Geriatr Soc* 67:21–28, 2019.

**Key words:** comparative effectiveness research; patient-centered outcomes research; geriatrics; older adults; treatment response heterogeneity

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## INTRODUCTION

The theme of this article is framing patient-centered comparative effectiveness research (CER) on health problems of older people. By patient-centered research, we mean the generation of evidence that helps clinicians and patients to choose a test or treatment that is tailored to the patient's needs and preferences. Accordingly, the article focuses on research approaches that provide strong evidence to inform individualized healthcare choices by older people and their clinicians.

The article begins with an introduction to the Patient-Centered Outcomes Research Institute (PCORI) and its portfolio of geriatric research. The middle section focuses on patient-level factors that drive differing treatment effects, each discussed in the context of the needs of older persons. The last section is about choosing outcome measures that best suit the preferences of older persons and how the PCORI engages older stakeholders in designing research that meets their needs. To illustrate some of these points, we present examples from the PCORI's current portfolio.

## The PCORI and Its Portfolio of Geriatrics Research

The PCORI is the first publicly supported funding organization whose primary mission is to fund clinical CER that examines clinical effectiveness, risks, and benefits of two or more medical treatments, services, or strategies used in diagnosis, treatment, management, and/or prevention of illness or injury.<sup>1</sup> The purposes of CER were articulated by the PCORI's legislative authorization<sup>1</sup> and by the Institute of Medicine (now the National Academy of Medicine).<sup>2,3</sup> The PCORI's Board of Governors focused the organization's mission on CER that is patient centered, and the PCORI has been a leader in the movement to involve patients and other stakeholders in developing its portfolio of CER.

The PCORI's research priorities, as established by its Board of Governors, address health disparities, improving health systems, communication and dissemination, methods, and interventions to assess, prevent, diagnose, and treat clinical conditions. Since 2012, the PCORI has funded \$1.7 billion in research that addresses these

priorities, particularly patient-centered clinical CER and approaches to improve the delivery of patient-centered care.

The PCORI has positioned itself to support important research that addresses the needs of older adults. The PCORI already has substantial experience in funding geriatrics research, with \$177 million (39 projects; 10% of \$1.7 billion total funding) awarded to date in research clearly targeting common geriatric conditions (eg, falls) or focused on older adult and Medicare populations. The PCORI's diverse "geriatrics portfolio" targets cancer (six projects), musculoskeletal diseases (six projects), mental illness, neurological diseases, and multiple comorbid conditions (four projects each). Other disease categories have one or two projects, and seven projects do not target a specific disease, but address problems experienced with many diseases, such as care transitions (Appendix Table).

Approximately two thirds of the PCORI's \$177 million investment addresses clinical comparative effectiveness questions (Appendix Table). Table 1 depicts two such in-process studies. In study 1-A, the PCORI together with the National Institute on Aging funded a \$30 million randomized trial comparing a multifactorial strategy for reducing the risk of serious falls and fall-related injuries to enhanced usual care among 5300 older adults at increased risk for serious falls. Study 1-B compares the effectiveness of different medication strategies for treatment-resistant depression in older adults.

The other one third of the PCORI's geriatrics-focused funding are studies of methods for making the delivery and/or organization of clinical care for older adults more effective and more patient centered. Our premise is that enhancing care delivery should lead to better clinical outcomes. These projects address shared decision making, care coordination and transitions, navigating the patient care system, palliative care and advance care planning, and home-based care delivery. Table 1 depicts two such studies. Study 1-C compares strategies to improve care coordination and self-management support for older people with asthma. Study 1-D compares the use of community-based patient advocates to usual care for supporting chronically ill older adults' transition from the emergency department to home.

Additional studies in the PCORI portfolio also address problems that affect adults of all ages (searchable on the PCORI's website at [https://www.pcori.org/research-results?f%5B0%5D=field\\_project\\_type%3A2984](https://www.pcori.org/research-results?f%5B0%5D=field_project_type%3A2984)) and complement the specific geriatrics portfolio described herein. As with other PCORI awards, the topics in our geriatrics portfolio were driven by the interests of individual investigators and PCORI stakeholders. To maximize the PCORI's contribution, the field of geriatrics and the community it serves should continue to take advantage of the PCORI's open invitation to stakeholders to tell us their needs for additional CER.

Simply focusing on specific clinical issues associated with aging or including older adults in research is not sufficient for generating the evidence to support individualized care. Table 2 outlines major strategies for conducting patient-centered CER. The next section details patient factors that can lead to differing effects from the same treatment and how these factors affect both research and clinical considerations in older adults. The following section discusses outcomes from the perspective of older

adults. The last section addresses a novel research strategy, one for which the PCORI has been a leader: involving patients and other stakeholders in the design and conduct of healthcare research.

### Healthcare Decision Making for Older Adults: How Individual Characteristics and Preferences Drive Treatment Choices and Net Benefit

Clinicians, older patients and their caregivers, and policy makers regularly face decisions about health and healthcare. The backbone of decision making in medicine is an assessment of the expected benefits, harms, and, ultimately, net benefit of the interventions for the individual. This assessment of benefits and harms should include the patient's feelings about the future health states that he or she may experience. Clinicians intuitively grasp that patients will vary in their response to treatments (heterogeneity of treatment effect), but the search for the factors that drive response has only recently begun in earnest.<sup>5</sup> In the PCORI's legislative mandate, Congress stipulated that the PCORI shall produce evidence about differences in comparative effectiveness in subpopulations and individuals;<sup>1</sup> this mandate is particularly important for research addressing older adults, who are a highly varied population. In a large community-based sample of older patients with heart failure, for example, the presence of any functional limitations greatly increased risk for death and other major adverse outcomes, particularly in the presence of two or more noncardiovascular comorbidities; however, 25% of patients with heart failure had neither multimorbidity nor functional limitations.<sup>6</sup>

Patient-level sources of differing effects from the same treatments can be considered under four main areas: baseline risk, treatment responsiveness and harms, competing risks, and patient preferences for health states.<sup>7</sup> These factors are based on individual characteristics and vulnerabilities<sup>8</sup> that commonly differ between younger and older adults and among older adults. We cover these each in turn briefly, with illustrative examples in Table 2.

#### Baseline Risk

The baseline risk of a disease drives treatment choice. Baseline risk reflects the pretreatment risk of experiencing the outcome the treatment intends to prevent.<sup>7</sup> Baseline risk already informs common treatment choices, such as therapies to prevent cardiovascular disease,<sup>9</sup> in which age plus risk factors predict 10-year cardiovascular event rates ranging from less than 2.5% to 20.0% or greater;<sup>10</sup> baseline risk could better inform other treatment choices if more consistently considered and reported in research,<sup>11</sup> as recommended.<sup>12</sup>

- The benefit of an intervention is often expressed as the relative risk (the ratio of benefits for treatment A to the benefits for treatment B), but absolute risk difference is usually more informative.<sup>8</sup> For example, the absolute risk difference (the mortality rate after treatment A minus the mortality rate after treatment B) describes a tangible result: the percentage reduction in outcome rates. Even when relative treatment effects are consistent across subgroups (ie, there is no statistical heterogeneity of treatment effect,<sup>13</sup> absolute treatment effects will differ among subgroups with meaningful differences in their

**Table 1. Selected PCORI Studies That Focus on the Needs of Older Adults**

Variable	Falls Prevention	Depression	Asthma Care	Hospital Use
Study title (PI name)	Randomized Trial of a Multifactorial Fall Injury Prevention Strategy: A Joint Initiative of PCORI and the National Institute on Aging (Shalender Bhasin, MD)	Optimizing Outcomes in Treatment-Resistant Depression in Older Adults (Eric Lenze, MD)	Clinic-Based vs. Home-Based Support to Improve Care and Outcomes for Older Asthmatics (Alex Federman, MD, MPH)	An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use (Donna Carden, MD)
Study ID <sup>a</sup>	1-A	1-B	1-C	1-D
Study purpose	To compare a multifactorial fall injury prevention intervention with enhanced usual care for reducing the risk of serious fall injuries among noninstitutionalized older adults.	To compare the benefits and risks of different antidepressant strategies (augmentation and switching drugs) among older adults.	To compare a clinic-based asthma care coach with a home-based community health worker coach with usual care for improving asthma-related outcomes among older adults.	To compare use of trained community-based patient advocates with usual post-ED care for improving outcomes after ED discharge.
Study population	Community-living persons ≥75 y who are at increased risk for serious fall injuries	Adults ≥60 y with major depressive disorder resistant to two or more antidepressant trials	African American or Hispanic/Latino adults ≥60 y who have poorly controlled asthma	Medicare fee-for-service beneficiaries with one or more chronic conditions
Interventions	Multifactorial fall injury prevention intervention: risk assessments, individualized fall care plans that address identified risk factors, and ongoing monitoring. Enhanced usual care: patients discuss booklet on falls with primary care provider.	Step 1 strategies: ADM + aripiprazole (augmentation), ADM + bupropion (augmentation), or switch from ADM to bupropion. Participants resistant to step 1 will be randomized to step 2: augment with lithium or switch to nortriptyline.	Routine PCP care + a community health worker work to support and coordinate patient care in their home. Routine PCP care + an asthma care coach for patient care in clinic. Usual care: routine PCP care without any additional care coordination or support provided.	ED-to-home transition intervention: home visit and telephone calls with a trained, community-based patient advocate who will help patients to attend follow-up physician visits, respond to signs of worsening disease, address medication concerns, and communicate with healthcare providers.
Out comes	Serious falls, fall injuries, concerns about falling, physical function and disability, anxiety/depressive symptoms, hospitalizations, nursing home admissions, and death	Psychological well-being, remission from depression, serious adverse events, falls and fall-related injuries, physical function, and social participation	Asthma control, quality of life, resource use, medication adherence, self-management behaviors, ability to conduct daily activities, and patient and caregiver satisfaction with care	Health-related quality of life (health status, satisfaction with care, physical function, and social and emotional health), ED visits, hospital admissions, ability of patients to make decisions about their health and healthcare

Abbreviations: ADM, antidepressant medication; ED, emergency department; ID, identification; PCORI, Patient-Centered Outcomes Research Institute; PCP, primary care provider; PI, principal investigator.

<sup>a</sup>The study ID is a code that appears next to text that refers to an example study described in a table. It enables the reader to find the detailed information to which the body of the text refers.

Study 1-A is available at <https://www.pcori.org/research-results/2014/preventing-serious-falls-among-older-adults-project-supported-pcori-and>; study 1-B is available at

<https://www.pcori.org/research-results/2016/comparing-treatments-older-adults-who-have-major-depression-does-not-respond>; study 1-C is available at <https://www.pcori.org/research-results/2013/comparing-two-ways-offering-treatment-older-adults-asthma-samba-study>; and study 1-D is available at

<https://www.pcori.org/research-results/2013/emergency-department-home-intervention-improve-quality-life-and-reduce>.

baseline outcome risk.<sup>5</sup> Recent meta-research suggests baseline outcome risk varies substantially in trials among selected candidates for pharmaceutical treatment.<sup>14</sup>

Risk for many diseases increases with age, and so absolute treatment benefit may also increase, and inform age-specific comparative effectiveness. For some years, cardiac surgery was deemed less effective in older people because

survival rates after coronary revascularization were considerably lower in older people. However, because survival rates of comparable older people with medical therapy were even lower relative to younger people, the difference in mortality rates after treatment (absolute risk difference for surgery vs medical therapy) was larger after treatment of older people than younger people.<sup>15</sup> Although age is a prominent risk factor for cardiovascular disease, among older adults, other risk

**Table 2. Strategies for Conducting Effective, Patient-Centered CER in Older Adult Patient Populations**

Strategies	Study ID <sup>a</sup>	Examples From the PCORI's Geriatrics Portfolio
Focus on conditions and/or clinical dilemmas that disproportionately or exclusively affect older adults	N/A	The PCORI's geriatrics portfolio includes many projects studying conditions or health topics that affect the health of older adults, such as falls, frailty, cognitive impairment, multiple chronic/comorbid conditions, communication and medical decision making, and palliative care.
Effectively engage older adults throughout the research process: hypothesis generation, study design, conduct of the study, data analysis, and dissemination of results	N/A	Refer to example studies in Table 3.
Include and engage caregivers of older adults throughout the research process	2-C	Example study: Improving Communication for Chemotherapy: Addressing Concerns of Older Cancer Patients and Caregivers (Supriya Mohile, MD, MS): caregivers provided significant input at all stages of this study's preliminary work, including helping to develop the geriatric assessment intervention and choose outcomes for the study. Patients and caregivers were both part of the study population, and caregiver satisfaction and burden were among the secondary outcomes being assessed.
Effectively target interventions for older adults by considering the following: <ul style="list-style-type: none"> <li>• Drivers of differing treatment effects (baseline risk, treatment responsiveness, treatment harm, and competing risks)</li> <li>• Importance of net benefit (ie, balance of benefits and harms)</li> <li>• Values and preferences of older adults</li> <li>• Difference between chronologic and biologic age</li> </ul>	2-D	Example study: Patient Valued Comparative Effectiveness of Corticosteroids Versus Anti-TNF Alpha Therapy for Inflammatory Bowel Disease (James Lewis, MD) <sup>2-D</sup> : this study compared the benefit-harm profiles of anti-TNF agents and corticosteroids for the treatment of inflammatory bowel diseases. By measuring both the benefits (reduced need for bowel resection surgery) and harms (serious infections and short-term mortality risks) of each therapy and by using patient preference weights for each outcome, this study could compare each therapy's net benefit (J Lewis, unpublished data, <a href="https://clinicaltrials.gov/ct2/show/NCT02316678">https://clinicaltrials.gov/ct2/show/NCT02316678</a> , 2012).
	2-E	Example study: Preparing Spanish-Speaking Older Adults for Advance Care Planning and Medical Decision Making (Rebecca Sudore, MD): this study was based on the key difference between chronologic and biologic age. The investigators chose to recruit older adult patients with a lower minimum age (55 y) than the traditional 65-y age limit because they recognized that adults in safety net settings (low socioeconomic status) experience accelerated aging, functional decline, and sequelae of chronic disease. <sup>9,10</sup>
Adapt study design to incorporate older adults' values and preferences, include broad, real-world older adult population and robust HTE analyses, and include longer length of follow-up (than typical trials) to adequately capture safety/adverse event outcomes	2-F	Example study: Comparative Effectiveness of Behavioral Interventions to Prevent or Delay Dementia (Glenn Smith, PhD): this study's broad inclusion criteria help to ensure a study population that represents a real-world population of patients with amnesic mild cognitive impairment. The investigators are planning to explore potential heterogeneity of treatment effects by assessing interactions between treatments and age, along with other baseline demographic variables.
Ensure study outcomes account for the importance of harms, baseline risk, both relative and absolute harms and benefits, provider-patient communication, and relevant patient-centered outcomes (eg, quality of life, functional ability, independence, and time at home)	2-G	Example study: A Practical Intervention to Improve Patient-Centered Outcomes After Hip Fractures Among Older Adults (REGAIN Trial) (Mark Neuman, MD, MS): the outcomes of this study include ability to walk (primary outcome), ability to live at home independently, overall health and disability, pain, mortality, and safety and tolerability outcomes (acute postoperative pain, satisfaction with care, and major adverse events during hospitalization).

Abbreviations: CER, comparative effectiveness research; HTE ; ID, identification; N/A, not applicable; PCORI, Patient-Centered Outcomes Research Institute; TNF, tumor necrosis factor.

<sup>a</sup>The study ID is a code that appears next to text that refers to an example study described in a table. It enables the reader to find the detailed information to which the body of the text refers.

Study 2-C is available at <https://www.pcori.org/research-results/2013/improving-communication-chemotherapy-addressing-concerns-older-cancer-patients>

study 2-D is available at <https://www.pcori.org/research-results/2013/anti-tnf-drugs-versus-long-term-steroid-use-patients-inflammatory-bowel>

study 2-E is available at <https://www.pcori.org/research-results/2013/preparing-spanish-speaking-older-adults-advance-care-planning-and-medical>

study 2-F is available at <https://www.pcori.org/research-results/2013/comparative-effectiveness-behavioral-interventions-prevent-or-delay-dementia>; and study

2-G is available at

<https://www.pcori.org/research-results/2015/comparing-how-two-types-anesthesia-affect-recovery-hip-fracture-surgery-regain>.

**Table 3. The PCORI Geriatrics Portfolio: Engagement of Older Adults and Their Caregivers in CER<sup>a</sup>**

Study	Group Exercise for Older Adults (3-A)	Navigating High-Risk Surgery (3-B)
Title	On the Move: Optimizing Participation in Group Exercise to Prevent Walking Difficulty in At-Risk Older Adults (Jennifer Brach, PhD) <sup>28</sup>	Navigating High Risk Surgery: Empowering Older Adults to Ask Questions That Inform Decisions About Surgical Treatment (Margaret Schwarze, MD, MPP) <sup>29</sup>
Study period	2013–2017	2015–2020
Engagement activities	Community-dwelling older adults and providers were involved throughout the research process, including preparation, execution, analysis, and dissemination phases.	A PFAC, surgeons, and community members met monthly and were involved in identifying the research question, developing the intervention, and executing the research project.
Impact on study design	<ul style="list-style-type: none"> <li>• New aim examining the sustainability of the intervention was added thanks to providers' feedback.</li> <li>• Older adults' preferences influenced the randomization scheme.</li> <li>• Inclusion/exclusion criteria were made more inclusive thanks to providers' feedback.</li> <li>• Focus groups of adults helped develop the exercise intervention.</li> </ul>	The PFAC identified the need for more information and decisional support during preoperative conversations. The PFAC stressed the importance of including family members as study participants. The PFAC, surgeons, and focus groups of community members helped design and revise the question prompt list intervention to specifically target the needs of patients considering high-risk surgery.
Impact on study outcomes	During focus groups, older adults identified maintaining independence as a key outcome. Investigators subsequently designated function, disability, and mobility as their three primary outcomes.	The PFAC helped identify impractical measures for patients to answer over the telephone, helped identify those outcomes that were relevant to patients and families, and stressed the need not to be "blindsided" by the outcomes of surgery. Outcomes included in the study were as follows: (1) patient engagement in decision making and (2) psychological well-being.

Abbreviations: CER, comparative effectiveness research; PCORI, Patient-Centered Outcomes Research Institute; PFAC, Patient and Family Advisory Council. <sup>a</sup>The study ID is a code that appears next to text that refers to an example study described in a table. It enables the reader to find the detailed information to which the body of the text refers.

Study 3-A is available at <https://www.pcori.org/research-results/2013/comparing-two-types-group-exercise-classes-help-older-adults-improve-walking>; and study 3-B is available at <https://www.pcori.org/research-results/2015/navigating-high-risk-surgery-empowering-older-adults-ask-questions-inform>.

factors have stronger relative effects and thus the absolute risk for cardiovascular disease varies widely.<sup>16</sup> Another advantage of absolute risk difference for clinicians is its easy translation to a number that implies the effort or exposure needed to achieve an outcome (eg, number needed to treat or number needed to harm), because the reciprocal of the absolute risk difference is the number of people exposed to an intervention to produce one person's outcome.

### ***Treatment Responsiveness and Vulnerability to Treatment Harms***

Net treatment benefit (benefits minus harms) should drive decision making. Therefore, even with a larger absolute benefit based on greater pretreatment risk, the desirability of a treatment is also affected by its absolute harms. For example, risk of gastrointestinal tract bleeding, which varies widely based on age, sex, and medical history,<sup>17</sup> influences the desirability of chemoprevention with aspirin.<sup>18</sup> Treatment harms may be more likely in older adults because of comorbidities and common use of multiple medications. Similarly, the magnitude of benefit (also known as treatment responsiveness) may vary in older adults because of differences in body composition (percentage body water), in function (balance or strength), or in other physiological factors (frailty) whose effects may require direct evidence in older adults rather than extrapolation from evidence in younger individuals.<sup>19,20</sup>

Study 2-D in Table 2 illustrates how investigators study benefits, harms, and net benefit from interventions.

### ***Competing Risks***

Competing risks may affect treatment choices. Competing risks from other disease processes can prevent an individual from experiencing the expected benefit from treatment. Screening for cancer illustrates this point; the mortality benefits of screening typically do not appear for several years after starting regular screening, during which time the patient may succumb from disease or injury.

Older individuals typically have more than one chronic disease, making competing risks important to factor into research and critical when choosing among comparative treatments.<sup>7</sup> The time horizon for achieving benefits or avoiding harms becomes important in treatment choices for older adults, so time-to-benefit analyses can be informative. Measuring the impact of common competing risks for a variety of decision dilemmas would be an important geriatrics research agenda.

Competing risks include considerations of life expectancy. Life expectancy (approximated by the inverse of the annual mortality rate) goes steadily down as a person gets older, but also shows wide variability among those of the same chronological age.<sup>21</sup> With advancing age, differences in life expectancy due to differences in health status become larger.<sup>22</sup> Therefore, expected net benefits (benefits minus

harms) of two interventions that differ based on post-intervention life expectancy are more prominent in comparative effectiveness decisions in older adults than in younger people. One way to compare the benefits of two interventions is to measure the life-years gained from the interventions. Comparing the likelihood that an older person will live long enough to benefit from the intervention (life expectancy after the intervention), while also considering the probability of experiencing adverse effects in the interim, can inform a decision between treatment choices for an individual patient.

In the future, one imagines that clinical practices and guidelines, such as those about when to stop screening, will become more nuanced and attuned to a person's life expectancy, which is longer for people in excellent health than for those in poor health, regardless of chronological age.<sup>22</sup> Study 2-E (Table 2) exemplifies how considering physiologic age instead of chronological age led one investigator to lower the inclusion criteria for a study of vulnerable older people from 65 to 55 years.

### *Patients' Preferences for Future Health States*

Although patients' preferences are important throughout all ages and healthcare choices, they are particularly important for older adults who seek to maintain their quality of life despite age-related deterioration. Life expectancy per se (a simple quantitative estimate of years of life remaining) does not reflect the value that people would place on the health states that they could experience in their remaining years. As a concrete example, prostate cancer screening trialists found that some patients' values for the adverse effects of prostate cancer treatment (sexual dysfunction, urinary incontinence, and bowel dysfunction) would decrease the expectation of life in good health after screening because screening led to health states that they especially wanted to avoid.<sup>23,24</sup> Health professionals participating in decision making with older adults and their caregivers must be sure that the conversation includes feelings about experiencing present and future health states (Table 3). Study 2-D in Table 2 illustrates how investigators integrate patient preferences into an assessment of net benefit from treatments with agents that have serious adverse effects.

These key considerations—baseline risk, the net benefit of treatment, competing risks, and patients' preferences for present and future health states—taken together with increasing life expectancy and healthy lifestyles in older people present funders with substantial opportunities. The PCORI and other funders can seize these opportunities by commissioning PCOR and CER that directly inform the healthcare decisions of older people—especially the rapidly growing group older than 80 years.<sup>25</sup> Accordingly, the PCORI's research framework includes a commitment to involving patients in the design and conduct of research, in addition to a requirement to test for treatment response heterogeneity.

### **Engaging Older Adults and Their Caregivers Throughout the Research Process**

Engaging patients, caregivers, and other interested stakeholders throughout the research process is a core tenet of the PCORI's mission. Stakeholders do drive PCORI-funded

research, from the identification and prioritization of research topics to the design and conduct of individual studies. We hope that meaningful stakeholder engagement in the research process will improve the relevance of research questions, increase the transparency of the research process, and accelerate the adoption of research findings into everyday practice.<sup>26</sup> In a recent example, community members helped ensure broad participation by older adults in research to determine barriers to help seeking, and these participants also suggested patient-centered strategies to overcome these barriers to safely support aging in place.<sup>27</sup> The PCORI believes that involving older adults and their caregivers in every phase of the research process is crucial to conducting CER that will ultimately lead to healthier older adults (Table 3). Caregivers and family members are an important target of PCORI-funded research in their roles as patient advocates, as support systems, and, at times, as surrogate decision makers for older adults with cognitive impairment.<sup>8,28</sup>

Active and methodical engagement of older adults in clinical research is especially important because they continue to be underrepresented in clinical trials despite their documented interest in participating in research.<sup>29</sup> Study 3-A (Table 3) is an example of meaningful engagement in the PCORI's portfolio. It compares a novel group exercise program vs a standard group exercise program on improving older adults' function, disability, and walking ability. Engaging older adults and their providers throughout this study led to several specific changes: the addition of a new aim examining the intervention's sustainability; a modified randomization scheme that incorporates older adults' preferences; broadened and more pragmatic inclusion criteria; and primary outcomes that align with older adults' wish to remain independent as they age.<sup>30</sup> Study 3-B (Table 3) compares usual care with a "question prompt list" intervention designed to empower older adult patients to participate more actively in decision making about high-risk surgery. This study established a Patient and Family Advisory Council that helped identify the research question, develop the intervention, and identify the most relevant outcomes for both patients and their family members.<sup>31</sup>

### **Choosing Outcomes and Study Design That Meet the Needs of Older Adults**

Older people have several characteristics that can alter the choice of outcome measures. Their life expectancy is measured typically in years, not decades. They have seen suffering as friends and family contend with chronic disease and with the decline that precedes death. As a result, the first priority for many is to maintain the highest quality of life during the years left to them, rather than live for more years with a lower quality of life. Consequently, primary outcome measures often include measures of function, such as the 12-item survey of functional health (SF-12), avoidance of disability, and time spent at home. The PCORI awardees often relegate to secondary outcomes such end points as mortality and discrete clinical events, such as major adverse cardiac events (all-cause mortality, myocardial infarction, or coronary revascularization). Study 2-G (Table 2) illustrates the extensive use of patient-reported outcomes in older adults recovering from hip fracture.

Decision aids can facilitate discussions between an older person and a health professional. The PCORI has a large portfolio of research whose results will fill evidence gaps in our knowledge of the effectiveness of decision aids in promoting decisions that align with how patients value the outcomes they may experience. These include PCORI-funded randomized controlled trials in which the researchers tested the quality of decisions using a decision aid compared with decisions made without the aid; some of these studies are specific to decisions made by older people.

As health declines, many older people require help in navigating life because of cognitive, mental, or physical ill health. Caregivers provide essential support, especially for free-living older persons. Caregivers are typically relatives, a sibling, or a child. Learning to become an effective caregiver and to deal with its emotional stresses can result in better caregiver health, which can trickle down to the health state of the declining older person. One PCORI-funded study compared two leading programs to train caregivers on reducing caregiver burden and caregiver symptoms of depression.<sup>32</sup>

## CONCLUSION AND FUTURE DIRECTIONS

In this article, we have provided an overview of the PCORI's CER portfolio on topics of interest to older adults and the research and clinical communities that serve them. The PCORI funds research on the factors that inform decision making by individual patients, especially expected net benefit, which varies widely in older adults. We have described the research considerations that influence net benefit. The PCORI wants to receive high-quality applications that reflect the needs and values of older adults. To that end, we have communicated our perspective on CER as applied to older adults.

Finally, we briefly describe how the geriatrics community can influence the PCORI's CER portfolio. Input from a wide variety of stakeholders, including patients and the research community, actively advocating for needed research through the PCORI's Advisory Panels and acting as applicants, merit reviewers, and peer reviewers of completed research, largely determines what we fund. In performing our board-directed theme of patient centeredness, the PCORI has become a leader in involving stakeholders, including patients and caregivers, in the research process at all levels. To continue to shape the PCORI's funding priorities in geriatrics research will take ongoing, committed effort by the stakeholder community.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

**Appendix Table 1.** The PCORI's Geriatrics Portfolio by Primary Disease/Condition.