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May 24, 2022

Karin Rhodes, MD, MS
Chief Implementation Officer
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Rhodes,

I am writing on behalf of the [Alliance for Aging Research](http://www.agingresearch.org), the leading nonprofit organization dedicated to accelerating research to improve the universal human experience of aging. We are grateful for the opportunity to bring this critical voice to the process with our comments on AHRQ's Proposed Patient-Centered Outcomes Research Trust Fund Strategic Framework. We applaud and support your vision of *equitable whole-person care across the lifespan* and appreciate that the proposed strategic framework reflects a concerted plan for improving health outcomes. In particular, the Alliance supports your cross-cutting strategies of building data, measurement, and analytic capacity to benchmark and evaluate uptake and use of evidence in learning health systems *to improve outcomes that matter to patients* and accelerating the uptake of evidence in practice *to optimize individual and population health with the goal of achieving health equity*. However, we are concerned that the critical issue of aging is not adequately reflected in your framework.

We note the proposed framework indirectly addresses issues of aging; for example, Priority A(1) notes reducing disparities among [AHRQ's "priority populations,"](#) and the "Elderly" is one of those priority populations. We also note that Priority D(3) refers to national priorities, which we presume refers to [CDC Healthy People 2020](#), which does include "older adults" in their long list of topics. We encourage AHRQ to include more direct language to confirm commitment to specific subpopulations, or to provide links or definitions for additional clarity.

We also appreciate Priority B(2), which highlights the need to "decrease fragmentation of care" for patients with multiple chronic conditions. Older people experience more chronic conditions and comorbidities than younger populations, leading to other unique challenges. For example, a [recent Kaiser Family Foundation report](#) found that nearly 9 in 10 adults ages 65 and older take at least one prescription medication (more than half take four or more). It may be worth considering reframing that priority to call for "improved care coordination for patients with multiple chronic conditions," which could include funding evaluation of medication therapy management (MTM) programs across Medicare Part D plans, or studies on the longstanding lack of coordination between Medicare and Medicaid for dual eligible

beneficiaries. We also appreciate that the AHRQ strategic framework focuses on wellness, better models of primary care, and improved retention of healthcare providers. These priorities are essential for all of us. More equity in access to quality, evidence-based healthcare will undoubtedly improve the lives of older Americans.

Priority D(2), “increased uptake of evidence-based practices that strengthen healthcare quality, safety, and value,” needs to include language that reinforces a commitment to PCORI’s authorizing statute. Provisions of the Affordable Care Act (ACA) prohibit the use of a cost-effectiveness analysis threshold and quality-adjusted life-years (QALYs) in PCORI clinical comparative effectiveness studies, which has been understood as a prohibition on support for PCORI conducting traditional cost-effectiveness analyses (CEA). Additionally, continuing work needs to be undertaken to create evidence-based value assessments, rather than relying on traditional CEA, which omits socioeconomic, equity, caregiver and societal burden, and other factors relevant to patients and families. Instead, the priority should include “*development and increased uptake of*” in its wording. This priority is especially relevant, given Congress’ interest in QALY-based direct negotiation drug pricing proposals for Medicare.

We believe a more targeted, coordinated focus on aging itself will better serve the vision of advancing equitable whole-person care across the lifespan, and this should be reflected in AHRQ’s strategic framework.

Our nation is aging.

We are an aging population, and our healthcare research priorities need to reflect that fact. According to [the U.S. Department of Health and Human Services \(Administration for Community Living\)](#), in 2019, the population age 65+ was more than 54 million, more than one in every seven Americans. That number is expected to grow rapidly; the number of older Americans has increased by 36 percent since 2009, compared to only 3 percent for the under-65 population. By 2040, there will be approximately 80.8 million older persons, more than twice as many as in 2000.

Aging is a unique phenomenon.

While chronological aging occurs equally for everyone, we now know that biological aging varies among individuals *and is modifiable*. Alliance for Aging Research founder and board member Dan Perry explains in his 2021 article, [Moving geroscience from the bench to clinical care and health policy](#). “Advances in our understanding of biological aging suggest that interventions modifying aging biology can slow its progression—resulting in the delay or prevention of the onset of multiple diseases and disorders.”

If healthy aging is not prioritized, it will be neglected.

Healthy aging includes prioritizing research that addresses health conditions and related issues in this population and including this population in those studies. Even for diseases more prevalent in aging populations, exclusion criteria in clinical trials often prevent including

individuals over 65 years of age. In the AMA Journal of Ethics, Gurwitz references a study by Cherubinia and Oristrell reviewing data from ongoing heart failure studies in the World Health Organization Clinical Trials Registry. “These investigators assessed the proportion of trials that excluded patients according to an arbitrary upper age limit or by criteria that might indirectly limit the participation of older persons. Of 251 trials, more than a quarter excluded patients based on an arbitrary age limit. Overall 109 trials (43 percent) had one or more poorly justified exclusion criteria that could limit the participation of older study subjects. Poorly justified criteria included comorbidity described in a non-specific manner, use of medications that would not impact the study protocol, and visual and hearing impairment that would not lead to safety concerns.” A more recent retrospective review of ClinicalTrials.gov data in cancer, cardiovascular disease, and type 2 diabetes addressing *Age-based exclusions in clinical trials: A review and new perspectives* show that cancer studies are the most inclusive for this population (exclusion rates of 22.18%, 24.13%, and 32.77% for Phases 1, 2, and 3 respectively) with exclusions in type 2 diabetes being the least inclusive (90.3%, 74.42% and 36.75% for Phases 1, 2, and 3 respectively).

All the comorbidities noted above pose additional health risks for severe [COVID-19 disease](#). Older adults are more susceptible to severe and long COVID for many reasons, and studies addressing this are limited or just starting to enroll participants. The ongoing effects of a worldwide pandemic for a disease that disproportionately impacts the older population highlights the importance of addressing health challenges for this population.

Clarification of Priorities and Desired Outcomes

While the Alliance recognizes that this framework is over-arching, it would benefit from additional clarification. For example, Priority D (High-Quality, Safe Care That is Aligned with National Health Priorities) seems to be duplicative of the High-level Goal; that is, achieving Priorities A, B, and C should result in Priority D. Similarly, Priority E (Primary Care Transformation) presents as more of a process than a priority, as its completion should lead to achieving Priorities A and B.

Importance of researcher buy-in

The framework addresses training and support of health service researchers but lacks any mention of ensuring meaningful researcher-patient collaborations. In the Alliance’s experience, many researchers, including those doing comparative effectiveness research (CER), do not meaningfully engage with the patient population of interest. Even those who profess to do so often make it a “check-the-box” exercise. Meaningful collaboration has been shown to improve [the pace](#) of healthcare research [as well as the quality](#), but researchers need clear expectations - and incentives - to invest in such partnerships. Explicit language to that effect will improve the likelihood that the research questions matter to patients and that the protocols are developed in an implementable and achievable way.

Per the question of how to apply resources, the Alliance supports investing resources in those populations that lack the appropriate amount of research to address their health challenges, such as the over 65 population, communities of color, and those with special challenges due to limited healthcare access (rural, inner-city, low income).

Emphasizing Dissemination and Collaboration

Dissemination of PCOR research is an ongoing challenge. The Alliance suggests AHRQ partner with a wide variety of stakeholder organizations (advocacy organizations such as the Alliance for Aging Research and AARP, the aging network through state units on aging and area agencies on aging, county and city-based care and wellness programs, etc.) to systematically share the results of research. The Alliance also supports disseminating the research results directly to the participants, who are often involved with multiple advocacy organizations and community groups that can disseminate that information to a wider audience.

The Alliance believes the key to achieving both AHRQ's vision and mission is effective communication between researchers and the populations the research is meant to help. Involving patients in the research process early on, ideally at inception, ensures that appropriate hypotheses are explored. Patient collaboration also improves the research process itself (SOPs, informed consent, protocols, protection of data, etc.), which in turn results in more efficient accrual, limited participants lost to follow-up, and broader populations included in phases 1 and 2 so that safety in vulnerable populations is not in question.

Research results that are not disseminated are meaningless. AHRQ's strategic framework needs to reflect a commitment to faster and more efficient dissemination.

Contact Information

The Alliance appreciates the opportunity to provide AHRQ with feedback on the proposed Patient-Centered Outcomes Research Trust Fund Strategic Framework. For additional questions or information, please contact me at bmadshaw@agingresearch.org.

Sincerely,

Beth Mathews-Bradshaw

Beth Mathews-Bradshaw
Vice President of Patient Engagement and Research