



AcademyHealth

November 13, 2020

Nakela L. Cook, M.D., M.P.H.
Patient-Centered Outcomes Research Institute
1828 L Street NW, Suite 900
Washington, DC 20036

Re: Response to RFI Soliciting Input on the Proposed Principles for the Consideration of the Full Range of Outcomes Data (2020)

Dear Dr. Cook:

AcademyHealth welcomes the opportunity to provide input to the Patient-Centered Outcomes Research Institute (PCORI) on the Proposed Principles for the Consideration of the Full Range of Outcomes Data (Proposal). We are the professional home of more than 5,000 health services researchers, policy experts, and practitioners, and we strongly support the production, dissemination, and use of evidence to inform policy and practice. Our membership is highly engaged with PCORI and its work, from informing the creation of the Institute to serving in PCORI's leadership to receiving funding support. AcademyHealth recognizes and applauds PCORI's unique contributions to the development and promulgation of practice- and policy-supporting evidence.

The authorizing language for PCORI in the Patient Protection and Affordable Care Act (ACA) states that the purpose of the Institute includes *“assist[ing] patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of evidence ... and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items.”*

In order to better assist patients, clinicians, purchasers, and policymakers in making informed health decisions, AcademyHealth supported in the 2019 reauthorization (Pub. L. 116–94, div. N, title I, § 104(a)) the mandate that: *“Research shall be designed, as appropriate, to take into account and capture the full range of clinical and patient-centered outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policy-makers in making informed health decisions. In addition to the relative health outcomes and clinical effectiveness, clinical and patient-centered outcomes shall include the potential burdens and economic impacts of the utilization of medical treatments, items, and services on different stakeholders and decision-makers respectively. These potential burdens and economic impacts include medical out-of-pocket costs, including health plan benefit and formulary design, nonmedical costs to the patient and family, including caregiving, effects on future costs of care, workplace productivity and absenteeism, and healthcare utilization.”*

The goal of the base and reauthorization language is to ensure that PCORI funded research produces holistic and real-world evidence that best informs patient decision making, as well as the needs of clinicians, purchasers, and policymakers. While the ACA specified that PCORI *“shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended (42 U.S.C. 1320e–1)”*, this language did not preclude PCORI from supporting research that included cost-related analyses, whether for patients or system-wide. The reauthorization language further clarifies the importance of costs and burdens in clinical environments, and the importance of



PCORI-funded research on them. The creation of the proposed Principles for the Consideration of the Full Range of Outcomes Data is a critical step in supporting the spirit and letter of the authorizing and reauthorizing legislation in providing necessary research guidance.

AcademyHealth feels strongly that research should not be hindered or biased by putting in restrictions on the topics pursued by researchers. Specifically, limiting studies to the clinical practice of medicine ignores the many factors that affects patients' and clinicians' ability to deliver the best possible care at the best value. Patients, caregivers, and providers need to understand the cost implications of treatment choices that are being made. Financial and hardship considerations are real and demonstrated issues in patient health care decisions, and incorporating and disseminating information to inform these decisions better aligns research with real-world experiences. There is no value to patients in recommending a treatment they cannot access due to cost or because of undue financial, time, or other constraints in adhering to prescribed care or driving non-adherence with an otherwise effective treatment protocol. These barriers can drive a gap between patient-centered research findings and the application of those findings in every day clinical care, particularly for patients and communities with more limited access to financial resources. Cost data can also be used by health care system leaders, insurers, and policymakers in making decisions that can reduce the cost burden for patients. Individual and societal costs and burdens are by their nature patient-centered and unquestionably are empirically factors that influence decision making. Indeed, financial wellbeing is, in of itself, a patient-centered outcome and central to the credo of medicine, "first, do no harm".

Identifying and reducing low-value care is not only a financial and clinical benefit to patients, but also to the health care system widely. Value is a measure of outcomes (e.g. quality, safety, effectiveness, equality, etc.) relative to cost (e.g. time, effort, money, etc.), where high value care has better outcomes at a lower cost. Identifying the value of a service therefore requires an understanding of not only the outcomes, but the costs to patients and the health care system to administer it. In a world of finite resources, that also means factoring in trade-offs with other interventions. For example, health systems continually invest in quality improvement efforts, yet it is unknown how much these efforts cost to achieve the desired improvement, hampering decisions to scale and sustain new, effective practices. Research that incorporates patient and system costs could help with allocating resources to those strategies with the highest value to improving patient outcomes and reduce the strain on system resources, which can then be redistributed to expand coverage and access, reduce out of pocket patient expense, or further invest in programs that reduce the social and racial determinants of health.

As a step towards full patient research support, the Principles should be able to expand and be flexible to ensure that the PCORI-funded studies of burdens and economic impacts faced by stakeholders are comprehensive and supports unforeseen costs. AcademyHealth additionally encourages PCORI to actively educate researchers on the scope of these principles, including a focus on methodology reviews.

For further comment, clarification, or inquiry, please email Josh Caplan at Josh.Caplan@AcademyHealth.org.