

March 3, 2023

Nakela Cook, MD, MPH
Executive Director
Patient-Centered Outcomes Research Institute
1828 L Street NW, Suite 900
Washington, DC 20036

Dear Dr. Cook:

The Partnership to Improve Patient Care (PIPC) is pleased to provide comments to the Patient-Centered Outcomes Research Institute (PCORI) related to *Stakeholder Views on Components of “Patient-Centered Value” in Health and Health Care*. We are pleased that PCORI is using a robust stakeholder-engaged process to identify the “the full range of clinical and patient-centered outcomes” and “the potential burdens and economic impacts” of healthcare services to the existing patient-centered outcomes and clinical effectiveness measures. We look forward to the ongoing work of the PCOR Economic Resource Center (PCOR-ERC) in supporting refinements in the guidance to applicants and awardees around collection of the full range of outcomes data. Understandably, the priority of outcomes and impacts will evolve and change over time and we are pleased that PCORI is setting itself up to respond to that evolution in real time.

We agree with engaged patient and disability stakeholders that trust is a significant factor in health care research and its use in decision-making. We applaud PCORI’s consistent emphasis on including the patient voice in every step of research, from developing the research question, to the design of the research project and its implementation and dissemination. As PCORI noted, a patient’s definition of value “encompasses considerations beyond clinical outcomes and cost.” When the perspectives of other stakeholders – who are more focused on costs and cost effectiveness – become the drivers of health care decision-making, mistrust is the likely outcome for patients and people with disabilities seeking the most clinically effective care related to their “needs, outcomes and preferences” (using the words of PCORI’s statute).

We are concerned that PCORI included disability-adjusted life years (DALYs) as an attribute of life and social impacts, per the feedback of some clinicians and payers. The disability community has long held concerns about the use of DALYs, similar to the quality-adjusted life year (QALY), due to their use to measure the magnitude, burden, or causes of disability. One study noted, “DALYs measure the perceived desirability of different health states and not disability as the term is used in public health practice.” Like QALYs, the DALY utilizes weights indicating that a condition is perceived as being more equivalent to death than to a state of health. The metric largely relies on the perception of disability, making it highly subject to bias.¹

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2646475/>

As stated by Colin Killick, currently the Executive Director of the Massachusetts Disability Policy Consortium, “At their heart, DALYs are built on a presumption—that a life lived with a particular disability is inherently and consistently less worth living than a life without one.”²

As PCORI advances this work, we urge consideration of the differences among patients based on their condition or disease, age, social determinants of health, etc. so that researchers are prioritizing the collection of data on attributes that matter to the patients in question. We agree with PCORI that, “Different attributes may have different relative importance to patients based on where they are in their care journey.” Before PCORI was created, there was a sense of frustration among our members representing patients, people with disabilities and practicing providers that comparative research was driven by academics and did not serve to improve health care decision-making. This work to identify attributes of patient-centered value will ensure PCORI-funded research is useful to patients, people with disabilities and providers in the real world.

We also applaud that PCORI is making these attributes publicly available and therefore useful to others in the field of research. Doing so will allow PCORI’s work to be used by others to improve upon existing health care quality and experience measures that may fail to capture the patient-centered attributes of interest to all stakeholders. To the extent that PCORI is able, we would urge PCORI to share publicly how patients and people with disabilities in their projects differentially weight the different attributes, whether by disease, condition, age, race and ethnicity, socioeconomic status or otherwise. We urge PCORI to synthesize and share the information gleaned from PCORI’s existing and future projects about outcomes patients and people with disabilities in the real world may value most. This information would be very useful throughout the lifespan of research, from developing clinical trials to quality measures.

We agree that health equity should be given significant weight as a measured outcome. As you may know, much work has been done toward improved methods for research that is inclusive and that considers factors such as social identities and the impact of social determinants of health. Addressing health equity starts with improved engagement practices. We urge consideration of a recent report from Sick Cells,³ as well as a report published by Global Liver Institute, the National Minority Quality Forum, the Preparedness and Treatment Equity Coalition and PIPC,⁴ as PCORI considers tactics to ensure health equity is given the significant weight needed to advance health equity as a health system priority. The Innovation and Value Initiative’s ongoing Health Equity Initiative will be an important resource for the evolving

² See appendix

³ https://thevalueinitiative.org/wp-content/uploads/2022/10/IVI_Sick-Cells_Equity-in-Value_2022.pdf

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http://www.pipcpatients.org/uploads/1/2/9/0/12902828/aligning_health_technology_assessment_with_efforts_to_advance_health_equity.pdf

understanding of health equity and innovative methods that address the historic shortcomings of research and value assessment that drive health inequity.⁵

We understand the challenges associated with measuring specific attributes of patient-centered value and urge PCORI to work collaboratively with others toward standardization. Significant work has been done to make qualitative measurement rigorous, as seen in patient perspective research.⁶ Essential to this type of research is its open source and transparent modeling to ensure users are able to understand how its conclusions were achieved.⁷

We could not agree more that patient-centered research “needs a specific framework of measurement to inform better methods for assessing value and collecting data.” Steps to do so will be inherently useful to policymakers that are similarly striving to identify standards for patient engagement and for identifying criteria demonstrating that research is centered on patients and people with disabilities. PCORI’s work to identify attributes through patient engagement and operationalize their measurement using methods that prioritize inclusivity and heterogeneity of treatment impact will inform how policymakers themselves engage patients and identify high-quality evidence.

The nuance of patient-centered value specific to an individual at a given point in time is a challenge that can be overcome by engaging partners from organizations representing affected patients and people with disabilities. Engaging these organizations will be useful to understanding the variability among affected patients and people with disabilities over their journey with a condition or disease. PCORI has an opportunity to ensure that these organizations have resources to be engaged partners with PCORI in this work, whether through Engagement Awards or otherwise.

We urge PCORI to use its contracting authority to advance the measurement of patient-centered value, emphasizing the attributes that patients and people with disabilities determined to be desirable outcomes. When PCORI was created, its statute set up a process for establishing priorities and a research agenda that is implemented through contracts as opposed to grants. PCORI’s contracting authority has the potential to change the culture of research to be more patient-centered by increasing community-based participatory research and by funding new researchers that may not represent the usual suspects in the field.

In conclusion, we encourage PCORI to continue to assess the attributes of patient-centered value as they evolve over time. In the final publication, PCORI will need to eliminate DALYs from the list of attributes, as they represent a biased metric for measuring health care value, the use

⁵ <https://thevalueinitiative.org/health-equity-initiative/>

⁶ <https://link.springer.com/article/10.1007/s40271-022-00596-6>

⁷ <https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/valuebased-evidence-across-health-care-sectors-a-push-for-transparent-realworld-studies-data-and-evidence-dissemination/61C65E1FBE9D28EF39E7BF93245C4C5A>



of which people with disabilities do not support and would not qualify as an attribute of patient-centered value. Otherwise, this initial effort is a good start and we look forward to future work to standardize these attributes and advance methods to ensure research advances health equity.

We appreciate the opportunity to comment and hope that our perspectives are useful to your work.

Sincerely,

A handwritten signature in black ink that reads "Tony Coelho". The signature is written in a cursive style with a large, sweeping initial "T".

Tony Coelho
Chairman, Partnership to Improve Patient Care