

EDITORIAL AND COMMENT

The Future of the Patient-Centered Outcomes Research Institute (PCORI)

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Congress will soon decide whether to re-authorize the Patient-Centered Outcomes Research Institute (PCORI). Over the last decade, PCORI's portfolio has focused new attention on comparative effectiveness and applied health services research. These activities generally support the Society of General Internal Medicine's mission to cultivate innovative educators, researchers, and clinicians "leading the way to better health for everyone," and many members have received PCORI grants.

Created as part of the Affordable Care Act (ACA) in 2009, PCORI differs in several important ways from other research funders. First, PCORI is not actually part of the federal government, unlike the National Institutes of Health (NIH), for example. Instead, it is an independent institution, supported by a federal surcharge on insurance companies.¹ Second, PCORI's application and submission process is more prescriptive and focused. For example, investigators submit letters of intent that are reviewed and evaluated before full applications are invited, and applications follow a much more structured template than is used for NIH proposals. Third, in keeping with its name, PCORI incorporates patients and other stakeholders into the research process at multiple stages, from the development of proposals, through the review process, and into the conduct and reporting of the research.²

The ACA authorized PCORI for 10 years, ending September 30, 2019. If Congress takes no action, then the insurance company surcharge will cease. Those surcharges flow into the PCORI trust fund, which pays for both PCORI core operations and approximately \$460 million annually in research grants and contracts. Without a reauthorization, PCORI could still function as a nonfederal entity using the funds already in the trust, but the funds will dwindle and eventually run out. The ACA also specified that a portion of the trust should support activities related to patient-centered outcomes research at the Agency for Healthcare Research and Quality (AHRQ). Since then, AHRQ's base funding was

reduced by approximately the same amount so that without PCORI reauthorization, AHRQ could lose around \$100 million annually or 22% of its budget.³ The House of Representatives is considering both 7-year and 3-year extensions, but at the time of writing, no legislation has been brought forward in the Senate.

Supporters have put forward several convincing reasons for reauthorizations. PCORI has been a pioneer in increasing the role of patients in research, a trend that has now begun to spread to other research funders. While difficult to implement meaningfully, patient advice can improve the relevance of research and increase the likelihood that it will be used. PCORI has developed the best methods for doing so despite the challenges, and these methods are still evolving. It is important to sustain at least one research funding to carry forward this explicit overarching goal.⁴

PCORI's original name during the drafting of the ACA was the Comparative Effectiveness Research Institute and comparing two or more active interventions in realistic clinical settings has remained a strong focus. Many SGIM members and JGIM authors use these types of rigorous methods for both interventional and observational studies to inform clinical decision-making and policy. In addition to support for studies of specific clinical questions, PCORI has invested in studying and defining the best methods for patient-centered outcomes research and comparative effectiveness research.⁵ American health care would miss out on important opportunities for better methods and more impactful research if PCORI should shut down just as it was hitting its stride. Even if the work were to shift to other funders, the taxpayer would be poorer for the inefficiencies of rebuilding the PCORI announcement, review, management, and dissemination infrastructure.

As PCORI-funded studies continue to publish their findings, the opportunities for continued work relevant to general internal medicine and health services research are clear. Recently published findings include interventions to reduce harmful medical errors in the hospital,⁶ to improve pain management⁷ and address opioid overprescribing,⁸ and improve emergency care for patients with chest pain.⁹ JGIM has published many papers supported by PCORI funding, including original investigations of clinical interventions,^{10, 11} systematic reviews of key clinical topics,^{12, 13} and overviews of methodological approaches.¹⁴

Follow-up investigations of these and many other PCORI-supported studies will provide clinicians and policy-makers with critical information to use at both patient and system levels. Increasing the volume of PCORI-funded studies focused on primary care could enhance the impact of its research portfolio.¹⁵ While PCORI's original authorizing legislation bars the evaluation of cost in PCORI-supported research, higher quality comparative effectiveness data will help all of those making decisions in the health care system to ensure that the interventions in which we invest are effective for the patients we serve.

We urge Congress to reauthorize PCORI, ideally for another 10 years, and avoid any gaps in funding. The specific contributions that PCORI has made to research and patient care thus far justify action, as does the potential that would be squandered if these initial efforts cannot continue. In a divisive time, we should all be able to agree that societal support for this sort of research does indeed lead the way to better health for everyone.

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Compliance with Ethical Standards:

Conflict of Interest: Dr. Fischer has received research support from PCORI contracts. Dr. Asch has not received PCORI funding, but is affiliated with and has received funding from the Department of Veterans Affairs. The views expressed in this work are unrelated to his VA affiliation and do not represent the VA.

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