

GAO Highlights

Highlights of [GAO-15-301](#), a report to congressional committees

Why GAO Did This Study

In 2010, PPACA authorized the establishment of PCORI as a federally funded, nonprofit corporation to improve the quality and relevance of CER. PCORI, which began operation in 2010, is required to identify research priorities, establish a research project agenda, fund research consistent with its research agenda, and disseminate research results, among other things. To fund PCORI, PPACA established the Patient-Centered Outcomes Research Trust Fund, through which the institute is expected to receive an estimated \$3.5 billion from fiscal years 2010 through 2019.

PPACA mandated that GAO review PCORI's activities by 2015 and 2018. This report examines (1) the extent to which PCORI established priorities and processes for funding and disseminating comparative clinical effectiveness research consistent with its legislative requirements; (2) the status of PCORI's efforts to fund comparative clinical effectiveness research; and (3) PCORI's plans, if any, to evaluate the effectiveness of its work. GAO reviewed relevant legislative requirements and PCORI documentation, including funding data, and interviewed PCORI officials. GAO also interviewed relevant stakeholders, including health policy experts and PCORI contractors. PCORI provided technical comments, which GAO incorporated as appropriate.

View [GAO-15-301](#). For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

March 2015

COMPARATIVE EFFECTIVENESS

Initial Assessment of the Patient-Centered Outcomes Research Institute

What GAO Found

The Patient-Centered Outcomes Research Institute (PCORI) has established priorities and processes for funding comparative clinical effectiveness research (CER)—which is research that evaluates and compares health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services, or items such as health care interventions—and is developing dissemination plans, consistent with the legislative requirements of the Patient Protection and Affordable Care Act (PPACA). In 2012, PCORI established five broad research priorities: (1) assessment of prevention, diagnosis, and treatment options; (2) improving health care systems; (3) researching communication and dissemination strategies; (4) comparing interventions to reduce health disparities; and (5) accelerating patient-centered outcomes research and methodological research. PCORI also developed a research agenda to identify how each priority would be addressed. PCORI has established a multi-step research funding process designed to assess and select contract applications for funding. Funded contracts are monitored by PCORI staff. Per legislative requirement, PCORI is developing a peer review assessment process to review final reports submitted by contract awardees and is in the process of developing a plan for the dissemination of funded research potentially beginning in 2015, in coordination with the Agency for Healthcare Research and Quality.

PCORI has started awarding contracts for research and plans to award additional contracts through 2019. As of October 2014, PCORI has awarded 360 contracts to fund research projects, committing a total of \$670.8 million to them. PCORI expects to commit about \$2.6 billion to research contracts, out of \$3.5 billion in total estimated spending. Approximately \$106 million in commitments to date are for PCORnet, a data research network aimed at improving the capacity for and speed of conducting CER. PCORI officials stated that they expect to spend a total of \$271 million on PCORnet through fiscal year 2019. PCORI officials stated that limited amounts of data will be available through PCORnet for researchers to use after September 2015 with the amount of available data increasing over time.

PCORI has established an evaluation plan and is developing efforts to measure outcomes. PCORI has developed initial plans for evaluating the institute's efforts against its three strategic goals, which are to increase information, speed implementation, and influence research. To do so, PCORI has developed primary outcome measures for assessing PCORI's progress related to these strategic goals. In its strategic plan, PCORI notes that these are meant to be long-term measures because research typically requires several years to complete and additional years for the results to be disseminated and implemented. Therefore, since 2013, PCORI has been using early and intermediate process and output measures—such as the number of people accessing or referencing PCORI information—as a way to monitor its progress toward its strategic goals. PCORI anticipates having some early results related to its primary outcome measures starting in 2017 after the first CER studies are completed and their findings released, although full evaluation of the results of these outcome measures will not be possible until around 2020.