

Improving the Science and Methods of PCOR

Developing and improving the science and methods of patient-centered outcomes research (PCOR) is a central part of PCORI's work. Improvements in the quality of PCOR studies will produce more valid, trustworthy, and useful information that will lead to better healthcare decisions and, ultimately, to improved patient care and outcomes.

Departures from good research practices are partially responsible for mismatches between the quality and relevance of the information research provides and the information needed to make informed health decisions. The **PCORI Methodology Standards** help ensure that PCOR studies are designed and conducted to generate the evidence needed to address patients' and clinicians' questions about what works best, for whom, and under what circumstances. The **PCORI Methodology Report** provides the context and rationale for these standards, which represent minimal requirements for the design, conduct, analysis, and reporting of PCOR studies. PCORI uses these standards in the review of applications (Merit Review), monitoring of funded awards, and peer review of final research reports.

In addition to working diligently to ensure methodological rigor in PCORI-funded studies, we support and encourage



other funders to do likewise. PCORI is also funding methodological research to address shortcomings of existing approaches and improve understanding and appropriate use of methods for PCOR.

Methodology Committee

The Methodology Committee, appointed by the Comptroller General of the United States, works to define and update methodological standards for PCOR and to develop a translation framework to guide the choice of study designs for specific research questions.

The committee's initial PCORI Methodology Standards were released in December 2012 and updated four times, most recently in 2019. In 2013, the committee released its first PCORI Methodology Report, which includes examples illustrating how good research practices make a difference to patients and their care. Updated versions were released in 2017 and 2019.

PCORI has developed 65 Methodology Standards in two broad categories and 16 topic areas

CROSS-CUTTING STANDARDS*

- [*Formulating Research Questions*](#)
- [*Patient Centeredness*](#)
- [*Data Integrity and Rigorous Analyses*](#)
- [*Preventing and Handling Missing Data*](#)
- [*Heterogeneity of Treatment Effects*](#)

*The first standard under Causal Inference Methods is cross-cutting.

DESIGN-SPECIFIC STANDARDS

- [*Data Registries*](#)
- [*Data Networks as Research-Facilitating Structures*](#)
- [*Causal Inference Methods*](#)
- [*Adaptive and Bayesian Trial Designs*](#)
- [*Studies of Medical Tests*](#)
- [*Systematic Reviews*](#)
- [*Research Designs Using Clusters*](#)
- [*Studies of Complex Interventions*](#)
- [*Qualitative Methods*](#)
- [*Mixed Methods Research*](#)
- [*Individual Participant-Level Data Meta-Analysis*](#)

As of August 2019, PCORI has awarded

\$108 MILLION TO FUND **112**

methods research studies to improve the science and methods of patient-centered outcomes research

STUDY SPOTLIGHTS

BANK OF QUESTIONS FUEL PATIENT SURVEYS

Researchers from Cedars-Sinai Medical Center developed and validated an item bank of survey questions to capture patient-reported outcomes and experiences related to childbirth, including experiences related to pain management and staff support. Hospitals and researchers can use the item bank to quickly develop surveys to collect data needed to better understand and improve patients' childbirth experiences. The research team is expanding the item bank to 10 more hospitals through a PCORI Dissemination and Implementation Award. Further details about this project are at www.pcori.org/Gregory069.

CALCULATING RESULTS FOR PRAGMATIC TRIALS

A research team from Harvard University's School of Public Health is developing evidence-based methodological guidance for the design and analysis of pragmatic randomized controlled trials. The team will examine how different approaches to characterizing treatment adherence (data collection and statistical methods) and other study factors might reduce (or increase) bias in research findings. The guidance will help researchers to generate evidence that improves patients' and clinicians' understanding of the benefits and risks of treatments based on how the treatments are used in real-world settings. Learn more about this project at www.pcori.org/Hernan270.

GUIDANCE HELPS ENSURE COMPLETE, RELIABLE DATA

University of Colorado Denver researchers developed guidance to assess the quality of data collected for nonresearch purposes but increasingly used for research, such as electronic health record (EHR) data. Researchers who use these data, and stakeholders who rely on the findings from such studies, need to have confidence that the data can support the conclusions. The research team identified key characteristics of high-quality EHR data, provided recommendations for reporting and assessing the quality of these data, and assessed the utility of the guidance and barriers to adherence. The findings were used to update PCORI Methodology Standards for data networks. Read more about this project at www.pcori.org/Kahn052.

RESEARCH CONTINUUM: WHY METHODS MATTER



**Improved Methods
for PCOR/CER**

Research supported by Methods
PCORI Funding Announcements



**Improved PCOR/CER
Studies**



**Improved Clinical
Evidence**