

PCORI Update Genomic Medicine 5 May 28, 2013

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Patient-Centered Outcomes Research Institute

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PCORI's Mandate

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PCORI



"The purpose of the Institute isto assist patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner Purpose in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of medical treatments, services."

Source: Affordable Care Act. Subtitle D—Patient-Centered Outcomes Research. Patient-Centered Outcomes Research Institute PUBLIC LAW 111-148-MAR. 23, 2010.

Understanding Patient Differences PCORI Legislation on Treatment Heterogeneity



An Act

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TAKING INTO ACCOUNT POTENTIAL DIFFERENCES

"Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate.

Source: Affordable Care Act. Subtitle D—Patient-Centered Outcomes Research.PCOT / PUBLIC LAW 111–148—MAR. 23, 2010. 3 Patient-Centered Outcomes Research Institute

PCORI's National Priorities and Research Agenda

Assessment of Prevention, Diagnosis, Treatment Options

• Comparisons of alternative clinical options; identifying patient differences in response to therapy; studies of patient preferences for various outcomes

Improving Healthcare Systems

• Improving system support of patient self-management, coordination of care for complex conditions, access to care; comparing alternative strategies for workforce deployment.

Communication & Dissemination Research

• Understanding and enhancing shared decision-making; alternative strategies for dissemination of evidence; exploring opportunities to improve patient health literacy

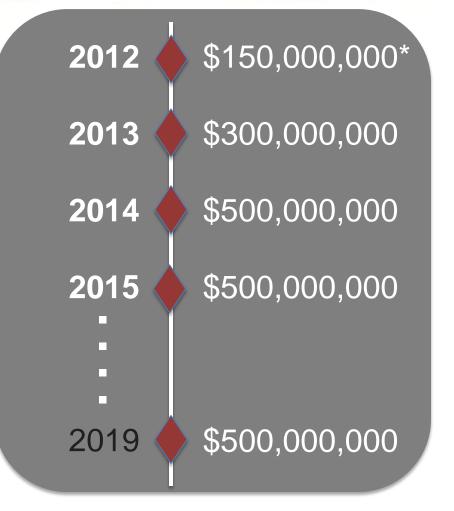
Addressing Disparities

Understanding differences in effectiveness across groups; understanding differences in preferences across groups; reducing disparities through use of findings from PCOR

Accelerating PCOR and Methodological Research

Improving study designs and analytic methods of PCOR; building and improving
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PCORI Funding – Approximate



* 20% each year goes to AHRQ/HHS

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Accelerating PCOR and Methodological Research

 Improving study designs and analytic methods of PCOR; building and improving DGOTI , data networks
Patient-Centered Outcomes Research Institute

Requirements of PCORI Applications

- Address a question relevant to choices faced by patients, clinicians; and consider patient-relevant outcomes
- Be comparative i.e., compare the competing choices
- Assess for differences in treatment effectiveness across subgroups of study population
- Include relevant patients and other stakeholders on research team
- Discuss potential for dissemination and implementation
- NOT include cost-effectiveness analyses or treat costs of care as an outcome that is compared

Comparative Clinical Effectiveness Research – PCORI Style

- Addresses practical questions especially those of interest to patients and providers – usually head-to-head comparisons
- Conducted in "typical" patients and "typical" care delivery settings
- Considers the full range of outcomes of interest to patients and clinicians
- Considers possible differences in treatment effectiveness in patient subgroups what works for whom?
- May be RCTs or observational studies
- But NOT cost-effectiveness or cost comparison studiepcori