Research Agenda and Opportunities for Co-Funding

Joe Selby, MD, MPH, Executive Director
Inter-agency Pain Research Coordinating Committee

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Agenda for Today

1. Introducing PCORI
2. Funding Mechanisms and Portfolio
3. Opportunities for Collaboration
PCORI Uses Engagement as a Path to More “Useful” Research

- Topic Generation and Prioritization
- Review and Conduct of Research
- Review Proposals and Partner in Research
- Help Us Share the Findings
- Dissemination and Implementation
- Portfolio Review
- Advise Us on What PCORI Should Study
- Tell Us How We’re Doing
What Do We Mean by Comparative Clinical Effectiveness Research?

- Compares two or more options for screening, diagnosis, treatment
  
  *(one option may be “usual care”)*

- Considers the range of outcomes important to patients

- Conducted in real world populations and real world settings

- Attends to differences in effectiveness and preferences across patient subgroups
PCORI’s National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication & Dissemination Research

Addressing Disparities

Accelerating PCOR and Methodological Research
PCORI’s Three Strategic Goals

1. Substantially increase the quantity, quality, and timeliness of useful, trustworthy evidence available to support health decisions.

2. Speed the implementation and use of patient-centered outcomes research evidence.

3. Influence clinical and health care research funded by others to be more patient-centered.
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Now Three Paths to PCORI Research Funding

#1: PCORI’s Broad Funding Solicitations

- PCORI issues broad funding announcements
- Researchers partner with stakeholders to generate questions
- Researchers, stakeholders apply review criteria in their applications
- Peer review prioritizes applications by level of alignment with criteria

Diverse portfolio addressing high-priority questions
Pain-related Studies funded through PCORI’s Broad Funding Announcements

- Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial
- Integrative Medicine Group Visits: A Patient-Centered Approach to Reducing Chronic Pain and Depression in a Disparate Urban Population
- Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis
- Optimizing Patient Engagement in a Novel Pain Management Initiative (OPEN)
- Effects of a Patient Driven Assessment Process with Complex Pain Patients (PDAP)
- Evaluation of a Patient-Centered Risk Stratification Method for Improving Primary Care for Back Pain
- Patient Assisted Intervention for Neuropathy: Comparison of Treatment in Real Life Situations (PAIN-CONTRoLS)
- Evaluation of a Health Plan Initiative to Mitigate Chronic Opioid Therapy Risks
- Comparative Effectiveness of Postoperative Management for Degenerative Spinal Conditions
- Long Term Outcomes of Lumbar Epidural Steroid Injections for Spinal Stenosis
- Improving Palliative and End-of-Life Care in Nursing Homes
#2: Patient/Stakeholder-Led Targeted Announcements

PCORI and stakeholders generate and prioritize questions based on review criteria. PCORI issues specific, targeted funding announcements for highest priority topics. Researchers and stakeholders develop responsive proposals. Peer review prioritizes applications by level of alignment with criteria. Diverse portfolio addressing high-priority questions.
PCORI’s Research Prioritization Process

Topics Come from multiple sources

- Board Topics
- Workshops, Roundtables
- 1:1 interactions w Stakeholders
- Guidelines Development, Evidence Syntheses
- Website, Staff, Advisory Panel Suggestions

Gap Confirmation

(PCORI Staff In Collaboration with AHRQ & others)

- Eliminating non-comparative questions
- Aggregating similar questions
- Assessing Research Gaps
- Preparing Topic Briefs

Research Prioritization

(Multi-stakeholder Advisory Panels)

Prioritized Research Topics
Post-Prioritization Process: Board Approval is Required for Targeted Funding Announcements

- Prioritized Research Topics
- Additional Topic Assessment and Refinement as needed (staff with PDC)
- Final Disposition
  - Proceed to targeted PFA
  - Neither
  - Pragmatic Studies Announcement

From Advisory Panel Process

Landscape Review

Topic-specific Workshop
PCORI’s First Targeted Funding Announcements

- Identified several high-priority, stakeholder-vetted topics for targeted PFAs
- Leverages stakeholder input from before PCORI’s existence
- Allows us to build on our engagement work

Research Topics:
- Treatment Options for Uterine Fibroids
- Safety and benefits of treatment options for severe asthma
- Fall Prevention in the Elderly
- Back Pain
- Prevention and management of obesity

December 12, 2012
Essential characteristics of Pragmatic Studies initiative

- Up to $10 million in direct costs; 5-year duration. Larger or longer studies will be evaluated and may be funded.
- Up to $90 million available, two cycles per year.
- Strong endorsement and involvement by relevant patient organizations, professional organizations, and/or payer or purchaser organizations.
- Conducted in typical clinical care and community settings.
- Broadly representative populations, sample sizes large enough to yield precise estimates of effect sizes and evaluate possible subgroup differences in treatment effects.
- Measures health outcomes that are meaningful to the patient population under study.
Comparators of interest in Pragmatic Studies

- Specific drugs, devices, and procedures
- Medical and assistive devices and technologies
- Techniques for behavioral modification
- Complementary and alternative medicine
- Delivery-system interventions
- Usual care or no specific intervention, if it is a realistic choice for patients (e.g., choosing not to have a procedure for cancer screening)
Topics of interest

- IOM 100 priority topics for CER
- AHRQ Future Research Needs Projects
- PCORI priority topics (as of 1/2014)

*Investigator initiated topics will also be considered*
Pathway #3: Pragmatic Studies Announcement

Comparing effectiveness of alternative treatments or strategies for:

- Diagnosis and management of bipolar disorder in children and adolescents
- Management of breast ductal carcinoma in situ
- Reducing cardiovascular disease risk in underserved populations (e.g., racial and ethnic minorities, rural communities)
- Preventing the progression of episodic acute back pain into chronic back pain
- Integration of mental and behavioral health services into the primary care of the general population
Topics for Pragmatic Studies Announcement

Comparing effectiveness of alternative treatments or strategies for:

- Integration of mental and behavioral health services into the primary care of persons at risk for disparities in health care and outcomes
- Enhancing patients’ adherence to medication regimens.
- Specific features of health insurance on access to care, use of care, and other outcomes that are especially important to patients
- **Adult patients with migraine headache**
- **Symptomatic osteoarthritis (OA), including joint replacement**
Topics for Pragmatic Studies Announcement

Comparing effectiveness of alternative treatments or strategies for:

- Patients with autism spectrum disorder
- Follow-up of pulmonary nodules identified by imaging studies
- People with opioid substance abuse
- Patients with multiple sclerosis
- Proton beam therapy for patients with lung, breast, and prostate cancer

And:

- IOM Top 100 Topics for CER
- AHRQ Future Research Needs
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Considerations for Collaboration

PCORI’s Board and its Strategic Plan express great interest in co-sponsoring and collaborative management with other funders.

Strong Board interest in “cross-cutting” topics such as pain.

Contracts/MOUs from PCORI to manage targeted PFAs – PCORI provides funding, Institute provides in-kind expertise.

Co-funded announcements – when mutual interests in a targeted PFA or pragmatic study make this feasible.

PCORI will be concerned to ensure that the innovations in terms of engagement and patient-centeredness are preserved in partnered relationships.
Consider PCORnet!

PCORI

PCORnet EXECUTIVE BODY
- Steering Committee
- Executive Committee

PCORnet COORDINATING CENTER
- Project Management Office

CLINICAL DATA RESEARCH NETWORKS
PATIENTS & POPULATIONS
PATIENT-POWERED RESEARCH NETWORKS

TASK FORCES
- Governance
- Data Privacy
- Ethics & Regulatory
- Data Standards & Security
- Health Systems Interaction
- Patient & Consumer Engagement
- Patient Reported Outcomes
- Clinical Trials
- Rare Diseases
- Biorepositories
- Obesity