

Communication and Dissemination Research (CDR)

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Welcome!



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In This Session

- CDR Portfolio overview
- LOI Responsiveness
- Common LOI pitfalls
- Discussion, Q + A



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CDR Team



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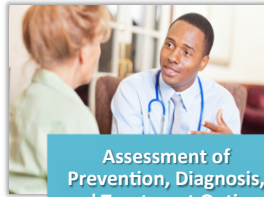


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Senior Program Officer



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The Research We Fund Is Guided by Our National Priorities for Research



Assessment of
Prevention, Diagnosis,
and Treatment Options



Improving Healthcare
Systems



Communication and
Dissemination Research



Addressing Disparities



Accelerating PCOR and
Methodological
Research



Portfolio Overview



Importance of CDR

Producing information is not enough.

- Clear communication approaches and active dissemination of findings to all audiences, in easy to understand formats, are critical to increasing the awareness, consideration, adoption, and use of the data by patients, caregivers, and healthcare providers
- In other words, information itself is of little use unless:
 - It reaches those who need it
 - It is clear and comprehensible



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Background

- Patients, caregivers, and clinicians need to be equipped with the best available information for making informed decisions.
- Knowledge about how to optimally communicate and facilitate the effective use of evidence, information, and tools by patients, caregivers, and providers is lacking in many areas.
- Strategies are needed to make existing patient-centered outcomes research information available to patients and providers and to make the dissemination and implementation of this knowledge feasible in various contexts.



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CDR Funding Objective

The CDR program seeks to fund comparative effectiveness research (CER) that:

- involves the direct comparison of effective health communication and dissemination interventions or strategies that engage patients, caregivers, and providers
- in the context of real-world clinical-care settings and situations
- to enable patients and caregivers to make the best possible decisions in choosing among available options for care and treatment



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CDR Funding Priorities

Focus on three key areas:

1. **Communication strategies** to promote the use of health and healthcare CER evidence by patients and clinicians
2. **Dissemination strategies** to promote the use of health and healthcare CER evidence by patients and clinicians
3. **Explaining uncertain health and healthcare CER evidence** to patients and clinicians



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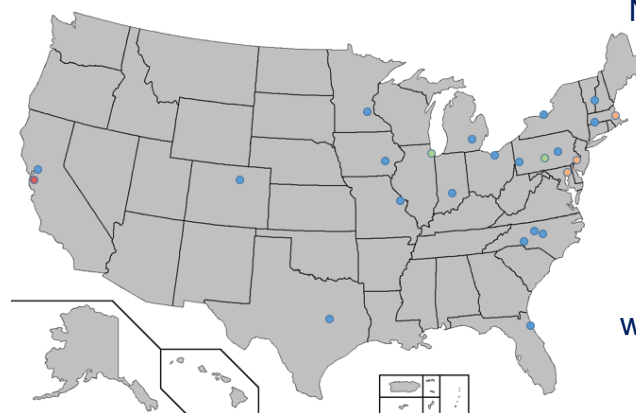
Communication and Dissemination Research

Available Funds: Up To \$8 Million

Total Direct Cost : \$1.5 million

Maximum Project Period: 3 years

Current Portfolio



Number of Projects:

35

Amount Awarded:

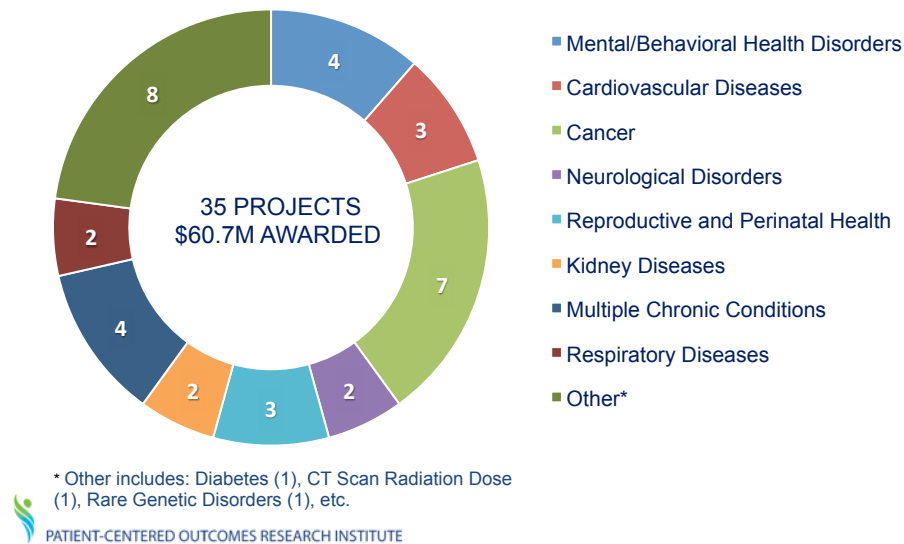
\$60.7 million

**Number of states
where we are funding
research:**

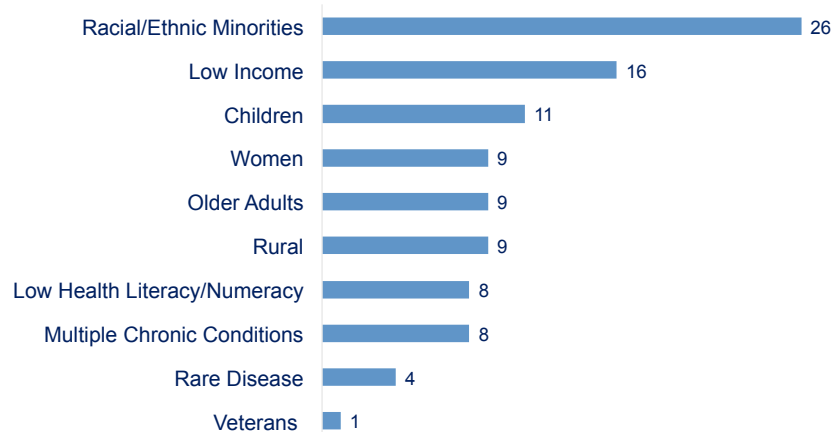
17

● =1 studies ● = 3 studies
● =2 studies ● = 4 studies

Portfolio by Disease/Condition



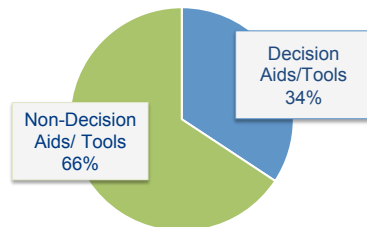
Portfolio by PCORI Priority Populations*



*Not mutually exclusive

Total number of projects =35

Decision Aids in CDR Portfolio



Tools that help patients understand:

- evidence about clinical management options
- their preferences about clinical outcomes
- so as to engage in shared decision making for making choices among those options

- In early cycles, several CDR projects focused significant effort towards the development, validation, and pilot-testing of decision aids and tools.
- The current focus is on head to head comparisons of demonstrated interventions, strategies, and tools.
- The development, testing, and validation of individual decision aids/tools is considered non-responsive to the CDR funding announcement.



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Letter of Intent Responsiveness:

What does PCORI look for when reviewing LOIs?



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LOI Responsiveness Review

- Letters of Intent are reviewed based on criteria detailed in each PFA
- Additional screening for
 - Comparative effectiveness research
 - NON inclusion of cost-effectiveness analysis
 - Administrative Guidelines
- Only responsive LOIs will be invited to submit a full application



What Does PCORI Look for When Reviewing LOIs?

- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guideline developers and/or recent relevant systematic review
- Clarity and credibility of applicants' responses to the LOI questions such as well-described comparators, clear research methods (e.g., study design, sample size, effect size)
- Programmatic fit and balance



What CDR looks for when reviewing LOIs?

- **Describe research that compares at least two alternative approaches.**
 - Approaches may address diagnostic methods or options, screening, interventions for prevention or treatment, or strategies to improve the healthcare system.



What CDR looks for when reviewing LOIs?

- **“Usual care” (or no specific intervention) may be an appropriate comparator if this is a realistic choice faced by patients and other stakeholders, but the clinical characteristics must be specified.**
 - Applications proposing to use usual care as the comparator must justify the choice to use it (e.g., usual care is guidelines-based) and should clearly describe its components that will be used or measured in the research.
 - A clear description of usual care is necessary to enhance the reproducibility of the research in other settings.



What CDR looks for when reviewing LOIs?

- **Describe research that compares two or more strategies that each have established efficacy. PCORI expects that the efficacy or effectiveness of each intervention be known.**
 - If the efficacy/evidence base is insufficient, then data need to be provided to document that the intervention is used widely.
 - The application must provide information about efficacy of the interventions and/or dissemination strategies that will be compared; pilot data may be appropriate.
 - Projects that aim to develop new or novel interventions, which lack evidence of efficacy or effectiveness, will be considered out of scope.



What CDR looks for when reviewing LOIs?

- **Describe research that studies the benefits and harms of interventions and strategies delivered in real-world settings.**
 - PCORI is interested in studies that provide practical information that can help patients and other stakeholders make informed decisions about their healthcare and health outcomes.



What CDR looks for when reviewing LOIs?

- **Describe research that is based on health outcomes that are meaningful to the patient population, their caregivers, and family members under study, and that are likely to guide their decisions.**
 - These outcomes must matter to patients, including measures of quality of life, symptoms of disease, relevant physiological measurements, treatment-related symptoms (side effects), healthcare utilization, and/or clinical outcomes.



What CDR looks for when reviewing LOIs?

PCORI discourages proposals in the following categories and will likely deem them nonresponsive:

- Study of the natural history of disease
- Instrument development
- Fundamental science or study of biological mechanisms
- Creation of clinical practice guidelines or care pathways
- Policy development
- Developing, testing, and validating new decision aids/tools or clinical prognostication tools
- Establishing efficacy for a new clinical strategy
- Pilot studies intended to inform larger efforts
- Comparisons of patient characteristics rather than clinical strategy options
- Studies comparing interventions for which the primary focus is the role of community health workers or patient navigators



We Also Work To Improve Research Methodology

In any study, methods matter. That's why we've developed methodology standards that patient-centered CER should follow, at a minimum.

Methodology Standards: 11 Broad Categories

- Formulating Research Questions
- Patient-Centeredness
- Data Integrity and Rigorous Analyses
- Preventing/Handling Missing Data
- Heterogeneity of Treatment Effects
- Data Networks
- Data Registries
- Adaptive and Bayesian Trial Designs
- Causal Inference
- Studies of Diagnostic Tests
- Systematic Reviews



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The Engagement Rubric



Planning the Study



Conducting the Study



Disseminating the Study Results



PCOR Engagement Principles



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Patient-Centeredness vs. Patient Engagement

- **Patient-Centeredness** is a component of what PCORI is looking for in research applications.
 - Does the project aim to answer questions or examine outcomes that matter to patients within the context of patient preferences?
 - Research questions and outcomes should reflect what is important to patients and caregivers.
- **Patient engagement** is about having patients as partners in, not merely subjects of, research.
 - Active engagement between scientists, patients, and stakeholders
 - Community, patient, and caregiver involvement already in existence or a well-thought out plan



Patient and Stakeholder Engagement

- Participating in the formulation of research questions
- Defining essential characteristics of the study participants, comparators, and outcomes
- Monitoring study conduct and progress
- Drafting a plan for disseminating research results



Questions?

Talk to a program officer!
sciencequestions@pcori.org

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Thank You!

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