

Board of Governors Meeting

via Teleconference/Webinar

January 27, 2015
12:00-1:30 p.m. ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00- 12:05 p.m.	Call to Order, Roll Call, and Welcome Consider for Approval: Minutes of Dec 8, 2014 Board Meeting
12:05- 12:10 p.m.	Consider for Approval: Retirement Plan Resolutions
12:10- 12:20 p.m.	Consider for Approval: Communication and Dissemination Research (CDR) Advisory Panel Charter
12:20- 12:35 p.m.	Consider for Approval: Development of Obesity PCORI Funding Announcement (PFA) and Budget: Demonstration Project for PCORnet
12:35- 1:15 p.m.	CDR Program Overview
1:15- 1:30 p.m.	Evaluation Update – Preliminary Results from Researcher Survey
1:30 p.m.	Wrap Up and Adjournment



Board Vote: Approval of December 8, 2014 Board Meeting Minutes

Call for a Motion to:

- **Approve** the December 8, 2014 Board Meeting Minutes

Call for the Motion
to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve/Adopt/Accept/Endorse** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Retirement Plan Resolutions

Mary Hennessey, Esq.

General Counsel

January 27, 2015



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Retirement Plan and Amendments; Delegation of Authority

The Board is asked to adopt and approve Resolutions to:

- Approve the Third Amendment to the PCORI Retirement Plan
- Ratify the PCORI Retirement Plan and the First and Second Amendments to the Plan
- Delegate authority to the Board Chairperson and/or Vice Chairperson to amend the Plan

- IRS Determination letter requires the Third Amendment to be approved by the Board by February 12, 2015 for the Plan to be valid.
- Ratification of the Plan and the 1st and 2nd Amendments, along with approval of the 3rd Amendment records Board approval of all documents in clear and unified minutes.
- Delegation to amend the Plan is subject to the limitations specified in the Plan.



Board Vote: Approve Resolutions Relating to PCORI Retirement Plan

Call for a Motion to:

- **Adopt and approve** each of the Resolutions as reflected in “Ratification of Defined Contribution Retirement Plan of PCORI and Amendments and Delegation of Authority”

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Advisory Panel on Communication and Dissemination Research

Jean Slutsky

Chief Engagement and Dissemination Officer and
Program Director, Communication and Dissemination Research

January 27, 2015



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Advisory Panel: Applicable Legislative Provisions

- PCORI's advisory panels are governed by the provisions of Public Law 111-148, which sets forth standards for the formation and use of Advisory Panels.
- PCORI's authorizing legislation allows the Institute to appoint permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda.



Advisory Panel: Purpose

The Advisory Panel on Communication and Dissemination Research will:

- Identify and prioritize critical research questions for possible funding initiatives under PCORI's Communication and Dissemination Research program; and
- Provide ongoing feedback and advice on evaluating and disseminating the research conducted under this program.

(NOTE: The panel will not serve in an official decision-making capacity.)



Advisory Panel: Function

The Communication and Dissemination Program at PCORI seeks to fund studies that investigate the comparative effectiveness of communication and dissemination strategies to promote the use of health and healthcare CER evidence by patients, caregivers, and clinicians.

The advisory panel will:

- Identify and prioritize health communication and dissemination research topics presented by the CDR program;
- Suggest new topics for the CDR program to vet and potentially develop for future prioritization;
- Provide feedback to PCORI on specific research questions related to CDR;
- Provide input on possible refinements to PCORI's research priorities as they relate to CDR; and
- Consider study findings and advise on targets and strategies for communication and dissemination efforts.



Advisory Panel: Composition

Membership Term	Three-year staggered terms (maximum one full 3 year term)
Composition	• 12 to 21 members • No fewer than 25 percent to be persons who are patients, caregivers, or representatives of patient advocacy organizations • At least 2 panel members will be selected from persons who have a background in health literacy, numeracy, and/or risk communication • At least 2 panel members will be selected from person with a background in dissemination and implementation research • The remainder to include representation by broad array of stakeholders consistent with legislation



Timeline and Next Steps

- With charter approval, PCORI will open the application process for this panel in the coming days to coincide with the current application process for the other advisory panels.
- First meeting: End of May 2015



Board Vote: Charter for Advisory Panel on Communication and Dissemination Research

Call for Motion to:

- **Approve** the charter for the Advisory Panel on Communication and Dissemination Research

Once the Motion Is Seconded:

- Move to **discuss, amend, or take another action** on the charter for the Advisory Panel on Communication and Dissemination Research

Voice Vote:

- Majority vote to **approve, disapprove, or take another action** on the motion



Development of Obesity PCORI Funding Announcement (PFA) and Budget: Demonstration Project for PCORnet

Rachael Fleurence, PhD

Program Director, CER Methods and Infrastructure

January 27, 2015



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About This Opportunity

- 🌐 All PCORnet CDRN Phase I awardees are required to develop an **obesity or weight cohort**
- 🌐 PCORI is requesting approval to fund **two studies** with a total cost not to exceed **\$9 million over 2 years** using these weight cohorts
 - 🌐 RTC is supportive of this initiative
 - 🌐 SOC formally approved the request on January 6, 2015
- 🌐 The studies will employ an **observational design** and will test the **technical and operational** aspects of PCORnet's Distributed Research Network
- 🌐 A significant objective of the demonstration projects is **to report on the testing of the emergent PCORnet data infrastructure**



Early Testing of PCORnet's Infrastructure

- 🌐 Use of the PCORnet **Distributed Research Network** is deemed essential for this demonstration project
- 🌐 The requested budget for these demonstration projects take into account significant testing activities related to PCORnet's emerging data infrastructure.
 - 🌐 Test Coordinating Center and network **technical and operational functionalities**
 - 🌐 Evaluate the use of distributed data for answering these type of questions
 - 🌐 Demonstrate network ability to use analysis-ready distributed datasets
 - 🌐 Test the ability to run analytical SAS code on completed datasets
 - 🌐 Formally report on the PCORnet infrastructure testing



Topic Generation and Prioritization

- 1 Topic generation and prioritization was conducted through the PCORnet Obesity Task Force in 2014
- 2 The Task Force prioritized the two following topics with respect to both the research question and their ability to test and evaluate the infrastructure:
 - 3 What is the comparative effectiveness with respect to weight loss and weight regain of different bariatric surgical procedures (Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding)?
 - 4 What are the comparative effects of alternative antibiotics used during the first two years of life on body mass index and risk of overweight and obesity during the third to fifth years of life?
- 5 Topic briefs and prioritization process were presented to the PCORnet CDRN and PPRN PIs for comment and approval
- 6 The top two highest priority topics were sent to the PCORI Addressing Disparities Advisory Panel for feedback



Topic 1: Bariatric Surgery

- 🌐 **Research Question:** What is the comparative effectiveness with respect to weight loss and weight regain of different bariatric surgical procedures (Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding)?
- 🌐 **Strong Support from the Advisory Panel recognizing the importance of generating this evidence**
- 🌐 **Suitability for PCORnet's demonstration project:**
 - 🌐 Exposure, outcomes, covariates largely captured by Electronic Health Records (EHR)
 - 🌐 Outcomes drawn primarily from PCORnet Common Data Model
 - 🌐 Large sample needed for subpopulations, rare adverse events



Topic 2: Long-term Effects of Antibiotics on Childhood Growth

- 🌐 **Research Question:** What is the comparative effects of alternative antibiotics used during the first two years of life on body mass index and risk of overweight and obesity during the third to fifth years of life ?
- 🌐 **Advisory Panel supported the topic and provided feedback that was addressed by the topic brief authors**
- 🌐 **Suitability for PCORnet's demonstration project:**
 - 🌐 Recent studies, which included 180,000 children, have documented an association between antibiotics and weight gain ¹
 - 🌐 The study engages a pediatric population
 - 🌐 The study leverages years of EHR exposure data on specific medications and patterns of medications and tests the use of prescription data in the Common Data Model
 - 🌐 The study also tests the complex query functionality of the distributed research network and processes for generating a patient-level data set within PCORnet

¹ Bailey L, Forrest C, Zhang P, Richards TM, Livshits A, DeRusso PA: Association of antibiotics in infancy with early childhood obesity. JAMA Pediatr. 2014 Nov;168(11):1063-9. doi: 10.1001/jamapediatrics.2014.1539.



Next Steps

- 🌐 The format of this award will mirror what was announced for PCORnet's first randomized controlled trial on Aspirin
 - 🌐 Topics will be issued as one limited PCORI Funding Announcement
 - 🌐 Reviewed by PCORI merit review
 - 🌐 The network will be asked to collaborate in submitting formal application(s) and study protocol
 - 🌐 Refine protocol post- selection pre- contract initiation
- 🌐 If approved, an announcement is expected in February 2015 with **applications due in the Spring of 2015**
- 🌐 Final selection of award will take place in the **Summer 2015**



Board Vote: Development of Obesity PCORI Funding Announcement (PFA) and Budget

Call for a Motion to:

- **Approve** the development of a PFA to fund up to two obesity studies in the areas of bariatric surgery and antibiotic use in children for a total amount of up to \$9 million to serve as PCORnet demonstration projects.

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative Motion**

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Communication and Dissemination Research Program

Jean Slutsky

Chief Engagement and Dissemination Officer and Program Director,
Communication and Dissemination Research

January 27, 2015



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Presentation Outline

- Portfolio overview
- Strategic shift
 - Exemplary projects
- Envisioning the future of CDR



Portfolio Overview



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



Communication and Dissemination Research (CDR) Program

We seek to fund projects that address critical knowledge gaps in the communication and dissemination process:

1. the communication and dissemination of research results to patients, their caregivers, and clinicians
2. The communication between patients, caregivers, and clinicians

To enable patients and caregivers to make the best possible decisions in choosing among available options for care and treatment.



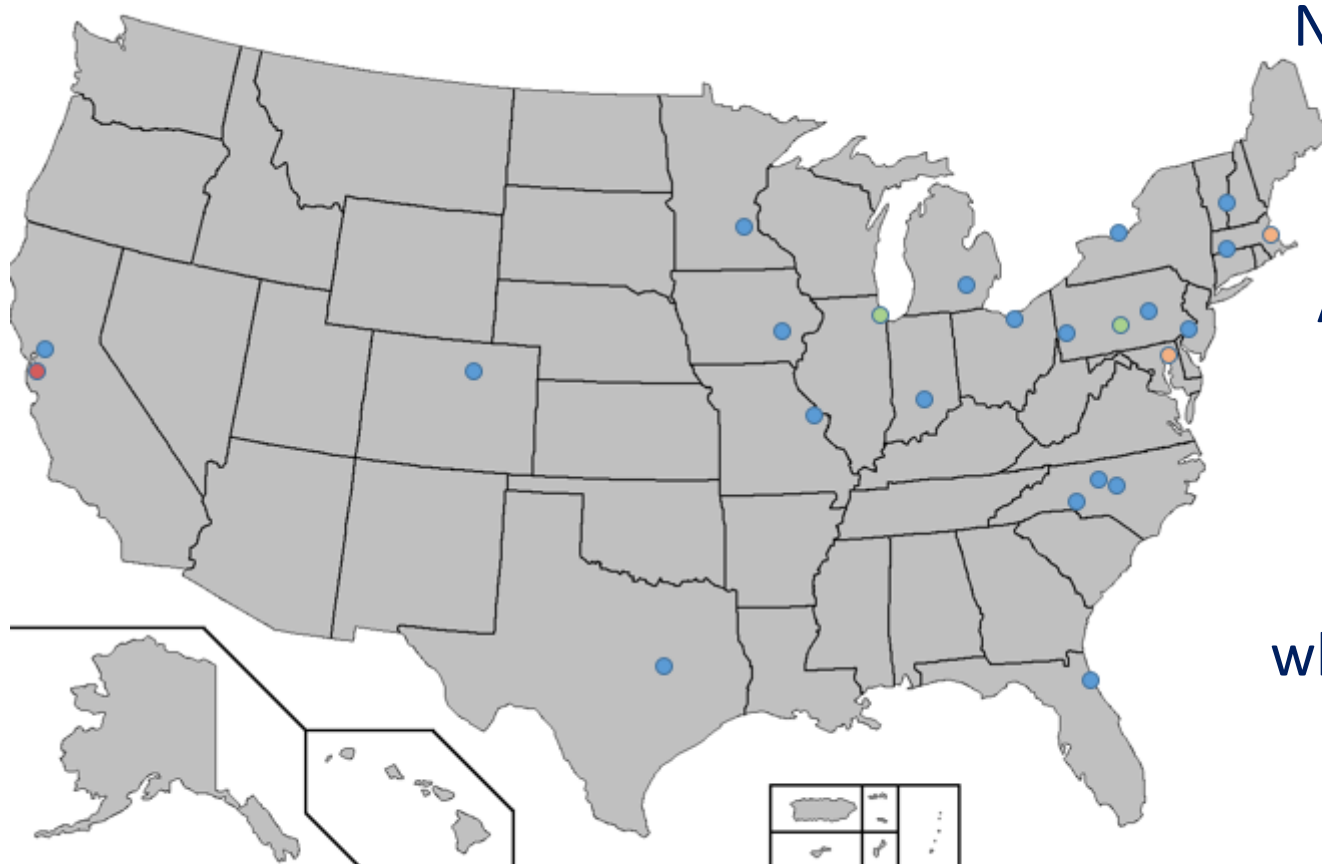
CDR Program

The CDR Program seeks to fund investigator-initiated research in:

- Head-to-head comparisons of demonstrated communication interventions, strategies, and tools
- Translation of research, decision support interventions, and risk communication
- Distribution of CER to patients, caregivers, and providers
- Patient, Clinician, and Stakeholder engagement with CER



Current Portfolio



Number of Projects:

33

Amount Awarded:

\$56.7 million

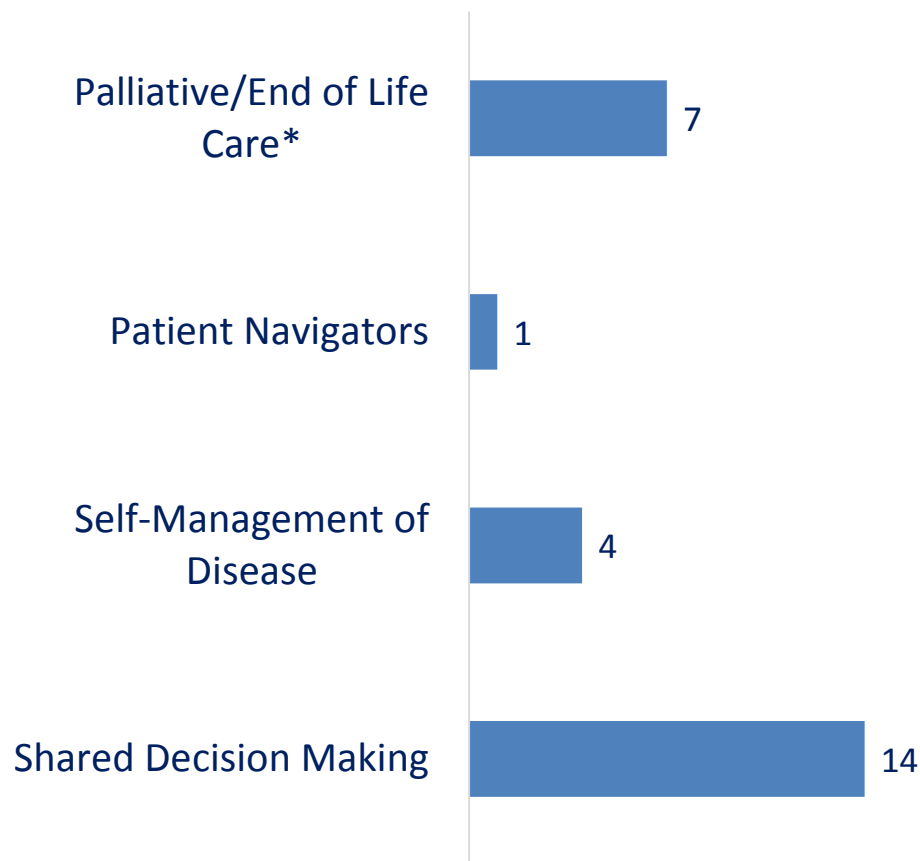
Number of states
where we are funding
research:

17

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

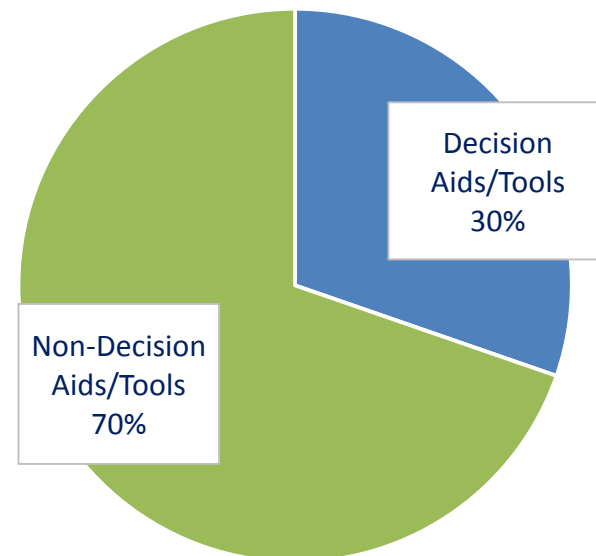


Portfolio by Common Themes

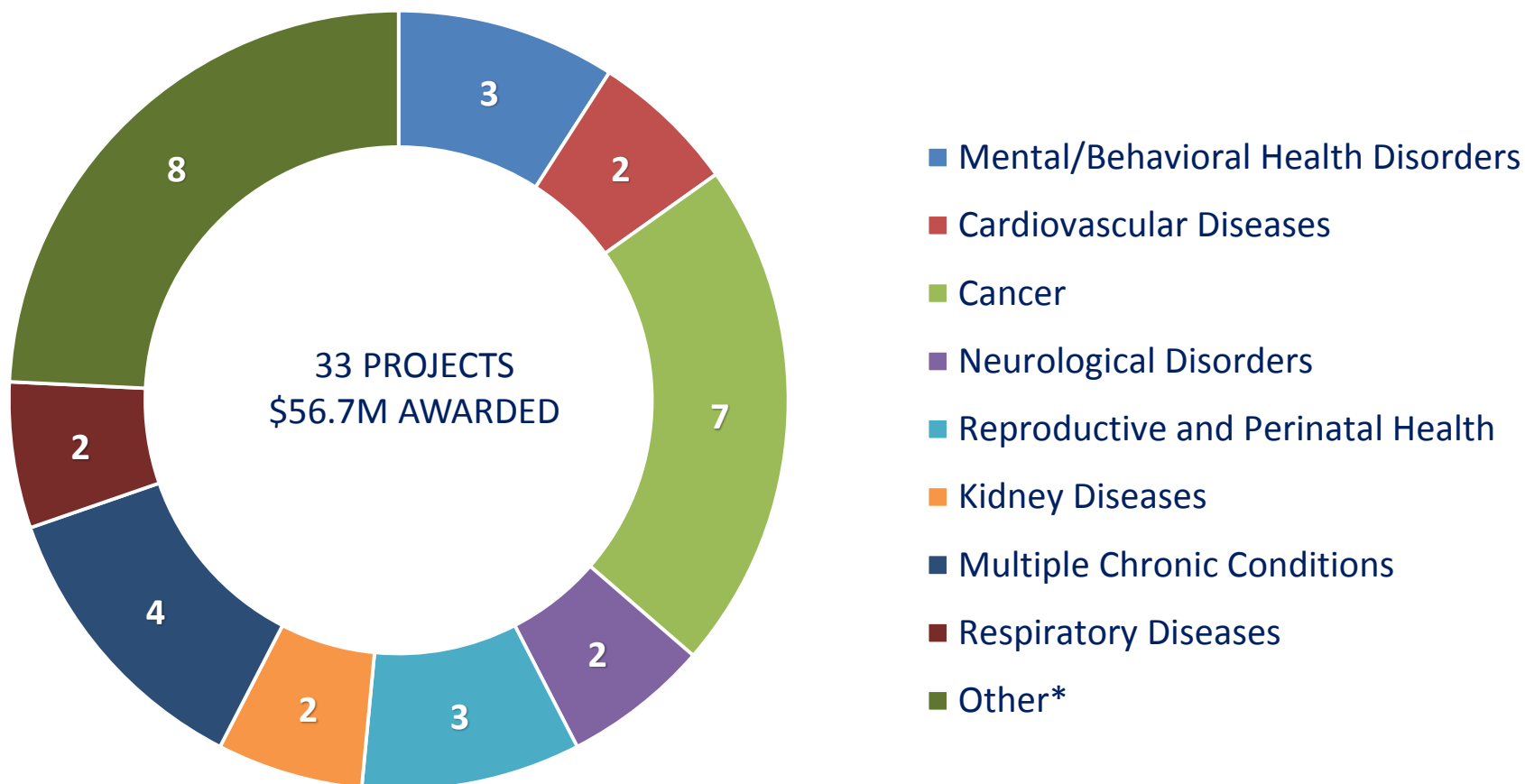


***Not mutually exclusive**

All Funded Studies, N=33



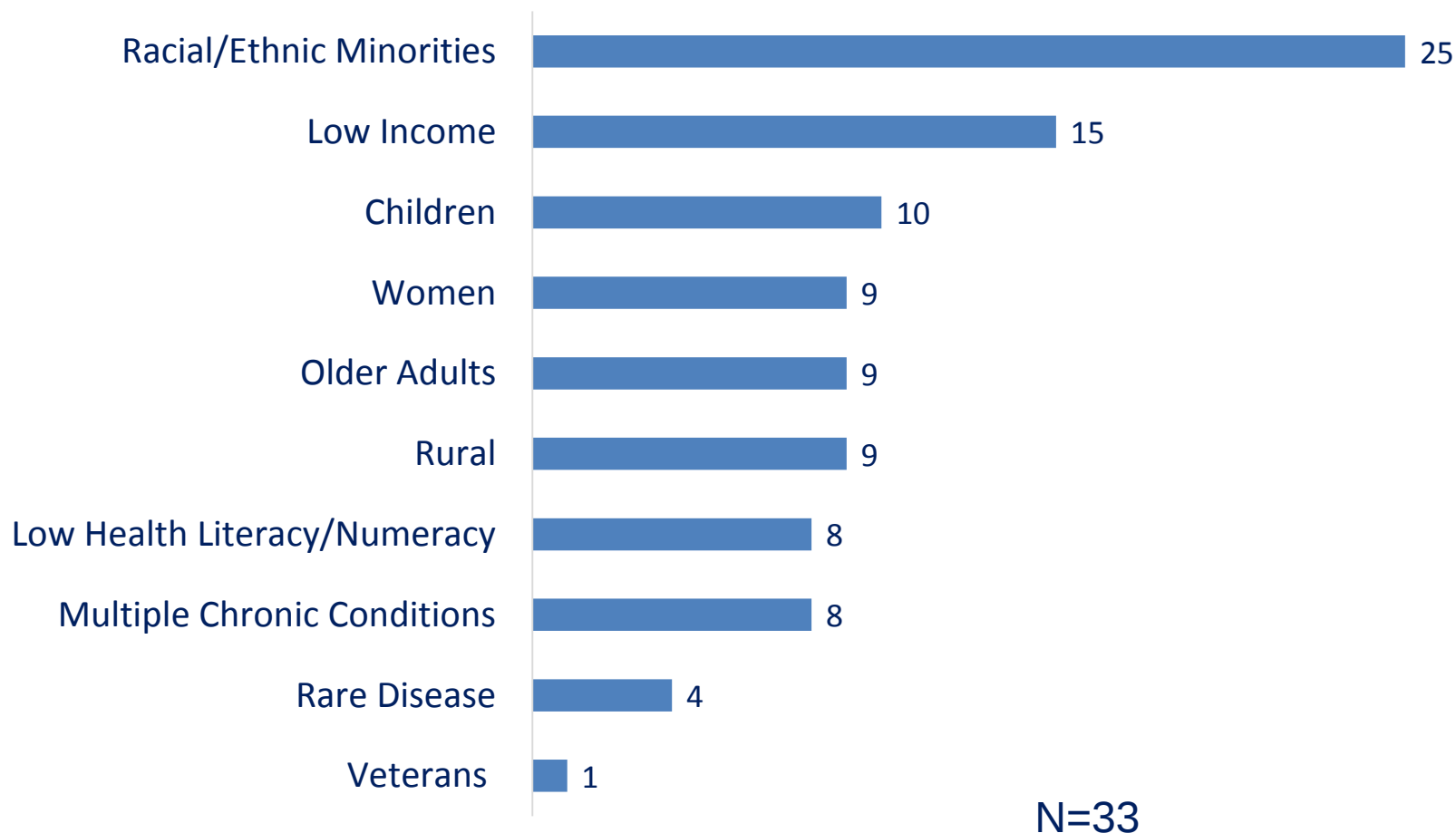
Portfolio by Disease/Condition



* Other includes: Diabetes (1), CT Scan Radiation Dose (1), Rare Genetic Disorders (1), etc.



Portfolio by PCORI Priority Populations*



***Not mutually exclusive**



Strategic Shift and Exemplary Projects



CDR Staffing Trajectory

Jean Slutsky, Program Director	(February 2014)
Bridget Gaglio, Program Officer	(June 2014)
Chris Gayer, Program Officer	(June 2014)
Sarah Chew, Program Assistant	(August 2014)
Michelle Henton, Program Associate	(February 2015)
Additional Program Officers	TBD



Period of Transition

Prior to June 2014:

- Many studies had been funded with significant effort toward intervention/tool development

Following CDR staffing:

- Emphasis on head-to-head comparisons of demonstrated interventions, strategies, and tools



Decision Aid Work Group

- Based on the large number of decision aids funded across PCORI, CDR created a science-wide work group to examine the decision aid portfolio
- Developed Task Order with a group at Duke to:
 - Conduct an extensive and exhaustive search to identify, categorize, and describe PCORI's decision aid/tool portfolio
- Findings will inform:
 - Strategic portfolio development
 - Potential targeted funding announcements



Exemplary Project

A Multicenter Trial of a Shared Decision Support Intervention for Patients and Their Caregivers Offered Destination Therapy for End-Stage Heart Failure

- Evaluates the effectiveness of a destination therapy left ventricular assist device (DT LVAD) shared decision support intervention for both patients and caregivers using a stepped wedge randomized trial design
- Assesses the adoption, implementation, and maintenance of the intervention across multiple providers and settings in order to maximize potential for dissemination and implementation in different settings and contexts

Larry Allen, MD
University of Colorado-Denver
Aurora, Colorado



Exemplary Project

Describing the Comparative Effectiveness of Colorectal Cancer Screening Tests: The Impact of Quantitative Information

- Evaluates the impact of viewing quantitative information in a decision aid on screening intention, screening behavior and perceptions of risk in patients eligible for colorectal cancer screenings
- Examines whether numeracy moderates the effect of quantitative information on screening behavior
- Uses a public deliberation exercise to review the results of the clinical trial and make recommendations about how decision aids should present quantitative information to patients

Peter Schwartz, MD, PhD
Indiana University
Indianapolis, Indiana



Envisioning CDR's Future



CDR Program Goals

- Launch the Advisory Panel on CDR
- Continue to refine the Broad PFA
- Contribute to PCORI Dissemination and Implementation Framework
- Consider larger, more targeted stakeholder-driven investments
 - Host a Program-Specific Pragmatic Trial
 - Develop a Targeted PFA



Coming Soon: Advisory Panel on CDR

- Identify and prioritize health communication and dissemination research topics
- Suggest new topics for future prioritization
- Provide feedback on specific research questions and study designs
- Review and comment periodically on the research portfolio, including identification of gaps, and the overall impact of the portfolio
- Bring perspectives from other disciplines, patients, and caregivers



Future Vision-Key Questions

- What will be the role of CDR in PCORI's dissemination strategy?
- How will the Decision Aid Work Group influence the future priorities of the CDR program?
- What impact with the Advisory Panel on CDR have on the future of CDR's research program?



PCORI CER Stakeholder Surveys: Update and Preliminary Results from Researchers

Laura Forsythe, PhD, MPH

Senior Program Officer, Science, Research Integration & Evaluation

Lori Frank, PhD

Program Director, Science, Research Integration & Evaluation

January 27, 2015



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Objectives

- 🧑 Researcher survey
 - Methods
 - Preliminary results
 - Discussion and next steps



Discussion Questions

- What steps should PCORI take to increase interest in CER among researchers?
- What messages should PCORI target to the research community to increase interest in applying to PCORI for funding?



CER Stakeholder Surveys

Patients

- Nationally representative sample of patients with chronic conditions
- Patients with rare diseases

Clinicians

- Nationally representative sample of primary care and specialty physicians, physician assistants, and nurse practitioners

Caregivers

- Family caregivers of those with chronic or rare conditions

Researchers



Researcher Survey: Objectives

- 🌱 Understand researcher attitudes towards and experience with patient-centered CER
- 🌱 Identify barriers to and facilitators of conducting CER and engaging with patients as partners
- 🌱 Understand attitudes toward and experiences with PCORI
- 🌱 Examine use of the Methodology Standards and identify opportunities for dissemination



Researcher Survey: Methods

- 🌱 Partnership with American Institutes for Research (AIR)
- 🌱 Guided by project specific multi-stakeholder advisory panel and researcher working group
- 🌱 Survey development included literature review and cognitive testing
- 🌱 Recruitment via mailing lists for professional research organizations, relevant AHRQ initiatives, and PCORI (Fall 2014)



Researcher Survey: Recruitment

- PCORI mailing list
- North American Primary Care Research Group
- International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
- International Society for Quality of Life Research (IOSQOL)
- Society for Medical Decision Making
- AcademyHealth
- Society of Behavioral Medicine: Evidence-Based Behavioral Medicine Special Interest Group
- Kaiser Permanente Research, Center for Effectiveness & Safety Research
- AHRQ Evidence-based Practice Centers (EPCs)
- AHRQ Innovative Adaptation and Dissemination of AHRQ Comparative Effectiveness Research Products (iADAPT) centers
- AHRQ Centers for Education and Research on Therapeutics (CERTs)
- AHRQ Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network



Researcher Survey: Sample (N=508)

- 68% from medical school or academic setting
- 41% with 16+ years research experience, 21% <6 years experience
- 78% have been a Principal Investigator (PI)
- 34% practicing healthcare clinicians
- 61% female



Preliminary Results

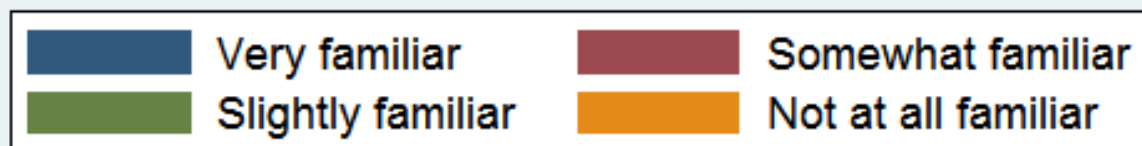
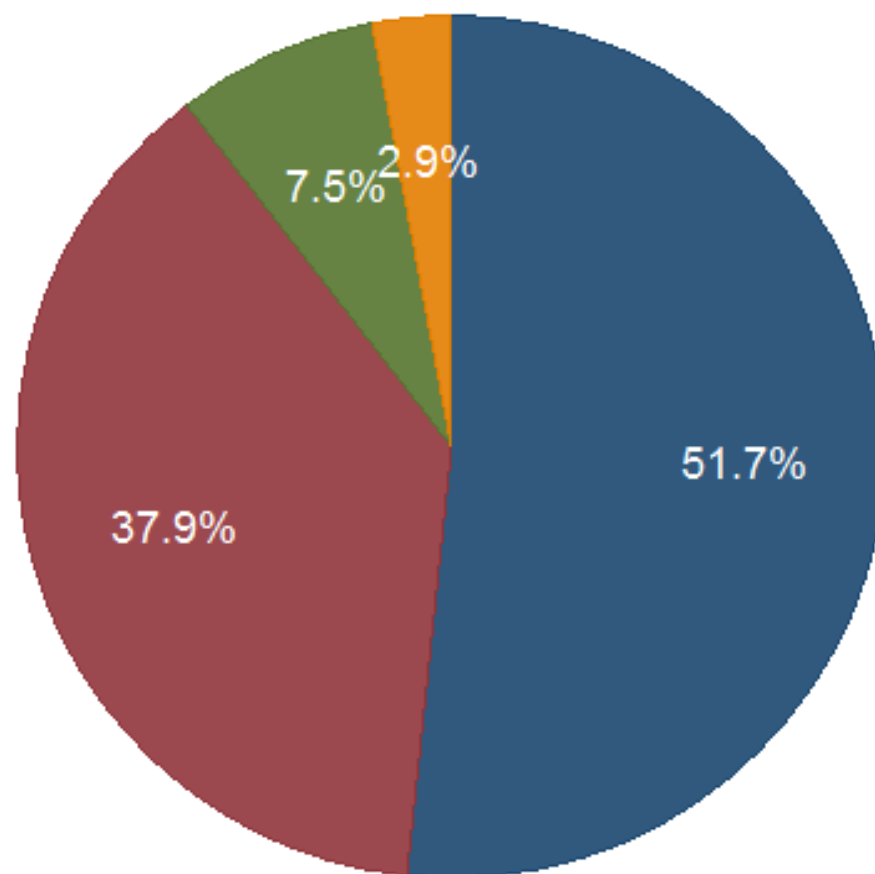


Q5: How important are each of the following factors when you are deciding to pursue a specific funding opportunity...? (% very important)

- 🌱 Alignment with research areas of interest (85%)
- 🌱 Balance between effort required and likelihood of award (54%)
- 🌱 Clinical or policy impact of the award (50%)
- 🌱 Award amount (48%)



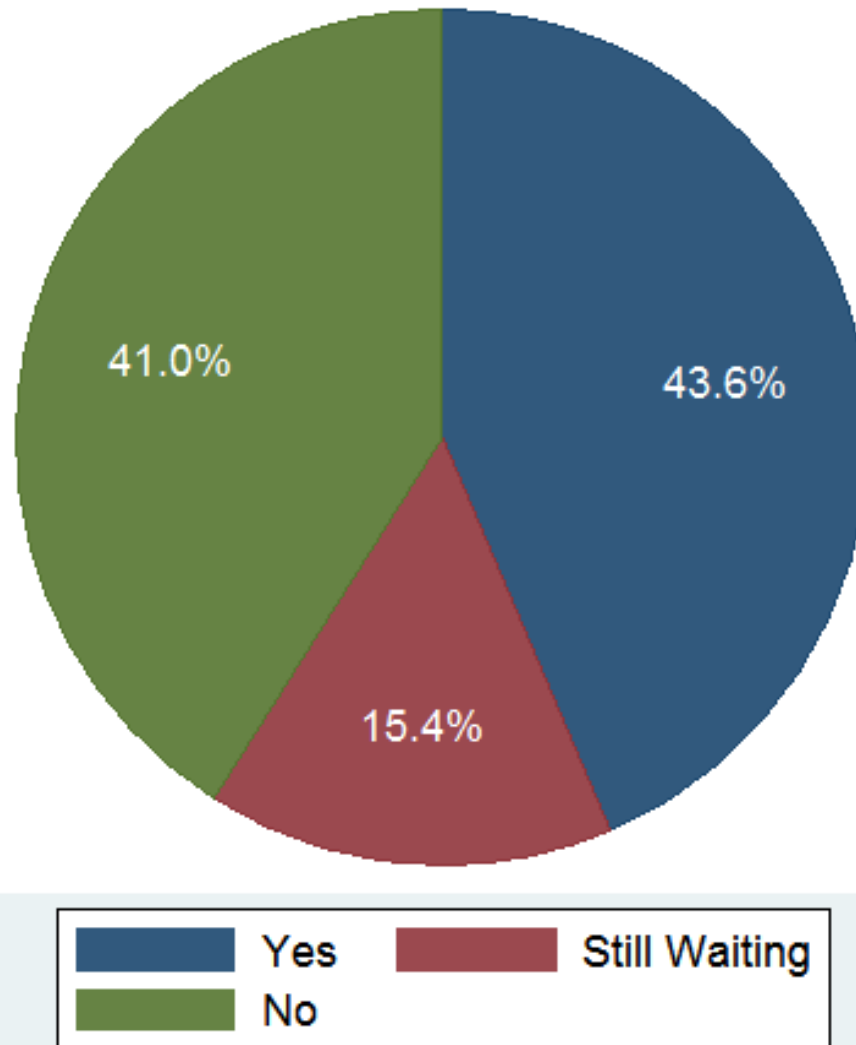
Q24: How familiar are you with PCORI?



N=480



Q31: Have you or your team ever had your research funded by PCORI?



N=273

Note: Among those who have applied to PCORI (N=273, 59%)

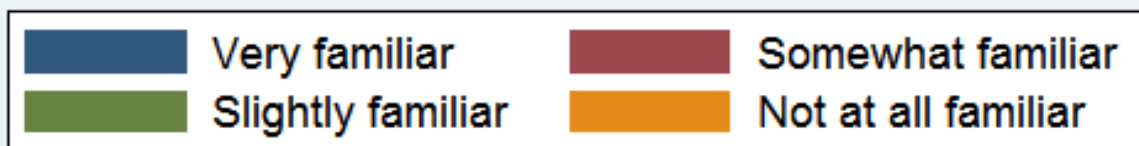
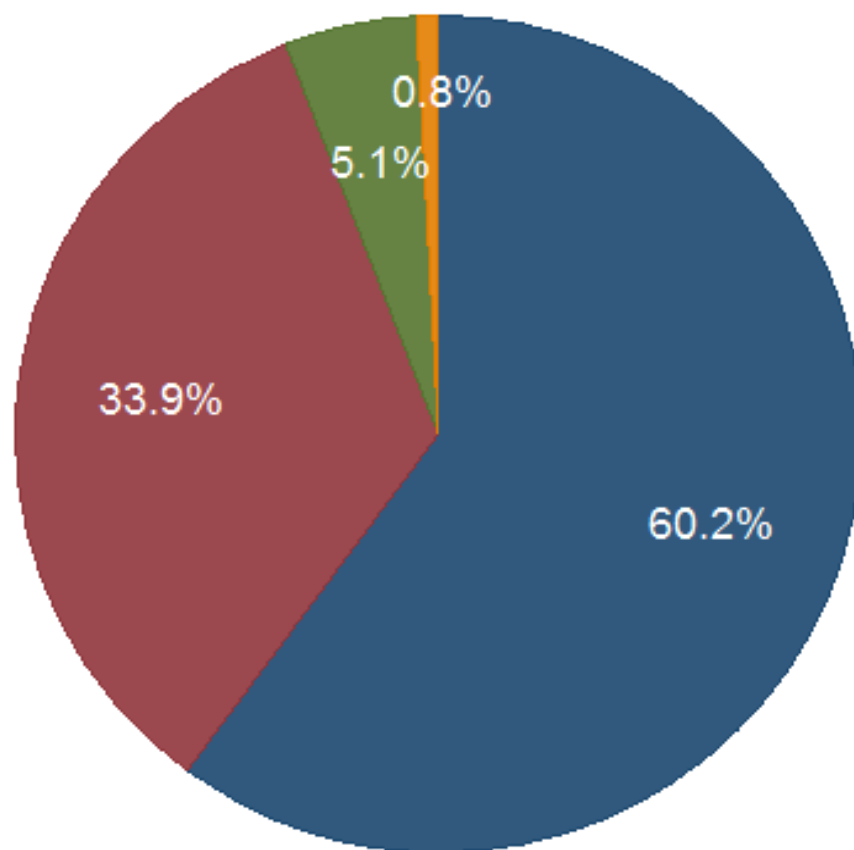


Reasons not applied to PCORI

- Lack of alignment between PCORI funding criteria and one's area of research (34%)
- Effort to complete a proposal given the size of the award (34%)
- Lack of clarity in PCORI requirements (23%)
- PCORI's requirement to engage patients (20%)
- Frequent changes to the application process (19%)



Q8: How familiar are you with the concept of CER?

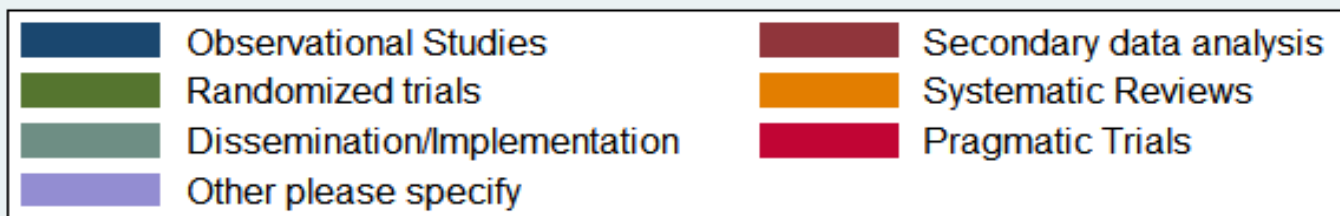
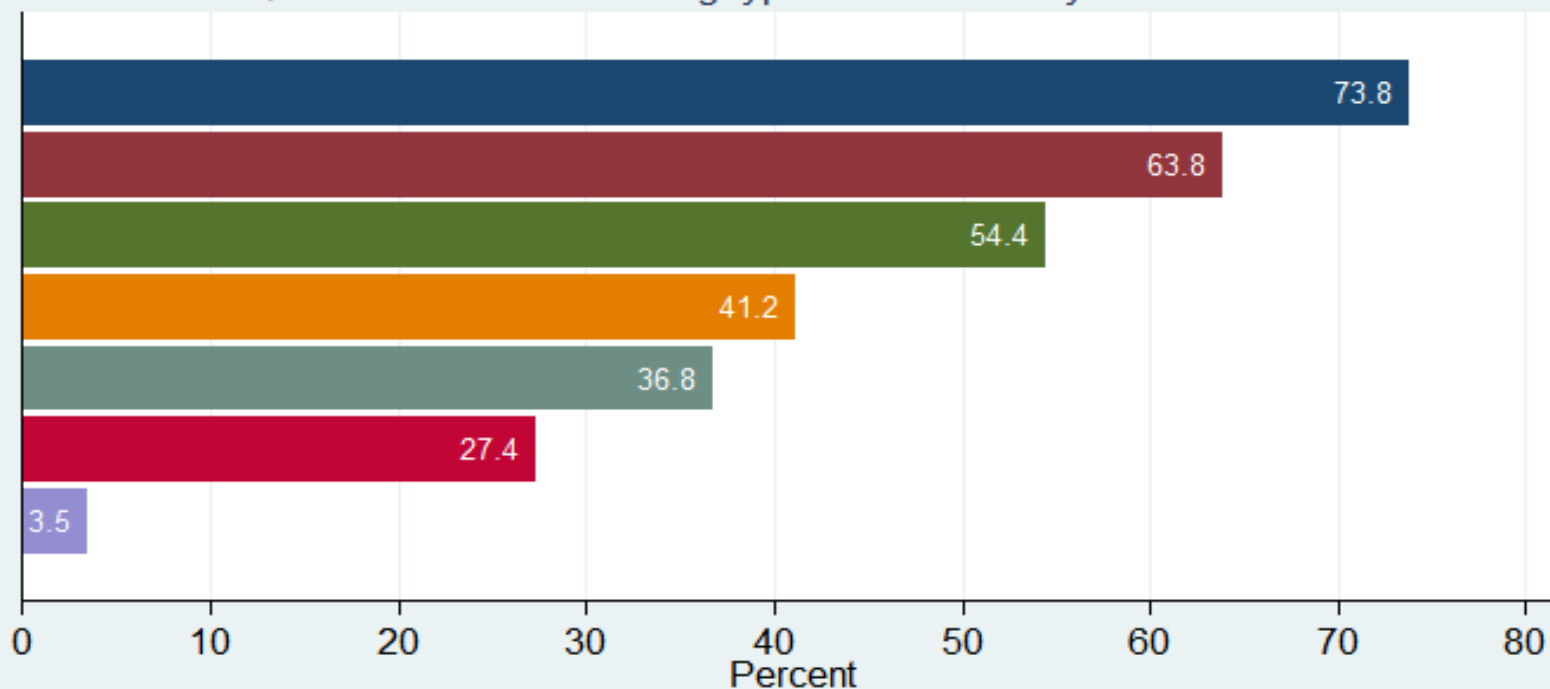


N=507



Of the 67% who had ever conducted CER:

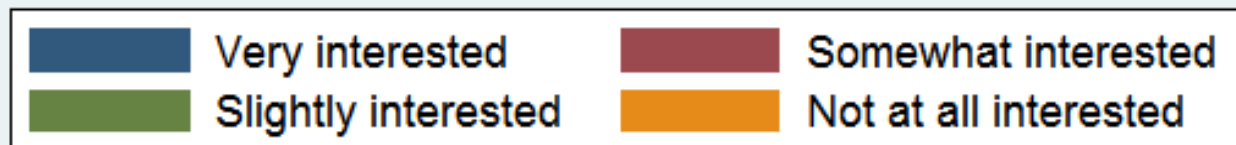
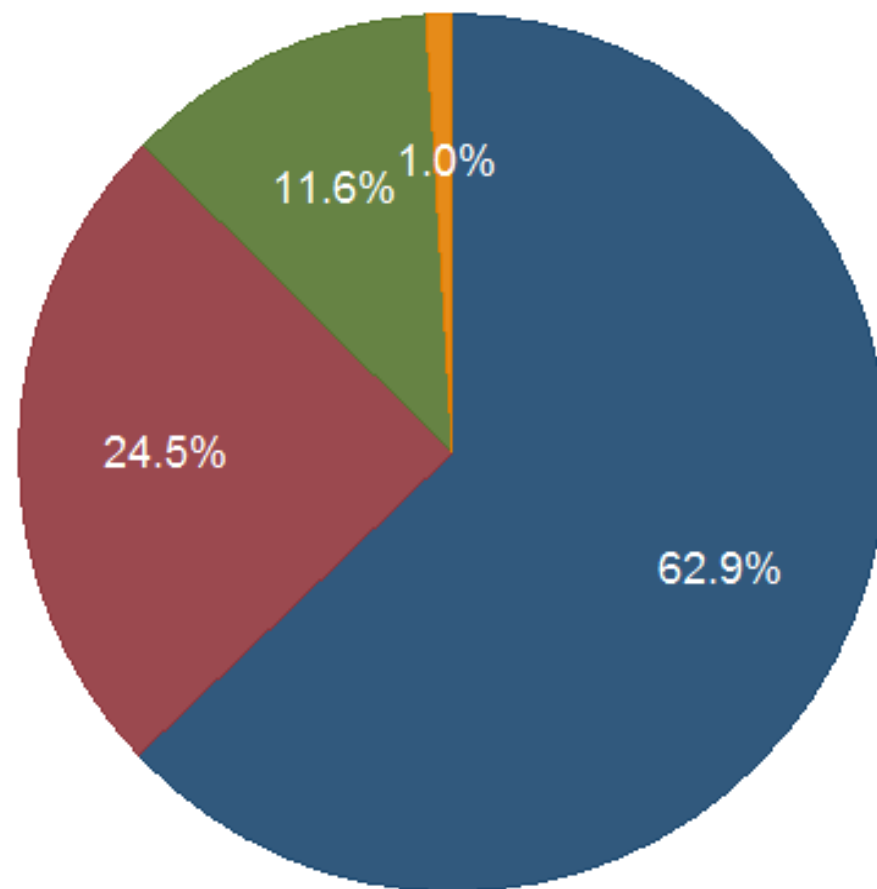
Q10: Which of the following types of CER have you conducted?



N=340



Q18: How interested would you be in involving patients/caregivers as research partners?

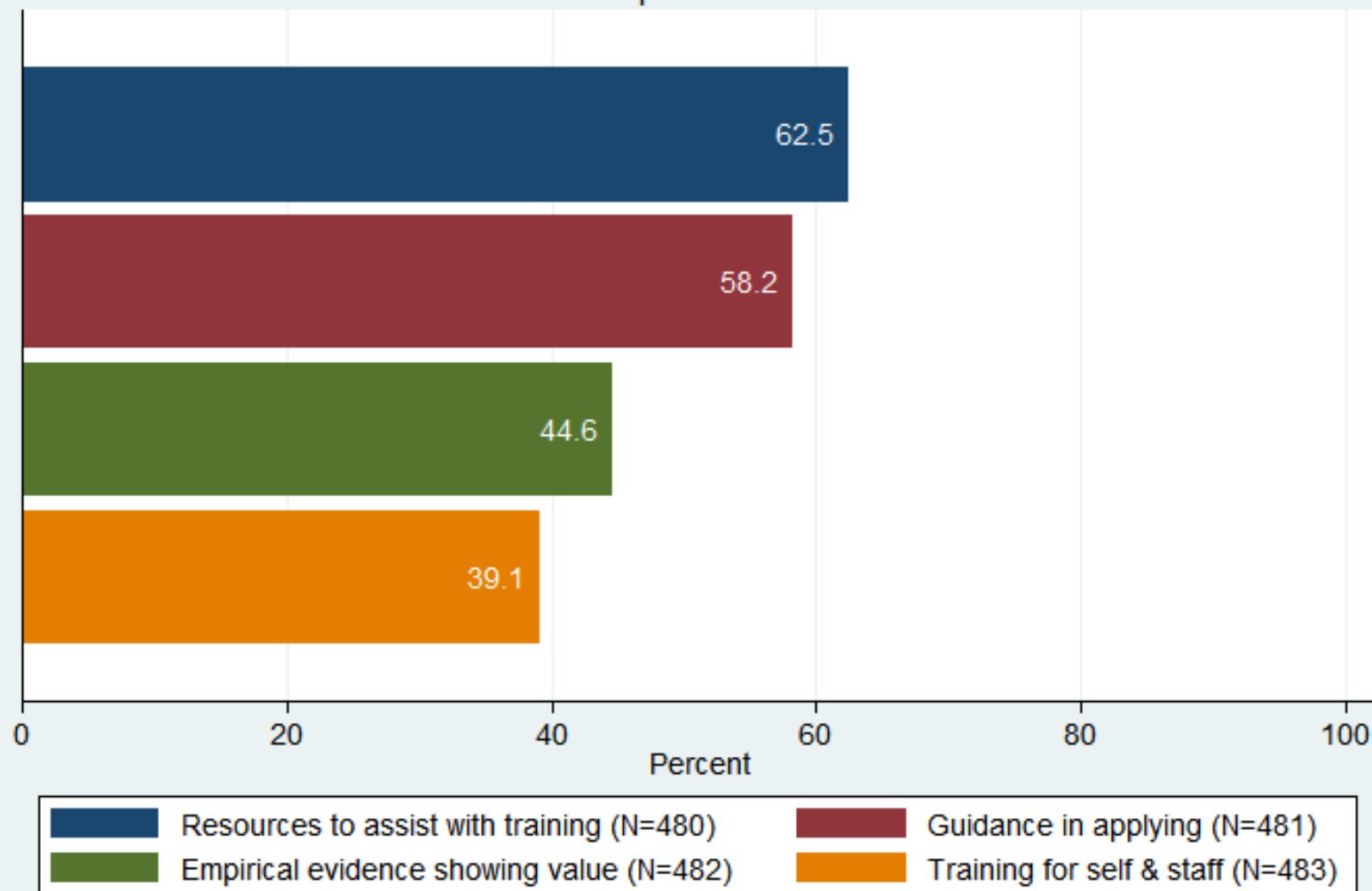


N=498



Q19: How much would each factor facilitate patient/caregiver involvement?

Percent responded A Great Deal



How much would each of the following factors hinder your involvement of patients and/or caregivers as partners? (% responding “a great deal”)

- 🌱 Lack of infrastructure for involving partners (48%)
- 🌱 Potential increased resources (e.g., staff) (37%)
- 🌱 Regulations (e.g., HIPAA, IRB concerns) (34%)
- 🌱 Added time needed (28%)
- 🌱 Complexity of managing partnered research (28%)
- 🌱 Challenges compensating partners (27%)



Summary

- This sample of researchers is familiar with CER, PCORI, and PCORI's application process
- Reasons for not applying for PCORI funding include researcher view of effort relative to award size and lack of clarity about requirements
- Interest in engaging patients and other stakeholders in research is high among these researchers; infrastructure, lack of resources, and limited time are perceived barriers



Discussion Questions

- What steps should PCORI take to increase interest in CER among researchers?
- What messages should PCORI target to the research community to increase interest in applying?



Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chair, Board of Directors



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