Board of Governors Meeting
via Teleconference/Webinar

September 30, 2014
12:00 - 1:30 pm ET

Patient-Centered Outcomes Research Institute

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director

GAO Appoints New Methodology Committee Members

On September 18, the U.S. Government Accountability Office (GAO) announced the appointment of three new members to fill open seats on PCORI's Methodology Committee:

- **Cynthia Girman, DrPh,** *Distinguished Scientist, Comparative and Outcomes Evidence, Center for Observational and Real World Evidence, Merck Research Laboratories, Merck & Co., Inc.*
- **Sally Morton, PhD,** *Professor and Chair, Department of Biostatistics, Graduate School of Public Health, University of Pittsburgh. Morton has served as a statistical methodology expert to the Committee since January 2012.*
- **Neil R. Powe, MD, MPH, MBA,** *Professor of Medicine, University of California, San Francisco, and Chief of Medicine, San Francisco General Hospital*

NIH Plans to Move Ahead with PCORI-Funded Blood Pressure Control Study

The NIH has issued a notice of intent to publish a Funding Opportunity Announcement (FOA) for a study of multi-level interventions to improve blood pressure control in racial/ethnic minority, low socioeconomic status, and/or rural populations.

- The project is supported by funding from PCORI under a memorandum of understanding with the NIH's National Heart, Lung and Blood Institute and National Institute of Neurological Disorders and Stroke.
- Up to two trials will be funded, totaling up to $25 million.
- The FOA is expected to be published in November with applications expected to be due in January 2015.

Agenda

Time	Agenda Item
12:00 – 12:05 pm	Call to Order, Roll Call, and Welcome
12:05 – 12:15 pm	Introductions: Summary of Proposed Awards
12:15 – 12:30 pm	Consider for Approval: Awards for Targeted PFA on Obesity Treatment Options Set in Primary Care for Underserved Populations
12:30 – 12:45 pm	Consider for Approval: Award for Targeted PFA on The Effectiveness of Transitional Care
12:45 – 1:10 pm	Consider for Approval: Awards for Spring 2014 Funding Cycle
1:10 – 1:25 pm	Update on PCORI / AHRQ Uterine Fibroids Funding Announcement
1:25 – 1:30 pm	Wrap-up and Adjournment

Summary of Proposed Awards

Christine Goertz, DC, PhD
Chair, Selection Committee
Member, Board of Governors

Bryan Luce, PhD, MBA
Chief Science Officer

Patient-Centered Outcomes Research Institute

Selection Committee Membership

From the Board of Governors

- Christine Goertz, DC, PhD, Chair
- Debra Barksdale, PhD, RN
- Alicia Fernandez, MD
- Leah Hole-Marshall, JD
- Harlan Krumholz, MD

From the Methodology Committee

- Michael Lauer, MD

Spring 2014 Cycle: Overview and Summary

Bryan Luce, PhD, MBA
Chief Science Officer

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Spring 2014 Cycle: Targeted PFAs

3
New Projects

Targeted PFA	Allotted	Proposed Total Budget*	*Difference*	Average Project Budget*
Obesity Treatment Options Set in Primary Care for Underserved Populations	$20,000,000	$19,998,962	*- $1,038*	$9,999,481
Effectiveness of Transitional Care	$15,000,000	$14,908,541	*- $91,459*	$14,908,541
TOTALS:	$35,000,000	$34,907,503	*- $92,497*	$11,635,834

*Budget = direct + indirect costs

Spring 2014 Cycle: Broad PFA

43*
New Projects

Broad PFA	Allotted	Proposed Total Budget**	*Difference*	Average Project Budget**
Addressing Disparities	$8,000,000	$7,396,564	*- $603,436*	$1,849,141
Assessment of Options	$32,000,000	$20,547,639	*- $11,452,361*	$1,867,967
Communications and Dissemination	$8,000,000	$8,564,727	*+ $564,727*	$1,712,945
Improving Healthcare Systems	$16,000,000	$14,483,239	*- $1,516,761*	$2,896,648
Improving Methods for Conducting PCOR	$17,000,000	$16,066,404	*- $933,596*	$892,578
TOTALS:	$81,000,000	$67,058,573	- $13,941,427	$1,595,502

*Includes 1 project from Winter 2014 cycle
**Budget = direct + indirect costs

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Spring 2014 Cycle: Targeted and Broad PFAs

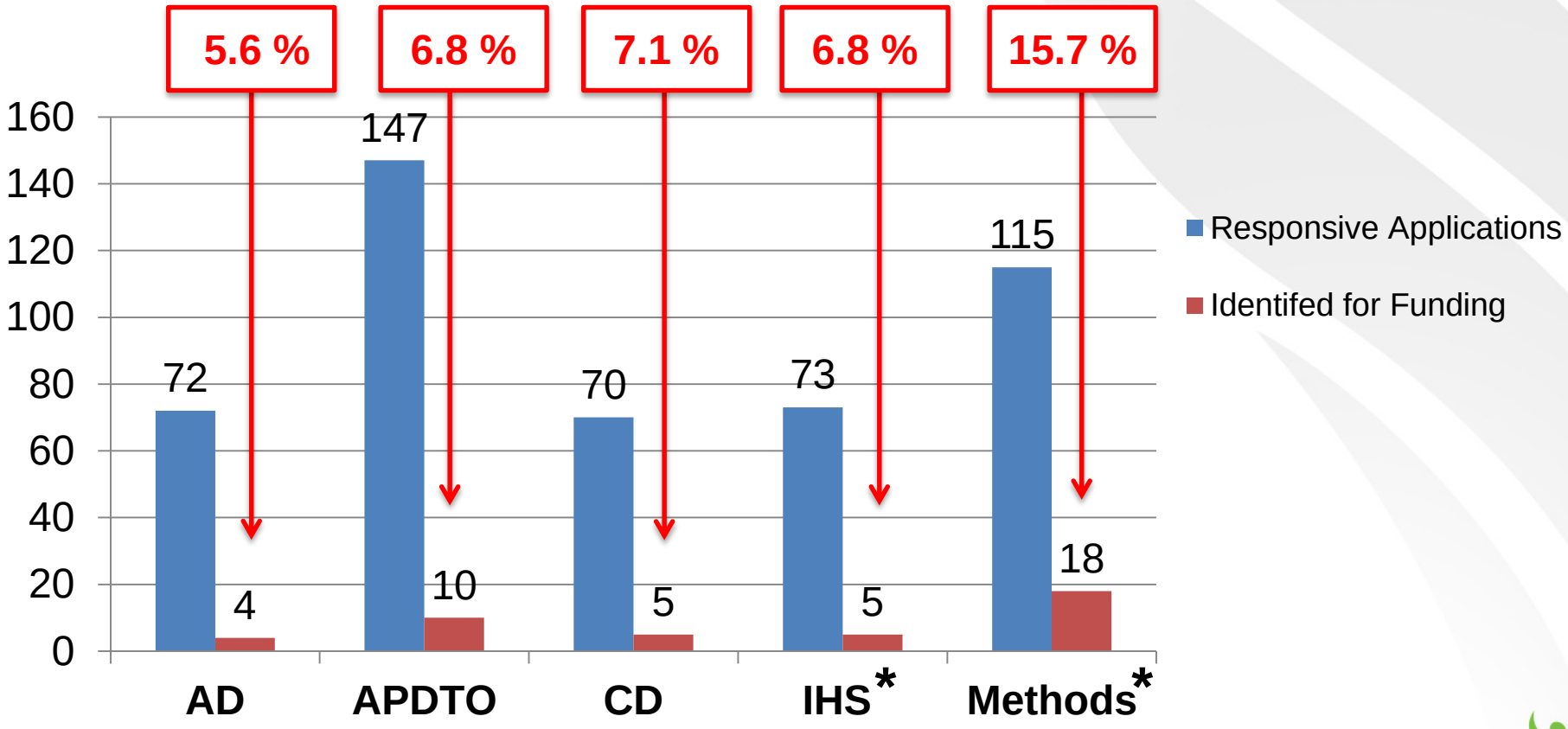
What is being recommended today?

PCORI staff recommend funding *9.2%* of responsive applications.

We are proposing 45 applications for funding out of 490 responsive applications.

Spring 2014 Cycle: Broad PFA

What percentage are we proposing to fund by Program?



*Methods and IHS program used a competitive LOI screen.

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Resubmissions and Funding Rates

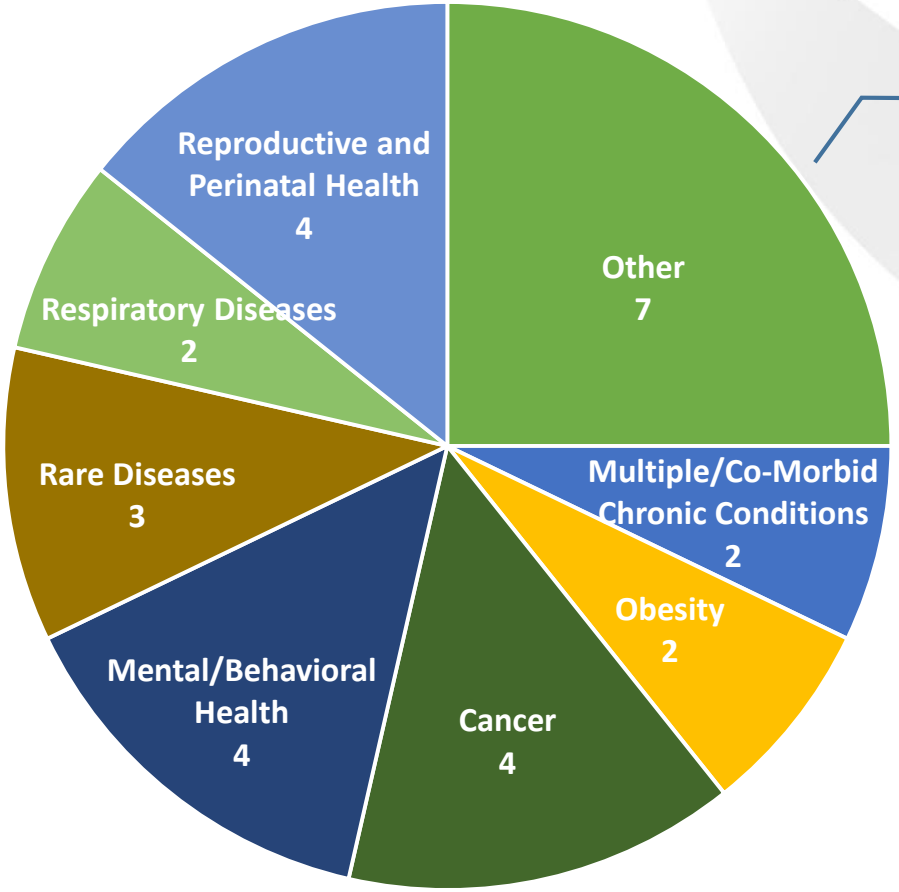
- Resubmissions received and reviewed: 19.4%
- Overall recommended funding rate of resubmitted applications vs. new submissions: 12.6% vs. 8.4%
- Percent of applications recommended for funding that were resubmissions: 26.7%

Obesity and Transitional Care Targeted PFAs

- AD Obesity Targeted PFA
  - Recommend funding **2 projects** out of 9 responsive applications
- IHS Transitional Care Targeted PFA
  - Recommend funding **1 project** out of 4 responsive applications received

What's in the Slate: Conditions

n=28* Projects

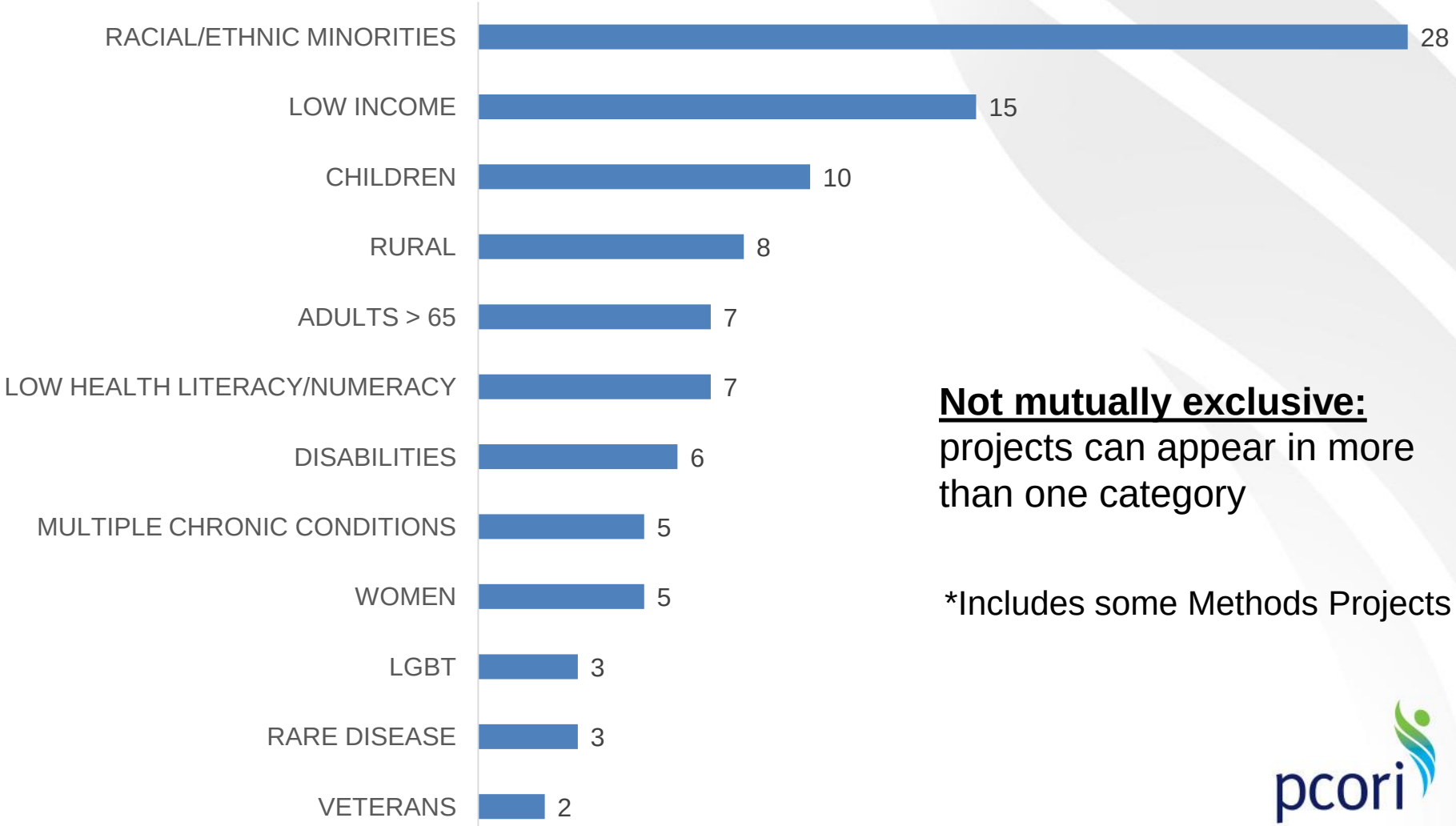


- Allergies and Immune Disorders
- Infectious Diseases
- Liver Disease
- Neurological Disorders
- Skin Diseases
- Trauma/Injury

*Does not include Methods Projects

What's in the Slate: Priority Populations

n=39* Projects



Not mutually exclusive: projects can appear in more than one category

*Includes some Methods Projects

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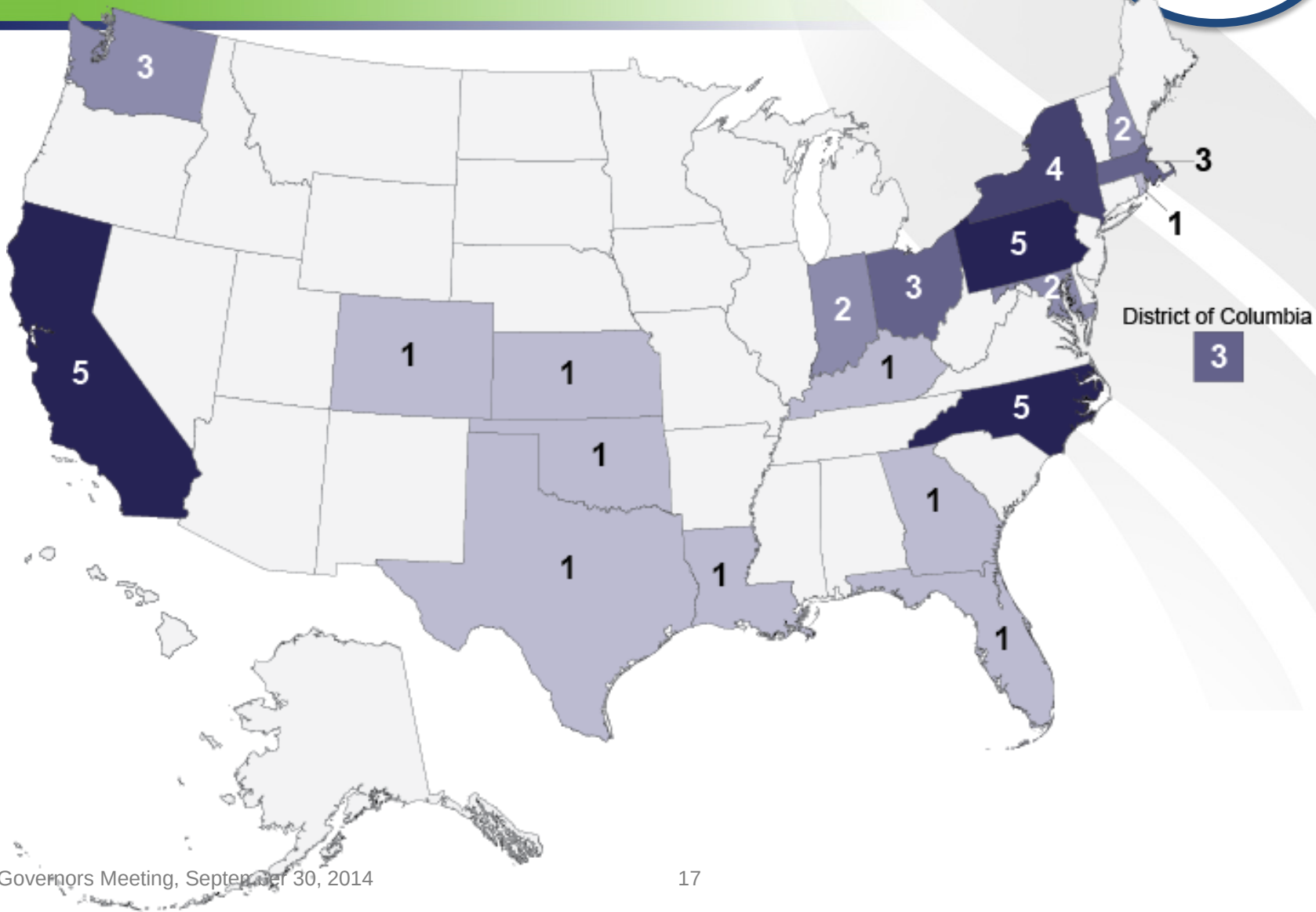
What's in the Slate: Locations

n=46 Projects



Spring 2014 Cycle: Targeted PFAs

Spring 2014 Cycle: Targeted PFAs

Targeted PFA	Project Length	Maximum Costs Allowed	Total Cycle Budget
Obesity Treatment Options Set in Primary Care for Underserved Populations	5 Years	$10 M	$20 M
Effectiveness of Transitional Care	3 Years	$15 M	$15 M

Obesity Treatment Options Set in Primary Care for Underserved Populations

Romana Hasnain-Wynia, PhD
Program Director, Addressing Disparities

Bryan Luce, PhD, MBA
Chief Science Officer

Patient-Centered Outcomes Research Institute

Addressing Disparities
Obesity Treatment Options in Primary Care for Underserved Populations Targeted PFA

- History:
  - **December 2012:** Prioritized by the PCORI Board
  - **April 2013:** Expert workgroup convened
  - **April-July 2013:** Gap analysis conducted by Addressing Disparities Program staff
  - **July 2013:** Small Task Force of Experts convened based on PDC (now SOC) recommendation
  - **February 2014:** Competitive Letter of Intent (LOI) review
    - Of the 48 LOIs received, 11 applications were invited
    - May 2014: Received 9 of 11 invited applications
  - **August 2014:** All 9 applications reviewed
  - **September 2014:** Selection Committee approved two awards

Focus of Targeted PCORI Funding Announcement

- **Multi-site** pragmatic clinical trials to test the comparative effectiveness of **multi-component behavioral therapy interventions** (e.g., cognitive behavioral therapy or other effective behavioral change strategies) set within **primary care** for achieving weight loss in obese patients who are at risk for experiencing disparities in outcomes
  - Racial/ethnic minorities
  - Low socio-economic status populations
  - Rural populations

Centers for Medicare & Medicaid Services (CMS) Covers

- The provision of intensive, but brief (15 minutes, weekly, for first month followed by every other week for 5 months), behavioral counseling to obese seniors in primary care settings by physicians, nurse practitioners, or physician assistants from the practice

Comparator and Intervention Arm Descriptions

- **Comparator Arm**
  - Primary care obesity treatment that is currently reimbursed by CMS (e.g., behavioral counseling in primary care settings by physicians, nurse practitioners, or physician assistants from the practice)
  - Practices might receive minimal input, such as a one-time seminar for clinicians that covers current obesity treatment guidelines
- **Intervention Arm(s)**
  - Test an evidence-based comprehensive lifestyle intervention
  - Intensity:
    - At least 14 in-person contact sessions in months 1–6
    - At least monthly contact sessions in months 7–24
  - Must have at least one component within primary care with linkages or partnerships with community-based programs and/or practitioners
  - Interventionists must have training in delivering an evidence-based behavioral weight-loss intervention

Addressing Disparities: Obesity Targeted PFA
*Recommended Projects**

Total Budget	Project Title
$9,999,000	The Louisiana Trial to Reduce Obesity in Primary Care
$9,999,962	Midwestern Collaborative for Treating Obesity in Rural Primary Care

Subject to the acceptance of PCORI's contract terms and conditions.

The Louisiana Trial to Reduce Obesity in Primary Care

- The **primary aim** of this trial is to develop and test the effectiveness of a 24-month, patient-centered, pragmatic, and scalable obesity treatment program delivered within primary care, in low-income and racial/ethnic minority populations.
- The intervention arm participants will receive a high-intensity, health literacy-appropriate, and culturally-adapted lifestyle intervention targeting increased physical activity and reduced dietary intake delivered by health coaches embedded in a primary care setting and supervised by providers trained in obesity science.

The Louisiana Trial to Reduce Obesity in Primary Care

- **Outcomes:**
  - Primary outcome is percentage change in body weight
  - Secondary outcomes include: improvements in quality of life, functional capacity, satisfaction with medical care, and improvement of obesity co-morbidities (e.g., hypertension, dyslipidemia, insulin resistance)
- **Strengths:**
  - Significant potential for the study to improve health care and outcomes
    - Because of limited time available during primary care visits, and lack of physician training in obesity treatment protocols, the trial uses the previously successful Look AHEAD program with adaptions, including adding a trained health coach within the primary care setting to deliver obesity treatment
  - Strong potential to disseminate practices broadly and replicate the intervention in other settings
  - Takes advantage of PCORnet infrastructure (LA CDRN)

Midwestern Collaborative for Treating Obesity in Rural Primary Care

- **Primary Aims:**
  - Test the hypothesis that **Primary Care Medical Home (PCMH)** is more effective than the obesity treatment covered by CMS in reducing weight at 24 months
  - Test the hypothesis that **Disease Management** (**DM)** is more effective than the obesity treatment covered by CMS in reducing weight at 24 months
- Intervention arm participants in both groups will receive a comprehensive lifestyle intervention modeled after the Diabetes Prevention Program with either in-person primary care medical home or remote disease management contact sessions

Midwestern Collaborative for Treating Obesity in Rural Primary Care

- **Outcomes:**
  - **Primary outcome** is weight loss at 24 months
  - **Secondary outcomes** are Quality of life, Stress and physical activity levels, Dietary changes, Blood pressure, Fasting glucose
- **Strengths:**
  - Potential for study to influence practice is high because the delivery models are already in place
  - Innovative applications of the primary care medical home and disease management models to obesity treatment
  - Takes advantage of PCORnet infrastructure (Greater Plains Collaborative CDRN)

Board Vote: Approve Funding for the Recommended Slate from the Obesity Treatment Options Targeted PFA

Call for Motion to:	• **Approve funding for the recommended slate from the Obesity Treatment Options Targeted PFA**
Once the Motion Is Seconded:	• **Move to discuss, amend, or take another action on the selected topic**
Roll Call Vote:	• **Majority vote to approve, disapprove, or take another action on the motion**

The Effectiveness of Transitional Care

Steven Clauser, PhD
Program Director, Improving Healthcare Systems

Bryan Luce, PhD, MBA
Chief Science Officer

Patient-Centered Outcomes Research Institute

Improving Healthcare Systems
The Effectiveness of Transitional Care Targeted PFA

- **History:**

Milestone	Date Completed
Prioritized by the IHS Advisory Panel	April 20, 2013
Convened an Expert workgroup	July 12, 2013
Approved by the PCORI Board • Targeted PFA for a single 3-year study	December 3, 2013
Released Targeted PFA	February 5, 2014
Completed Competitive LOI Review • 4 of 22 applicants invited	March 10-21, 2014
Conducted Merit Review • 4 applications	August 4, 2014
Selection Committee Approval of one award	September 16, 2014

This is the first topic prioritized by a PCORI Advisory Panel to complete this entire process.

Goals of The Effectiveness of Transitional Care Targeted PFA

- Identify forms of transitional care (clusters of specific services) that produce the best patient-centered results for different patients in different healthcare contexts
- Produce usable information that healthcare and community organizations, and patients and caregivers can use to choose which clusters of transitional care services will best meet the needs of unique patient populations
- Identify the factors that could promote or impede the scalability of different forms of transitional care

Improving Healthcare Systems
*Recommended Project**

Total Budget	Project Title
$14,908,541	Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health In Care Transitions by Evaluating the Value of Evidence)

Subject to the acceptance of PCORI's contract terms and conditions.

IHS Transitional Care Targeted PFA Project ACHIEVE Study Aims

- Identify the transitional care outcomes and components that matter most to patients and caregivers
- Determine which evidence-based transitional care service clusters most effectively yield outcomes desired by patients and caregivers overall, and among diverse subpopulations, in different types of care settings and communities
- Identify the barriers and facilitators to the implementation of specific transitional care service clusters for different types of care settings or communities
- Develop actionable recommendations for dissemination and implementation of the research findings

IHS Transitional Care Targeted PFA
Description of Project ACHIEVE: A Two-Phase Approach

Study Design: Retrospective/Prospective observational cohort study

- *Phase 1 – Design Phase*
  - Identify transitional care outcomes and service components that matter most to patients and caregivers
  - Refine criteria for selection of transitional care service clusters for Phase 2
  - Survey instrument refinement and validation
  - Agreements with health care systems and community organizations participating in the study
- *Phase 2 – Data Collection, Analysis and Dissemination*
  - Retrospective data analysis (6-year) to select a subset of transitional care clusters for the prospective study
  - Prospective cohort analysis will compare patients and caregivers exposed to pre-defined clusters of transitional care services vs. matched cohorts exposed to little or no transitional care services (40 hospitals; 12,000 patients) to determine which clusters work best in which settings for whom

IHS Transitional Care Targeted PFA Rationale for funding Project ACHIEVE

- **Project fills a key evidence gap** concerning which transitional care programs/services are most effective for which patients and their caregivers under what circumstances
- **Study design is well suited for the research aims** and demonstrates a clear understanding of contextual factors that influence implementation of transitional care services across different populations and settings
- **Involvement of key stakeholders** (e.g., CMS, American Hospital Association, Joint Commission, National Area Agencies on Aging) throughout the research demonstrates high potential for impact and dissemination
- **Very strong research team** with leaders in transitional care research and methods and patient/stakeholder co-investigators involved throughout

Board Vote: Approve Funding for the Recommended Slate from the Transitional Care Targeted PFA

Call for Motion to:	• **Approve funding for the recommended slate from the Transitional Care Targeted PFA**
Once the Motion Is Seconded:	• **Move to discuss, amend, or take another action on the selected topic**
Roll Call Vote:	• **Majority vote to approve, disapprove, or take another action on the motion**

Spring 2014 Cycle Broad PFA

Bryan Luce, PhD, MBA
Chief Science Officer

Patient-Centered Outcomes Research Institute

Spring 2014 Cycle: Broad PFA

Broad PFA	Project Length	Maximum Direct Costs Allowed	Total Cycle Budget
Addressing Disparities	3 Years	$1.5 M	$8 M
Assessment of Prevention, Diagnosis and Treatment Options	3 Years	$2 M	$32 M
Communications and Dissemination Research	3 Years	$1.5 M	$8 M
Improving Healthcare Systems	3 Years	$1.5 M (small)	$16 M
	5 Years	$5 M (large)	
Improving Methods for Conducting Patient-Centered Outcomes Research	3 years	$750,000	$17 M
	2 years	$500,000 (PROMIS)	

Assessment of Prevention, Treatment and Diagnosis Options

*Recommended Projects**

11 projects

Project Title
Stopping Anti-Tumor Necrosis Factor Agents in Rheumatoid Arthritis (STARA) Clinical Trial
Patient-Centered CER of Home-Based Interventions to Prevent CA-MRSA Infection Recurrence
Optimization of Home Oxygen Weaning in Premature Infants
Comparing Mobile Health (mHealth) and Clinic-Based Self-Management Interventions for Serious Mental Illness: Patient Engagement, Satisfaction, and Outcomes
CHoosing Options for Insomnia in Cancer Effectively (CHOICE): A Comparative Effectiveness Trial of Acupuncture and Cognitive Behavioral Therapy
Preventive sexual health screening among female-to-male (FTM) transgender adult patients
Randomized Comparison of Evidence-Based Protocols for Adolescents with ADHD in Specialty Care: Behavioral Only versus Integrated Behavioral and Medication Interventions
Comparative Effectiveness of Rehabilitation Interventions for Traumatic Brain Injury
Comparative Efficacy of Therapies for Eosinophilic Esophagitis
Anterior versus posterior entry site for cerebrospinal fluid shunt insertion
North Carolina Prostate Cancer Comparative Effectiveness & Survivorship Study (NC ProCESS): Stakeholder-Driven, Population-Based Prospective Cohort Study

Subject to the acceptance of PCORI's contract terms and conditions.

Improving Healthcare Systems
*Recommended Projects**

5 projects

Project Title
Patient-centered physical activity coaching to improve outcomes in COPD: A pragmatic trial
Peer support after NICU discharge: Can parent navigation improve parental mental health and infant outcomes?
Delivering patient-centered adolescent preventive care with training and technology
Improving specialty care delivery in chronic skin care
Comparing patient-centered outcomes in the management of pain between emergency departments and dedicated acute care facilities for adults with sickle cell disease

Subject to the acceptance of PCORI's contract terms and conditions.

Addressing Disparities
*Recommended Projects**

4 projects

Project Title
Active and Healthy Brotherhood: a program for chronic disease self-management for Black men
A Comparative Trial of Improving Care for Underserved Asian Americans Infected with Hepatitis B (HBV)
Acupuncture Approaches to Decrease Disparities in Outcomes of Pain Treatment - A Two Arm Comparative Effectiveness Trial (AADDOPT-2)
Programa Esperanza (Project Hope)

Subject to the acceptance of PCORI's contract terms and conditions.

Communication and Dissemination Research

*Recommended Projects**

5 projects

Project Title
Describing the comparative effectiveness of colorectal cancer screening tests: The impact of quantitative information
Aligning the visit priorities of complex patients and their primary care providers
Using question prompt lists during asthmatic visits to increase adolescent involvement
The comparative effectiveness of patient- and provider-directed strategies for increasing shared decision making in reproductive health care
Improving communication between cancer patients and oncologists using patient feedback on actual conversations and the ABIM maintenance of certification

Subject to the acceptance of PCORI's contract terms and conditions.

Improving Methods for Conducting PCOR

*Pure Analytics and Patient/Stakeholder Recommended Projects**

10 projects

Project Title
Causal analyses of electronic health record data for assessing the comparative effectiveness of treatment regimens
Engaging Stakeholders in Building Patient-centered, N-of-1 Randomized and Other Controlled Trial Methods
Methods for Heterogeneity of Treatment Effects: Random Forest Counterfactual Machines
Technology-Assisted Qualitative Research: How Does Modality Affect Outcome?
Privacy-preserving analytic and data-sharing methods for clinical and patient-powered data networks
Better Rehabilitation Through Better Characterization of Treatments: Development of the Manual for Rehabilitation Treatment Specification
Patient-Centered Approaches to Research Enrollment Decisions in Acute Cardiovascular Disease
Estimation of multi-treatment effects from observational data with application to diabetes mellitus
Propensity Score-Based Methods for CER Using Multilevel Data: What Works Best When
Development of a Patient-Directed Queries Network to engage Patients and Prioritize their Questions to inform the PCORI Research Agenda

Subject to the acceptance of PCORI's contract terms and conditions.

Improving Methods for Conducting PCOR
*PROMIS-related Recommended Projects**

8 projects

Project Title
Making PROMIS Meaningful to Patients and Providers in Clinical Practice
Expanding PROMIS Item Bank Development to the Pregnant Population
Expanding PRO assessment integrated into routine clinical care of patients with HIV to new PROMIS domains
Extending PROMIS Pain Item Banks: Pain Self-efficacy and Pain Catastrophizing
Feasibility of Implementing Patient-Reported Outcome Measures
Measuring the Context of Healing: Using PROMIS in Chronic Pain Treatment
Development of the PROMIS Pediatric Sleep Health Item Banks
Incorporating PROMIS Symptom Measures into Primary Care Practice

Subject to the acceptance of PCORI's contract terms and conditions.

Board Vote: Approve Funding for the Recommended Slate from the Spring 2014 Cycle Broad PFA

Call for Motion to:	• **Approve funding for the recommended slate of awards from the Spring 2014 Cycle Broad PFA**
Once the Motion Is Seconded:	• **Move to discuss, amend, or take another action on the selected topic**
Roll Call Vote:	• **Majority vote to approve, disapprove, or take another action on the motion**

PCORI-AHRQ Fibroids Project Awardee

Joe Selby, MD, MPH
Executive Director

Richard Kronick, PhD
Board Member, PCORI
Director, Agency for Healthcare Research and Quality

Patient-Centered Outcomes Research Institute

The PCORI-AHRQ Partnership

- Creates opportunities for collaboration in generating information that health care providers and patients can use to improve outcomes
  - Agreed in 2013 to collaborate on research to fill evidence gaps related to treatment of uterine fibroids
    - $20 million committed by PCORI
    - AHRQ will administer the 5-year project

Award Recipient: COMPARE-UF

Comparing Options for Management: Patient-Centered Results for Uterine Fibroids (COMPARE-UF)

- **Principal Investigator:** Evan Myers, MD, MPH
  - Duke University School of Medicine's Department of Obstetrics and Gynecology
  - Duke Clinical Research Institute (DCRI)
- Project includes a research and data coordinating center at DCRI and nine clinical centers across the country

Building The Evidence Base

- **Patient Registry**
  - Research and Data Coordinating Center at DCRI
  - Nine clinical centers contributing information
- **Large-Scale Observational Research**
  - PCOR studies of management options for women with UF
  - Emphasis on capturing real treatment experiences and outcomes that matter most to patients
- **Stakeholder Engagement**
  - Direct involvement in determining the direction of the research
  - Engagement throughout the research process

Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Patient-Centered Outcomes Research Institute