

# Board of Governors Meeting via Teleconference/Webinar

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December 13, 2016

12:00 - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# Welcome and Introductions

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**Gray Norquist, MD, MSPH**

*Chairperson, Board of Governors*

**Joe Selby, MD, MPH**

*Executive Director*



# Agenda

| Time        | Agenda Item                                                                                                                                                                             |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12:00       | Call to Order, Roll Call, and Welcome                                                                                                                                                   |
| 12:00-12:05 | <b>Consider for Approval: Consent Agenda</b> <ul style="list-style-type: none"><li>• Minutes of the October 31, 2016 Board Meeting</li><li>• Committee Appointments</li></ul>           |
| 12:05-12:25 | <b>Consider for Approval:</b><br>Cycle 1 2016 Broad                                                                                                                                     |
| 12:25-12:35 | <b>Consider for Approval:</b><br>Policy Delegating to Science Oversight Committee (SOC) the authority to reopen Targeted PCORI Funding Announcements (PFAs) and Special Emphasis Topics |
| 12:35-12:55 | Q4 Dashboard Review                                                                                                                                                                     |
| 12:55-1:15  | PCORI Funds Management Planning                                                                                                                                                         |
| 1:15-1:30   | Annual Meeting Debrief                                                                                                                                                                  |
| 1:30        | Wrap up and Adjournment                                                                                                                                                                 |

# Consent Agenda Items

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**Gray Norquist, MD, MSPH**

Chairperson, Board of Governors



# Motion for Consent Agenda Items

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That the Board approves:

- Minutes from October 31, 2016 Board meeting
- Nomination of Dr. Russell Howerton to serve on the Science Oversight Committee (SOC), and
- Nomination of Kathleen Troeger to serve on the Research Transformation Committee (RTC)



# Board Vote

## Call for a Motion to:

- **Approve** each of the Motions on the Consent Agenda

## 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



# Cycle 1 2016 Broad PFA Slate

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**Christine Goertz, DC, PhD**

Chair, Selection Committee

**Evelyn P. Whitlock, MD, MPH**

Chief Science Officer



# Funding Opportunities

## *Broad Cycle 1 2016*

| Broad PFA                                                           | Maximum Project Length | Maximum Direct Costs Allowed | Funds Announced |
|---------------------------------------------------------------------|------------------------|------------------------------|-----------------|
| Addressing Disparities                                              | 3 Years                | \$1.5M                       | \$8M            |
| Assessment of Prevention, Diagnosis, and Treatment Options          | 3 Years                | \$2M                         | \$32M           |
| Communication and Dissemination Research                            | 3 Years                | \$1.5M                       | \$8M            |
| Improving Healthcare Systems                                        | 3 Years                | \$1.5M                       | \$16M           |
|                                                                     | 5 Years                | \$5M                         |                 |
| Improving Methods for Conducting Patient-Centered Outcomes Research | 3 Years                | \$750,000                    | \$12M           |



# Broad Cycle 1 2016

## *Merit Review Criteria*

| Broad PFAs (except Methods)                                                                                                                                                                                                                                                                                                                                                       | Improving Methods for Conducting Patient-Centered Outcomes Research                                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"><li>1. Potential for the study to fill critical gaps in evidence</li><li>2. Potential for the study findings to be adopted into clinical practice and to improve delivery of care</li><li>3. Scientific merit (research design, analysis, and outcomes)</li><li>4. Patient-centeredness</li><li>5. Patient and stakeholder engagement</li></ol> | <ol style="list-style-type: none"><li>1. Study identifies critical methodological gap(s) in PCOR/CER</li><li>2. Potential for the study to improve PCOR/CER methods</li><li>3. Scientific merit (research design, analysis, and outcomes)</li><li>4. Patient-centeredness</li><li>5. Patient and stakeholder engagement</li></ol> |



# Slate Overview—Broad Cycle 1 2016

## *Process Overview*

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- 233 Letters of Intent (LOIs) submitted
  - 93 LOIs invited to submit a full application (**40%**)
  - 66 applications were received (71% of invited LOIs)
  - We are proposing to fund 17 applications\* out of 66 received applications (**26%**)
    - **29%** (5) of applications recommended for funding were resubmissions
- \*Recommended by the Selection Committee

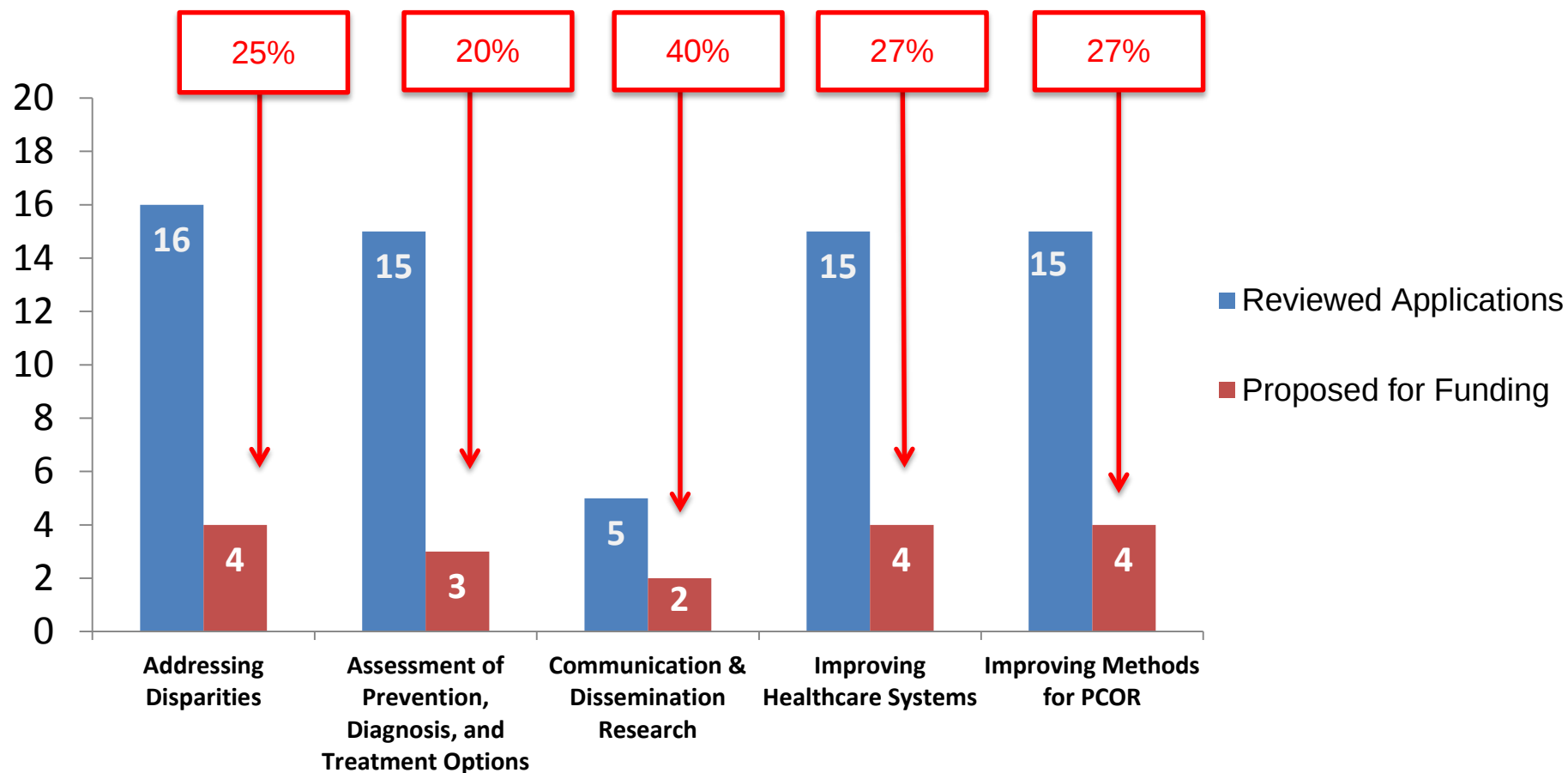


# Cycle 1 2016 Broad

*What is being proposed today?*

## Overall funding rate is 26 percent

(17 applications out of 66 reviewed applications)



# Addressing Disparities

## *4 Recommended Projects\**

| Project Title                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Improving Outcomes for Low-Income Mothers with Depression: A Comparative Effectiveness Trial of Two Brief Interventions in the Patient-Centered Medical Home                 |
| A Randomized Controlled Trial to Compare the Reach, Effectiveness and Maintenance of Two Family-based Childhood Obesity Treatment Programs in a Medically Underserved Region |
| Comparative Effectiveness of Diabetes Prevention Programs                                                                                                                    |
| Addressing Childhood Hearing Loss Disparities in an Alaska Native Population: A Community Randomized Trial                                                                   |

**Resubmissions in bold.**

\*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.



# Assessment of Prevention, Diagnosis, & Treatment Options

## *3 Recommended Projects\**

| Project Title                                                                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SETPOINT2: A Pragmatic Trial to Test the Effectiveness of Early vs. Delayed Percutaneous Tracheostomy in Patients with Severe Stroke and Respiratory Failure |
| Acupressure Intervention to Reduce Treatment-related Symptoms in Children with Cancer                                                                        |
| <b>A Stakeholder-driven Comparative Effectiveness Study of Treatments to Prevent Coronary Artery Damage in Patients with Resistant Kawasaki Disease</b>      |

Resubmissions in bold.

\*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.



# Communication and Dissemination Research

## *2 Recommended Projects\**

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| Project Title                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Smoker-to-Smoker Peer Marketing and Messaging to Disseminate Tobacco Interventions</b>                                                 |
| <b>Integrating the Patient Voice into a Comparative Effectiveness Trial of Communication Strategies in the Management of Chronic Pain</b> |

**Resubmissions in bold.**

\*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.



# Improving Healthcare Systems

## *4 Recommended Projects\**

| Project Title                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Expanding Access to Home-based Palliative Care through Primary Care Medical Groups                                                                      |
| <b>Ambulatory Cancer Care Electronic Symptom Self-Reporting (ACCESS) for Surgical Patients</b>                                                          |
| Improving Patient-Centered Communication in Primary Care: A Cluster Randomized Controlled Trial of the Comparative Effectiveness of Three Interventions |
| Comparing Patient-Centered Outcomes for Adults and Children with Asthma in High-Deductible Health Plans with and without Preventive Drug Lists          |

**Resubmissions in bold.**

\*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.



# Improving Methods for Conducting PCOR

## *6 Recommended Projects\**

| Project Title                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------|
| Statistical Methods for Development, Validation and Implementation of Absolute Risk Models                                                 |
| Development of Computational Methods for Evaluating Doctor-Patient Communication                                                           |
| <b>Privacy Preserving Interactive Record Linkage (PPIRL) via Information Suppression</b>                                                   |
| Improving Study Design and Reporting for States Choice Experiments                                                                         |
| Development of Reporting Guidelines for Psychometric Research on Patient Reported Outcome Measures <sup>†</sup>                            |
| How Well do Clinical Prediction Models (CPMs) Validate? A Large-Scale Evaluation of Cardiovascular Clinical Prediction Models <sup>†</sup> |

<sup>†</sup> These are additional projects from Cycle 2 2015.

### **Resubmissions in bold.**

\*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.



# Slate Overview – Cycle 1 2016

## *Broad PFAs*

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| Proposed Total<br>Number of Projects | Proposed Total<br>Award Amount |
|--------------------------------------|--------------------------------|
| <b>19</b>                            | <b>\$42M</b>                   |

*The proposed total award amount is within the budget for Cycle 1 2016*



# Board Vote

## Call for a Motion to:

- **Approve** funding for the recommended slate of awards

## Call for the Motion to Be Seconded:

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

## Roll Call Vote:

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



# Policy on Reissuing Targeted PFAs and Including Special Emphasis Topics in Pragmatic Clinical Studies PFAs – Delegation to the Science Oversight Committee

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**Evelyn P. Whitlock, MD, MPH**

Chief Science Officer



# Background

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- **The Science Oversight Committee (SOC) approved the policy on Reissuing Targeted PFAs and Including Special Emphasis Topics in Pragmatic Clinical Studies PFAs on 10/4/2016**
- The Board of Governors is being asked to approve the policy which sets forth the circumstances under which the Board delegates to the SOC the review and approval of requests from the PCORI Science Staff to either
  - Reissue a targeted PFA
  - --OR--
  - Approve the inclusion of Special Emphasis topics in Pragmatic Clinical Studies PFAs



# Policy on Reissuing Targeted PFAs & Special Emphasis Topics

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- **Purpose:** Policy delegates to the SOC the review and approval of requests from science staff to either reissue a targeted PFA and/or approve inclusion of Special Emphasis Topic in Pragmatic Clinical Studies PFAs
  - SOC may approve reissuing of a targeted PFA when relevant targeted PFA has not used maximum available Board-allocated funding
  - SOC may approve inclusion of Special Emphasis Topics for a Pragmatic Clinical Studies PFA with a related specific funding allotment and cycle assignment (based on criteria noted in the policy)



# Board Vote

## Call for a Motion to:

- **Approve** Policy on Reissuing Targeted PFAs and Including Special Emphasis Topics in Pragmatic Clinical Studies PFAs

## Call for the Motion to Be Seconded:

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

## Voice Vote:

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



# Dashboard Review

## End of FY-2016

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**Joe Selby, MD, MPH**

Executive Director

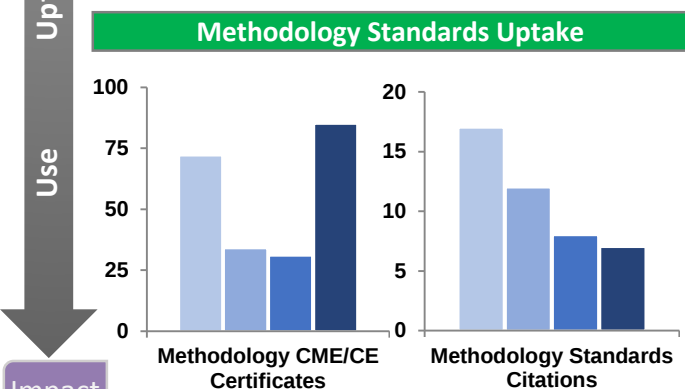
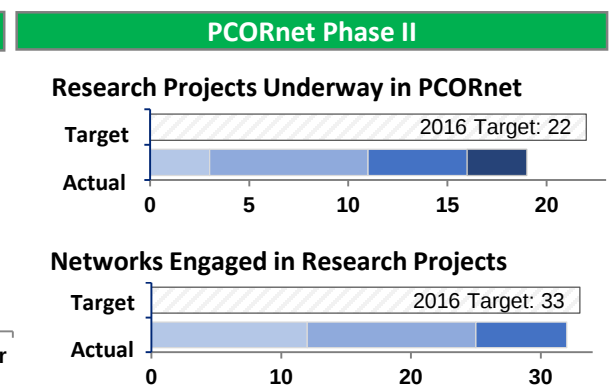
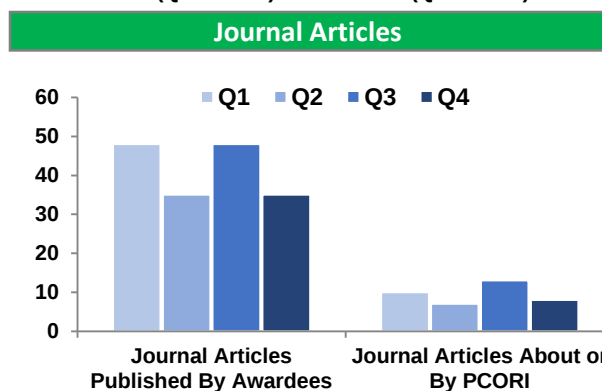
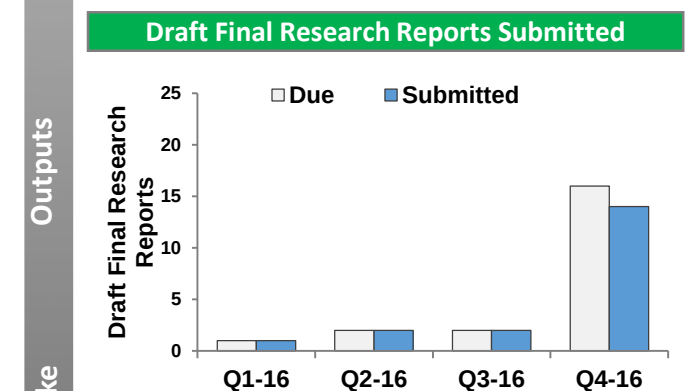
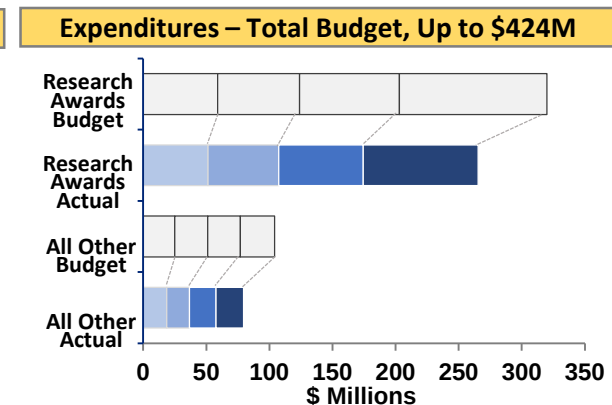
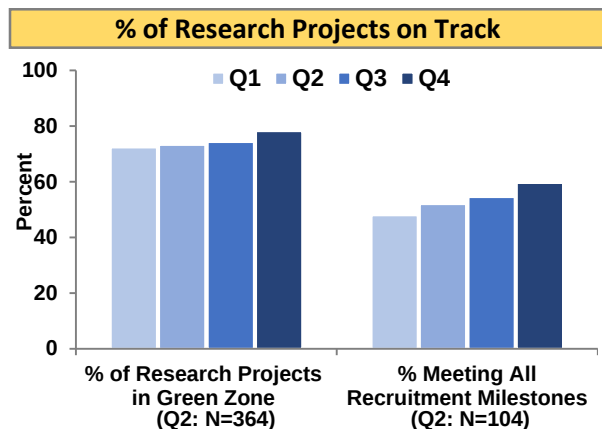
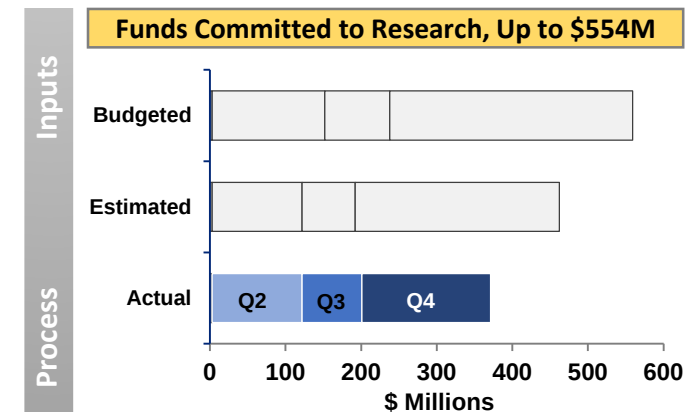


# Discussion Questions for Q4-16:

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- Do our FY-2016 Dashboard and associated background materials cover the ***topics that are most important for the Board*** to review?
- Do you have ***questions or comments about our progress or performance*** on any of our Dashboard indicators?
- Does the in-depth focus this quarter on our ***cumulative results as of the end of the fiscal year and year-to-year trends*** tell you what you need to know about where we are now and how we got here?
- ***What changes would you like to see in our FY-2017 Dashboard?***





**Results: Increasing Information**

- For post-discharge treatment of complicated **appendicitis** in children, oral antibiotics are associated with lower rates of treatment failure and hospital revisits when compared with intravenous antibiotics
- For post-discharge treatment of complicated **pneumonia** in children, oral antibiotics are associated with lower rates of complications when compared with intravenous antibiotics

**Results of Engagement in Research**

A Pipeline to Proposal project that developed capacity for patient-engaged CER for diabetes health among Latinos from low-income households was funded for a PCORI Research Award to compare diabetes self-care programs

**Results: Influence**

The Center for Medicare and Medicaid Services (CMS) Quality Measure Development Plan recognizes PCORI's patient/caregiver engagement framework as a best practice

## Results of PCORI Research:

# Oral Antibiotics Safer than Intravenous for Post-Discharge Treatment of Three Serious Infections in Children

This three-part retrospective cross-sectional cohort study assessed the comparative effectiveness of oral vs. intravenous antibiotics for post-discharge treatment of **acute osteomyelitis, complicated appendicitis, and complicated pneumonia** in children. Across conditions, **use of intravenous antibiotics is associated with higher of rates all-cause hospital revisits than oral antibiotics.**

| Condition                          | Publication                          | Primary Outcome                                                  | Secondary Outcomes                                                                     |                                                                   |
|------------------------------------|--------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
|                                    |                                      | Treatment Failure<br>(matched odds ratio, 95% CI)                | Complications<br>(matched odds ratio, 95% CI)                                          | All Hospital Re-visits<br>(matched odds ratio, 95% CI)            |
| Acute<br><b>Osteomyelitis</b>      | <i>JAMA Pediatrics</i><br>Feb 2015   | No significant difference                                        | Adverse drug reactions<br><b>Slightly higher in PICC group</b><br>OR 1.83 (1.03, 3.25) | <b>Higher re-visit rate in PICC group</b><br>OR 3.61 (2.64, 4.93) |
| Complicated<br><b>Appendicitis</b> | <i>Annals of Surgery</i><br>Jul 2016 | <b>Higher failure rate in PICC group</b><br>OR 1.74 (1.05, 2.88) | Related hospital re-visits<br><b>Higher in PICC group</b><br>OR 2.11 (1.44, 3.11)      | <b>Higher re-visit rate in PICC group</b><br>OR 2.21 (1.33, 3.70) |
| Complicated<br><b>Pneumonia</b>    | <i>Pediatrics</i><br>Nov 2016        | No significant difference                                        | Adverse drug reactions<br><b>Higher in PICC group</b><br>OR 19.1 (4.2, 87.3)           | <b>Higher re-visit rate in PICC group</b><br>OR 4.71 (2.97, 7.46) |

- Awarded 2012, Assessment of Prevention, Diagnosis, and Treatment Options project
- Principal Investigator: Ron Keren, MD, MPH, The Children's Hospital of Philadelphia



*A key reason that doctors may often recommend the IV approach is lack of evidence about the effectiveness of oral antibiotics as an alternative.*

Ron Keren, Principal Investigator



## Influence Example:

# CMS Recognizes PCORI's Patient/Caregiver Engagement Framework as a Best Practice

### Partnering With Patients in the Measure Development Process

The Center for Medicare and Medicaid Services (CMS) Quality Measure Development Plan outlines key considerations and strategic approaches for supporting the transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). CMS names **PCORI's patient/caregiver engagement framework as a best practice.**



**Strategic Approach** – CMS evaluates best practices related to patient/caregiver involvement in the measure development process and disseminates this information through a variety of channels, such as measure developer forums and updates to the MMS Blueprint. **Recent best practices identified for partnering with patients and caregivers include:**

- Adopting principles from the *Patient Centered Outcomes Research Institute (PCORI)* person-family engagement framework.
- Conducting outreach through patient organizations, other entities that focus on engaging patients (e.g., PatientsLikeMe, *Patient-Centered Outcomes Research Institute*), and condition-specific organizations (e.g., Arthritis Foundation, Cancer Support Center)...



CMS Quality Measure Development Plan, Page 54, May 2016 ([link](#))



## Results of Engagement in PCORI Research:

# First Pipeline to Proposal (P2P) project approved for PCORI Research Award

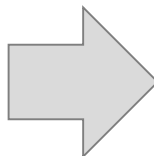
### Pipeline to Proposal Project (2013-2016)

*Culturally Appropriate Options for Diabetes Prevention and Care for Low-Income Latinos*

- ❖ Project Lead: Lidia Regino, BS, East Central Ministries/One Hope Centro de Vida Health Center

This P2P Project sought to develop capacity for patient-engaged CER related to diabetes health for Latinos from low-income households.

- Build capacity of patient partners to better understand research process
- Update and revise outreach plan and conduct targeted outreach to external stakeholders
- Generate list of CER research questions



### PCORI Research Project (2016):

*A Patient-Centered Framework to Test the Comparative Effectiveness of Culturally and Contextually Appropriate Program Options for Latinos with Diabetes from Low-Income Households*

- ❖ Awarded 2016, Assessment of Prevention, Diagnosis, and Treatment Options project
- ❖ PI: Janet Page-Reeves, MA, PhD, University of New Mexico Health Sciences Center
- ❖ Aims to identify effective approaches in ensuring the integration of contextual and cultural competency in self-care programs



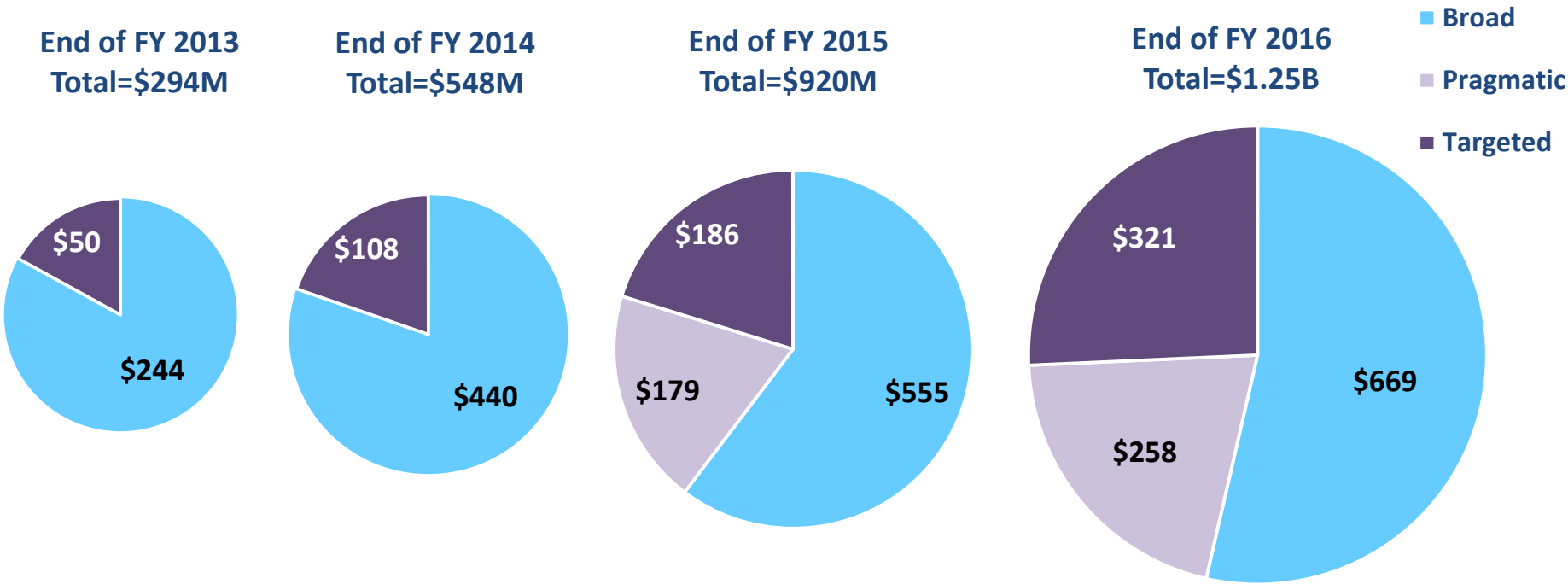
*Our Patient Advisors told us that gathering data from individuals alone misses important social aspects of Latino patients' lives, so we will recruit patients and ask them to invite someone close to them to participate too.*

-From the funded study application



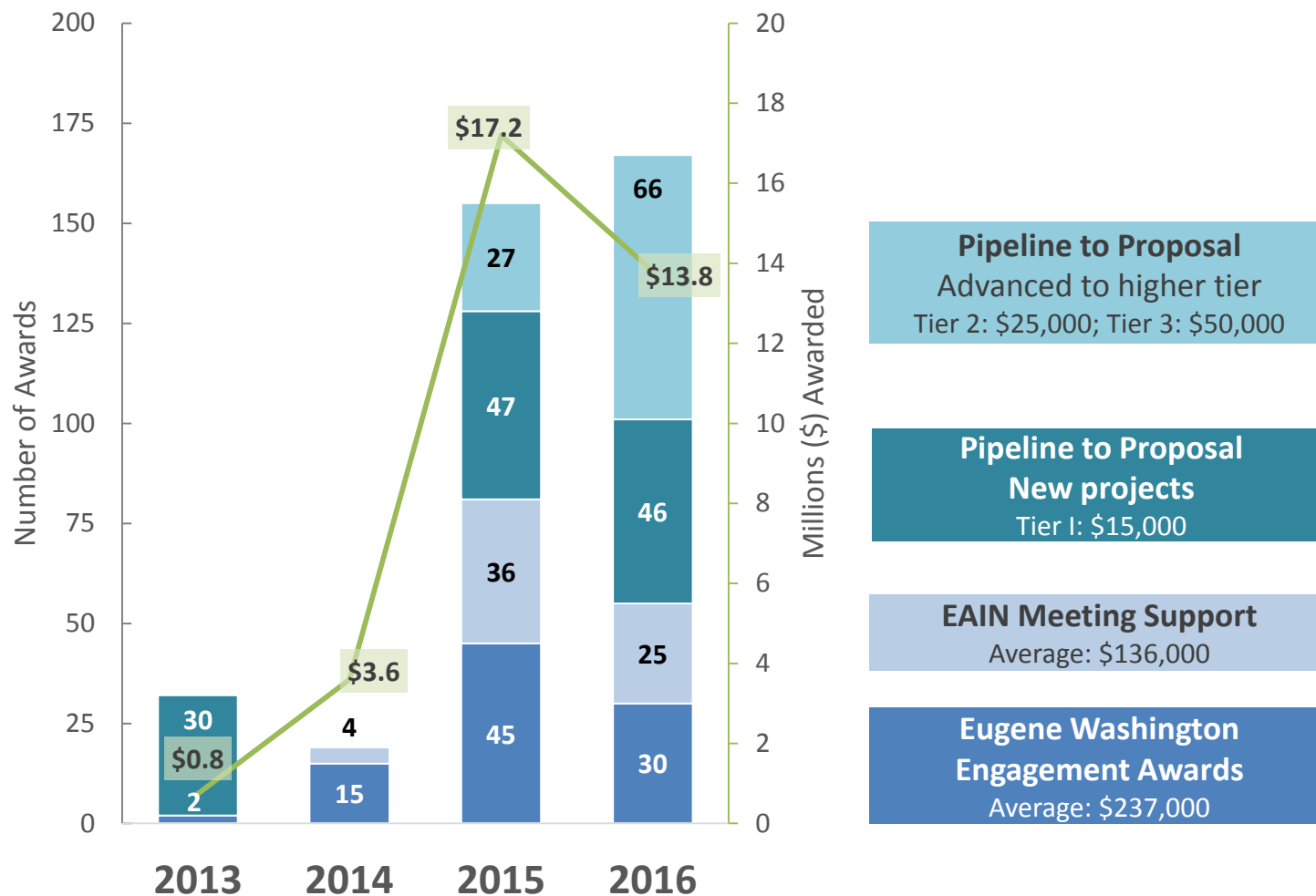
**We are making progress on our Strategic Priority to “*Increase the proportion of research funding going to focused and targeted topics*”**

**Funds Committed by Type of PFA  
Cumulative Total by Fiscal Year**



# Engagement Awards

## Number of Projects Awarded, Total \$ Awarded



# Coming Soon: FY-2017 Dashboard

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## Focus on CER Results & Uptake:

- Publication of CER Results
- Timeliness of Draft Final Research Reports
- Timeliness of PCORI Peer Review
- Timeliness of posting results to PCORI.org
- Dissemination and Implementation Awards
- Uptake of results posted to PCORI.org



## Improved Measures:

- Changes to monitoring Progress of Projects
- New metrics for Portfolio Management
- New metrics on use of PCORnet

**What else would you like to see for the FY-2017 Dashboard?**



# PCORI Funds Management Planning

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**Larry Becker**

Chair, Finance and Administration Committee



# Preliminary Summary of the 2016 PCORI Annual Meeting

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**Joe Selby, MD, MPH**

Executive Director



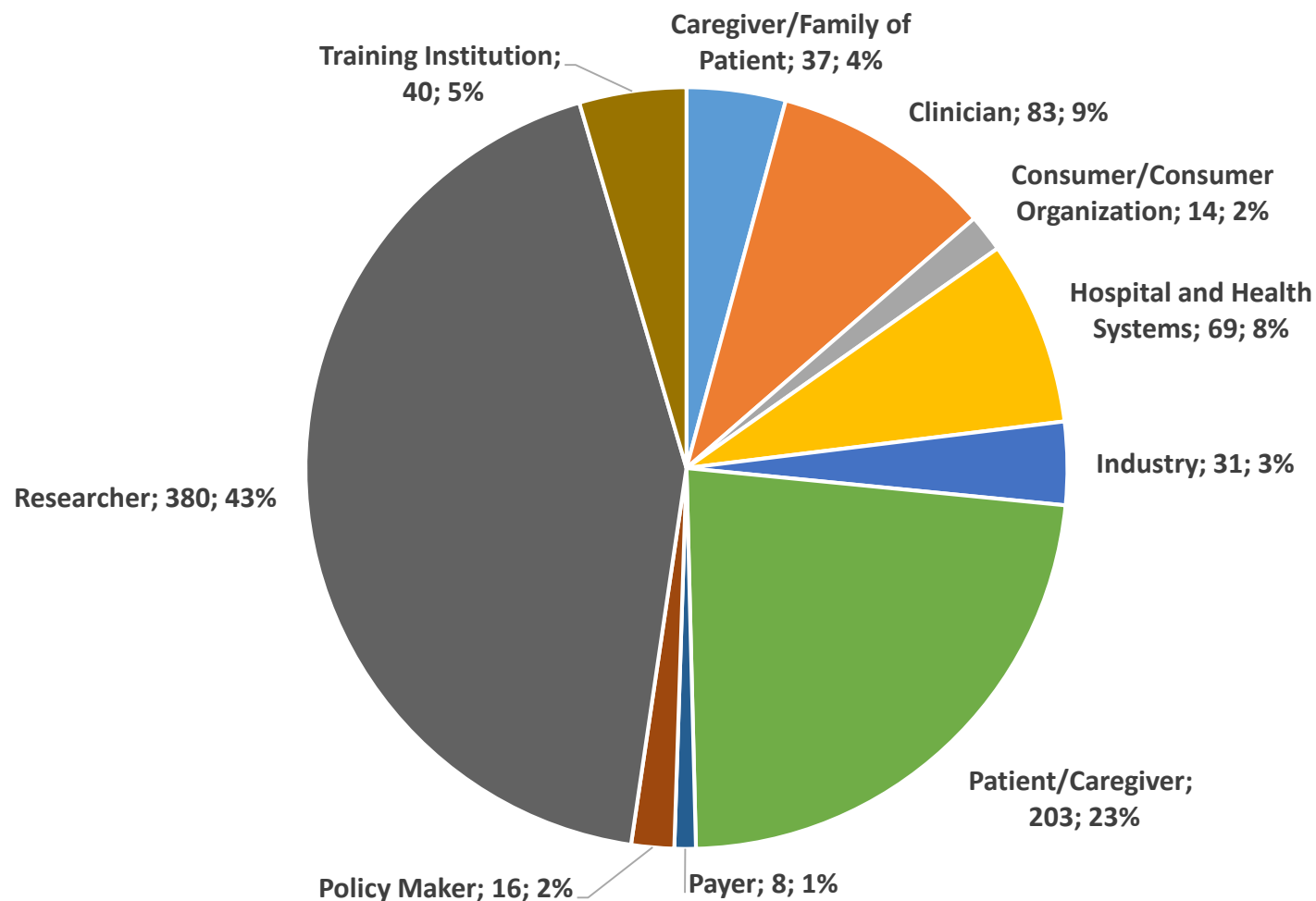
# Summary Statistics

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- Total attendees: 881 (1,083 with staff)
- Results of participant surveys will be reviewed by the Engagement, Dissemination, and Implementation Committee in January
- **Twitter activity:**
  - Number of tweets using hashtag #PCORI2016: **6,500**
  - Reach (# of people who could have seen tweets): **12.3M+**
- **Facebook Live event: “Smarter, More Appropriate Use of Antibiotics”**
  - Unique viewers: **360**
  - Reactions, Comments, Shares: **162**
  - Negative feedback: **0** (hide, spam, unlike page)



# Stakeholder Breakdown (N=881)



# Board and Methodology Committee Participation

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This year, we expanded the role of the Board and Methodology Committee (MC) in meeting planning and programming

- The Engagement Dissemination and Implementation Committee (EDIC) of the board provided oversight of the event
- Our multi-stakeholder Steering Committee, charged with reviewing overall meeting themes and direction for plenary sessions, included two Board members (**Goertz** and **Levine**) and one MC member (**Newhouse**)
- A number of Board and MC members (**Barksdale, Becker, Flum, Hunt, Girman, Goertz, Krumholz, Levine, Norquist, Tinetti, and Zwolak**) provided remarks during the plenaries and served as moderators, discussants or panelists during the breakouts



# Wrap Up and Adjournment

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**Gray Norquist, MD, MSPH**

Chairperson, Board of Directors

