



Board of Governors Meeting via Teleconference/Webinar

*November 18, 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

Agenda

Time	Agenda Item
12:00 – 12:05 pm	Call to Order, Roll Call, and Welcome
12:05 – 12:15 pm	Consent Agenda: Minutes of September 15 and September 30, 2014 Board Meeting, Appointment of Barbara McNeil to a Strategy Committee
12:15 – 12:25 pm	Consider for Approval: Additional Funding for PCORnet Coordinating Center
12:25 – 12:50 pm	Consider for Approval: Collaboration Principles
12:50 – 1:00 pm	Update on Public Comments on the Peer Review and Release of Research Findings Proposal
1:00 – 1:25 pm	Evaluation Update
1:25 – 1:30 pm	Wrap-up and Adjournment



Approval of Consent Agenda

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Patient-Centered Outcomes Research Institute

Consent Agenda Items

- Approval of Minutes for September 15, 2014 Board meeting
- Approval of Minutes for September 30, 2014 Board meeting
- Appointment of Barbara J. McNeil to serve on the Science Oversight Committee (SOC)

Barbara J. McNeil, MD, PhD

- 🌐 Ridley Watts Professor and founding head of the Department of Health Care Policy at Harvard Medical School
- 🌐 Professor of Radiology at Harvard Medical School and at Brigham and Women's Hospital
- 🌐 Research activities have focused on several areas, most notably technology assessment and quality of care



Motion to approve the Consent Agenda

Call for Motion to:

- **Approve** the Consent Agenda as reflected.

Once the Motion Is Seconded:

- Move to **discuss, amend, or take another action** on the selected topic

Voice Vote:

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



Additional Funding for PCORnet Coordinating Center

Rachael Fleurence, PhD

PCORI Program Director, CER Methods and Infrastructure

Joe Selby, MD, MPH

Executive Director

Patient-Centered Outcomes Research Institute

Overview/Background

- PCORnet Coordinating Center was invited to submit a supplemental budget request for their two-year contract ending in October 2015 due to an unanticipated increase in scope and complexity of work and unforeseen needs
- Supplemental budget request was submitted in March for \$3.3 million
- Portions of the request totaling \$1.9 million were immediately recommended for approval by PCORI staff
 - Board of Governors approved these on August 26, 2014
- Remainder of the request was further evaluated by staff
- Several additional components totaling \$1.195 million are now recommended for funding based on appropriate documentation of progress from the CC

Additional Funding Scope

- Scope of work for the components totaling \$1.195 million:
 - **PCORnet Resource Center (\$180,000)**
 - Not funded at all in the original budget
 - Supports activities such as managing the PCORnet.org website, hosting weekly “Grand Rounds”, hosting network “office hours”, responding to external PCORnet inquiries
 - Unanticipated need for technical assistance in **Health Systems Interaction & Sustainability (HSIS) Task Force (\$195,000)**
 - Nearly 200 health systems, versus the 100 originally estimated
 - Support for PPRNs through technical assistance and a value proposition working group
 - Additional **Project Management needs (\$820,000)**
 - Support activities that were not planned for in September 2013 that have emerged as critical to PCORnet progress, including work groups (access to CMS data, access to longitudinal data, computable phenotypes) and increased needs for coordination and technical assistance to the networks
 - Significant meeting support
- On October 22, 2014, the Research Transformation Committee (RTC) reviewed the request and approved to recommend it to the Board for final approval

Consider for Approval: Additional Funding for PCORnet Coordinating Center

Call for Motion to:

- **Approve** \$1.195 million PCORnet Coordinating Center Budget Supplement

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 Collaboration Principles

Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute

Background

Strategy Goal 3: Influence clinical and health care research funded by others to be more patient-centered

- Collaboration is a primary strategy for **influencing** research funded by others to be more patient-centered
- The Research Transformation Committee (RTC) set an objective for 2014 to propose a strategy for collaborations, partnerships and co-funding
- The RTC endorses the Collaboration Principles presented today and asks the Board to approve them for public posting and dissemination

Benefits of PCORI Collaborations

Increase Influence

- Through collaboration, PCORI can encourage other research to be more patient-centered

Ensure Scientific Excellence

- Collaborations allow PCORI to combine our expertise with our partners (e.g., clinical content, trials management)

Maximize Impact

- Collaborations help to avoid redundancy in research funding

The Legislation Gives Guidance on Collaborations

“(I) IN GENERAL.— In accordance with the research project agenda established under paragraph (1)(B), the Institute shall enter into contracts for the management of funding and conduct of research in accordance with the following:

“(aa) Appropriate agencies and instrumentalities of the Federal Government.

“(bb) Appropriate academic research, private sector research, or study-conducting entities.

“(II) PREFERENCE.—In entering into contracts under subclause (I), the Institute shall give preference to the Agency for Healthcare Research and Quality and the National Institutes of Health, but only if the research to be conducted or managed under such contract is authorized by the governing statutes of such Agency or Institutes.

-- from *Patient Protection and Affordable Care Act*, section (d)(2)(B)



Principles of Collaborative Arrangements

1. Should combine the expertise and resources to maximize the impact of all PCORI investments and their contributions to improving health decision-making and outcomes
2. Should embody and promote PCORI's unique approach to research
3. Should meet all applicable requirements and parameters of PCORI's relevant statutory requirements (*e.g. adherence to PCORI Methodology Standards and Peer Review Policy*)

Principles of Collaborative Arrangements (*cont.*)

4. Should preserve PCORI's ability to impact decisions at key points in the research initiative or project
5. Should be entered into with the collaborating entity with the most appropriate experience and expertise, requisite capacity, and a record of success for the project
6. Should adhere to PCORI's standards for communication, acknowledgement and attribution (*e.g. citing PCORI in public announcements, use of the PCORI logo*)

Three Types of Collaborative Arrangements:

1. *Co-funding*

Structure:

- PCORI and the partner agree to share responsibility for the funding and management of a research initiative or project
- Contributions from either side may include direct funding, in-kind contributions of staff, or both
- One party or the other will typically take primary responsibility for the solicitation, review process, award and management of the contract(s)

Benefits:

- Leverages the resources (scientific, management, fiscal) of PCORI and that of the co-funder
- Allows for critical research that would be unlikely or infeasible to be conducted by either entity on its own

Existing examples:

- Falls Prevention (research initiative with NIA),
- Uterine Fibroids (research initiative with AHRQ)
- Pilot Project on Coordination of Care for Frail Elderly (research project John A. Hartford Foundation)

Three Types of Collaborative Arrangements:

2. *Contracting for Management*

Structure:

- PCORI contracts with an outside entity to oversee or conduct one or more aspect of contract or project management

Benefits:

- Combines the management expertise of PCORI and that of the co-funder
- Maximizes PCORI's stewardship of resources and funding

Existing examples:

- PCORnet Coordinating Center (oversight and support for specific aspects of PPRNs and CDRNs activities)
- NIH management of Pilot Project Merit Review Process

Three Types of Collaborative Arrangements:

3. Staff Detail

Structure:

- PCORI obtains an agreement with another entity that allows for the services of scientific staff employed by that entity to assist with oversight of an individual project or multiple projects

Benefits:

- Brings special expertise of other entities to PCORI
- Provides opportunity for PCORI staff to collaborate with experts and acquire new expertise

Existing examples:

- None to date

Questions for the Board

- 
- Do these principles capture the essence of PCORI collaborations?

- 
- In what ways can PCORI and the RTC seek to promote and disseminate these principles?

Consider for Approval: Collaboration Principles

Call for Motion to:

- **Approve** the Collaboration Principles

Once the Motion Is Seconded:

- Move to **discuss, amend, or take another action** on the selected topic

Voice Vote:

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



Proposal for Peer Review and Public Release of Primary Research

Public Comment Period Preliminary Results

Bill Silberg

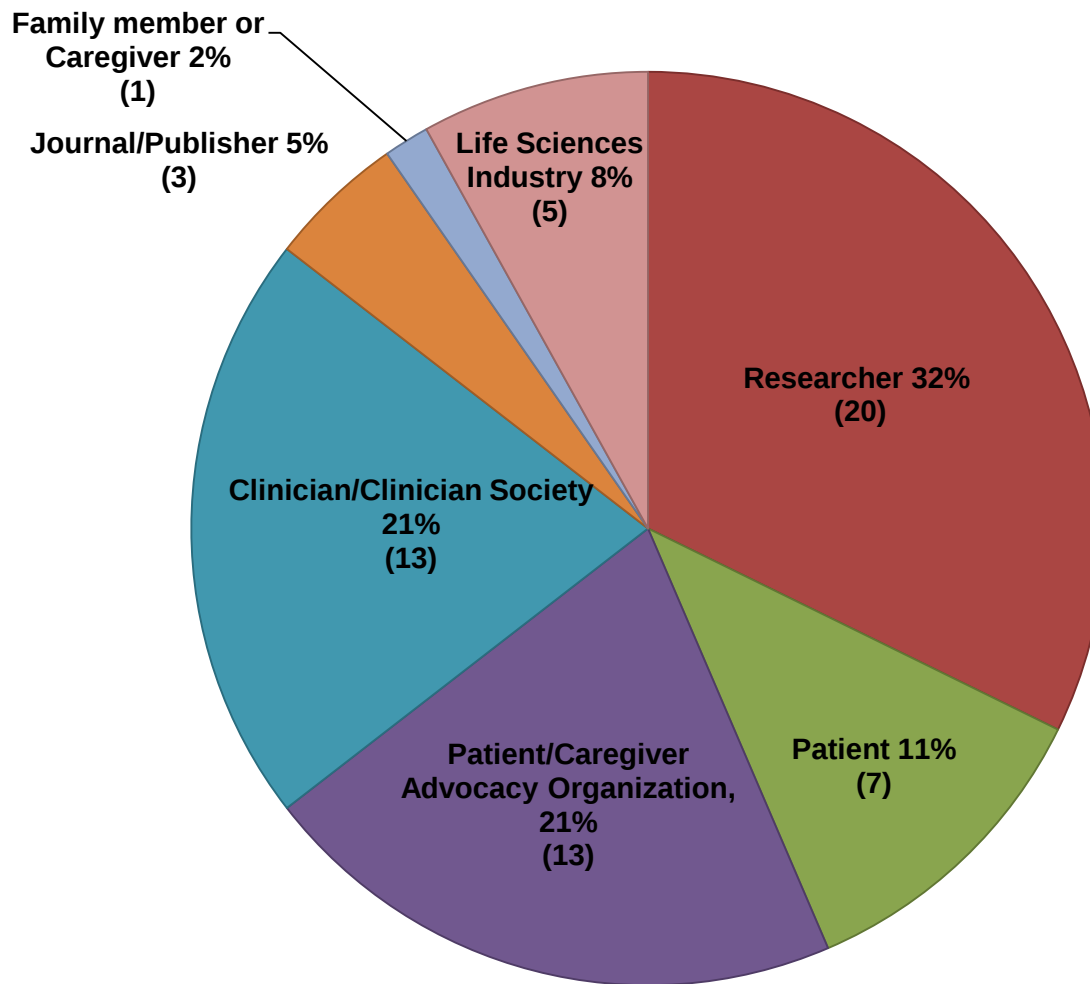
Communications Director

Patient-Centered Outcomes Research Institute

Results of Public Comment Period

- Proposal posted Sept. 15 per Board direction
- 54-day public comment period closed Nov. 7
- 63 submissions received from individuals and organizations
- 835 discrete comments

Submissions by Stakeholder Category (n=63)



Organizations Submitting Comments

Clinician/Clinician Societies

- 🌐 American Academy of Family Physicians
- 🌐 American College of Physicians
- 🌐 American Nurses Association
- 🌐 American Nursing Informatics Association (ANIA)
- 🌐 American Occupational Therapy Association (AOTA)
- 🌐 American Thoracic Society
- 🌐 American Society of Health-System Pharmacists
- 🌐 Association of American Medical Colleges
- 🌐 Association of American Physiatrists
- 🌐 Association of Rehabilitation Nurses
- 🌐 College of American Pathologists
- 🌐 Deans of Nursing Schools Coalition
- 🌐 Society of General Internal Medicine
- 🌐 Wound Ostomy and Continence Nurses' Society
Center for Clinical Investigation

Journal/Publisher

- 🌐 Annals of Family Medicine
- 🌐 BMJ
- 🌐 PLOS Medicine

Life Sciences Industry

- 🌐 Advanced Medical Technology Association (AdvaMed)
- 🌐 Biotechnology Industry Organization
- 🌐 GlaxoSmithKline
- 🌐 Pharmaceutical Research and Manufacturers of America
- 🌐 National Pharmaceutical Council

Patient/Caregiver Advocacy Organizations

- 🌐 AllTrials Campaign
- 🌐 American Cancer Society Action Network
- 🌐 CaReNet
- 🌐 Consumer Reports
- 🌐 Community Campus Partnerships for Health
- 🌐 March of Dimes Foundation
- 🌐 National Alliance on Mental Illness
- 🌐 National Health Council
- 🌐 National Consumers League
- 🌐 National Family Caregivers Association
- 🌐 ThinkWell & Empower2Go

Next Steps

Analysis in process at American Institutes for Research

- Seek input from Stakeholder Advisory Committee
- Code/organize comments for analysis
- Develop key themes
- Identify recommendations for revision
- Draft report to PCORI: December 4
- Final report to PCORI: January 5, 2015
- PCORI strategy committee review: January/February
- Board considers revised proposal: February 24, 2015



Evaluation Update

Michele Orza, ScD

Senior Advisor to the Executive Director

Patient-Centered Outcomes Research Institute

For Discussion

Please tell us what you would like to know about PCORI's work so that we can be sure we are answering, or at least thinking about ways to answer, your questions about:

- 🌱 How well we are working
- 🌱 Whether we are progressing toward our goals
- 🌱 What difference our engaged and patient-centered approach is making
- 🌱 What impact we are having

Overview

- Recap May Discussion of Evaluation
- Review Evaluation Web Pages
- Results!

In May, we discussed our main tasks:

- Building our ***Evaluation Framework*** – delineating, organizing, and prioritizing the questions we've identified about PCORI's work and about PCOR in general – ***posted***
- Determining how we can measure some of the elements that will be central to answering many of these questions, especially ***our three goals and Engagement in Research*** – ***posted***
- Undertaking evaluation activities that have emerged as high priorities, such as surveys and ***assessing the impact of Engagement on the early phases of research*** – ***launched, initial results soon***

Since then, we have added:

A focus on ***communicating*** our evaluation plans, activities, and results to various audiences:

- Board of Governors' Dashboard – ***refined***
- Presentations at meetings – ***several***
- Handouts – ***first one posted***
- “Evaluating Our Work” web pages – ***just launched!***

Evaluating Our Work

PCORI takes a unique approach to funding comparative clinical effectiveness research—ensuring that we focus on options and outcomes important to patients, and that patients and others across the healthcare community have a meaningful role in guiding our work.

Patients and other stakeholders help us determine which research topics we should consider for funding, and they help us review proposals. We also require that patients be included as meaningful partners in the research we support, helping to develop and conduct the studies and disseminate the results. We're committed to this approach, which we call "research done differently," to focus the research we fund on producing useful information to answer the questions of greatest importance to patients and those who care for them. But is our approach succeeding? As proponents of evidence-based practice, we're eager to learn what works best to produce useful information that leads to improved health outcomes.



Our [Board of Governors](#) oversees our evaluation plans and activities, and our [Methodology Committee](#) guides the designs and methods. Each of three [Strategy Committees](#), comprised of Board and Methodology Committee members, focuses on the activities aligned with a specific goal in our [strategic plan](#).

Assisting PCORI with evaluation is the [PCORI Evaluation Group](#), a consultative task force that includes Board and Methodology Committee members, as well as external experts.

PCORI is committed to functioning as a "learning organization," so staff from all departments participate in monitoring our progress toward our goals and in learning how we can improve our work. The [Office of the Executive Director](#) coordinates PCORI's extensive evaluation activities. It works in close partnership with our [Research Integration and Evaluation program](#), which implements most of the evaluation activities, and our [Engagement program](#), which ensures the meaningful engagement of patient and other healthcare communities in our evaluation process.

Read our recent [blog posts](#) on this work. We welcome your feedback on our evaluation work - Email info@pcori.org with inquiries or comments about our activities and progress.



Does Research Done Differently Make a Difference?

PCORI Evaluation Activities are guided by several groups representing diverse healthcare stakeholders:



PCORI has
 **THREE STRATEGIC GOALS**

A PCORI committee focuses on each of these goals and the evaluation of our progress toward it:

 **GOAL**
Substantially increase the quantity, quality, and timeliness of useful, trustworthy information available to support health decisions

 *The Science Oversight Committee*

 **TRACKING PROGRESS**
We are examining our portfolio of funded studies and collecting and analyzing data on our processes for developing and managing it.

Currently, we are studying:

- How well applicants understand our Methodology Standards and the adherence of our projects to relevant standards
- Implementation of our topic prioritization and merit review processes and the results they are yielding
- The composition of our funded portfolio and how it compares to the portfolios of other funders
- Whether our projects are proceeding as planned and the effectiveness of our management of them
- Whether our processes, particularly those for determining which studies to fund, are resulting in a portfolio of studies with potential to yield useful information

 **GOAL**
Speed the implementation and use of patient-centered outcomes research evidence

 *The Engagement, Dissemination and Implementation Committee*

 **TRACKING PROGRESS**
When the studies we are funding are complete, we will track the dissemination and uptake of their results and assess changes in health decisions, care, and outcomes.

For all or a subset of all studies, we plan to measure:

- **Dissemination:** whether PCORI-funded study results are reported back to study participants, open access to PCORI funded study reports, presentations to scientific and lay audiences, publication of study findings, and coverage and consumption of study findings
- **Uptake and Use:** adoption of study findings in the study setting; incorporation of findings into systematic reviews, training curricula, practice guidelines, and policy at the institutional, local, state, and national level
- **Impact:** improvement in health decisions or healthcare quality and improved health outcomes in relevant populations

 **GOAL**
Influence clinical and health care research funded by others to be more patient-centered

 *The Research Transformation Committee*

 **TRACKING PROGRESS**
We are examining whether and how researchers and research funders endorse, adopt, and disseminate components of PCORI's approach.

Currently, we are studying:

- Endorsement, Promotion, and Dissemination of PCORI work
- Use of PCORI Methodology Standards for Patient-Centeredness
- Use of PCORI approaches to Topic Generation and Research Prioritization, Merit Review, Engagement, and Communication and Dissemination
- Use of PCORI guidance re: Patient-Centered CER
- Use of PCORI-supported curricula or training
- Collaborations/Co-funding with other funders

Planning Our Evaluation, Reporting the Results



Our Evaluation Work Flows from Our Strategic Plan

Our [strategic plan](#) focuses on funding and conducting highly relevant research likely to change practice and improve patient outcomes; on disseminating and promoting implementation of the results of that research; and on influencing how clinical research is done by others, so a greater proportion of all clinical research is useful to patients and other healthcare decision makers.

Our evaluation process focuses on whether we are accomplishing what we set out to do. Are our strategies and priorities advancing us toward our goals? Are we having the desired impact of improving health outcomes?

Our Evaluation Plans Are Organized into a Framework

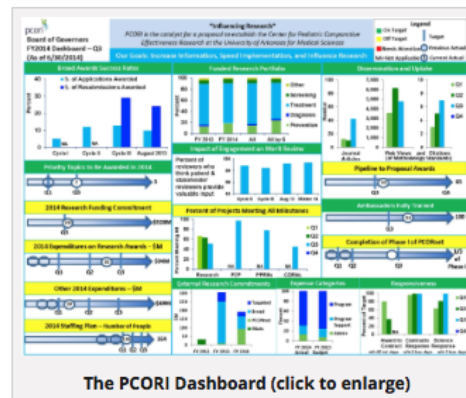
The [PCORI Evaluation Framework](#) contains all of the questions our stakeholders and staff have submitted about our work and describes how we'll go about answering them. It addresses how we conduct our day-to-day work, how we are progressing toward our strategic goals, and ultimately, if and how "research done differently" will make a difference for patients and public health. Our framework reflects our strategic plan and evolves along with our work because, even as we attempt to answer the initial questions, new ones arise. [Read more here](#) about our discussion at the Advisory Panel on Patient Engagement January 2014 Meeting and at the [Board of Governors May 2014 Meeting](#).

We Use a "Dashboard" to Report to Our Board

We use a visual representation of metric tracking, or "dashboard," for reporting to our [Board of Governors](#) what we are learning and how we are incorporating our findings into our work. Our dashboard continues to evolve, and we update it and its supporting materials quarterly to present to the Board in a public meeting.

View our following "dashboards":

- [May 6, 2013](#)
- [September 23, 2013](#)
- [January, 28 2014](#)
 - [Blog: Tracking Progress Toward Our Strategic Goals](#)
- [May 5, 2014](#)
- [September 15, 2014](#)



How We Evaluate Progress Toward Our Goals

As described in our strategic plan, PCORI has three goals: to increase useful information, to speed the use of that information, and to influence research to be more patient-centered. Each of three Strategy Committees, made up of members of our Board and [Methodology Committee](#), focuses on one of these goals and the metrics and evaluation activities associated with it. [Read more here](#) about the Background on PCORI's Strategic Goals.

PCORI Evaluation Group (PEG)



What is the PCORI Evaluation Group (PEG) and What Does It Do?

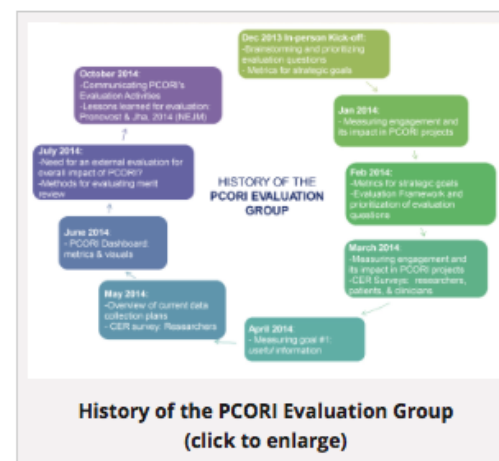
The PCORI Evaluation Group (PEG) is a consultative task force that advises us on how best to measure and evaluate the effectiveness of our work—from the usefulness of the studies we fund, to the extent to which the findings from these studies affect health decisions. The PEG is comprised of members of our [Board of Governors](#) and [Methodology Committee](#), external advisors selected for their expertise in specific areas of evaluation research, and PCORI staff. [Meet our PEG members here.](#)

The PEG provides targeted feedback on:

- Our evaluation goals
- Methods for achieving those goals
- Dissemination opportunities for results of our evaluation

PEG Meeting Slides:

- [December 2013: PEG Kick-Off Meeting](#)
- [January 2014: Prioritizing Our Evaluation Framework Questions](#)
- [February 2014: Measuring Our Three Strategic Goals](#)
- [March 2014: Plans for Measuring Engagement and Surveys of Patients, Researchers, and Clinicians](#)
- [April 2014: Measuring Our First Goal: Increasing Useful Information](#)
- [May 2014: Reviewing Data Collection at PCORI and Our Research Survey](#)
- [June 2014: Our Dashboard](#)
- [July 2014: Role of PCORI in Measuring the Impact of PCORI and What is the Appropriate Methodology for Evaluating Merit Review](#)
- [October 2014: Communicating PCORI Evaluation Activities and Lessons Learned for Evaluation in the Literature](#)
- [November 2014: Measuring the Impact of PCORI's Topic Capture and Research Prioritization](#)



HISTORY OF THE PCORI EVALUATION GROUP

Dec 2013 In-person Kick-off:

- Brainstorming and prioritizing evaluation questions
- Metrics for strategic goals

Jan 2014: Measuring engagement and its impact in PCORI projects

Feb 2014:

- Metrics for strategic goals
- Evaluation Framework and prioritization of evaluation questions

March 2014:

- Measuring engagement and its impact in PCORI projects
- CER Surveys: researchers, patients, & clinicians

April 2014: Measuring goal #1: *useful* information

May 2014:

- Overview of current data collection plans
- CER survey: Researchers

November 2014: Measuring the Impact of PCOR's Topic Capture and Prioritization Process

October 2014:

- Communicating PCORI's Evaluation Activities
- Lessons learned for evaluation: Pronovost & Jha, 2014 (NEJM)

July 2014:

- Need for an external evaluation for overall impact of PCORI?
- Methods for evaluating merit review

June 2014: PCORI Dashboard: metrics & visuals

How We Evaluate Key Aspects of Our Work

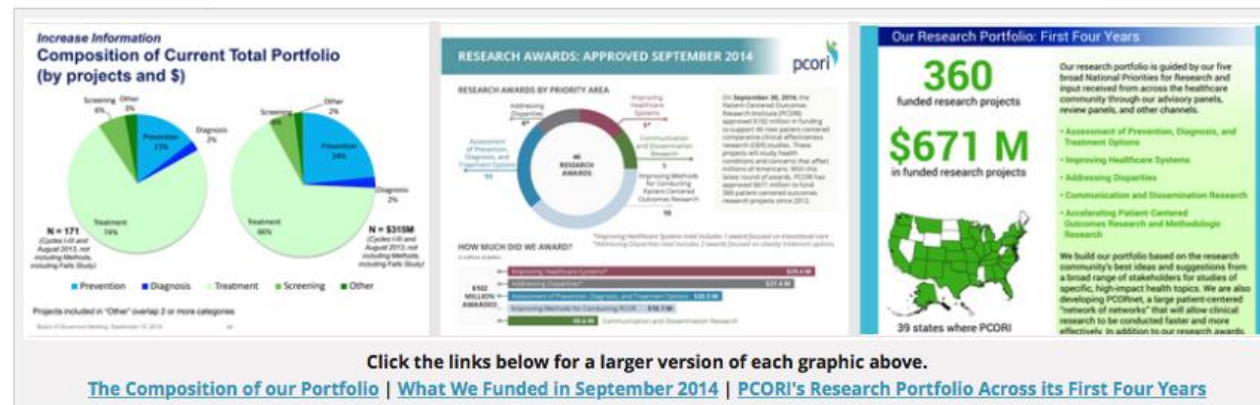
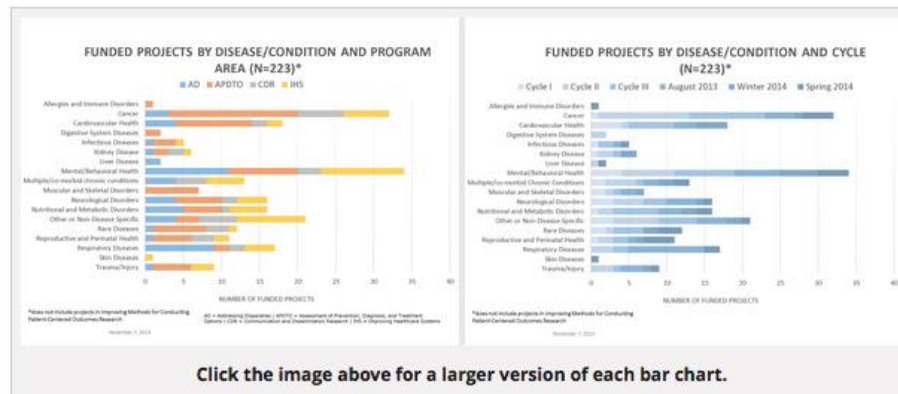


How Are We Evaluating Our Portfolio?

We analyze and report on the research we fund to ensure that our portfolio is meeting the needs prioritized by our stakeholders. We review our portfolio to determine the distribution of projects by therapeutic area, priority population, study design, intervention type, systems level, and location on the care continuum, such as prevention, diagnosis, or treatment.

We compare the distribution of the funded projects to that of the suggested research topics submitted to the PCORI website by stakeholders and the general public. We also examine how our funded projects align with other organizations' priorities for comparative clinical effectiveness research.

With this information, we can identify gaps in research funding and trends to help us make strategic decisions about how to prioritize topics for future funding.



Results!



From:

- Ongoing analyses of our ***processes and portfolio*** of funded studies (on Dashboard since 2013)
- Surveys of Engagement ***Workshop participants*** (May Board meeting)
- Surveys of our ***Merit Reviewers*** (September Board meeting)



Coming Soon:

- Additional analyses of our ***portfolio***
- Results of our exploration of the potential ***usefulness*** of our studies
- Initial look at ***Engagement in Research*** (WE-ENACT)
- Analyses of our ***Topic Capture and Prioritization*** process
- Results from our ***surveys of patients, caregivers, clinicians, and researchers***, about attitudes toward, experience with, and use of comparative effectiveness research

For Discussion

Please tell us what you would like to know about PCORI's work so that we can be sure we are answering, or at least thinking about ways to answer, your questions about:

- 🌱 ***How well*** we are working
- 🌱 Whether we are progressing toward ***our goals***
- 🌱 ***What difference*** our engaged and patient-centered approach is making
- 🌱 What ***impact*** we are having



Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Patient-Centered Outcomes Research Institute