Executive Director's Report

Joe Selby, MD, MPH, Executive Director
Board of Governors Meeting
Chicago, IL
May, 2013

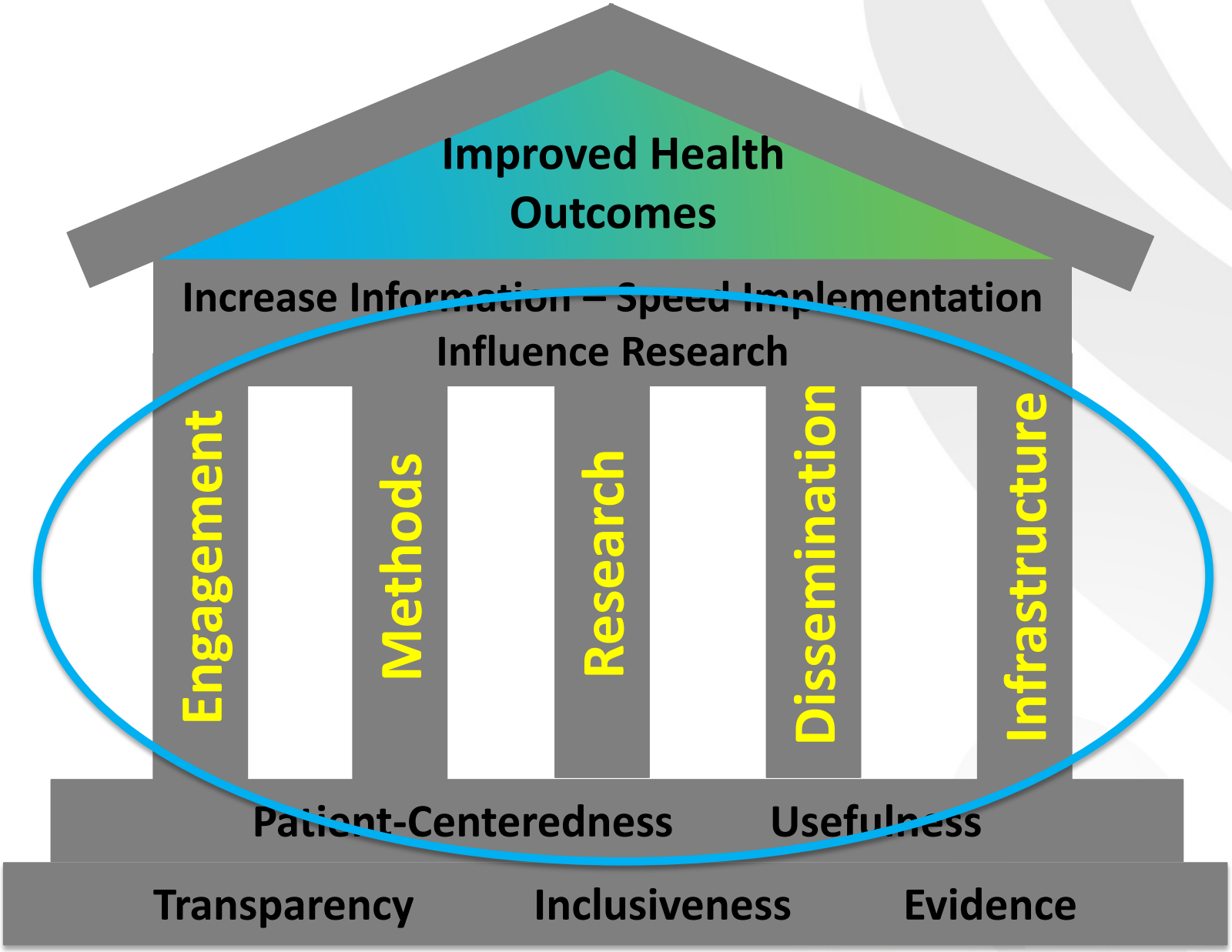
Patient-Centered Outcomes Research Institute

Session Topics and Agenda

PCORI Activities	• Review of recent activities and events taking place at PCORI
Legislative Mandates	• Update on progress towards meeting legislative mandates
Office of the Executive Director	• Update on additions to the Office of the Executive Director
New PCORI Staff	• Update on PCORI staffing

PCORI Activities

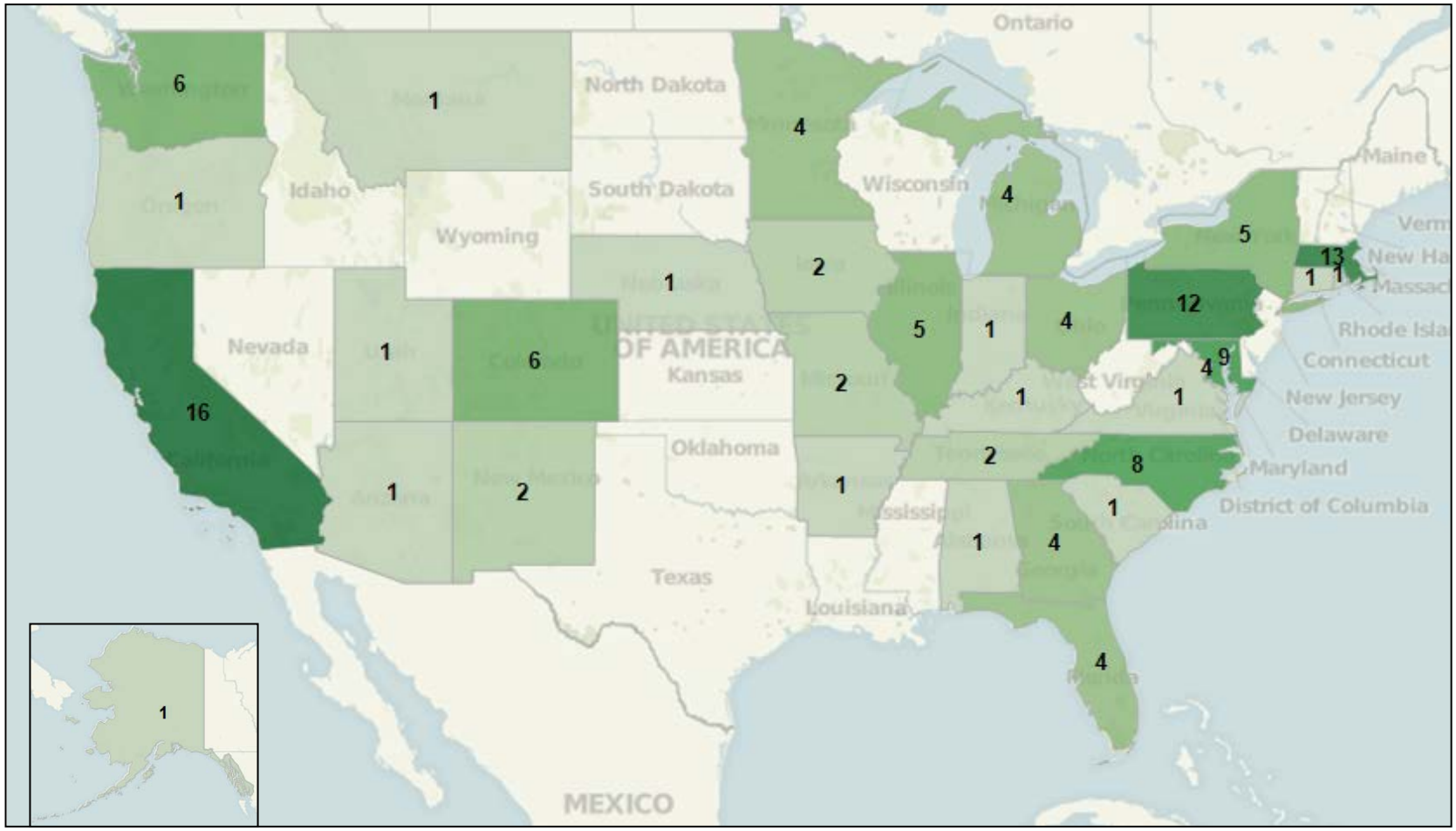
All of our activities are centered on PCORI"s Strategic Imperatives



Engagement

- **Training for Patient/Stakeholder Reviewers – April 26-27th**
  - 17 new mentors trained to support patient/stakeholder reviewers in merit reviews
- **Regional Workshop – March 9-10th**
  - "The Power of Partnership in Research: Improving Healthcare Outcomes in Rural Settings" brought together 63 patients and stakeholders in Wichita, KS
- **Roundtables**
  - Events targeted to priority populations (persons with disabilities, Latinas) to gain input, share ideas, and discuss PCORI opportunities for engagement and research
  - Additional roundtables are being planned
- **Engagement Awards**
  - Funding announcement due out this summer for micro-contracts

Location of PCORI's First 126 Awards



Total: 126

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Methods

- **Methodology Report**
  - Revisions are currently underway to incorporate public comments into the updated report; release expected shortly
- **Improving Methods for Patient-Centered Outcomes Research**
  - Multiple town hall sessions hosted in late-April to discuss Methods PFA applications; initial scores expected in mid-June
- **Observational Studies in a Learning Health System – April 25-26th**
  - PCORI and Institute of Medicine (IOM) workshop focused on analytic methods for improving the validity and reliability of observational studies

Research

- **Merit Review and Cycle II Awards**
  - In-person panel discussions of Cycle II applications in new single phase format
  - Announcement today of Cycle II awards

- **Targeted PFA Workgroups**
  - Five events hosted on TPFAs on Asthma, Back Pain, Uterine Fibroids, Falls in the Elderly, and Obesity from March 1st to April 16th

- **Advisory Panels Training and Inaugural Meeting – April 19-20th**
  - Three panels dedicated to research prioritization and portfolio evaluation
  - One panel devoted to evaluating and refining patient engagement practices

- **PCORI Pilot Projects Learning Networks**
  - "Share and tell" webinars
  - Collaborative dissemination opportunities

Infrastructure

- **Building a National Patient-Centered Clinical Research Network**
  - $68 million funding announcements for CDRN's and PPRN's posted in April 23rd
  - LOI due June 19th
  - Applications due Sept 27th

Dissemination

- **Recent PCORI Publications**
  - ***Network News: Powering Clinical Research*** by J. Selby, H. Krumholz, R. Kuntz, F. Collins appeared in *Science Translational Medicine* on April 23rd
  - ***How The Patient-Centered Outcomes Research Institute Is Engaging Patients And Others In Shaping Its Research Agenda***" by R. Fleurence, J. Selby, K. Odom-Walker, G. Hunt, D. Meltzer, J. Slutsky, and C. Yancy appeared in February 2013 *Health Affairs*

- **Scientific Publications Committee**
  - Papers on PCORI's review, research prioritization, and patient engagement in preparation
  - Papers on opportunities PCORI presents for nursing research in preparation

- **Dissemination and Implementation Blueprint**
  - Developing a comprehensive strategy for dissemination and implementation
  - A webinar roundtable held in mid-late June
  - Face-to-face multi-stakeholder workshop October 15th (tentative)
  - Final plan presented to Board before end of 2013

Legislative Mandates

Legislative Mandates

THE INSTITUTE SHALL:	STATUS	PROGRESS REPORT
Identify national priorities for research		• National Priorities for Research adopted by Board (May 21, 2012) • Scientific programs organized accordingly
Establish and update a research project agenda		• Original Research Agenda adopted by Board (May 21, 2012) • Multi-stakeholder advisory panels established to refine and update research agenda over time
Carry out research project agenda		• Pilot Projects • Broad PFA Awards • Targeted PFAs
Enter into contracts for management of funding and conduct of research		• All PCORI funding is through contracts • This language refers to management and oversight of research funding

Legislative Mandates

THE INSTITUTE SHALL:	STATUS	PROGRESS REPORT
…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 Agency or Institutes		• PCORI has or has had established contracts (or MOUs with transfer of funds) for both AHRQ and NIH • Currently exploring plans for further collaborations with each
Conditions for Contracts: • Transparency, COI • Methodology standards • Expert advisory panels • Allows publication • Data privacy and ethics		• Contracts include necessary language to cover all but the expert advisory panels • Development of expert advisory panels on Clinical Trials and Rare Diseases is underway

Legislative Mandates

THE INSTITUTE SHALL:	STATUS	PROGRESS REPORT
Design [research] as appropriate, to take into account the potential for differences in the effectiveness of health care treatments…		• All funding announcements require this • Methodology report provides standards for treatment heterogeneity
Review and update evidence on a periodic basis as appropriate		• Meaning is not entirely clear • PCORI research will begin producing evidence in 2015, and reviewing thereafter
Appoint expert advisory panels in carrying out randomized clinical trials		• Beginning to plan this in collaboration with MC and PDC • Will present Charter at September Board meeting

Legislative Mandates

THE INSTITUTE SHALL:	STATUS	PROGRESS REPORT
In the case of a research study for rare disease….. appoint an expert advisory panel		• Meetings scheduled with rare disease community • Draft charter will be presented to Board at September meeting
Provide support and resources to help patient and consumer representatives effectively participate on the Board and expert advisory panels		• Mentor training programs support patients and stakeholders on merit review panels • Training RFP now released to develop broader patient and stakeholder training
Not later than 18 months, develop and periodically update: • Methodological Standards for Research; • Translation table		• Draft version of Methodology Standards submitted to Board (May 23, 2012) • Final version adopted (November 19, 2012) • PCORI-IOM workshop on observational methods • Translation table to be completed during 2013

Legislative Mandates

THE INSTITUTE SHALL:	STATUS	PROGRESS REPORT
Ensure that there is a process for peer review of primary research. …provide for a public comment period of …45 - 60 days prior to the adoption [of the process]		• This legislative language requires further evaluation • Scientific journal's peer review process may suffice
Not later than 90 days after the conduct or receipt of research findings, …make such research findings available to clinicians, patients, and general public.		• This requirement is incorporated into contracts for research • Will use PCORI's website, potentially other organizations for dissemination
Submit an Annual Report to Congress and the President		• 2011 report submitted to Congress and the President; available to the public • Draft report for 2012 now in review

Legislative Mandates

THE INSTITUTE SHALL:	STATUS	PROGRESS REPORT
Disclose a conflict of interest [for]: • Members of advisory panels • Peer reviewers • MC members • Board members • PCORI staff		• PCORI's COI Policy has been made available to the public • Disclosures are posted on our website. • Annual disclosures presented in Annual Report

Office of the Executive Director

Office of the Executive Director

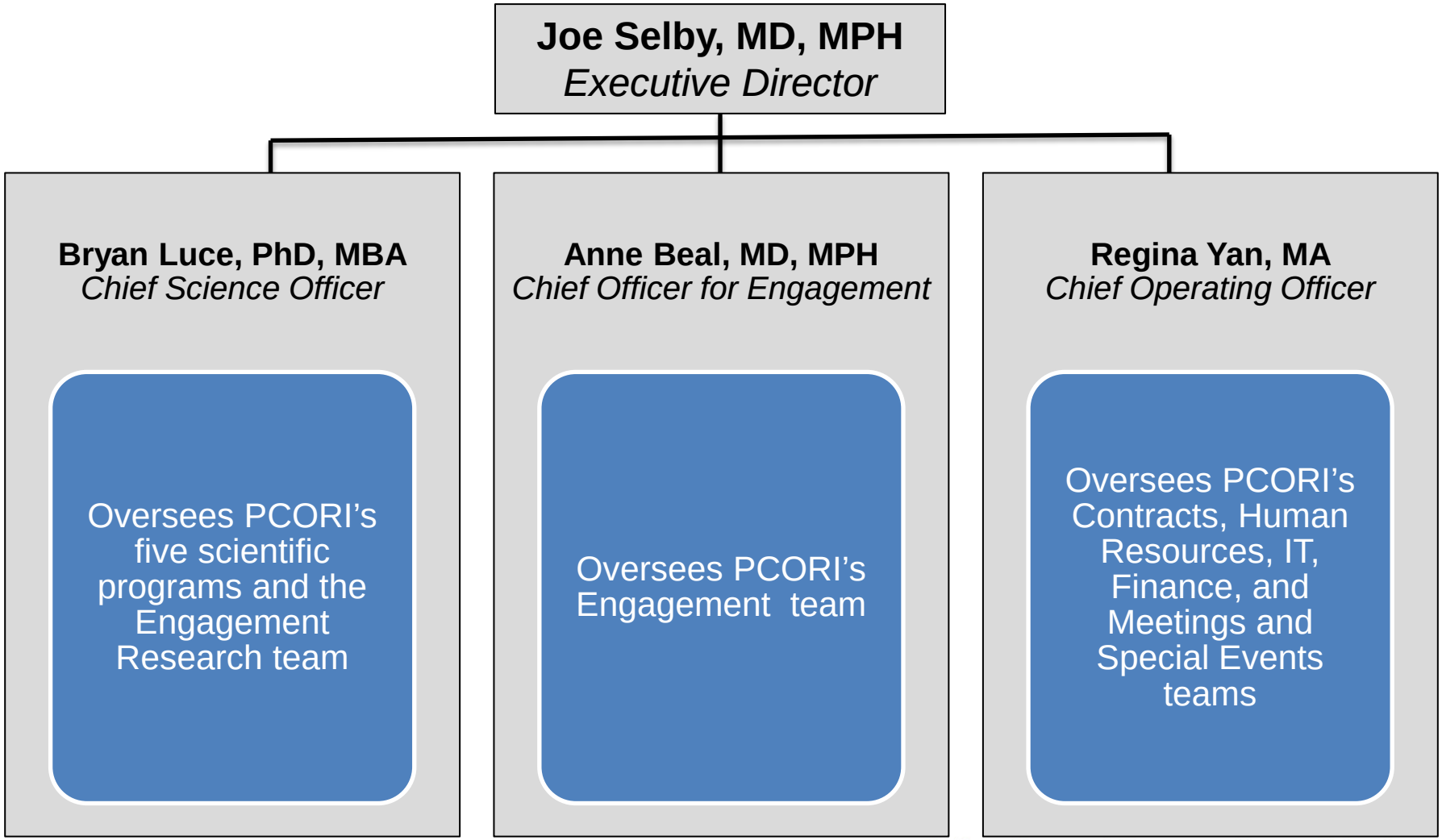
Bryan Luce, PhD, MBA
Chief Science Officer

Regina Yan, MA
Chief Operating Officer

Office of the Executive Director

Anne Beal, MD, MPH
Chief Officer for Engagement
& Deputy Executive Director

Office of the Executive Director



New PCORI Staff

New PCORI Staff

January 28, 2013 – April 8, 2013

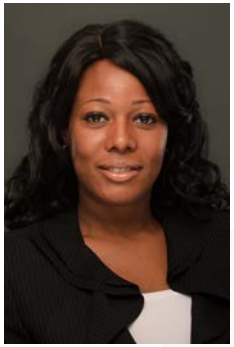
Victoria Lee
Senior Administrative Assistant
January 28, 2013

Adaeze Akamigbo, PhD, MPP
Senior Program Officer
January 29, 2013

Suzanne Schrandt, JD
Deputy Director, Patient Engagement
February 15, 2013

Kelly Dunham, MPP
Senior Program Associate
February 25, 2013

Rochelle Bent, MPA
Senior Administrative Assistant
February 25, 2013



Kisha Curry
Senior Administrative Assistant
February 25, 2013

New PCORI Staff

January 28, 2013 – April 8, 2013

Sandi Myers
Senior Administrative Assistant
March 4, 2013

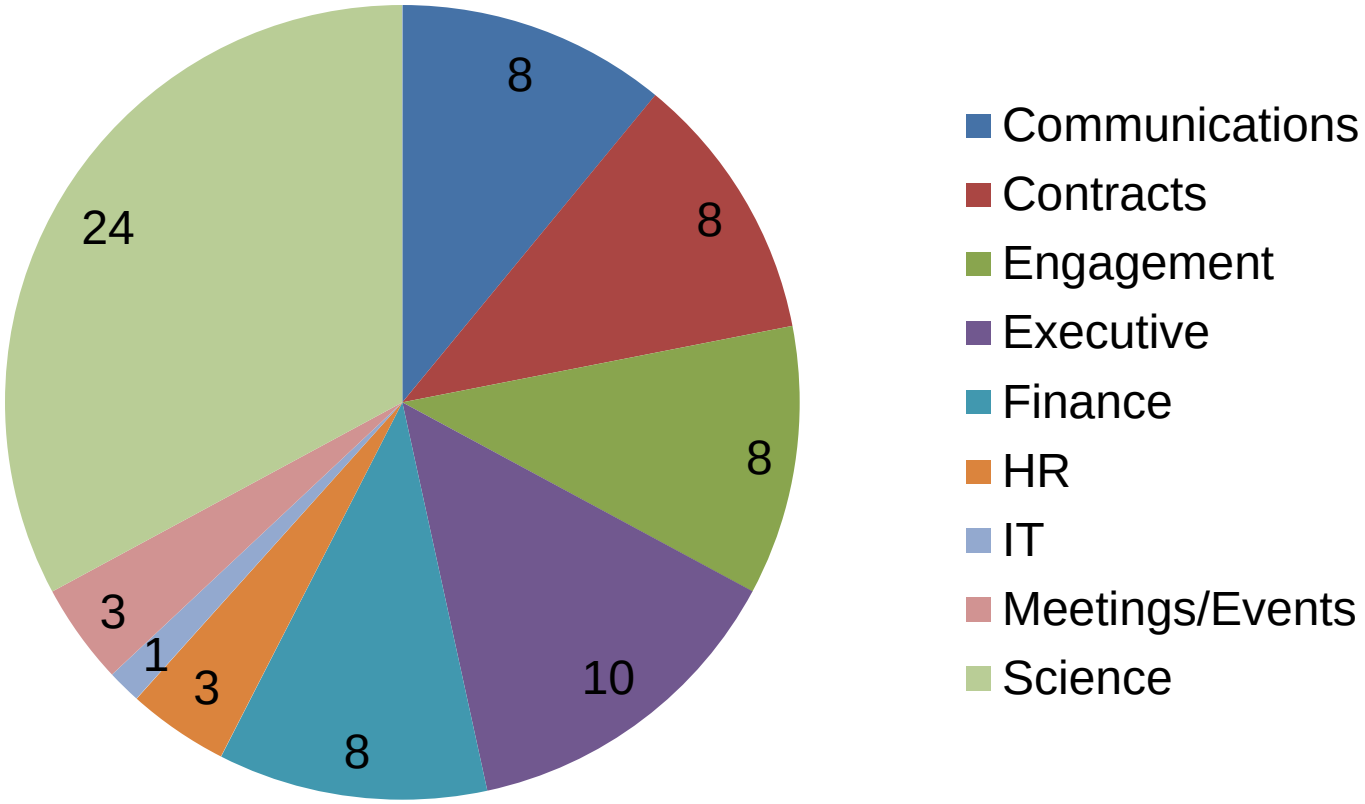
Katrina Wilkins-Jackson, MS
Financial Compliance Administrator
March 11, 2013

Not Shown:
Tomica Singleton, Senior Administrative Assistant – January 28, 3013
Katie Rader, Program Coordinator – March 4, 2013
Scott Solomon, Deputy Director, Finance-Compliance – March 11, 2013
Stanley Ip, MD – Senior Program Officer – April 8, 2013
Christine Stencel – Associate Director, Media Relations – April 8, 2013

PCORI Staff – by Functional Group

Current: 73 Full-Time Staff

Planned: 90 Full-Time Staff



Strategic Planning

Joe V. Selby, MD, MPH
PCORI Board of Governors Meeting
Chicago, IL
May 2013

Patient-Centered Outcomes Research Institute

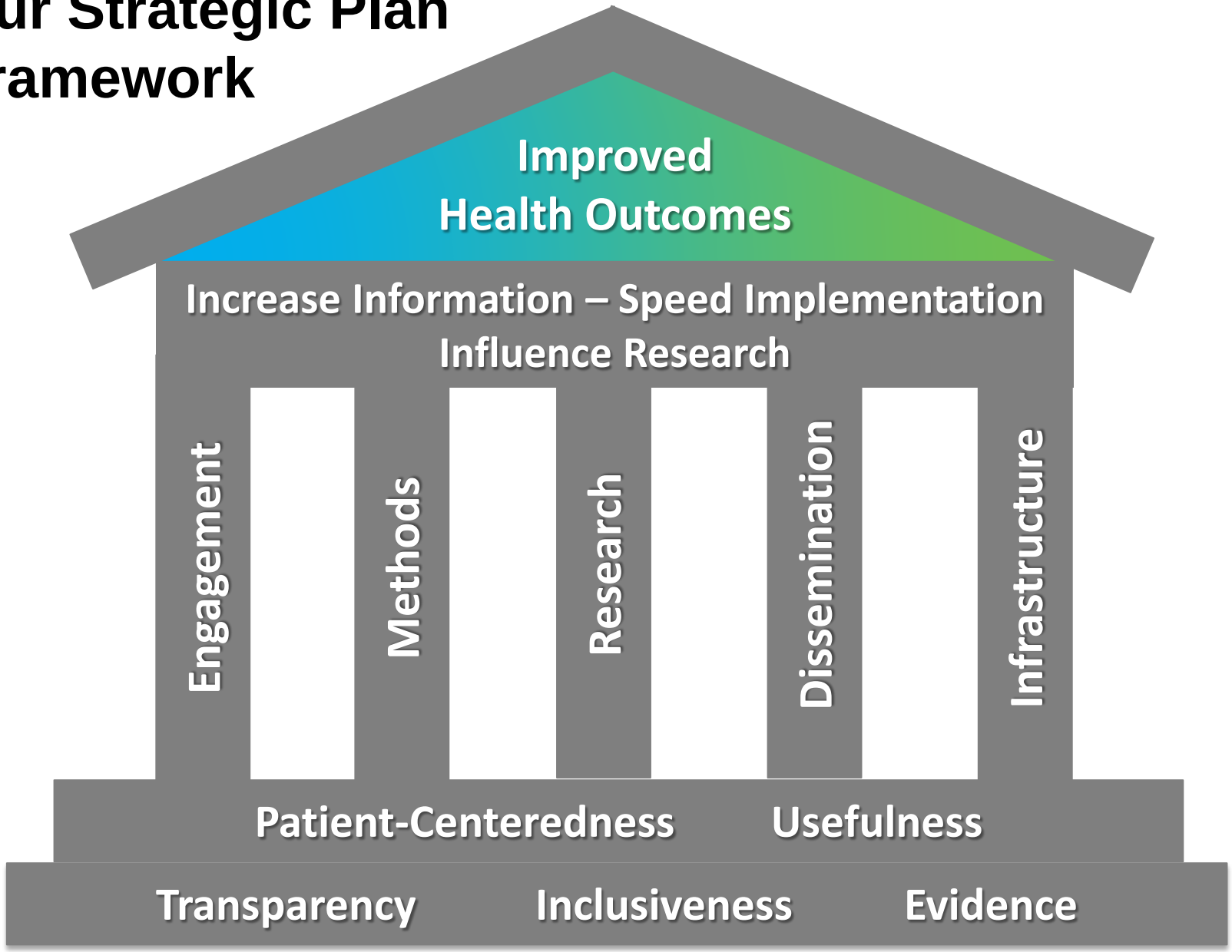
Agenda

- Recap Our Strategic Plan
- Focus on 2013 Implementation of Plan – Priority Activities
- Review plans for Monitoring Our Progress
- Discuss Strategies for Developing Our Research Portfolio
  - Portfolio Planning, Management, and Evaluation
  - Evolution from predominantly via broad funding announcements to predominantly via targeted ones

The Big Picture

Cycle	2010 - 2013	2014 - 2016	2017 - 2019	2020 - 2022
Congressional Oversight and Evaluation	Yearly GAO Financial Audits	First GAO 5-year Review	GAO 8-year Review	Second GAO 5-year Review
	Congressional inquiries may occur at any time			
PCORI Emphasis or Theme	Building Implementing	Implementing Results	Implementing Results	Results Impact
Primary Evaluation Metrics	Inputs Process	Process Outputs	Outputs Outcomes	Outcomes Impact
Key Words from GAO Review Mandate in Our Legislation	Processes established Research priorities and projects Objective and credible information Transparent process Dissemination and training activities Data networks		Overall effectiveness of activities Use by health care decision-makers Reducing practice variation and disparities Effect on innovation and health economy Use by public and private payers	

Our Strategic Plan Framework



PCORI Strategic Plan

Our Values

- Patient-Center-edness
- Useful-ness
- Trans-parency
- Inclusive-ness
- Evidence

Our Strategic Imperatives

- ***Engage*** *patients, caregivers, and all other stakeholders in our entire research process from topic generation to dissemination and implementation of results*
- *Develop and promote* ***methodological knowledge****, standards, and best practices*
- ***Fund*** *a comprehensive agenda of high quality Patient-Centered Outcomes* ***Research*** *and evaluate its impact*
- ***Disseminate*** *Patient-Centered Outcomes Research to all stakeholders and support its uptake and implementation*
- *Promote and facilitate the development of a sustainable* ***infrastructure*** *for conducting patient-centered outcomes research*

Our 2013 Priority Activities

- Fund research through broad solicitations on assessing options; improving systems; addressing disparities; research methods; and communication and dissemination.
- Fund research on targeted topics.
- Develop the framework for evaluating our work and establish baselines
- Develop a skilled community… to participate in our research processes
- Establish programs to build capacity of patient groups and to match patients with researchers
- Develop dissemination plan and infrastructure in collaboration with AHRQ
- Launch PPRN, CDRN, and a coordinating center
- Establish multi-stakeholder advisory panels and work groups
- Launch dissemination and implementation plan to promote methodology standards
- Implement portfolio planning, management, and evaluation system to maximize our research

Our Goals

- Increase Information
- Speed Implement-ation
- Influence Research

Our Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.

Our Vision

Patients and the public have information they can use to make decisions that reflect their desired health outcomes.

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How We Determined Our 2013 Priorities

- Focused on our goals
- Applied our logic model
- Gave highest priority to:
  - Mandated activities (for example, Methodology Report)
  - Foundational activities (for example, PCORI Infrastructure)
  - Rate-limiting activities (for example, Needs Assessments)
- Considered resources available (staff, funds, time)
- Moved some activities to 2014, 2015, and beyond (or maybe out of consideration)

2013 Priority Activities: Our Provisional "Dashboard"

Fund research through broad solicitations related to PCORI's five priority areas

Fund research on targeted topics

Develop the framework for evaluating our work and establish baselines

Develop a skilled community to participate in our research processes

Establish programs to build capacity of patient groups and to match patients with researchers

Develop dissemination plan and infrastructure in collaboration with AHRQ

Launch PPRN, CDRN, and a coordinating center

Establish multi-stakeholder advisory panels and work groups

Launch dissemination and implementation plan to promote methodology standards

Implement portfolio planning, management, and evaluation system to maximize our research

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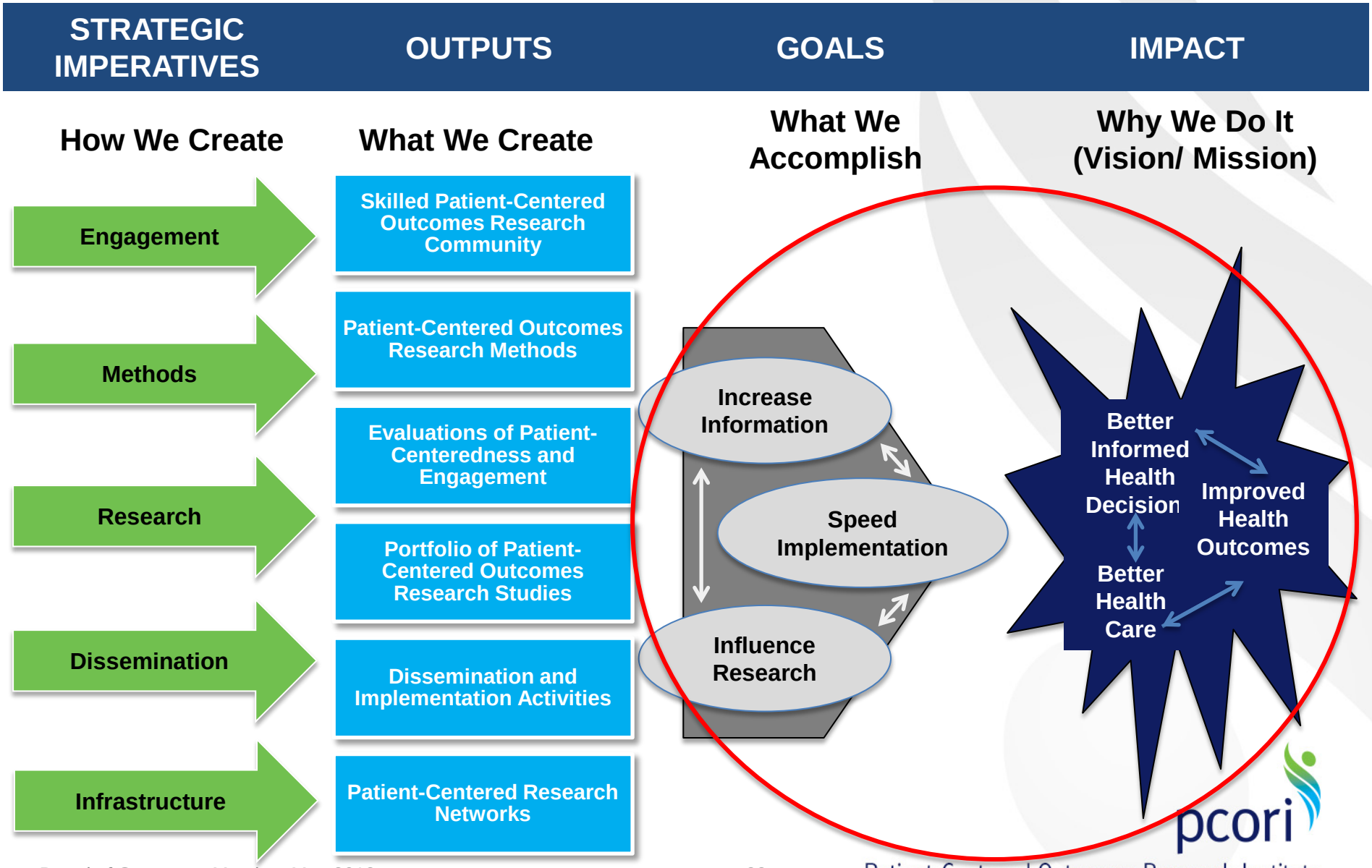
Our Basic Logic Model



Monitoring Our Progress: Building toward Our Dashboard

We are primarily focused on our goals and intended impact, but…

Increase Information

Proportion of study results that are usable

Speed Implementation

Proportion of study results implemented within 5 years

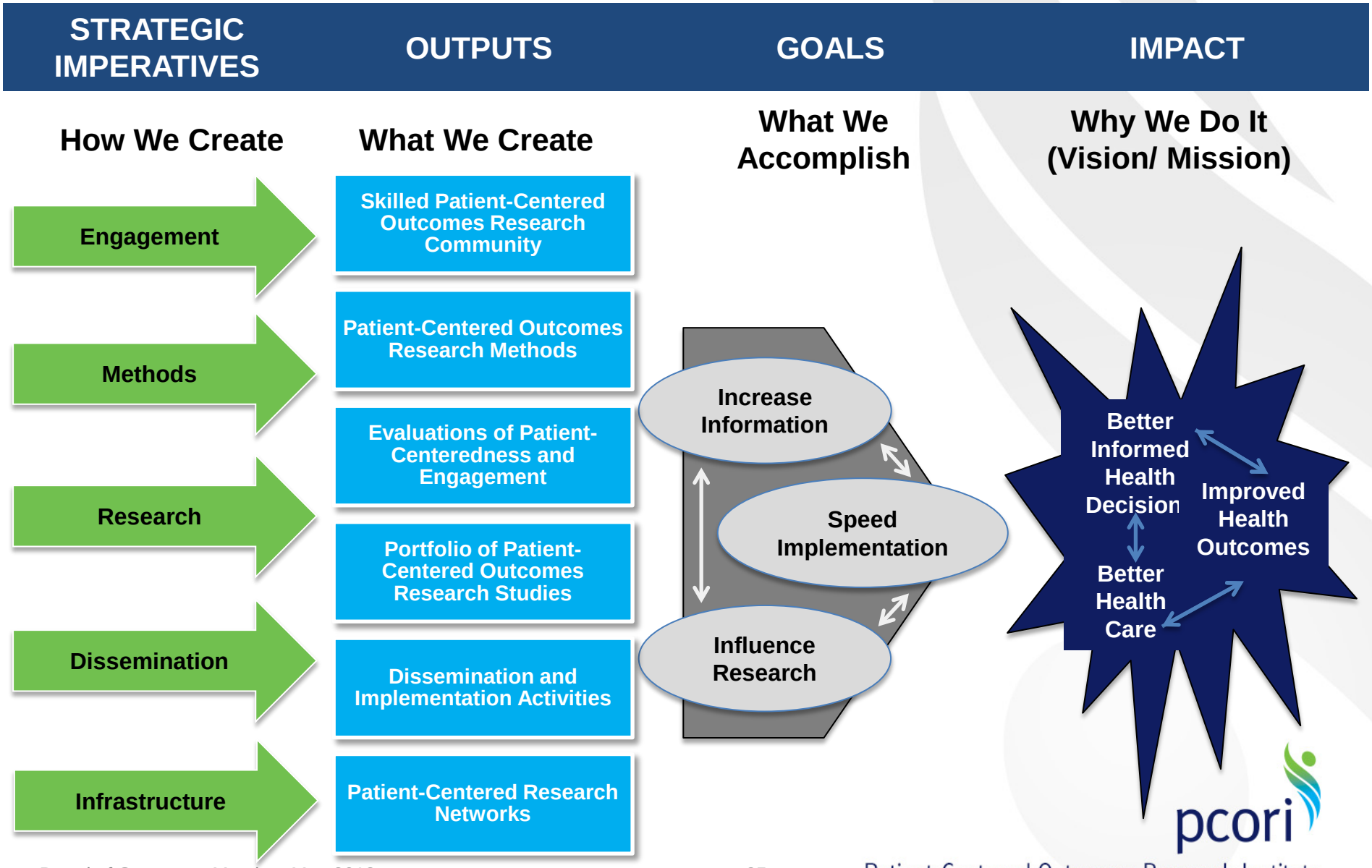
Impact: Improved Health Outcomes

Influence Research

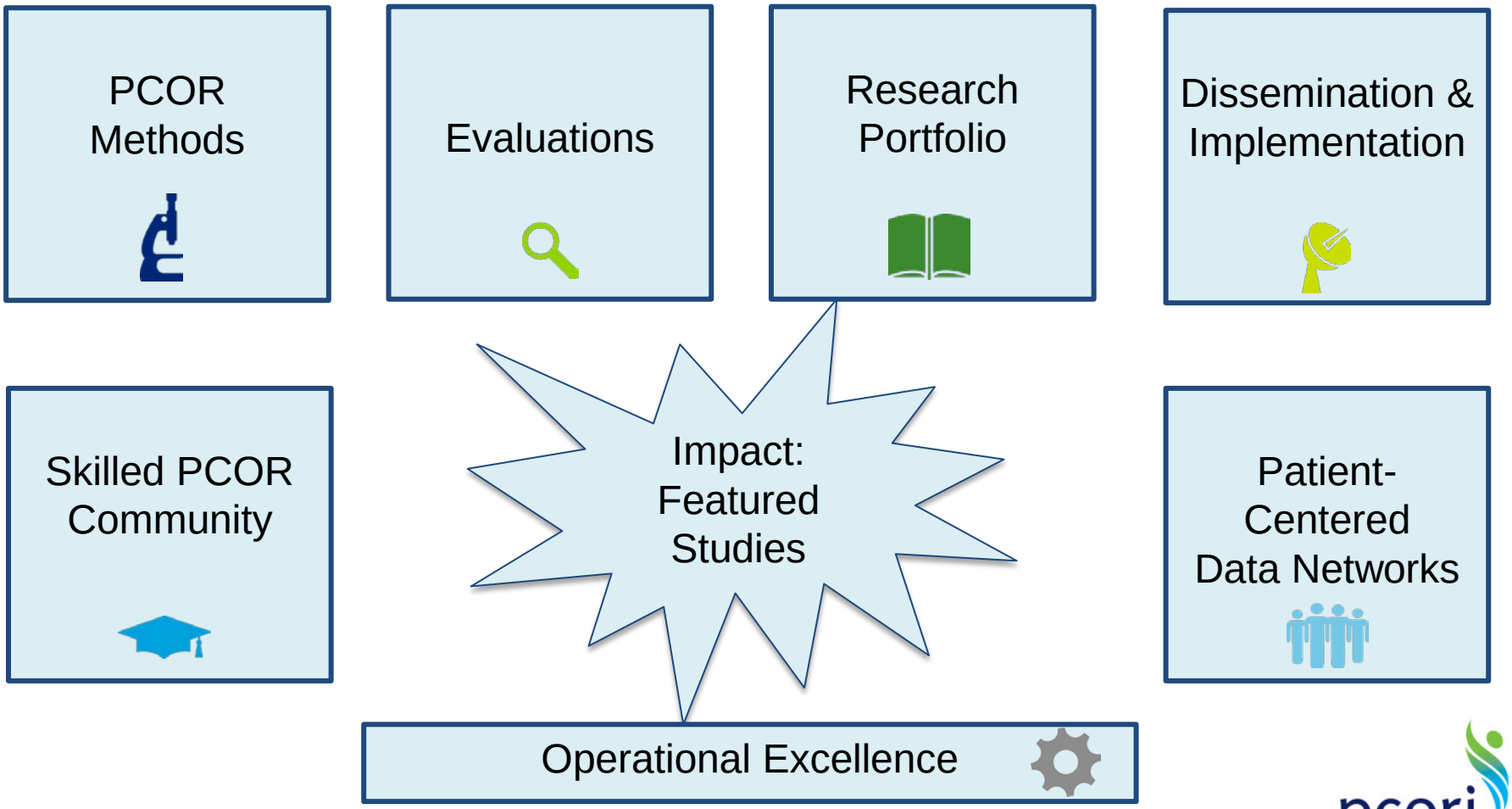
Proportion of PCOR funding from other funders

Operational Excellence

In the meantime, we monitor our outputs



Initially, Our Dashboard Features Outputs, Operational Excellence, and a Qualitative Focus on Impact



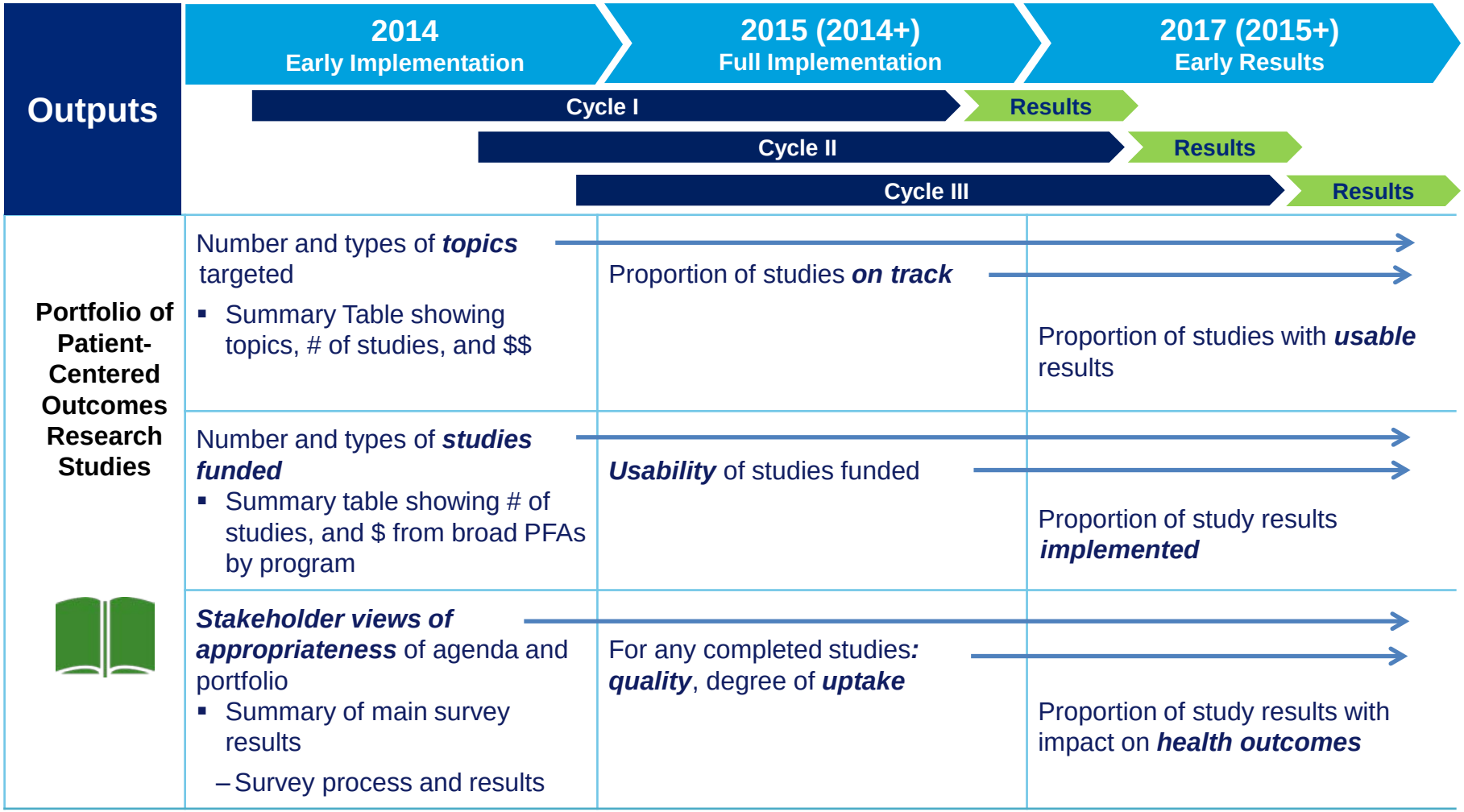
Outputs

Over Time, Metrics Focus Less on Outputs and More on Goals

	2014 Early Implementation	2015 Full Implementation	2017 Early Results
Skilled Patient-Centered Outcomes Research Community	▪ Number of ***people trained*** by PCORI and involved in PCORI work (by stakeholder category)	▪ Number of ***people involved in PCOR*** who have been trained with PCORI support ▪ Level of interest in ***PCOR careers***	▪ **Availability of *PCOR training from others*** ▪ Availability of ***opportunities to work on PCOR*** outside of PCORI
Patient-Centered Outcomes Research Methods	▪ Number and types of methods ***standards developed*** ▪ Number and types of methods research ***projects funded***	▪ Number of methods ***gaps filled*** ▪ Extent of ***uptake*** and ***adherence*** to methods standards	▪ Proportion of PCOR studies ***adhering*** to methods standards ▪ ***Quality, usability, uptake*** of results from studies adhering to standards
Evaluations of Patient-Centeredness and Engagement	▪ Survey results, ***baselines*** ▪ Number and types of ***evaluations*** internally and as components of ***funded*** studies	▪ Change in ***stakeholder views of value*** of patient-centeredness and engagement ▪ Degree of ***uptake*** by others of proven approaches	▪ Proportion of ***research funded by others*** that is patient-centered and engaged
Portfolio of Patient-Centered Outcomes Research Studies	▪ Number and types of ***topics*** targeted and ***studies funded*** ▪ ***Stakeholder views of appropriateness*** of our agenda and portfolio	▪ Proportion of studies ***on track*** ▪ ***Usability*** of studies funded ▪ For any completed studies: ***quality,*** degree of ***uptake***	▪ Proportion of studies with ***useable*** results ▪ Proportion of study results ***implemented*** or with impact on ***health outcomes***
Dissemination and Implementation Activities	▪ Extent of **dissemination** and **uptake** of methods standards ▪ Number and types of **publications** (re: what we're learning)	▪ Change in ***accessibility and useability*** of PCOR for stakeholders ▪ Change in level of ***awareness and influence*** of PCOR among stakeholders	▪ Change in speed and degree of ***uptake, use, and implementation*** of PCOR
Patient-Centered Research Networks	▪ Number of ***PPRNs*** and ***CDRNs*** funded ▪ Number of ***patients*** and ***conditions*** represented	▪ Number and ***efficiency*** of studies conducted in the networks	▪ ***Quality, usability, uptake*** of study results from the network

Shift from Outputs Metrics to Goals Metrics

Example: Portfolio of Patient-Centered Outcomes Research Studies



Our 2014 "Early Implementation" Dashboard: Focus on Outputs

2014 – Early Implementation | 2015 | 2017

PCOR Methods

- Number and types of methods ***standards developed***
- Number and types of methods research ***projects funded***

Evaluations

- Survey results, ***baselines***
- Number and types of ***evaluations*** internally and as components of ***funded*** studies

Research Portfolio

- Number and types of ***topics*** targeted and ***studies funded***
- ***Stakeholder views of appropriateness*** of our agenda and portfolio

Dissemination and Implementation

- Extent of **dissemination** and **uptake** of methods standards
- Number and types of **publications** (re: what we're learning)

Skilled PCOR Community

- Number of **people trained** by PCORI and involved in PCORI work (by stakeholder category

Studies from our portfolio with ***high potential for impact***

Operational Excellence

Patient-Centered Data Networks

- Number of ***PPRNs*** and ***CDRNs*** funded
- Number of ***patients*** and ***conditions*** represented

Our 2015 "Full Implementation" Dashboard: Transitioning Focus from Outputs to Goals

2014 | **2015 – Full Implementation** | 2017

PCOR Methods

- Number of methods ***gaps filled***
- Extent of ***uptake*** and ***adherence*** to methods standards

Evaluations

- Change in ***stakeholder views of value*** of patient-centeredness and engagement
- Degree of ***uptake*** by others of proven approaches

Research Portfolio

- Proportion of studies ***on track***
- ***Usability*** of studies funded
- For completed studies***: quality***, degree of ***uptake***

Dissemination and Implementation

- Change in ***accessibility and usability*** of PCOR for stakeholders
- Change in level of ***awareness and influence*** of PCOR among stakeholders

Skilled PCOR Community

- Number of ***people involved in PCOR*** who have been trained with PCORI support
- Level of interest in ***PCOR careers***

Studies from our portfolio identified for **early development of dissemination plan**

Operational Excellence

Patient-Centered Data Networks

- Number and ***efficiency*** of studies conducted in the networks

Our 2017 "Early Results" Dashboard: Focus on Goals

2014 | 2015 | 2017 – Early Results

PCOR Methods

- Proportion of PCOR studies ***adhering*** to methods standards
- ***Quality, usability, uptake*** of results from studies adhering to standards

Evaluations

- Proportion of ***research funded by others*** that is patient-centered and engaged

Research Portfolio

- Proportion of studies with ***usable*** results
- Proportion of study results ***implemented*** or with impact on ***health outcomes***

Dissemination and Implementation

- Change in speed and degree of ***uptake, use, and implementation*** of PCOR

Skilled PCOR Community

- Availability of ***PCOR training from others***
- Availability of ***opportunities to work on PCOR*** outside of PCORI

Completed studies with ***early evidence of substantial uptake*** and potential for impact

Operational Excellence

Patient-Centered Data Networks

- ***Quality, usability, uptake*** of study results from the network

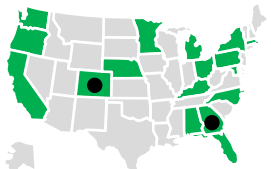
Board of Governors

Key Milestones (Target Date)

- TBD (Date)
- TBD (Date)
- TBD (Date)

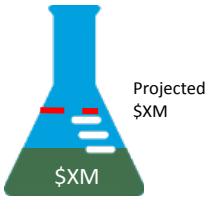
Impact

Program Overview



Funded ● Project Spotlight

Total Funds for Research



Projected $XM

Operational Excellence FY13 Information

Description	Actual	Target
Total Funded	$XM	$XM
# of Funded Projects	#	#
Employees	#	#
Staff Morale	X%	X%

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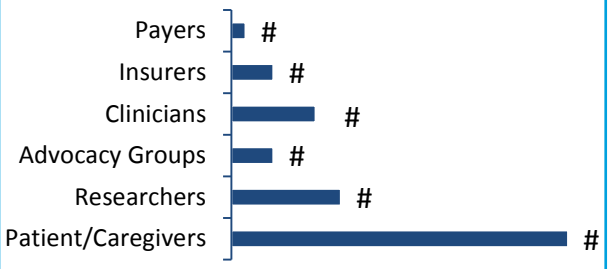
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Jan 2014

Our Goals: Increase Information - Speed Implementation - Influence Research

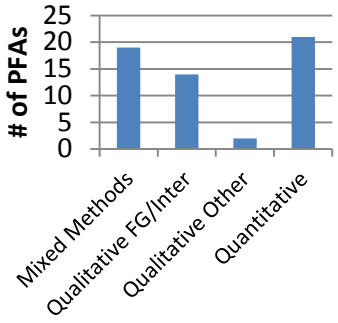
Skilled PCOR Community

Number of Stakeholders Trained (N=#)



How can we increase advocacy groups training?

PCOR Methods



National Priority #5 Projects and Amount

How can we increase Mixed Methods PFAs?

Evaluations

Awareness and Influence Among Stakeholders (N=#)

Excellent Good Poor

Patient/ Caregiver (#)	Insurers (#)	Advocacy Groups (#)
Researchers (#)	Payers (#)	Clinicians/ Doctors (#)

How do we engage and influence more Researchers and Clinicians?

Research Portfolio

 # Cycle I Awards

$XM Actual

$XM Projected

Types of Funding

Engagement = $XM (#)

Targeted = $XM (#)

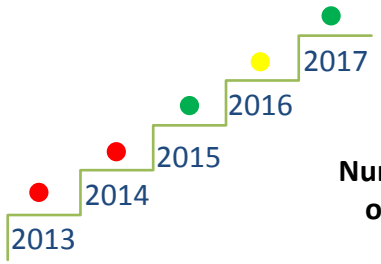
Broad = $XM (#)

Assessment of Options: $X
Improving HC Systems: $X
Communications and Dissemination: $X
Addressing Disparities: $X
Accelerating PCOR and Methodological Research: $X

Is this the right mix of projects to focus on?

Dissemination and Implementation

Methods Standards Uptake over Time

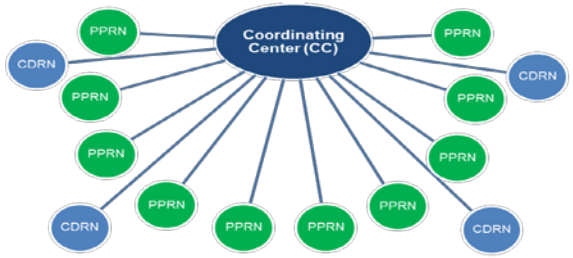


Number and Types of Publications

What actions should we take to increase implementation?

Patient-Centered Data Networks

PCORI Networks



Target

PPRN=# ↑ CDRN=# ↓ CC=# ↓

How can we learn from our PPRN success?

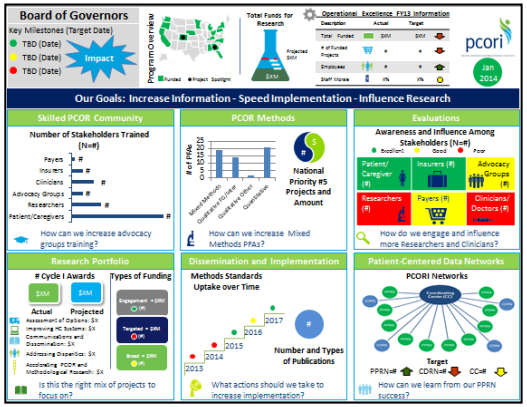
The Evolution of Our Dashboard

Based on "Big Rocks" Which Link to Outputs

2013 Provisional "Dashboard"

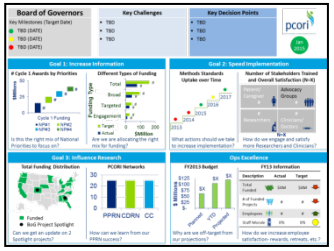
Qualitative and Quantitative Infographics Focused on Outputs and Operational Excellence

2014 Dashboard

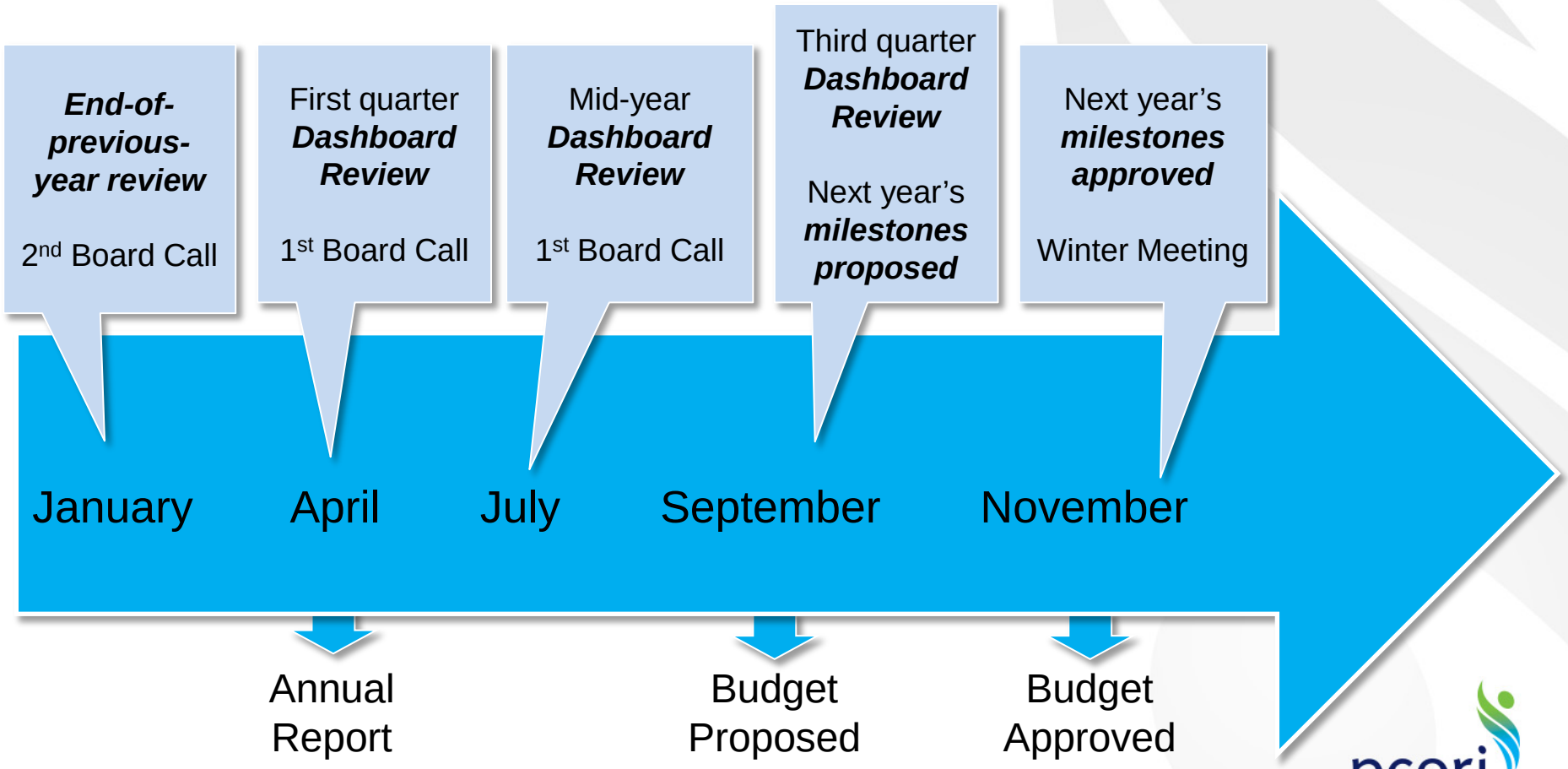


Infographics Focused Less on Outputs and More on Goals and Impact

2015 and Beyond Dashboard

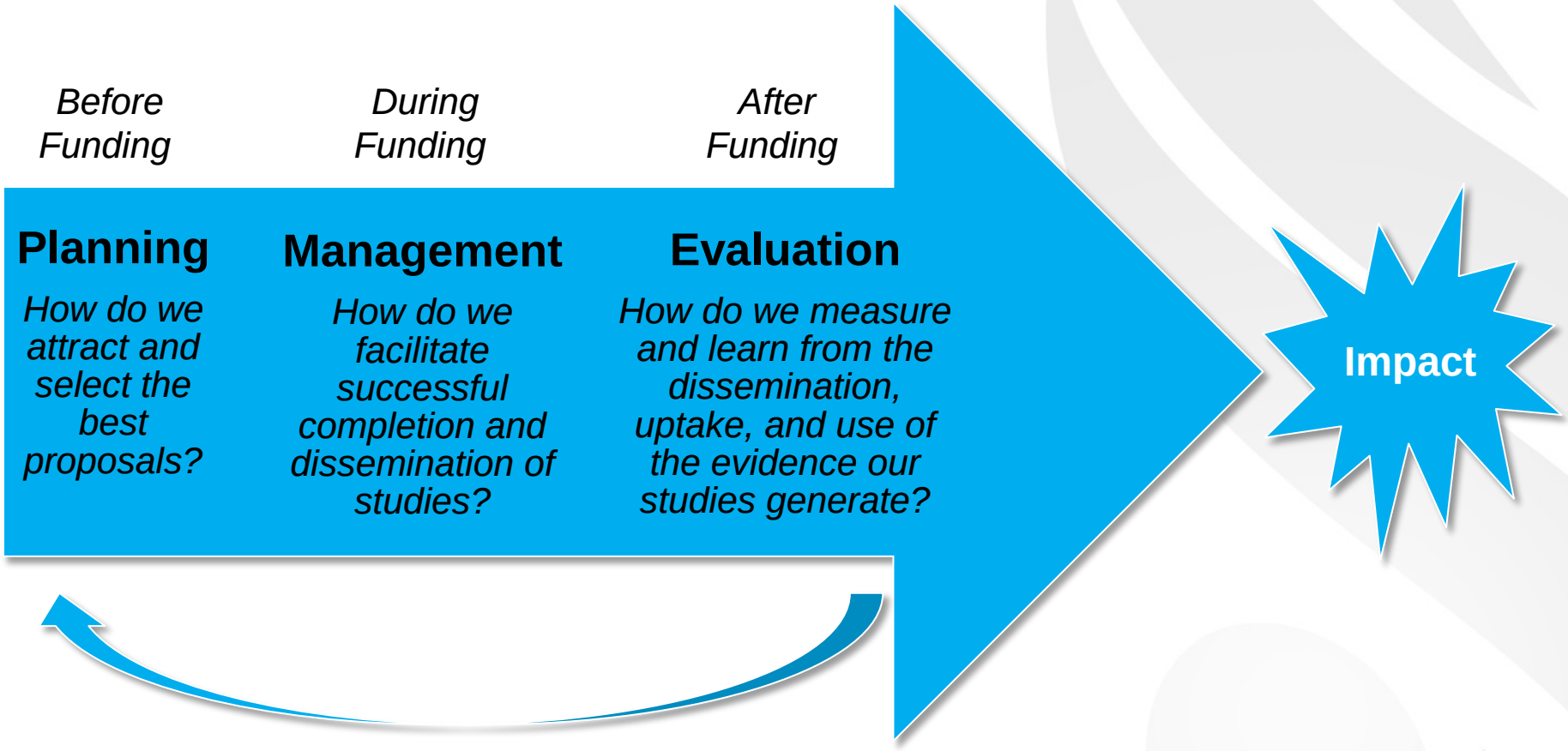


Aligning Planning, Budgeting, and Evaluation Proposed Reporting Schedule for 2014 Onward



Patient-Centered Outcomes Research Institute

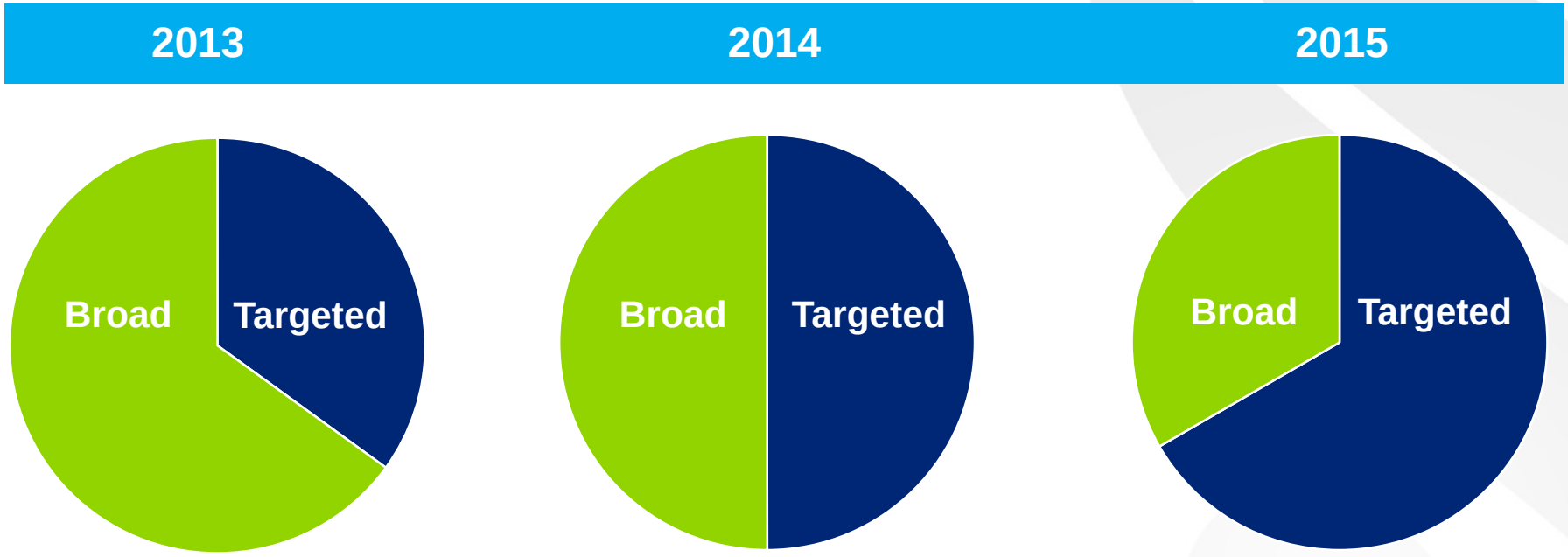
Maximizing Our Research Portfolio's Efficiency and Impact



Patient-Centered Outcomes Research Institute

Evolution of Our Research Portfolio

Envisioned Balance of Funding for Broad and Targeted PFAs



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Next Steps

- After today's feedback, finalize the draft plan
  - Seek Board approval
  - Seek public input
- Continue building our evaluation framework, developing metrics, and creating our dashboard
- Revisit strategic plan periodically, and refine planning and reporting processes continuously as we learn more about what works best

Appendix

Our Mission and Vision

Mission (**July 2011**)

The Patient-Centered Outcomes Research Institute helps people make informed health care decisions, and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.

Vision (**May 2012**)

Patients and the public have information they can use to make decisions that reflect their desired health outcomes.

Our Overarching Goals

PCORI's contributions to improving health will be to:

- Substantially ***increase*** the quantity, quality, and timeliness of useful, trustworthy ***information*** available to support health decisions
- ***Speed*** the ***implementation*** and use of patient-centered outcomes research evidence
- ***Influence*** clinical and health care ***research*** funded by others to be more patient-centered

Our Strategic Imperatives
What We Do to Reach Our Goals

To increase information, speed implementation, and influence research, we:

- ***Engage*** patients, caregivers, and all other stakeholders in our entire research process from topic generation to dissemination and implementation of results.
- Develop and promote rigorous Patient-Centered Outcomes Research ***methods***, standards, and best practices.
- Fund a comprehensive agenda of high quality Patient-Centered Outcomes ***Research*** and evaluate its impact.
- ***Disseminate*** Patient-Centered Outcomes Research to all stakeholders and support its uptake and implementation.
- Promote and facilitate the development of a sustainable ***infrastructure*** for conducting patient-centered outcomes research.

Our Core Values

- ***Patient-Centeredness:*** Patients are our true north: we rely on patient perspectives and values to guide and improve our work.
- ***Usefulness:*** We focus on funding rigorous research to find timely, implementable answers to questions important to patients and the healthcare community.
- ***Transparency:*** We work in the open and facilitate public access to build trust, encourage participation, and promote implementation.
- ***Inclusiveness:*** We bring together stakeholders with diverse backgrounds, experiences, and perspectives and involve them meaningfully in everything we do.
- ***Evidence:*** We rely on the best available science and evaluate our work in order to expand the evidence base.

BREAK

Join the conversation on Twitter via #PCORI

Preventing Injuries from Falls in the Elderly

Chad Boult, MD, MPH, Director
Improving Healthcare Systems
May 2013

Patient-Centered Outcomes Research Institute

Products of the Workgroup

- The Workgroup (3/12/13) identified four research questions related to preventing injuries from falls in the elderly. What is the comparative effectiveness of different models of:
  - Medication management?
  - Tailored treatments for specific balance deficits?
  - IT for measurement, monitoring, and messaging?
  - Multi-factorial, personally tailored falls prevention programs in institutional and/or community settings?

Factors in Selecting a Research Topic

- Selection of the topic for the research funding initiative was based on:
  - The need for the research
  - The likelihood that new evidence would lead to widespread improvement in practice and fewer injurious falls
  - The time needed to produce results
  - Opportunities to leverage PCORI support in collaboration with other organizations

Proposal

Collaborate with NIA (or another trials center) to:

Solicit and review applications,

Co-manage a cooperative agreement with an awardee,

Implement and evaluate the effectiveness of a preventive program of *screening, assessment, and multi-factorial tailored treatment* of older people who are at increased risk for falls.

- Contractor will comprise falls experts, health services researchers, provider organizations and a patient advocacy organization.
- Design: randomized trial (controls receive usual care).
- Sample: persons aged 65 years or older.
- Outcomes: rates of fall-related injuries, total falls, fear of falling, functional independence, and other outcomes that are important to patients, caregivers and providers.

Decision by the Board of Governors

Should PCORI's staff continue to develop and implement plans to support a research study of an injurious falls prevention program for older people along the lines of the proposal presented here?

Board Vote: Falls Prevention TPFA

Call for Motion to:	• **Approve the development of a TPFA on "Preventing Injuries from Falls in the Elderly"** as endorsed by the PDC
Once the Motion Is Seconded:	• Move to **discuss, amend, or take another action** on the Falls Prevention TPFA
Vote:	• Majority vote to **approve, disapprove, or take another action** on the motion

Development of Targeted Funding Programs

Assessment of Prevention, Diagnosis and Treatment Options

David Hickam, MD, MPH
Director, Assessment of Prevention, Diagnosis, and Treatment Options Program
May 6, 2013

Patient-Centered Outcomes Research Institute

Background on these Initiatives

- BOG identified two priority topics assigned to our program.
  - Treatment options for uterine fibroids.
  - Treatment options for episodic and chronic low back pain
- Multi-stakeholder work group meetings held in March 2013.
- Background work conducted as a follow-up to recommendations made by the work groups.
  - Horizon scans.
  - Feasibility assessments.

Uterine Fibroids: Common Cause of Symptoms and Infertility

- Half of women develop uterine fibroids within their lifetime.
- Highest incidence among women of child bearing age (30 to 40 years old).
- Hysterectomy (traditional curative treatment) prevents future child bearing.

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Research Questions: Uterine Fibroids

- Do symptoms and patient functioning differ among the options for the following treatment categories:
  - Medical therapies, dietary modification and lifestyle changes.
  - Uterine-sparing procedural modalities.
- Do reproductive outcomes (ovarian function, fecundity, pregnancy complications) differ among the alternatives to hysterectomy for symptomatic fibroids?
- Does the use of a patient classification system (based on imaging, symptoms, anatomy, other metrics) guide treatment choice?

Scope of Targeted Funding Program for Uterine Fibroids

- Direct comparison of alternative uterine-sparing treatments.
  - Surgical myomectomy.
  - Ablation techniques.
  - Uterine artery embolization.
- Outcomes include both symptoms and fertility.
- Potential for long-term follow-up in with future funding.

Clinical Issues in Low Back Pain

- Usually an episodic problem with irregular frequency of recurrence.
- Clinical goals:
  - Relief of symptoms in acute episodes.
  - Delay time to next recurrence.
  - Prevention of transition to chronic back pain.
- Multiple categories of treatment:
  - Physical therapy.
  - Manipulation.
  - Medications.
  - Devices.

Research Questions: Low Back Pain

- Comparative effectiveness of non-surgical treatments.
- Duration/intensity of treatments.
- Need for better systems to classify patients and plan treatments.

Scope of Targeted Funding Program for Low Back Pain

- Focus on selected categories of treatments (rather than all treatments used in this disorder).

- Examine multiple categories of outcomes.
  - Duration of acute symptoms.
  - Time interval until recurrence.
  - Patient functioning.
  - Transition to chronic back pain.

Addressing Health Disparities: Targeted Funding Announcement Topics

Romana Hasnain-Wynia, PHD
Director, Addressing Health Disparities Program
May 2013

Patient-Centered Outcomes Research Institute

Addressing Health Disparities: Program Goals

- **Identify** high priority **research questions** relevant to addressing long standing gaps in disparate populations
- **Fund research** with the highest potential to address health care disparities
- **Disseminate** and facilitate the adoption of research and **best practices** to reduce health care disparities

Addressing Health Disparities

Targeted Funding Announcements

- **Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos**

  (Ad Hoc Work Group Met March 1, 2013)

- **Obesity Treatment Options in Diverse Populations**

  (Ad Hoc Work Group Met April 16. Continued to receive input regarding topics/questions through April 30)

Targeted PFA Workgroup Goals

- Obtain input from researchers, patients, and other stakeholders
- Identify high-impact research questions that will result in findings that are likely to endure and are not currently studied
- Understand the potential for research to lead to rapid improvement in practice, decision-making, and outcomes
- Confirm the importance and timeliness of particular research topics
- Seek consensus on identified knowledge gaps and specific questions within those topics

Synthesize this information to propose a targeted funding announcement

Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos

Ad Hoc Workgroup Meeting

March 1, 2013

Patient-Centered Outcomes Research Institute

Chair and Moderator: Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos

- **James Kiley, MS, PhD,** Chief of the Airway Biology and Disease Program in the Division of Lung Diseases at The National Heart, Lung, and Blood Institute, National Institutes of Health (NHLBI)

Criteria for Knowledge and Research Gaps

- Knowledge gaps should:
  - **Be patient-centered:** Is the proposed knowledge gap of specific interest to patients, their caregivers, and clinicians?
  - **Assess current options:** What current guidance is available on the topic and is there ongoing research? How does this help determine whether further research is valuable?
  - **Have potential to improve care and patient-centered outcomes:** Would new knowledge generated by research be likely to have an impact in practice?
  - **Provide knowledge that is durable:** Would new knowledge on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?
  - **Compare among options:** Which of two or more options lead to better outcomes for particular groups of patients?

Key Themes

- Communication
- Integration of Care
- Systems
- Response to Therapy
- Behavior
- Environment

Research Gaps

- **Communication**
  - Compare/evaluate tools that could impact provider and patient communication (e.g., tools that address language barriers, continuity of care, cultural differences, and social barriers).
  - Compare innovative education methods (e.g., current technologies such as video storytelling or social media) to tailor the education to varying patient characteristics (e.g., health beliefs, literacy level, levels of self-efficacy).

Research Gaps

Integration of Care

- Compare models that integrate care (e.g., team based care with various team members such as nurse case managers, community health workers, pharmacists, physicians, and linking clinical care with home visits) and determine effect on health outcomes and patient and provider experience.
- Evaluate models to improve transitions in care (e.g., transitions from ED to outpatient or from pediatrics to adult care).

Research Gaps

- **Systems**
  - Evaluate models that use data integration (e.g., programs, interventions) to identify and target high risk communities and conduct comprehensive interventions in those communities that link systems for healthcare, home, school, and workplace to support care.
- **Behavior**
  - Compare interventions to facilitate patient and provider engagement.
  - Compare the ability of innovative education methods (e.g., current technologies such as video storytelling or social media) to improve patient outcomes in patients with varying characteristics (e.g., health beliefs, literacy level, levels of self-efficacy).

Research Gaps

- **Response to Therapy**
  - Evaluate the effect of adapting evidence based guidelines to sub-populations on health outcomes.
  - Compare modifiable mechanisms that underlie differential responses to therapy (e.g., mechanisms specific to African-American and Hispanic/Latino populations that respond differently to pharmacologic therapy).
  - Compare modifiable factors including environmental and genetic markers that could contribute to the high risk for greater morbidity and mortality in these two populations and compare factors that could be used to identify patients who would benefit from aggressive intervention.

Research Gaps

- **Environment**
  - Compare mechanisms for mitigating the effects of stress, violence, psychosocial dysfunction play in asthma, particularly in those who cannot get out of the environment?
  - Which environmental interventions (e.g., home visits, school/ work interventions) are effective and sustainable?
  - Among patients failing maximal medical therapy does the addition of a novel environment interventions affect patient outcomes?

Board Vote: Asthma TPFA

Call for Motion to:	• **Approve the development of a TPFA on "Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos"** as endorsed by the PDC
Once the Motion Is Seconded:	• Move to **discuss, amend, or take another action** on the Asthma TPFA
Vote:	• Majority vote to **approve, disapprove, or take another action** on the motion

Obesity Treatment Options in Diverse Populations

Ad Hoc Workgroup Meeting

April 16, 2013

Patient-Centered Outcomes Research Institute

Chair and Moderator: Obesity Treatment Options in Diverse Populations

William H. Dietz, MD, PhD

Former Director, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention

Key Themes

- **Communication (approaches, messages)**
- **Healthcare Systems and Integration of Care (delivery models, alternative sites, training)**
- **Effectiveness of Treatment Options**
- **Behavior (adherence, weight maintenance, incentives)**

Research Gaps

Communication (approaches)

- Compare innovative approaches to effectively implement weight loss interventions in physician offices that improve prevention/treatment outcomes in children, people from rural communities, racial and ethnic minorities
  - For example:
    - Communication tools (e.g., smartphone apps)
    - Decision support tools
    - Links between PCP and community resources
    - Addition of one or more approach to create an additive intervention

Research Gaps

Communication (messages)

- Compare innovative communication messages to engage obese individuals from disparate populations (poor, rural, minority) to make weight-loss attempts
  - For example:
    - Culturally-specific terms/language/health-literacy education used by providers
    - Incentives for healthy weight

Research Gaps

Healthcare Systems and Integration of Care (delivery models)

- Compare effective delivery system models for obesity treatment
  - For example:
    - Strategies to maximize the effectiveness of primary care/physician's office for the primary treatment of obesity
    - Scalable systems linked to EHR that deliver lifestyle intervention counseling
    - Individual vs. group model interventions

Research Gaps

Healthcare Systems and Integration of Care (partnering with alternative sites)

- Compare alternative sites for care delivery that work in conjunction with the health care system to improve obesity outcomes in disparate populations (children/adolescents, minorities, rural) who may experience social or environmental barriers to healthy living (e.g., physical activity, safe neighborhoods).
  - For example:
    - Worksites, churches, school-based health care, community-based organizations

Research Gaps

Healthcare Systems and Integration of Care (training)

- Compare methods to develop, scale, and deploy a more diverse and culturally competent clinical work force capable of treating the complexity of obesity in disparate populations.
  - For example:
    - Working with Physicians, dieticians, exercise professionals, PCPs, nurses, NPs, promotores de salud, community health workers, health educators, pharmacists, psychologist.
    - Addressing weight bias/attitude of providers
    - Adapting standard approaches to address cultural/language issues
    - Improving the health of providers to improve the effectiveness of their counseling

Research Gaps

Effectiveness of Treatment Options

- Compare effectiveness of obesity treatment options
  - For example:
    - Compare the effectiveness and safety of surgical and non-surgical (behavioral, pharmaceutical, holistic, surgical, staged) obesity treatments to engage patients in joint decision making and obtain better functional outcomes in targeted populations, stratified by patient characteristic.
    - Does aligning obesity severity with intensity of treatment improve outcomes?
    - Are there more effective tools than BMI to determine obesity severity
    - Compare tools to evaluate readiness for weight loss

Research Gaps

Behavior (adherence, weight maintenance, incentives)

- Compare strategies to prevent or treat obesity
  - For example:
    - Compare methods to reduce the high rates of non-adherence to traditional behavioral/non-behavioral or other types of weight management programs
    - Compare innovative approaches for maintaining weight loss achievements after a lifestyle intervention
    - Compare weight gain prevention interventions during critical times
    - Compare incentives (financial or non-financial) to health care providers to improve the quality/quantity of care provided.
      - Compare incentives or disincentives (financial or non-financial) to patients to improve obesity outcomes

Advisory Panels

Rachael Fleurence, PhD
Acting Director, Accelerating PCORI Methods
PCORI Board of Governors Meeting
May 2013

Patient-Centered Outcomes Research Institute

Questions for the Board to Consider

1. Feedback on the run of the first Advisory Panel meetings

2. Feedback on the outcomes of the first Advisory Panel meetings

3. Recommendations for future Advisory Panel activities

Advisory Panel Recap

Legislative Authorization

- Expert advisory panels should include clinicians, patients, and experts with the appropriate experience and knowledge to assist PCORI in achieving its goals.

Purpose

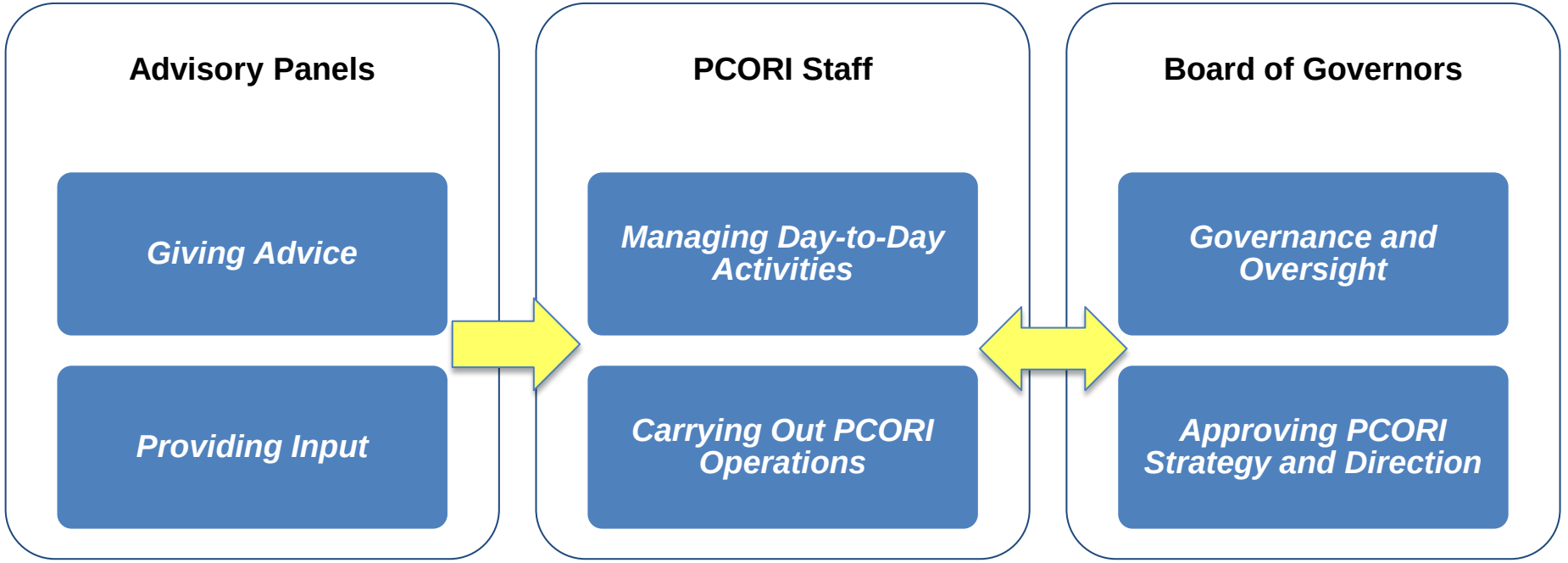
- Advisory panels will work with PCORI's staff and Board to identify research priorities and topics.
- Leveraging members' expertise will help better inform PCORI's mission and work.

Framework and Composition

- Each 10–21 person panel has a unique charter, term duration, and clearly defined scope of work.
- PCORI staff selected each panel's members. Each panel has a chair.
- Members were selected based on their expertise and ability to contribute to the work of specific panels.

PCORI Roles

Where Do Advisory Panels Fit?



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Advisory Panel Meetings: Recap

Scientific Advisory Panel Role

- To identify and prioritize **research questions** for potential targeted funding announcements
- Provide feedback and advice on **evaluating and disseminating the research** under their respective programs

Scientific Advisory Panel Tasks

- Identify and prioritize **research topics** within their area
- Provide feedback on **specific research questions** and study designs
- Review and comment on PCORI's **research portfolio**, including the identification of gaps
- Consider study findings and advise on **dissemination and implementation** efforts

Patient Engagement Advisory Panel Primary Role

- To assure the highest **patient engagement standards** and a culture of patient-centeredness in all aspects of the work of PCORI

Patient Engagement Advisory Panel Tasks

- Advise on how to identify **research topics** and priorities that are **important to patients**
- Advise on **stakeholder review** of research applications
- Advise on the conduct of **patient-centered research**
- Advise on how to evaluate **the impact of patient engagement** in research
- Advise PCORI on **communications, outreach, and dissemination** of research

Orientation to the Research Prioritization Process

- Panelists completed an orientation to support the ranking of research topics:
  - PCORI 101 training
  - Research prioritization training
  - Ranking 10–20 topics using PCORI's five criteria

Orientation to the Research Prioritization Process

Outcomes of Advisory Panels: Patient Engagement

Patient Engagement outcomes:

- Patient Engagement Panel work plan framework
- Suggested improvements to the PCORI Ambassadors Program and the Engagement Awards
- Recommendations and enhancements for best practices in meaningful patient engagement in research

Highest priority topics: Assessment of Options

Topics recommended:

- **Ductal Carcinoma in situ:** Compare the effectiveness of management strategies for ductal carcinoma in situ (DCIS) among women diagnosed after undergoing screening mammography.

- **Osteoarthritis:** Compare the effectiveness of alternative strategies for stabilizing symptoms in people with osteoarthritis.

- **Migraine Headache**: Compare the effectiveness of treatment strategies for adults with episodic and chronic migraine headaches.

- **Bipolar disorder**: Compare the effectiveness of medication regimens for adolescents and young adults with bipolar disorder.

Highest priority topics: Addressing Disparities (1)

Topics recommended:

- **Health communication associated with competing treatments**: Compare the effectiveness of clinician/patient health communication models on improving outcomes in minority populations, patients with low literacy and numeracy, people with limited English proficiency, underserved populations, and people with disabilities.

- **Heart attacks among racial & ethnic minorities:** Compare the effectiveness of health interventions (including place-based interventions in community health centers) to enhance the “Million Hearts” program and reduce major vascular events among the economically disadvantaged, including racial and ethnic minorities and rural populations.

Highest priority topics: Addressing Disparities (2)

Topics recommended:

- **Hypertension in minorities**: Compare the effectiveness of different delivery models (e.g., home blood pressure monitors, utilization of pharmacists or other allied health providers) for controlling hypertension in racial minorities.

- **Interventions for improving perinatal outcomes**: Compare the effectiveness of multi-level interventions (e.g., community-based, health education, usual care) on reducing disparities in perinatal outcomes.

- **Reduce lower-extremity amputations in minorities**: Compare the effectiveness of interventions on reducing disparities in lower extremity amputations in racial and ethnic minorities.

Highest priority topics: Improving Health Systems (1)

Topics recommended:

- **Models of Patient-Empowering Care Management**: Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on patient-centered outcomes among patients with chronic or progressive conditions, disability, cancer or other potentially life-changing illnesses.

- **Models of Transitional Care**: Compared to usual care, what are the effects of different models of transitional care on patient safety and other patient-centered outcomes?

- **Models of Integration of Mental Health Care and Primary Care**: Compared to primary care alone, what is the effect of primary care co-located with mental health services on mental health symptoms, medication use, and other PCOs?

Highest priority topics: Improving Health Systems (2)

Topics recommended:

- **Models of Perinatal Care**: Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on PCOs among pregnant and post-partum women?

- **Different Features of Health Insurance Coverage**: What are the relative effects of different insurance features (i.e. benefit designs, utilization management, cost sharing) on chronically ill patients' access to care, quality of care, and PCOs?

Timeline for Publishing Targeted PFAs

Month	April 2013	May 2013	June 2013	July 2013	August 2013	Sept 2013	Oct 2013	Nov 2013	Dec 2013
Advisory Panels Prioritize Research Topics	★								
Board Informed of Topics Recommended by Advisory Panels		5/6							
Landscape Reviews Completed for 1–5 Topics per Program Area									
PCORI Staff Evaluates Results of Landscape Reviews									
PCORI Staff Develops Concept Briefs with PDC Input for Board Approval									
PCORI Staff Writes Targeted Funding Announcements									
Targeted PFA Published and Application Period									★

BoG Mtgs

PDC Mtgs

Funding awarded 5–6 months after PFA published

Advisory Panel Charters

Advisory Panels: Chairperson vs. Chairpersons

- **At Training and Kick-Off, our panelists suggested having a co-chairperson to more effectively facilitate panel activities with PCORI staff.**
- **Currently, the Advisory Panel Charters address only selection of a chairperson.**
- **A vote to allow for selection of a co-chairperson would trigger identical amendments to the following charters:**
  - Charter of the Advisory Panel on Addressing Disparities
  - Charter of the Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options
  - Charter of the Advisory Panel on Improving Healthcare Systems
  - Charter of the Advisory Panel on Patient Engagement

Advisory Panel Charters: Proposed Changes

If approved, Advisory Panel Charters would be amended as follows:

Advisory Panel Chairs	
Current Language	***Amended Language***
A chairperson will be selected by the Institute's Board of Governors…	A chairperson (and a co-chairperson if desired) will be selected by the Institute's Board of Governors…
Compensation is not to exceed $1,500 annually for each member or $2,000 annually for the chairperson.	Compensation is not to exceed $1,500 annually for each member or $2,000 annually for the chairperson and co-chairperson.

Advisory Panel Charters: Board Approval

Call for Motion to:	• **Approve amended language in Charters** for all four PCORI Advisory Panels
Once the Motion Is Seconded:	• Move to **discuss, amend, or take another action** on the amended Charters
Vote:	• Majority **vote to approve, disapprove, or take another action** on the motion

Appendix

Appendix

- Charter of the Advisory Panel on Addressing Disparities
- Charter of the Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options
- Charter of the Advisory Panel on Improving Healthcare Systems
- Charter of the Advisory Panel on Patient Engagement

Questions for the Board to Consider

1. Feedback on the run of the first Advisory Panel meetings

2. Feedback on the outcomes of the first Advisory Panel meetings

3. Recommendations for future Advisory Panel activities

LUNCH

Join the conversation on Twitter via #PCORI

Funding Portfolio Management

Lori Frank, Director of Engagement Research
David Hickam, Director, Program on the Assessment of Prevention, Diagnosis, and Treatment Options

PCORI Board of Governors Meeting
Chicago, IL
May 2013

Patient-Centered Outcomes Research Institute

Goals of this Presentation

- Review status of PCORI portfolio management plan
- Review insights gained from work with PCORI pilot project program
- Seek input from BOG on key priorities

Why Actively Manage a Funding Portfolio?

1. Optimize the yield of useful knowledge gained from funded projects and rapidly disseminate and apply this knowledge to advance the field
2. Course correction—risk management
3. Learning from portfolio adaptively—apply to decisions on future funding decisions
4. Facilitate cross-project learning and collaboration
5. Build networks of researchers engaged in PCOR

Questions for Board

- Are PCORI's goals for portfolio management appropriate? Should any additional goals be included?
- Which best practices should PCORI adapt for this activity?
- What methods should PCORI use to identify and rapidly respond to promising areas for supplemental funding?
- What methods should be used to measure the success of the portfolio?

Ties to the PCORI Strategic Plan

PCORI Goals:

- Increase quantity, quality, and timeliness of useful, trustworthy information
- Speed implementation and use of PCOR evidence
- Influence clinical and healthcare research funded by others to be more patient-centered

Implement portfolio planning, management, and evaluation to maximize the efficiency and impact of our research

Elements of Active Portfolio Management

- Pre-award:
  - Identify key gaps within each priority area
  - Identify potential for cross-collaborative opportunities
  - Identify co-funding opportunities
  - Publish PFAs that build on portfolio planning efforts
- Awardee selection
- Post-award:
  - Conduct risk evaluation and address through monitoring plan
  - Identify early findings that can inform portfolio planning
  - Identify opportunities for collaboration among funded investigators
  - Use supplemental funding for exceptional opportunities.

Assessing Risk of Individual Research Projects

- Qualifications of team of investigators
- Study setting and data requirements
  - Access to research participants
  - Construction of data files
- Institutional/procedural barriers
- Limitations of methodologies/methods for data analyses
- Barriers to dissemination
- Patient/stakeholder engagement challenges

Optimizing the Portfolio: Synthesize and Communicate

- Identify key messages and lessons learned
- Provide timely sharing of key products:
  - Meetings
  - White papers
  - Presentations
  - Peer-reviewed papers
- Identify any themes that emerge across multiple projects
- Enhance additional dissemination and implementation plans

Post-award Portfolio Management Example from Pilot Projects

- Identify cross-collaborative opportunities
- Establish communication between research teams
- Determine outputs for cross-collaborations
- Identify and provide needed support

Outputs of Collaboration

- Collaborative writing (e.g., peer-review, blog)
- Joint presentations at professional meetings
- Public webinars
- Workshops
- Establish technical assistance groups for problem-solving/solution-sharing
- Address common challenges to research engagement

Questions for Board

- Are PCORI's goals for portfolio management appropriate? Should any additional goals be included?
- Which best practices should PCORI adapt for this activity?
- What methods should PCORI use to identify and rapidly respond to promising areas for supplemental funding?
- What methods should be used to measure the success of the portfolio?

Current Activities of PCORI Methodology Committee

Sherine E. Gabriel, MD MS, Robin Newhouse PhD RN, David Hickam MD MPH
Methodology Committee
May 6, 2013

Patient-Centered Outcomes Research Institute

Overview

- Methodology Standards
- Recommended Actions
- Finalizing the Methodology Report
- Other Initiatives

Methodology Standards

- **Goal**: focus on standards where standards do not exist and/or standards would improve PCOR
- MC reviewed report, public comments, other input ….for new standard development
- Possible Candidates: Cluster Randomized Trials, Research Prioritization, Evaluation of System Interventions,….others

Methodology Standards

- MC will propose to Board (September) next set of standards, after PDC input
- Concurrently we will develop a process for soliciting and synthesing broad stakeholder input for subsequent set of standards: ~AHRQ, RFI

Recommended Actions

- Asked by the Board December 2012 to prioritize
- Categorized into 4 topic areas and assigned workgroups to assess progress and prioritize
  - Methodological Research Gaps & Evaluation
  - Training in PCOR Methods
  - Infrastructure/Support for Applicants
  - Policies, Procedures & Dissemination

Recommended Actions

- Described according to the following:
  - Recommended Action
  - Timeline
  - Responsibility
- More than 1/3 already underway
- Prioritized Remainder – see handout

Finalizing the Methodology Report

- Goals:
  - Demystify the Standards using explanatory stories:
    1. Patient Stories illustrating the centrality of the patient's voice in PCOR Methods
    2. Research Stories/Research in Practice: real-world examples of how methodological principles applied
  - Disseminate via paper, web, e-book to enhance interactivity
  - Derivative Projects: PPT, CME/CE, education modules etc.

Other Initiatives

- Methodology Guidance Panel
- Workshops on methodological issues.
  - IOM workshop of observational studies, April 2013.
  - Academy Health workshop on implementation of methodology standards, June 2013.
  - PCORI workshop on patient-reported outcomes, September 2013.
  - Others in discussion

Other Initiatives

- Dissemination/implementation of methodology standards.
  - Development of tools for assessing and applying the standards, by end of 2013.
  - Comprehensive implementation/dissemination plan.
  - Targeted dissemination activities/conferences.
- MC review of research projects considered for funding by PCORI for alignment with MC goals

PUBLIC COMMENT

Join the conversation on Twitter via #PCORI

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Cycle II Applications

Funding Recommendations

Grayson Norquist, Chair of selection committee
Joe Selby, Executive Director

May 6, 2013

Contracts

Patient-Centered Outcomes Research Institute

Institute Policies

Regina Yan, MA, Chief Operating Officer

Kerry Barnett, JD, Chair, Finance, Audit, and Administration Committee

Board of Governors Meeting

Chicago, IL

May, 2013

Patient-Centered Outcomes Research Institute

Session Topics and Agenda

Project Update	• Update on the work being done to develop a robust set of policies and procedures at PCORI
Decision-Making Matrix	• Review and vote to approve PCORI's decision-making structure
Institute Policies and Procedures	• Board vote on completed policies and procedures requiring their approval
Timeline and Next Steps	• Review timeline for regular reviews of PCORI's policies and procedures, bylaws, and committee charters

Project Update

Project Update

- **PCORI's policies and procedures are being developed from three sources:**
  - Mandates from PCORI's authorizing legislation
  - PCORI's Bylaws and explicit directives from the Board of Governors
  - Rules instituted by PCORI's executive officers per the delegated authority

- **PCORI's policies and procedures will:**
  - Provide the framework for a performance audit
  - Set definite boundaries, provide clear instructions, and give useful guidelines
  - Help reduce the range of individual decisions and discourage management by exception
  - Minimize inconsistencies in decision making across the programmatic and administrative areas

Policy Categories

Board of Governors

- **Institute Policies:** Policies that directly affect the mission, reputation, viability, and financial health of the organization. At PCORI, these policies would encompass the following:
  - Governance
  - Risk Management
  - Finance and Contracts

Executive Director

- **Administrative/Operational Policies:** Policies governing internal rules, regulations, and operations. At PCORI, these policies would encompass the following areas:
  - Human Resources
  - Programmatic Operations (Procedures)

Decision-Making Matrix

Decision-Making Matrix: Proposed Changes

	Board	Staff	In Consultation With…
CORPORATE GOVERNANCE			
Conflict of Interest Policy	**BOG**		**SCCOI/FAAC**
Board Bylaws and **Institute Policies**	**BOG**		**FAAC**
Administrative/Operational Policies		**ED/COO**	**DIRECTORS**

Decision-Making Matrix: Proposed Changes

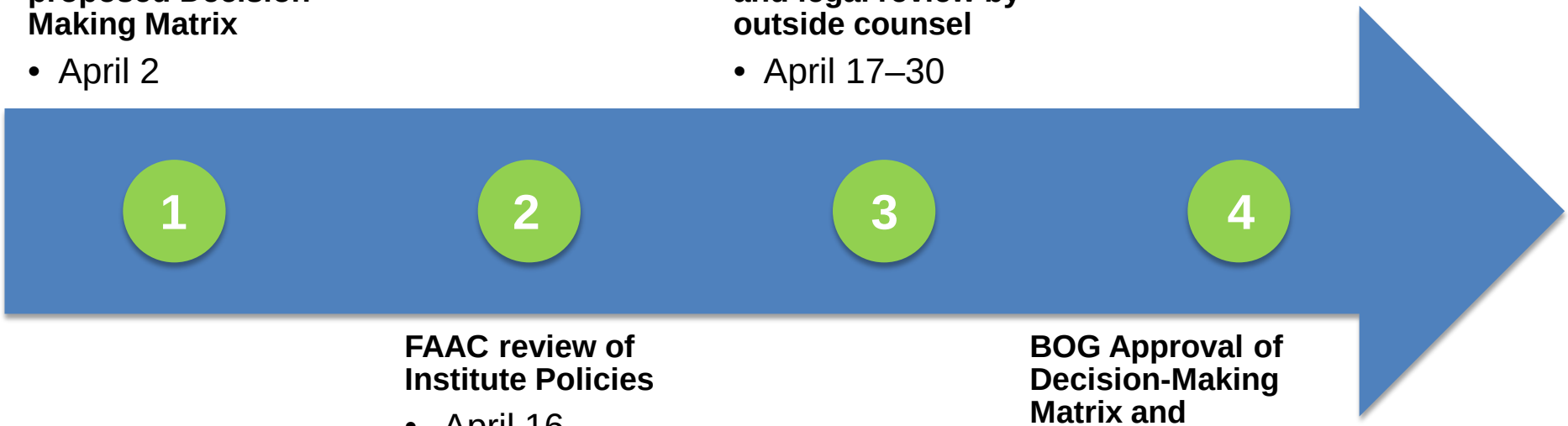
	Board	Staff	In Consultation With…
FINANCIAL & REGULATORY MANAGEMENT			
Procurement of Goods & Services, Equipment, Leases and Property ($101,000 to $499,000)		**ED, DED, or COO**	
Procurement of Goods & Services, Equipment, Leases and Property ($2,501 to $100,000)		**ED, DED, COO, or DOF**	
Procurement of Goods & Services, Equipment, Leases and Property (< $2,500)		**ED, DED, COO, DOF, or DIRECTORS**	

Decision-Making Matrix: Board Approval

Call for Motion to:	• **Approve PCORI's decision-making structure** and authorize identical changes to PCORI's Delegation of Authority Policy
Once the Motion Is Seconded:	• Move to **discuss, amend, or take another action** on the changes to PCORI's decision-making structure
Vote:	• Majority vote to **approve, disapprove, or take another action** on the motion

Institute Policies

Institute Policies



FAAC review of proposed Decision-Making Matrix

- April 2

FAAC review of Institute Policies

- April 16

Staff edits reflecting FAAC changes to Institute Policies and legal review by outside counsel

- April 17–30

BOG Approval of Decision-Making Matrix and proposed Institute Policies

- May 6

Institute Policies

The following draft Institute Policies appear on PCORI's public website and require Board approval:

- Acceptance of Gifts and Payments
- Employee Participation in Political Activities
- Role and Duties of the Board
- Appointment of the Board
- Term Limits and Vacancies
- Board Meetings and Hearings
- Committees of the Board
- Board Compensation and Reimbursement
- Bylaws
- Insurance and Indemnification
- Pre-award
- Post-award

Institute Policies: Board Approval

Call for Motion to:	• **Approve Institute Policies** as reviewed by legal counsel and approved by the FAAC
Once the Motion Is Seconded:	• Move to **discuss, amend, or take another action** on the Institute Policies being presented
Vote:	• Majority **vote to approve, disapprove, or take another action** on the motion

Timeline and Next Steps

Next Steps for 2013

Action Step	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
BOG approval of new Decision-Making Matrix and completed Institute Policies for Q3	✓							
First meeting of PCORI's staff-led **Policy Review Team (PRT)** to discuss revisions for Q4		✓						
Ongoing review by PRT and legal counsel to update all Institute and Administrative/ Operational Policies		✓	✓	✓				
Staff works with BOG and Committees to update Institute Bylaws and Charters		✓	✓	✓				
FAAC reviews of all revised Institute Policies				✓				
BOG votes to approve revised Institute Policies, Bylaws, and Committee Charters					✓			
PRT meets to begin ongoing review process of all Institute and Administrative/Operational Policies for presentation in Q1 in 2014						✓	✓	✓

Appendix

Appendix

1. Decision-Making Matrix
2. Institute Policies: Recommended for Approval by FAAC

WRAP-UP & ADJOURN

Join the conversation on Twitter via #PCORI