Patient-Centered Outcomes Research Institute

Board of Governors Meeting
Denver, CO
May 21-22, 2012

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Patient-Centered Outcomes Research Institute

Executive Director's Report

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

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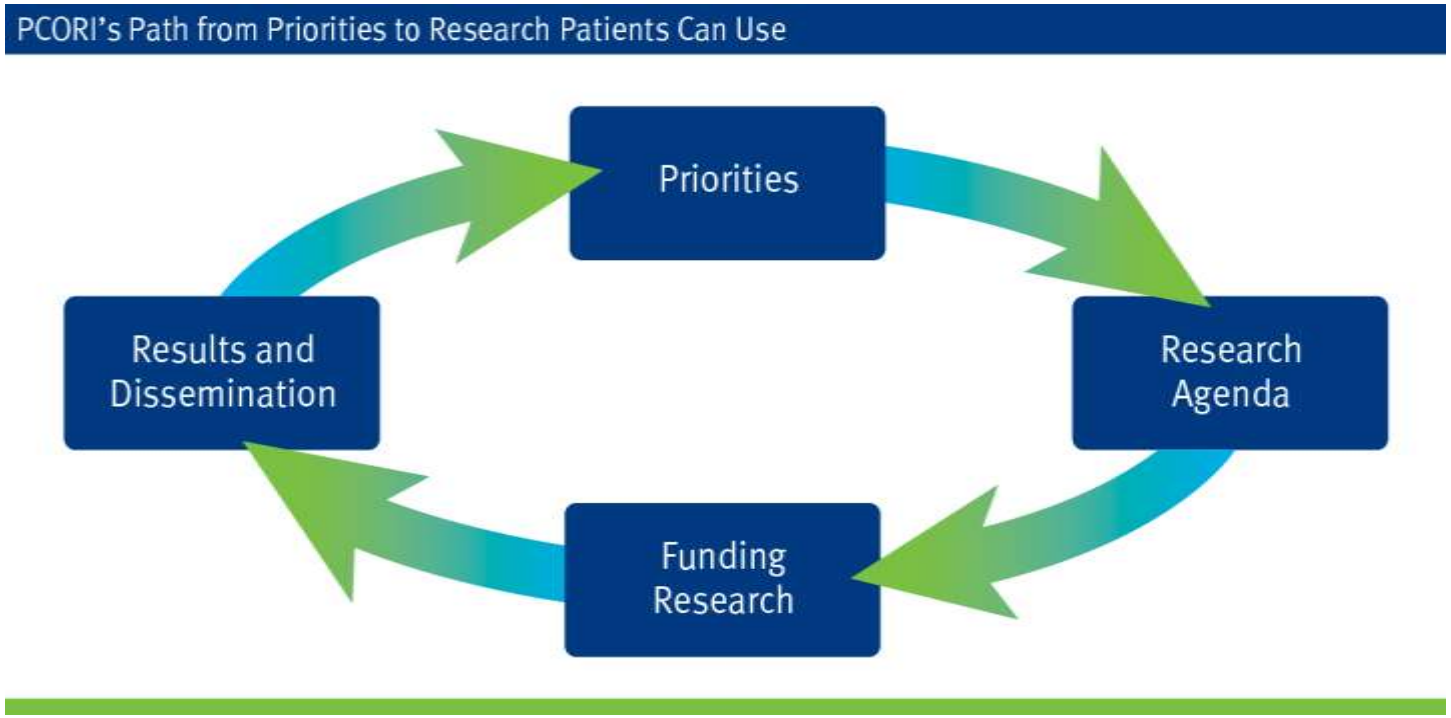
From Questions to Research Patients Can Use

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

In Collaboration with Patients and Other Stakeholders:



Virtuous cycle fueled by ongoing patient and stakeholder engagement, identifying and prioritizing key research questions, refining the PCORI agenda, funding research, and reviewing the research results

3

Achievements and Next Steps

- We've moved!
- PCORI Pilot Projects awarded
- Methodology Report delivered to Board
- PCORI Strategic Plan developed
- National Priorities and Research Agenda finalized
- PCORI Funding Announcements presented
- Initial Plan for Patient and Stakeholder Engagement, Topic Generation and Prioritization will be presented
- News on results of first PCORI Audit
- Proposal on Conflict of Interest policy from PCORI's New Standing Committee on COI

PCORI's Long-Term Home

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

1828 L Street, DC

- Attractive, not extravagant
- 13,000 sq ft
- Close to Metro
- Green building

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Welcoming a PCORI Scientist:

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Rachael Fleurence PhD

University of York, Health Sciences

Expertise in: Value of Information

Indirect Comparisons

Health Economics

PCORI Pilot Projects Awarded

- 50 PCORI Pilot Projects approved for funding
- Targeted at methods for engaging patients and other stakeholders in the research process
- Total funding:
  - Year One: $15,843,724
  - Year Two: $15,005,483
  - TOTAL: $30,849,207

Funded Pilot Projects – By Area of Interest

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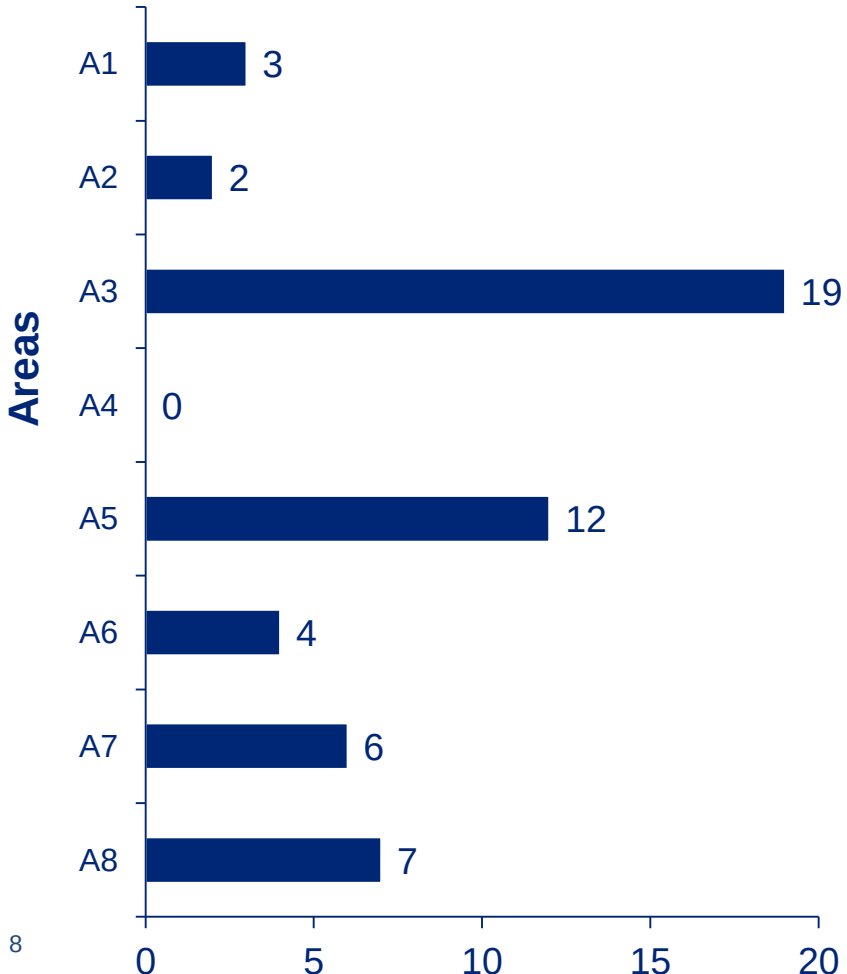

Methods for engaging patients and stakeholders in:

1. **Informing PCORI's national priorities**
2. **The research process, along with other stakeholders**
3. **Developing evidence-based decision support tools that account for patient preferences**
4. **Identifying gaps in CE knowledge**
5. **Developing patient-centered outcomes instruments**
6. **Researching behaviors, lifestyles, and choices**
7. **Studying patient care team interactions in situations where multiple options exist**
8. **Analytical methods for CER**

Priority Populations Studied

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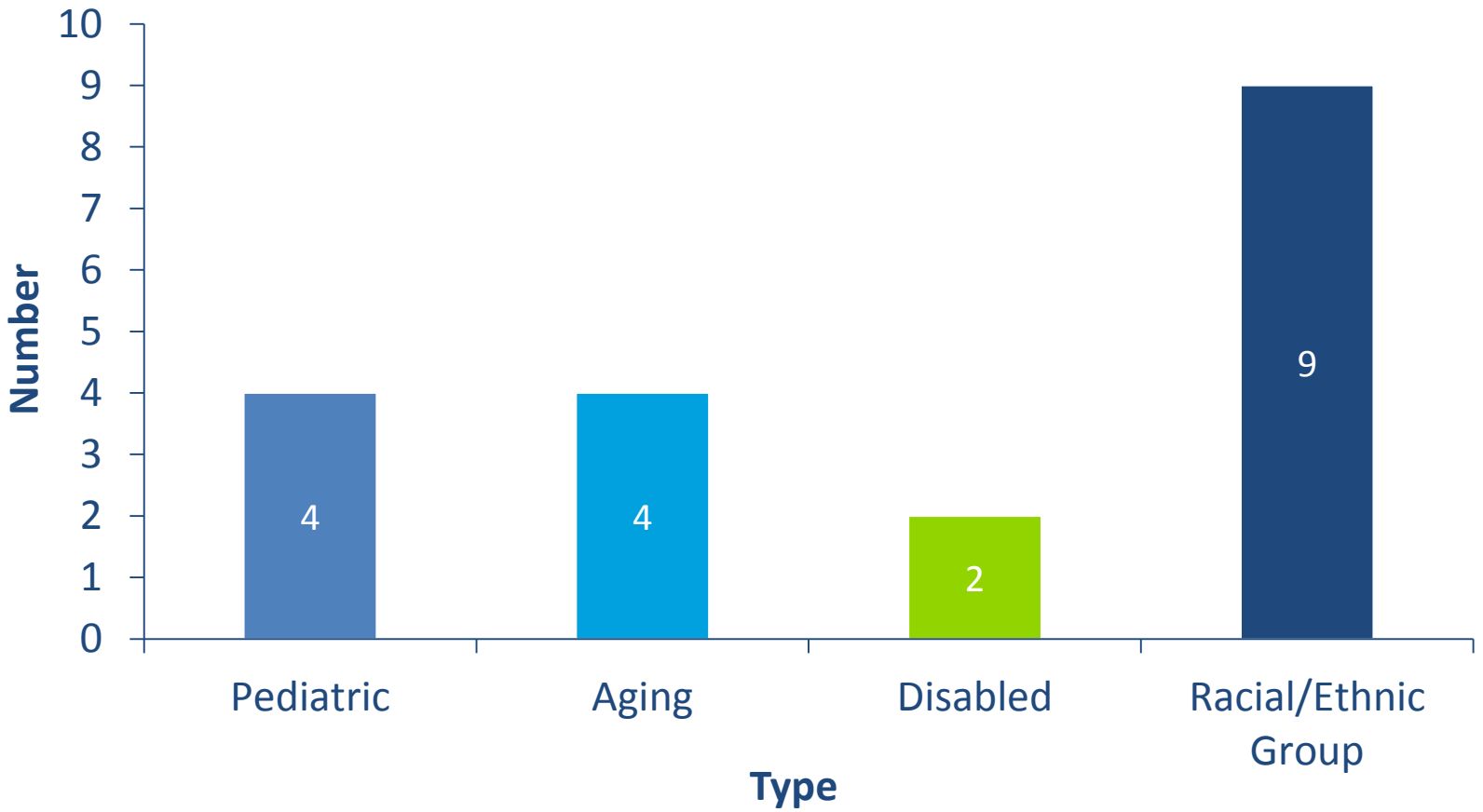

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Pilot Projects: Condition(s) Studied

Type	Number	Percentage
Chronic Condition	7	14%
Mental Health	5	10%
Cardiac Health	4	8%
Cancer Screening	3	6%
Autism	2	4%
Pain	2	4%
Vascular Health	2	4%
Motor Rehabilitation	1	2%
Rare Disease	3	6%
No Specific Condition	22	44%

Funded Pilot Projects By State

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Projects funded in 24 States and DC:

Alaska	1
Arkansas	1
Arizona	1
California	8
Colorado	3
Connecticut	1
District of Columbia	1
Florida	1
Georgia	1
Iowa	1
Illinois	1
Massachusetts	8
Maryland	3

Michigan	2
Minnesota	1
Missouri	1
North Carolina	3
New York	1
Ohio	2
Pennsylvania	4
Rhode Island	1
South Carolina	1
Tennessee	1
Virginia	1
Washington	1

Thank Yous

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Board Leads on PFA Development

- Christine Goertz
- Gail Hunt

Selection Committee Members

- Kerry Barnett
- Carolyn M. Clancy
- Arnold Epstein
- Sherine Gabriel
- Leah Hole-Curry
- Grayson Norquist
- Joe Selby
- Clyde Yancy

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Honoring Sharon Levine

2012 Woman of the Year: Women Health Care Executives (WHCE), a SF Bay Area organization dedicated to providing women leaders in health care a forum for networking, education, and support.

Industry Leader Award: Professional Business Women of California (PBWC), an organization promoting development of women as leading business professionals in California and nationwide.

Transition in Board Meeting Format

From Committee Reports to Agenda based on Imperatives from PCORI's Strategic Plan:

- Funding and Conducting Patient-Centered Research
- Establishing Patient and Stakeholder Engagement
- Developing and Disseminating Rigorous Research Methods
- Building Infrastructure for Conducting PCOR
- Disseminating Research Findings
- Efficient, Transparent Operations

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Methodology Committee (MC) Report

PCORI Board of Governors
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"This is going to be research done differently!"

PCORI Board Member **Harlan Krumholz, MD**
National Patient and Stakeholder Dialogue
National Press Club, Washington, DC
February 27,2012

The Methodology Committee is writing the source code

PCORI Board Member
Lawrence M. Becker

Agenda

AGENDA ITEM FOR TODAY	REQUEST TO BOARD
1. 1st Methodology Report ➢ Background ➢ Overview ➢ Report Next Steps • Public Comment • Communications Plan	Discuss & Ok to Post for Review Discuss & OK Plans for Public Comment and Communication
2. Methodology Committee Next Steps	Discussion

…… a short surprise

Setting the Stage

- Steps taken to deliver 1st Methodology Report to PCORI BoG
- A major milestone! …. a preliminary foundational document
- Requires deeper and broader input and comment
- Over coming months, systematic, iterative & transparent review and editing process
- Formal Board Approval/Adoption 11/2012

TODAY:

  - Keep conversation at a high level
  - Specific comments welcome but will **not** be specifically addressed to maintain integrity of review process

1. 1st Methodology Report

- Background
  - Statutory Language
  - Objectives

Methodology Committee Statute

Public Law 111–148
111th Congress

An Act

Entitled The Patient Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Subtitle D-Patient Centered Outcomes Research

The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

(C) **FUNCTIONS.—**

Subject to subparagraph (D), the methodology committee shall work to ***develop and improve the science and methods*** *of comparative clinical effectiveness research by, not later than 18 months after the establishment of the Institute, directly or through* ***subcontract****, developing and* ***periodically updating*** *the following*:

(i) Methodological standards for research

(ii) A translation table

Methodology Committee Statute

(i) Methodological standards for research (a report).

…. shall provide specific criteria for internal validity, generalizability, feasibility and timeliness of research and for health outcomes measures, risk adjustment and other relevant aspects of research and ***assessment with respect to the design of the research. ….. shall be scientifically based*** *and include methods by which new information, data or advances in technology are considered and* ***incorporated into ongoing research projects by the Institute,*** *as appropriate. …* ***input from relevant experts, stakeholders and decision makers*** *and shall provide opportunities for* ***public comment****… shall include methods by which* ***patient subpopulations*** *can be accounted for and evaluated in different types of research… build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of CER (determined as of the date of enactment of the Patient Protection and Affordable care Act).*

Methodology Committee Statute

(ii) A Translation Table

*…designed to provide **guidance and act as a reference for the Board** to determine research methods that are most likely to address each specific research question.*

(D) CONSULTATION AND CONDUCTION OF EXAMINATIONS

….MC may consult and contract with IOM and academic nonprofit or other private and governmental entities with relevant expertise to carry out activities described in subparagraph (C) and may consult with relevant stakeholders to carry out such activities.

(E) REPORTS

….submit reports** to the Board on committee performance of the functions described in subparagraph (C). Reports shall contain **recommendations for the Institute to adopt methodological standards developed and updated by the MC as well as other actions deemed necessary to comply with such methodological standards.

Methodology Report Objectives

The MC is charged with making recommendations to the Board regarding methods for PCORI, including:

- ✓ **guidance** about the appropriate use of **methods** in such research
- ✓ establishing **priorities** to address **gaps in research methods** or their application
- ✓ recommending **actions** to support standards
- ✓ mapping research methods to specific research questions (**Translation Table**)

1. 1st Methodology Report

- Overview
  - Development Process
  - Content and Outline

Methodology Report - Development Process

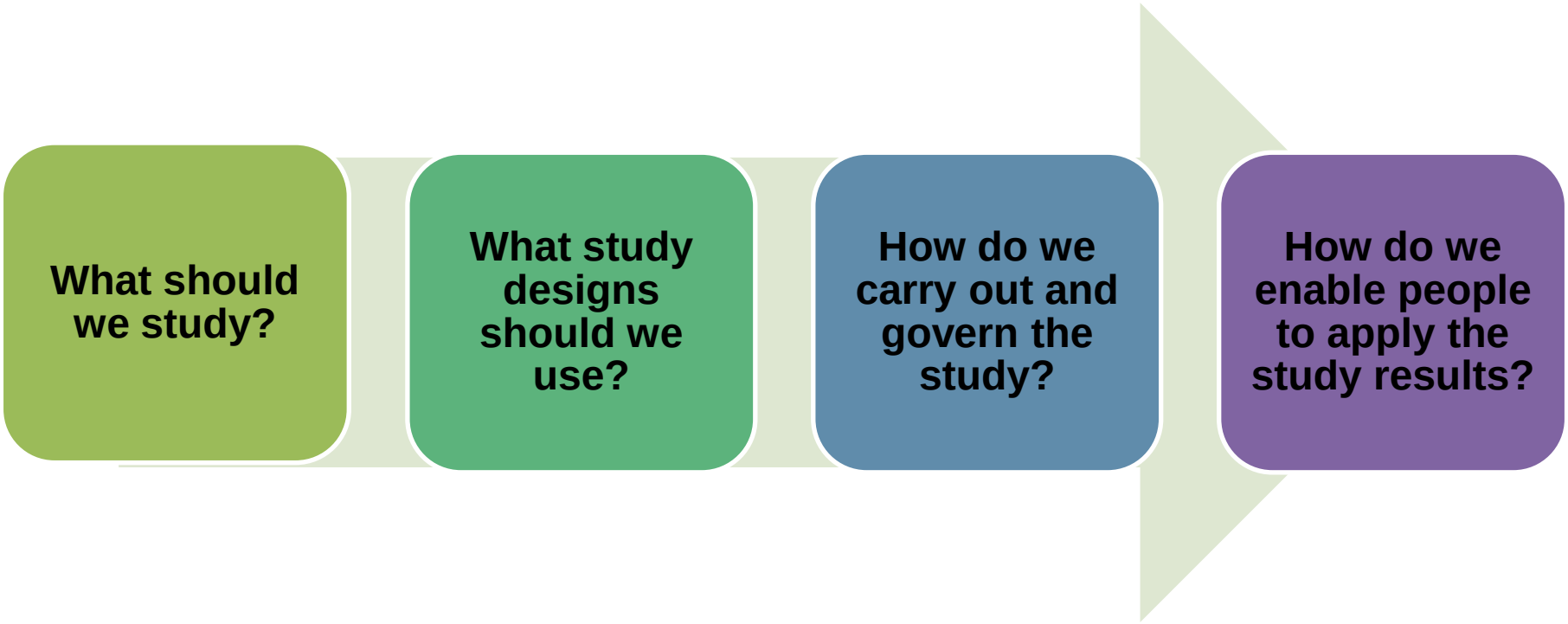
How We Developed the Report

Committee Expertise

1 **Methods Selection**	• Working groups identified and prioritized major research methods questions to be addressed
2 **Information Gathering**	• Researchers contracted to address selected topics • Contractors developed research materials (e.g., reports, summary templates for proposed standard) • MC solicited for external feedback on the translation table (RFI) • Workshops held to discuss contractor findings, with invited experts in attendance
3 **Internal Review**	• MC conducted in-depth internal review of materials developed by contractors, and support staff • MC independently submitted preliminary votes on proposed standards • MC deliberated to reach consensus on recommendations to be endorsed in the report
4 **Report Generation**	• Refined recommendations and report content per committee evaluations and discussions

1 Methodology Report – Methods Selection

The MC sought to address selected topics in 4 broad phases of activities in the first Methodology Report:



1 Methodology Report – Methods Selection

Building on the work of the IOM*, the MC defined a standard as…

- A process, action, or procedure for performing PCOR that is deemed essential to producing scientifically valid, transparent, and reproducible results; a standard may be supported by scientific evidence, reasonable expectation that the standard helps achieve the anticipated level of quality in PCOR, or by broad acceptance of the practice in PCOR
- The recommendation is actionable, feasible, and implementable
- Proposed standards are intended for use by the PCORI Board, in PCORI policies and procedures, and by PCORI researchers

*Reference:
National Research Council. Find What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press; 2011.

2 Methodology Report – Information Gathering

Research Teams	~100 individuals comprised of 17 groups from across the country were contracted to conduct research from Nov. 2011 to May 2012 (totaling ~$1.5M)
Workshop External Invitees	15 experts attended two workshops in March 2012 to provide additional perspectives
Translation Table RFI Respondents	24 submissions were received in response to a Request for Information (RFI) to provide input on the translation table framework

2 Methodology Report – Information Gathering

Electronic Data Systems Interviewees	57 stakeholders were interviewed to understand CER-use in electronic health records and informatics
Independent Consultants	8 individuals were contracted to serve as report editors and interim researchers
Reproducible Research Results	An interim PCORI researcher, in partnership with Steven Goodman (Chair, Research Methods Work Group) and with input from the MC, conducted a literature review on reproducible and transparent research; findings directly informed PCORI's reproducible and data sharing policies

2 Methodology Report – Information Gathering

17 reports* addressing 15 topics, from MC-led contracted research, informed 1st Methodology Report

Topics

1. Design, Conduct, and Evaluation of Adaptive Randomized Clinical Trials
2. Conduct of Registry Studies
3. Design of Patient-Reported Outcomes Measures (PROMS)
4. Use of Collaborative or Distributed Data Networks
5. Prevention and Handling of Missing Data
6. Design, Conduct and Evaluation of Diagnostic Testing
7. Causal Inference Methods in Analyses of Data from Observational and Experimental Studies
8. Addressing Heterogeneity of Treatment Effects: Observational and Experimental PCOR

**Reports are available on PCORI's website*

Contracted Research Reports (Cont'd)

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Topics

9. Involving Patients in Topic Generation
10. Value-of-Information in Research Prioritization
11. Peer Review as a Method for Research Prioritization
12. Examination of Research Gaps in Systematic Reviews for Research Prioritization
13. Integrating Patients' Voices in Study Design Elements with a Focus on Hard-to-Reach Populations
14. Evidence for Eliciting Patient Perspective – Stakeholder Interviews
15. Evidence for Eliciting Patient Perspective – Literature Review

**Reports are available on PCORI's website*

3 Methodology Report – Internal Review

The MC deliberated and agreed upon standards using standardized template, based on the following:

Patient-Centeredness	*Respect for and responsiveness to individual patient preferences, needs, and values*
Scientific Rigor	*Objectivity, minimizing bias, improving reproducibility, complete reporting*
Transparency	*Explicit methods, consistent application, public review*
Empirical/ Theoretical Basis	*Information upon which a proposed standard is based*
Other Considerations	*Practicality, feasibility, barriers to implementation, and cost*

3 Methodology Report – Internal Review

Process:

Recommendations Proposed by Work Groups

- Reviewed and refined contractors' deliverables and findings
- Reached consensus on recommendations to propose for inclusion in the 1st report

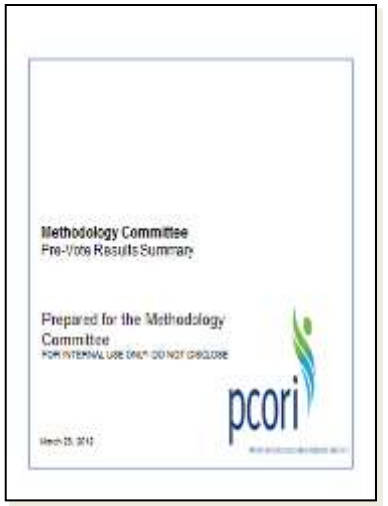
Full Committee Pre-Vote

- Independently reviewed and voted on 82 proposed recommendations
- 51 recommendations received at least two-thirds approval, thus qualifying for inclusion in the report

Committee Consensus Meeting

- Discussed 31 recommendations where discrepancies arose during the pre-vote
- Submitted final votes and considered each standard as a minimum requirement for PCORI

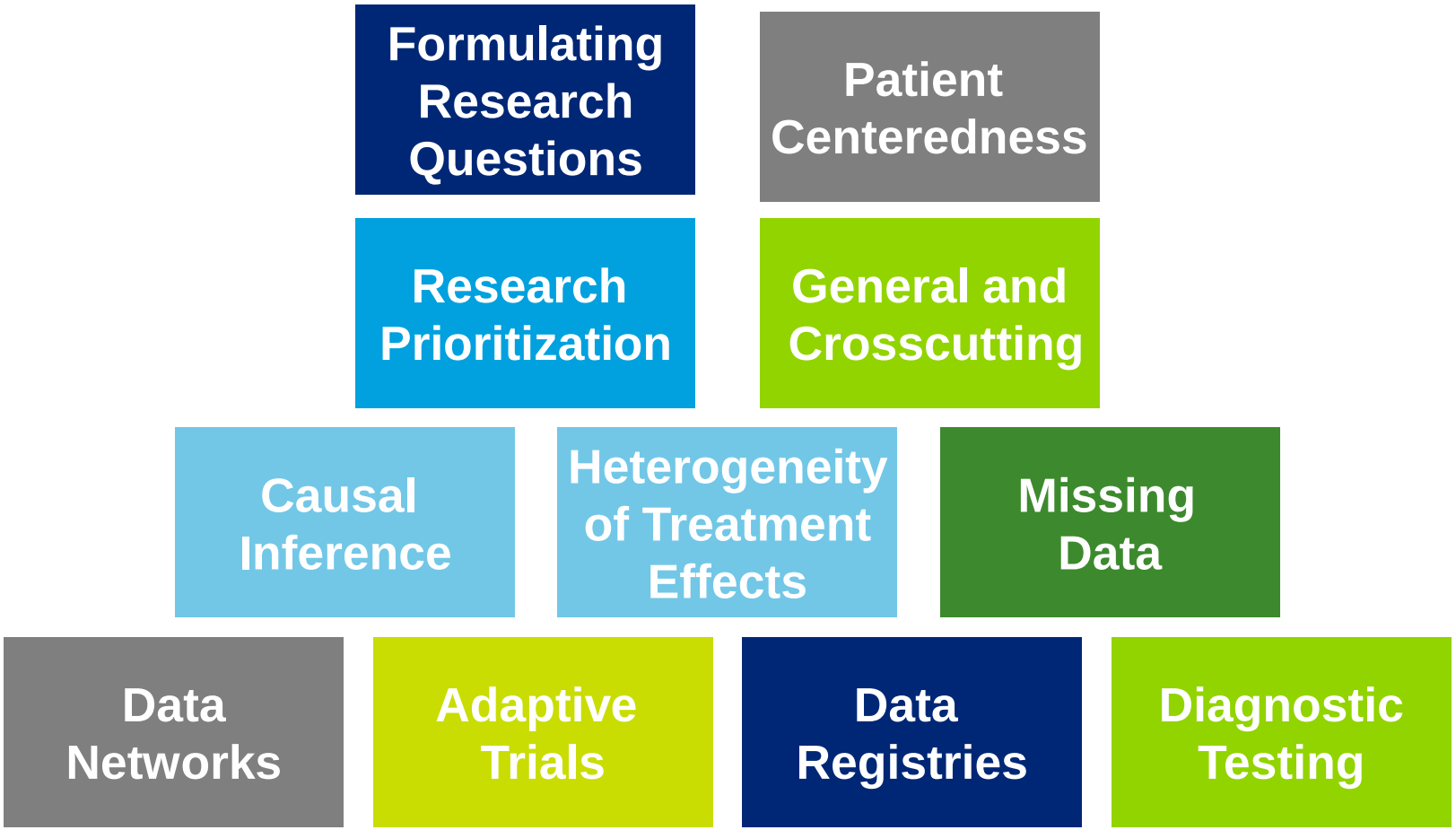
Chairs Review



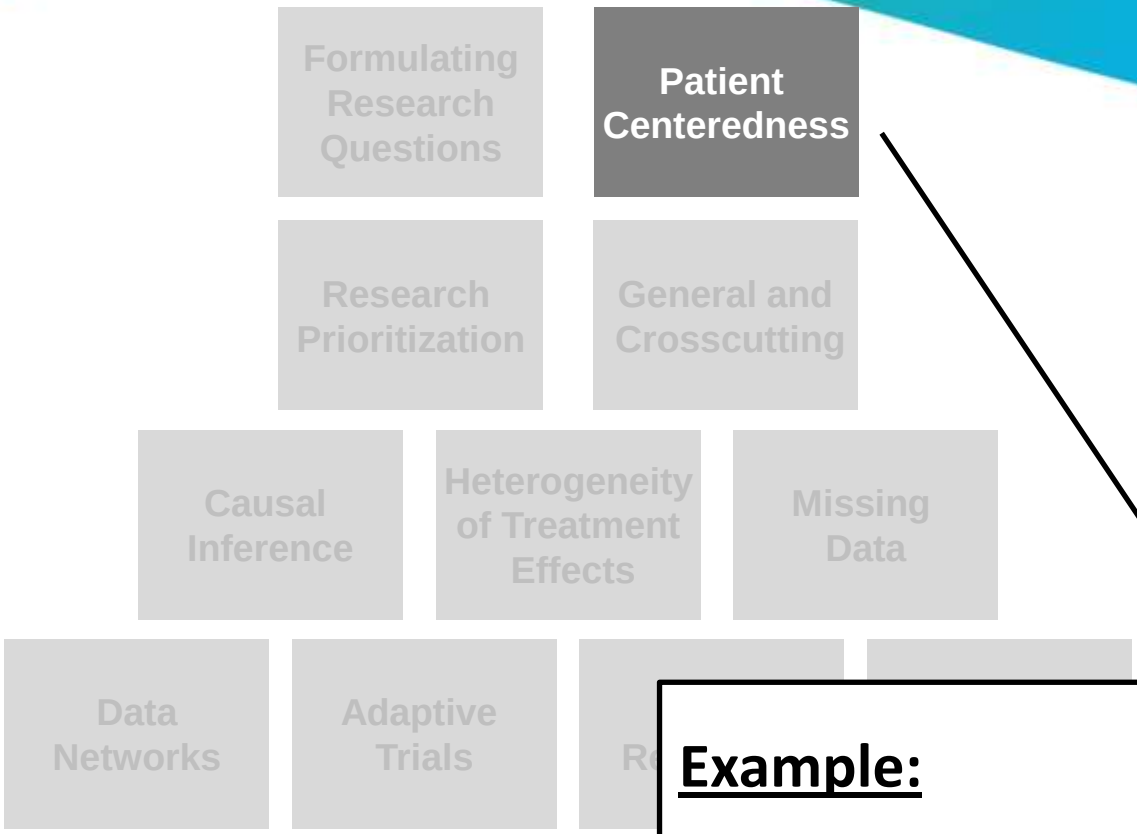
The MC during the Consensus Meeting in Washington, DC on April 3, 2012:

4 Methodology Report – Generation

Through consensus, the MC recommends methodologic standards across ten research domains



4 Methodology Report – Generation



Example:

Engage Patient Informants, Persons Representative of the Population of Interest, in All Phases of PCOR

Standard # 4.1.1 on page 25 of the Report

4 Methodology Report – Generation

Translation Table maps research methods to specific research questions

Research Question

- Prioritized research questions
- Formulated patient-centered research question

Interface

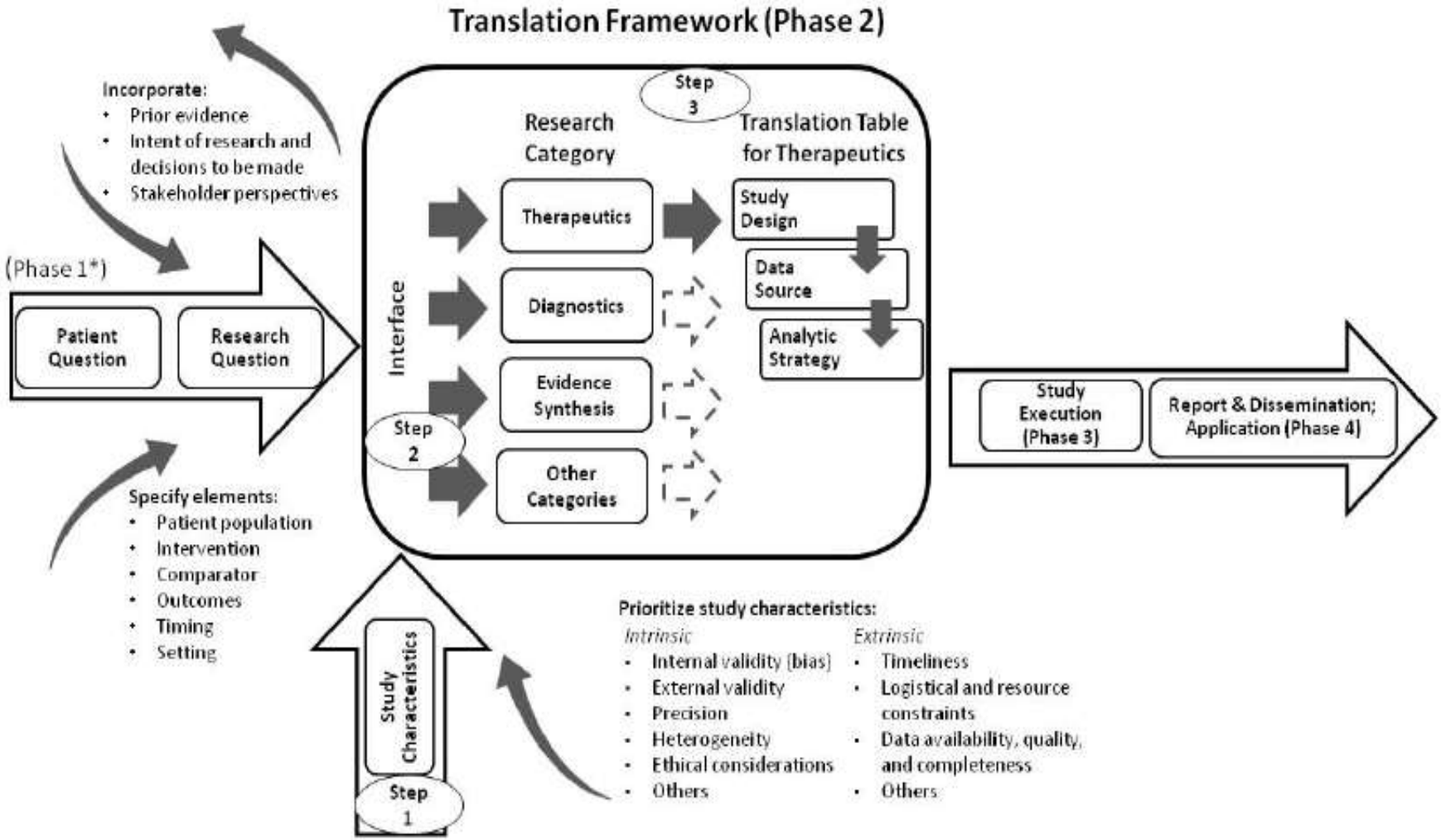
- Defines relative importance of *Evidence Characteristics*
- Identify *intrinsic and extrinsic study characteristics*
- Facilitates choices/tradeoffs on a set of dimensions

Translation Framework

- Matches research question to study design, data source, analytic strategy
- Separate *Frameworks* for different *Research Dimensions*, e.g. therapeutics, diagnostics, evidence synthesis, etc.

4 Methodology Report – Generation

Proposed Structure and Function of the Translation Framework



4 Methodology Report – Generation

1. 1st Methodology Report

- Report Next Steps:

Presented by Bill Silberg, Director of Communications, PCORI

Initial Release/Public Comment Period Plan

- Release “prepublication” copy of report for initial professional review and reference during PFA period
- Define scope and purpose of public comment period and associated analysis process
- Based on above decision, prepare report and any support materials needed to solicit and analyze meaningful and broad-based public comment
- Implement communications/outreach plan to drive public comment
- Concurrent planning for longer-term outreach and dissemination efforts

Public Comment Period Plan

- If public comment is to be broad-based and meaningful, analysis plan needs to be defined and staff needs time to prepare adequately
- Board directs PCORI staff to work with appropriate MC members, COEC and DWG to prepare report and needed support materials (comment tool, webinars, non-technical summaries, outreach tactics, etc.)
- Recommendation: start comment period early-to-mid-July to allow sufficient time to prepare all elements required for comment period and robust analysis and revision process

Initial Communications Plan Elements

- Post report to www.pcori.org
- Biweekly e-alerts to all PCORI email lists
- Promotional tweets
- “Why Methods Matter” column by selected MC/PCORI author(s)
- Stakeholder roundtables/webcasts
- Personal outreach by engagement team, Board members and MC members to high-level professional and consumer contacts
- Targeted media outreach (professional and consumer)
- Brief videos from MC chair or designee and patient representative on “Why Methods Matter”

Report Dissemination/Implementation Plan

Elements of the Implementation Plan

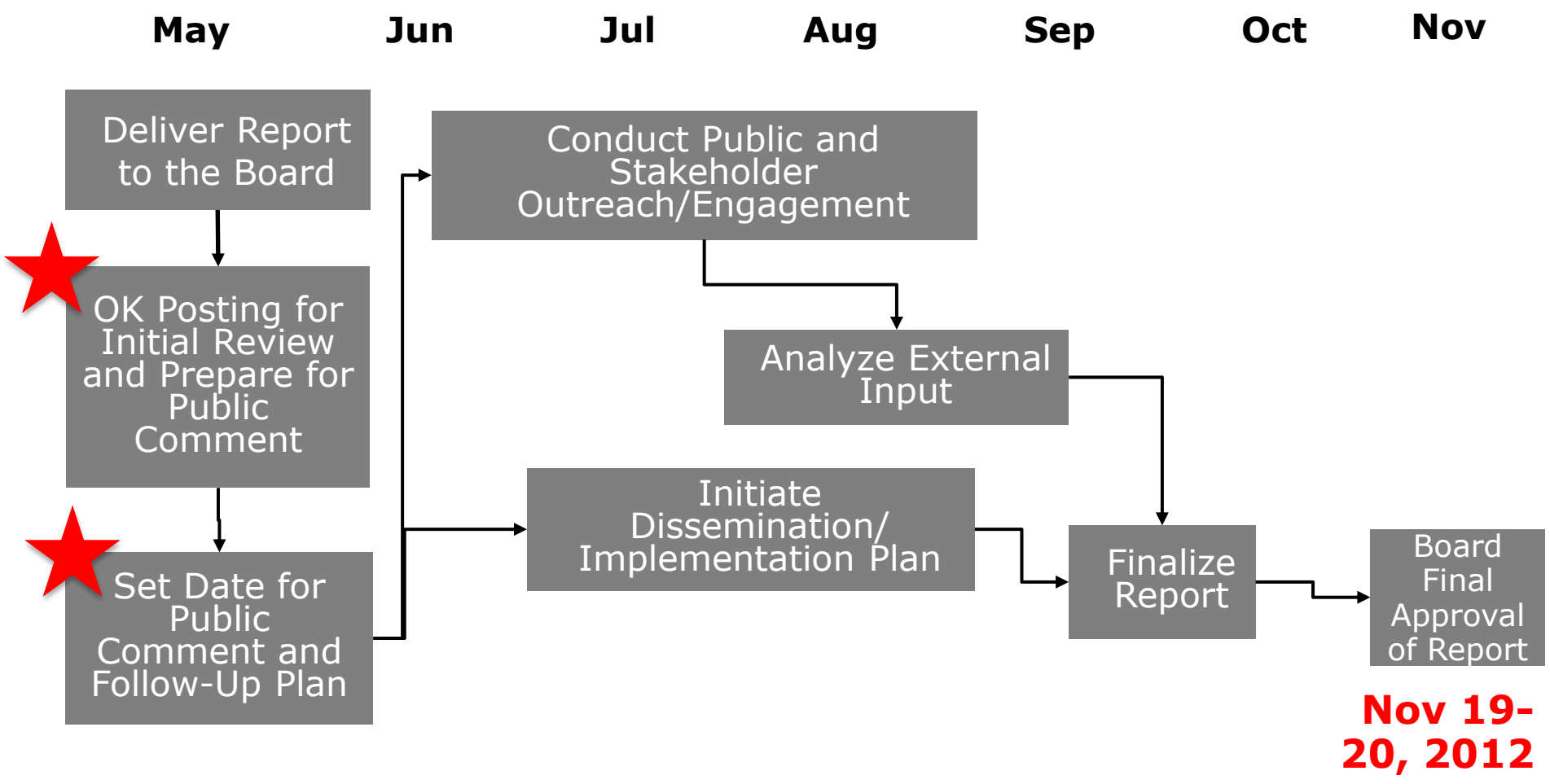
- Multi-faceted coordinated “campaigns”/“packages” of implementation strategies
- Collaborative/partnership planning, design and deployment of the implementation plan with key stakeholders
- Common practice change strategies (education, socialization, decision-support tools/checklists, audit-and-feedback to monitor and publicize adherence rates)

Key Activities

- Widespread but targeted dissemination/promotion through multiple channels: web sites, e-mail, media, webinars (with key stakeholders)
- Dissemination through professional community and other trusted channels
- Joint/partnership activities to disseminate and implement standards, such as new programs and existing/planned training programs
- Develop open-access online reference tool + community elements

Next Steps: Requests to the Board

= Request for Today



2. Methodology Committee

Next Steps

Looking Ahead & Extending our Reach

- Versions/tools for various stakeholders
- Methodological Research Agenda
- Report updates
- Synthesis of Committee Feedback/Evaluation
  - All participated in interviews
  - All but 2 completed an online survey
- June 2012 Retreat/Future Planning
- July 2012 Electronic Data Systems Conference
- Advisory Groups (Professional societies and stakeholders)
  - Electronic Data Systems
  - Implementation
  - Study Designs (clinical trials and observational studies)
  - …..
- 1st Annual PCOR conference

A Special Thank You to…

Editing Team/ Interim Researchers

Andrew Holtz MPH
Heidi D. Nelson, MD, MPH
Ed Reid, MS, MAT
Annette Totten, PhD
Tim Carey, MD, MPH
Howard Balshem
Justine Siedenfeld
Crystal Smith-Spangler, MD

Workshop External Attendees

Kate Bent, PhD
Karl Claxton, PhD
Christine Laine, MD, MPH, FACP
Richard Nakamura, PhD
Evelyn Whitlock, MD, MPH
Tanisha Carino, PhD
Steve Phurrough, MD, MPA
Cynthia Chauhan, M.S.W.
Pat Deverka, M.D.
Kay Dickersin, M.A., Ph.D
Lorraine Johnson, J.D., M.B.A
David Osoba, B.Sc., M.D., F.R.C.P.C
Dennis Revicki, Ph.D.
John Santa, M.D., M.P.H.
Albert Wu, M.D., M.P.H

Principal Investigators and Research Team Members

- University of Maryland, Pharmaceutical Health Services Research Department (Daniel Mullins, Ph.D.)
- Mayo Clinic, Knowledge and Evaluation Research Unit (M. Hassan Murad, M.D., MPH)
- Oregon Health & Science University, The Center for Evidence-Based Policy (Pam Curtis, M.S.)
- Oxford Outcomes, Ltd., Patient Reported Outcomes (Andrew Lloyd, Ph.D.)
- Northwestern University/UNC Chapel Hill (Zeeshan Butt, Ph.D. /Bryce Reeve, Ph.D.)
- Johns Hopkins University (Tianjing Li, MD, MHS, PhD)
- Johns Hopkins University – School of Medicine (Ravi Varadhan, PhD)
- Berry Consultants (Scott Berry)
- Brown University (Constantine Gatsonis, PhD)
- Brigham and Women's hospital and Harvard Medical School (Josh Gagne, PharmD, ScD)
- Outcome Sciences, Inc. (A Quintiles Company) (Richard Giklich, MD)
- University of California San Diego (UCSD) (Lucila Ohno-Machado, MD, PhD)
- Hayes, Inc. (Petra Nass, PhD)
- NORC at the University of Chicago (David Rein, PhD)
- Duke Evidence-Based Practice Center (Evan Myers, MD, MPH)
- Medical College of Wisconsin (Theodore Kotchen, MD)

Electronic Data Systems Interviewees

*57 interviewees from:
- Government
- Associations
- Academia
- Commercial
- Health Care Provides

Respondents to RFI — *Input Draft Translation Table Framework*

*Over 15 submissions received

PCORI Staff

Interim Consultants

Thank You

Roll video

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Patient-Centered Outcomes Research Institute

Preliminary Strategic Planning 2010-2019

PCORI Board of Governors
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Contents

PCORI Vision and Mission

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Vision

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

PCORI Mission

The Patient-Centered Outcomes Research Institute (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.

Engaging Patients and Stakeholders

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Patients, caregivers, and other stakeholders participate meaningfully in the PCORI research enterprise from topic generation to final dissemination of research results.

Strategic Priorities

1. Invite, value, and apply the wisdom and experience from a broad cross-section of patients, caregivers, clinicians and other stakeholders in the PCORI research enterprise; eliminate barriers to participation.
2. Establish a community of trained and informed patients, caregivers, clinicians, researchers, policymakers and others who participate as valued partners and whose collaboration is required in all stages of the research.
3. Communicate transparently and regularly about PCORI's approach and methods for prioritization, decision-making and funding to all stakeholders to create trust.
4. Evaluate and refine patient engagement processes to continually learn and incorporate best practices and methods for developing a robust and engaged community of stakeholders in PCORI work.

Advancing Rigorous PCOR Methods

PCORI methodological knowledge and standards are adopted as best practices across the nation.

Strategic Priorities

1. Identify gaps in knowledge regarding PCOR methods.
2. Generate cutting edge research on methods.
3. Incorporate PCOR methods into PCORI funded research.
4. Advance methodological standards that make a difference in health decisions, and offer guidance about the appropriate use of these methods.
5. Enhance the capacity of researchers to use PCOR methods and their ability to partner meaningfully with patients and other stakeholders.
6. Promote and accelerate adoption of PCOR methods, starting with research funding by PCORI.

Conducting PCOR

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI impacts decision-making, practice and patient outcomes through a research agenda that is uniquely responsive to patient and stakeholder input.

Strategic Priorities

Engage patients and other stakeholders in identifying, prioritizing and conducting comparative effectiveness research to:

1. Assess outcomes of prevention, diagnosis, and treatment options.
2. Improve healthcare systems by comparing distinct system-level delivery models or interventions.
3. Study approaches for disseminating and communicating CER information to patients and the public.
4. Address disparities by identifying differences in treatment effectiveness or clinical outcomes across patient populations.
5. Accelerate Patient-Centered Outcomes and Methodological Research to improve the Nation's capacity to conduct PCOR.

Communicating and Disseminating PCOR Findings

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Patients, caregivers, clinicians, and other decision-makers use PCOR to improve health care decisions, health care delivery and health outcomes.

Strategic Priorities

1. Partner with AHRQ to create a PCOR-specific framework for communications and dissemination that will: drive interest in, create "pull" for and facilitate use of research by patients, caregivers, clinicians and other stakeholders.
2. Establish PCORI as a trusted, "must-have" information resource across stakeholder groups through the development of valued products and services and the establishment of a series of strategic partnerships.
3. Create, maintain, and enhance a portfolio of communications platforms, channels and tools that are used to engage key stakeholders and encourage their consistent use of PCOR and PCORI's products and services.
4. Evaluate PCORI's effectiveness in building awareness and communicating with critical audiences about its work, and contributing to stakeholder uptake and use of PCOR over time.
5. Contribute to PCORI's programmatic focus on investing in research that advances methods of PCOR dissemination and uptake by key stakeholders.

Developing Infrastructure

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI promotes and facilitates the development of a sustainable infrastructure for conducting PCOR.

Strategic Priorities

1. Determine best approaches for expanding, linking, or enhancing current research data infrastructure to increase the quality and efficiency of PCOR.
2. Support the development of innovative methodologies for the design of electronic research infrastructure or associated methods to extract data that enhance the quality or efficiency of PCOR.
3. Participate in national efforts to assure that infrastructure is built with primary focus on serving patient needs, both through assuring they are designed for PCOR, and that they incorporate appropriate patient interests.
4. Enhance the capacity of researchers to conduct PCOR.
5. Facilitate the use of PCOR results to improve patient outcomes.

APPENDIX

Future Planning

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Activity	By When
Perform current state assessment or SWOT analysis for PCORI relative to our vision.	July 20, 2012
Revise imperatives (including cross-cutting themes) as necessary.	August 10, 2012
Compare current state to ideal state (vision) and craft strategies that move PCORI toward the vision.	August 24, 2012
Create roadmap (with milestones, accountabilities, and metrics) to operationalize strategic plan.	September 14, 2012
Update preliminary strategic plan accordingly.	September 21, 2012
Board of Governors to approve updated plan.	September 24, 2012

Patient-Centered Outcomes Research Institute

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Patient-Centered Outcomes Research Institute

Draft National Priorities for Research and Research Agenda

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

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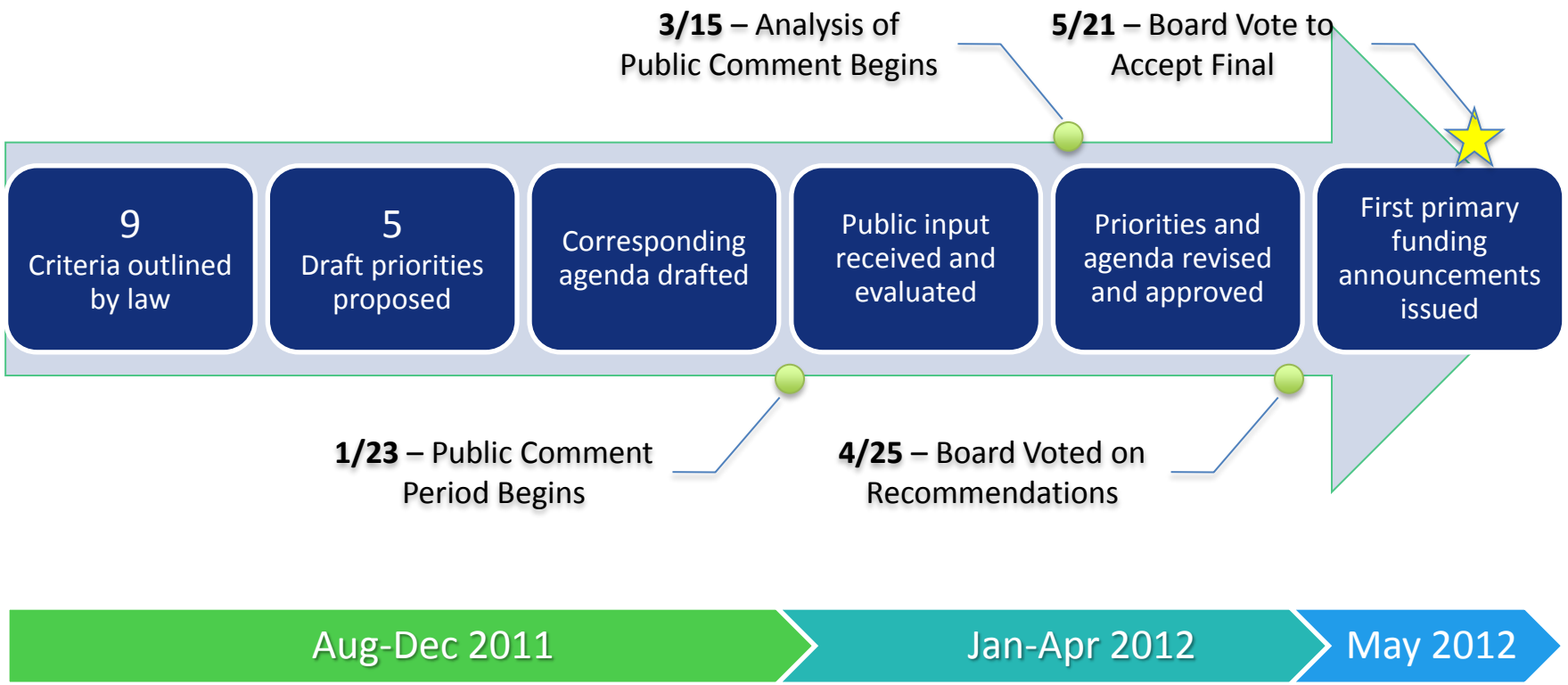
Objectives for Today

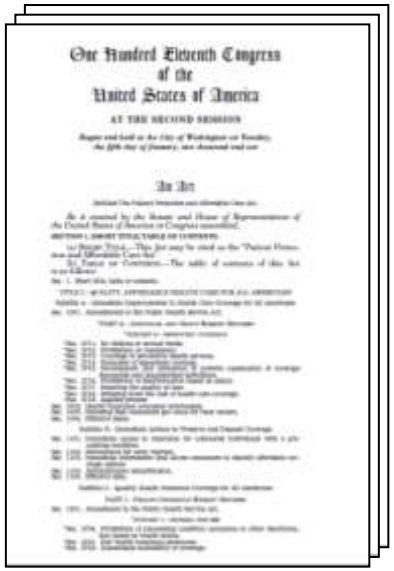
- Review Genesis of National Priorities and Research Agenda
- Review Public Comment Process
- Share Public Comment Findings
- Board Vote to Accept Final National Priorities and Research Agenda Document

Establishing PCORI's First National Priorities for Research and Initial Research Agenda



The What and Why of the National Priorities and Research Agenda

- Mandated in the legislation (including Public Comment period)
- Pre-requisite for releasing funding announcements
- Preliminary roadmap for PCORI research activities
- Envisioned as a living document


One Hundred Eleventh Congress
of the
United States of America
AT THE SECOND SESSION

An Act

Development of Draft of the National Priorities and Research Agenda

Initial Stakeholder feedback	Environmental scan of existing priorities and criteria	Candidate priorities and criteria identified	Framework to inter-relate Priorities and Criteria
Reviewed initial stakeholder input advising us to not "reinvent the wheel"	Reviewed prior CER frameworks (e.g., IOM, FCCCER, National Priorities Partnership, and NQF)	Identified broad priorities from prior frameworks and the statutory criteria for PCORI	Developed Framework to be used for refining priorities and for determining Research Agenda and funding announcements

A Commitment to Public Engagement

Formal 53-day Public Comment Period

- Nearly 500 comments received through website, e-mail or postal mail
- All comments will be posted at pcori.org

Additional Forums

- National Patient and Stakeholder Dialogue
- Patient, caregiver and clinician focus groups
- Individual meetings with diverse mix of stakeholders

Rigorous, Systematic Review and Analysis of Comments

- Computer algorithm to identify key terminology
- Each narrative comment reviewed and analyzed by 3 people
- Stakeholder comments aggregated to 15 key themes
- Themes compared to National Priorities and Research Agenda to identify gaps
- Gaps reviewed to determine options for PCORI response to themes

Options for Response

A. Decide conceptually if a change is in order or not, or if the comment was Not Applicable

B. Decide on response approach

    1. Change Language Within the Research Agenda

    2. Embed in PCORI Operations and Processes

    3. Address in Summary Document

    4. Future Consideration

Overview of Themes

What We Heard	Change/No Change//Not applicable	Response Approach
1. Specificity in condition, disease area	No Change	3 – Summary Document 4 – Future Consideration
2. Partner with organizations and stakeholders	Change	2 – Operations and Processes 3 – Summary Document
3. Patient engagement	Change	1 – Change Language 3 – Summary Document
4. Care coordination	Change	1 – Change Language 3 – Summary Document
5. Patient/provider health literacy and education	Change	1 – Change Language 3 – Summary Document
6. Health IT infrastructure, networks, tools, patient data	No Change	3 – Summary Document
7. Role of caregivers and other stakeholders	Change	3 – Summary Document
8. Access to care, social and environmental determinants	Change	1 – Change Language 3 – Summary Document
9. Rationale and transparency	Change	2 – Operations and Processes 3 – Summary Document
10. Practice setting, behavioral change for shared decision making	Change	1 – Change Language 3 – Summary Document

Overview of Themes

What We Heard	Change/No Change//Not applicable	Response Approach
11. Multiple conditions, especially chronic	Change	1 – Change Language 3 – Summary Document
12. Allied health professionals	Change	1 – Change Language 3 – Summary Document
13. International models	Not Applicable	3 – Summary Document
14. Novel methods	No Change	3 – Summary Document
15. Rare diseases	Change	1 – Change Language 3 – Summary Document

DISCUSSION

BOARD VOTE: Recommend Approval

PCORI NATIONAL PRIORITIES AND RESEARCH AGENDA

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Thanks

- PCORI Stakeholders
  - Thank you for your thoughtful input into the first version of the PCORI National Priorities for Research and Research Agenda
- PCORI Program Development Committee
  - Thank you for all your hard work in the development and refinement of these documents
- The detailed Summary Document of changes to the National Priorities and Research Agenda was posted on pcori.org May 16, 2012

APPENDIX

PCORI Response to Key Themes-1

1. **Recommends that PCORI choose a specific condition, disease area, or other issues in the Research Agenda and National Priorities**

   Response: PCORI has proposed a condition-neutral Research Agenda and has introduced specificity through its comparative nature and emphasis on patient centeredness. While future funding announcements may specify conditions, the overall mission of PCORI is not served by excluding any conditions if there is compelling reason for a patient-centered, comparative clinical effectiveness study.

2. **Recommends that PCORI partner with organizations and stakeholders to carry out its mission**

   Response: PCORI is committed to efficient use of its research investments. Where appropriate, PCORI will partner with other organizations after a transparent decision-making process and consideration of conflicts of interest. This theme impacts PCORI processes, rather than funding subjects, so no specific language changes were made to the document.

3. **Recommends greater focus on the patient, with particular attention to methods of engagement**

   Response: PCORI has fully endorsed and appreciates the centrality of patient engagement to its mission. The National Priorities and Research Agenda reflect the patient centered focus of PCORI and include many of the themes from the public comments. Language has been added to the Agenda to specifically reflect the need for study of self care and to more clearly define personalized medicine.

PCORI Response to Key Themes-2

4. **Recommends a greater focus on care coordination**

   Response: PCORI appreciates the need to study care coordination and has expanded the language in the Research Agenda to reflect its importance.

5. **Recommends funding towards improving patient and provider health literacy and education**

   Response: Improving communication between patient and provider is one of the five PCORI National Priorities for Research. Language has been added to the Research Agenda to reflect the importance of health literacy to achieving this goal.

6. **Recommends funding for and use of health IT infrastructure, networks, tools and patient data acquisition efforts in and outside the practice setting**

   Response: The foundation for performing comparative clinical effectiveness requires substantial health IT and data infrastructure. The National Priorities and Research Agenda contain substantial language about this infrastructure. Therefore, no additional language was added to the document. PCORI will support reusable infrastructure for comparative clinical effectiveness research.

PCORI Response to Key Themes-3

7. **Recommends that PCORI pay greater attention to the role of caregivers and other stakeholders in the patient decision making process**

   Response: PCORI appreciates the role of caregivers in patient centered care and has mentioned them in the document and included studies of caregiving in the Research Agenda. Therefore, no additional language was added to the document.

8. **Recommends that PCORI pay greater attention to access to care, including the social and environmental determinants that determine access and use of care**

   Response: Access to care is a key issue for patients. Language has been added in both the comparative assessment and the healthcare systems Research Agenda topics to include the comparative study of access as a determinant of health.

9. **Recommends that PCORI provide greater rationale and transparency in the public comment, grants, and research evaluation processes, as well as the performance measurement process for PCORI as a whole**

   Response: PCORI is committed to fully transparent processes as it works towards achieving its mission. The Research Agenda articulates the ongoing engagement that will occur continuously as PCORI evolves and funds research. Therefore, no additional changes were made to the document. PCORI intends to roll out a comprehensive communications and engagement plan that will clearly define when and how stakeholders can provide input into PCORI decision making.

PCORI Response to Key Themes-4

10. **Recommends that PCORI's research and funding should impact the practice setting, with particular attention to patient and provider behavioral change needed to obtain true shared decision making**

    Response: PCORI is fully committed to the idea that its research should improve decision making and help patients at the point of care. Language has been added to the section "Establishing the Scope of the Research Agenda" to emphasize the importance of using the evidence developed through PCORI research to change the way medicine is practiced.

11. **Recommends that PCORI place stronger emphasis on patients with multiple conditions, especially chronic conditions**

    Response: PCORI understands the difficulty of managing multiple chronic conditions when most evidence is generated in trials that exclude these patients. Language has been added to emphasis this in the Research Agenda.

12. **Recommends that PCORI study new and expanded roles for allied health professionals**

    Response: PCORI recognizes the diverse health professionals involved in patient centered care. In the Research Agenda, the description of allied health professionals has been expanded to be more inclusive of all of potential members of a health care team.

PCORI Response to Key Themes-5

13. Recommends paying attention to international models

Response: PCORI recognizes the significant achievements of many countries in developing the methods and practices of patient engaged comparative clinical effectiveness research that may inform investigators as they seek PCORI funding. As this is not central to PCORI research, no change is proposed to the priorities or agenda.

14. Recommends exploring novel methods to obtain patient centered focus

Response: PCORI supports the approach of exploring innovative methods for focusing on the patient. The fundamental basis of PCOR, however, is the science of evidence-based medicine. PCORI will support and promote approaches that seek rigorous, scientific results; therefore no changes were made to the document.

15. Recommends that PCORI study rare diseases

Response: PCORI recognizes the challenges faced in studying rare diseases. In the Research Agenda, language about rare disease has been expanded.

Patient-Centered Outcomes Research Institute

Board of Governors Meeting
Denver, CO
May 21-22, 2012

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Patient-Centered Outcomes Research Institute

PCORI Funding Announcements (PFAs)

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

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Presentation

- Background and History of the PFAs
- Description of PFA Development Process
- Unique Features of PCORI Research
- Brief Description of Each PFA
- Review Plans for Review Process

Developing PCORI's First Announcements

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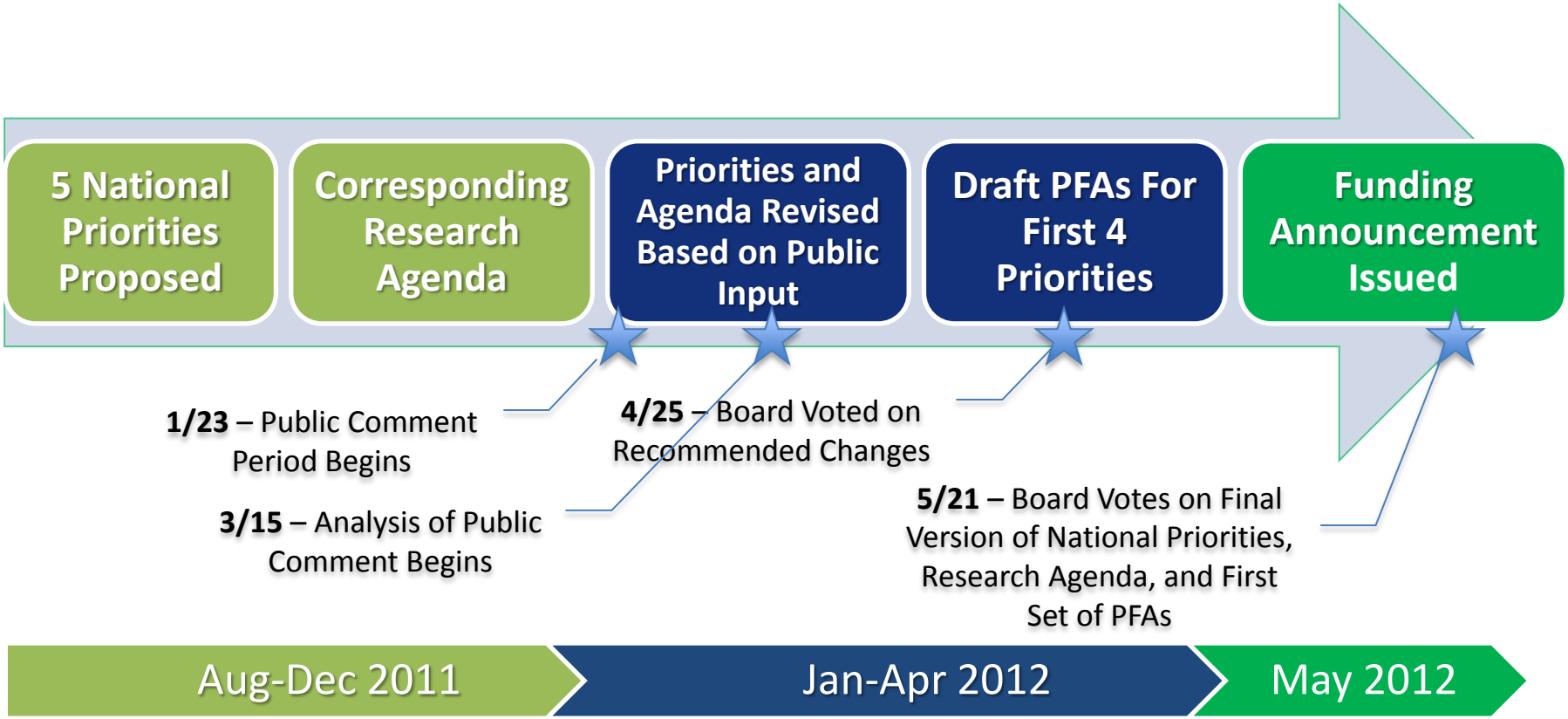

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PFA Writing Groups

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board Members	Advise on PCORI's strategic interests and offer content expertise to help refine background and exemplar questions.
PCORI Scientists and Staff	Group leads, overall responsibility for work of team, content expertise to help refine background and exemplar questions.
Contract Scientists	Survey literature, primary responsibility for background, highlight evidence gaps, and provide exemplar questions.
NIH Advisor	Provide expert knowledge of landscape in the priority area ; particular focus on the NIH activities and learning in order to prevent duplication efforts.
AHRQ Advisor	Provide expert knowledge of landscape in the priority area; particular focus on the AHRQ activities and learning in order to prevent duplication efforts

Board Members on the Four PFA Teams

1. Assessment of Prevention, Diagnosis, Treatment Options	2. Improving Health Care Systems
• Harlan Krumholz • Ellen Sigal • Harlan Weisman	• Arnie Epstein • Christine Goertz • Leah Hole-Curry
3. Communications and Dissemination Research	4. Addressing Disparities
• Allen Douma • Gray Norquist • Sharon Levine	• Debra Barksdale • Carolyn Clancy

From Research Agenda to PFAs

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Research Agenda


PCORI Research Agenda-DRAFT

Research Agenda Process

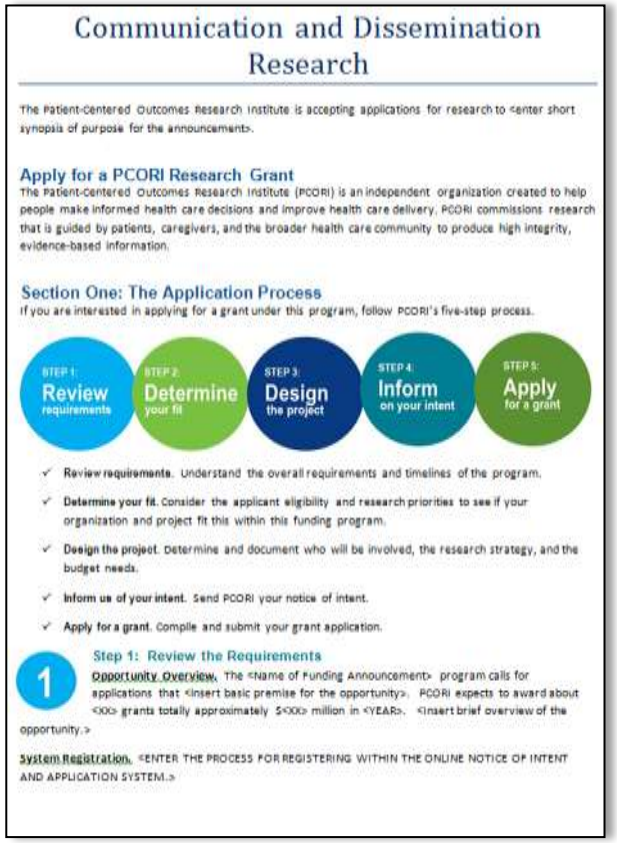
Framework for Translation of PCORI National Priorities into the Research Agenda

Priorities

PCORI Research Agenda

RFPs and PFAs

PFAs


Communication and Dissemination Research

The Patient-Centered Outcomes Research Institute is accepting applications for research to <enter short synopsis of purpose for the announcements>.

Apply for a PCORI Research Grant

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed health care decisions and improve health care delivery. PCORI commissions research that is guided by patients, caregivers, and the broader health care community to produce high integrity, evidence-based information.

Section One: The Application Process

If you are interested in applying for a grant under this program, follow PCORI's five-step process.

STEP 1: Review requirements
STEP 2: Determine your fit
STEP 3: Design the project
STEP 4: Inform on your intent
STEP 5: Apply for a grant

- ✓ **Review requirements.** Understand the overall requirements and timelines of the program.
- ✓ **Determine your fit.** Consider the applicant eligibility and research priorities to see if your organization and project fit this within this funding program.
- ✓ **Design the project.** Determine and document who will be involved, the research strategy, and the budget needs.
- ✓ **Inform us of your intent.** Send PCORI your notice of intent.
- ✓ **Apply for a grant.** Compile and submit your grant application.

1 Step 1: Review the Requirements

Opportunity Overview. The <Name of Funding Announcement> program calls for applications that <insert basic premise for the opportunity>. PCORI expects to award about <XX> grants totally approximately $<XXX> million in <YEAR>. <Insert brief overview of the opportunity.>

System Registration. <ENTER THE PROCESS FOR REGISTERING WITHIN THE ONLINE NOTICE OF INTENT AND APPLICATION SYSTEM.>

The first four National Priorities: Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; Addressing Disparities

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Each PFA Has Two Primary Building Blocks

1 Application Guideline


PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Communication and Dissemination Research

The Patient-Centered Outcomes Research Institute is accepting applications for research to <enter short synopsis of purpose for the announcement>.

Apply for a PCORI Research Grant

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System Registration. <ENTER THE PROCESS FOR REGISTERING WITHIN THE ONLINE NOTICE OF INTENT AND APPLICATION SYSTEM.>

4 Funding Announcements


Improving Healthcare Systems

- PCORI's Special Features, Including:
  - Patient & Stakeholder Engagement Plan
  - Dissemination and Implementation Assessment
  - Reproducible and Transparent Research Plan
  - PCORI Criteria
  - References to Methodology Standards
- Unique Features of each PFA
  - Specific Purpose
  - Background
  - Broad Areas of interest
  - Example questions

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PCORI Review Criteria

1.	Impact of the Condition on the Health of Individuals and Populations
2.	Innovation and Potential for Improvement
3.	Impact on Health Care Performance
4.	Patient-Centeredness
5.	Rigorous Research Methods
6.	Inclusiveness of Different Populations
7.	Research Team and Environment
8.	Efficient Use of Research Resources

Characteristics of each PFA

- Remain “broad” with respect to interest in any condition, as well as cross-cutting questions.
- Points out interest in patients with rare diseases
- Includes vignettes drawn from focus groups
- Emphasizes outcomes that matter to patients

#1 Assessment of Options for Prevention, Diagnosis, and Treatment

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Research that:

- Compares effectiveness of two or more strategies for prevention, treatment, screening, diagnosis, or management.
- Compares use of prognostication/risk-stratification tools with usual clinical approaches to treatment selection or administration.
- Investigates the key individual determinants of outcomes following treatment decisions
- Emphasizes studies in typical clinical populations, full range of relevant patient-centered outcomes , possible difference among patient groups.

#2: Improving Health Care Systems

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Research comparing alternative systems approaches* to improving:

- Access to care, receipt of appropriate evidence-based care, safety of care
- Personalized decision-making and self-care.
- Coordination of care across healthcare services or settings
- Efficiency and reduction in use of ineffective, redundant, wasteful care
- Timeliness of referrals and transitions in care.

*Approaches include applications of health information systems, electronic health records, patient portals and personal health records, incentives directed at either clinicians or patients, new/extended roles for allied health professionals – with emphasis on patient-centered outcomes.

#3: Communication and Dissemination Research

Research comparing the effectiveness of approaches to:

- Increase awareness of healthcare options among patients, caregivers and clinicians.
- Encourage effective patient, caregiver, or clinician participation in shared-decision making.
- Elicit or include patient-desired outcomes in healthcare decision-making process.
- providing new information to patients, caregivers or clinicians, via public health approaches and social media.

#4: Addressing Disparities

Research comparing alternative approaches to:

- Reducing or eliminating disparities in patient-centered outcomes
- Reducing the impact of contextual factors such as socio-economic, demographic, or community factors on clinical outcomes
- Overcoming patient, provider or systems level barriers to identifying and making preferred choices for preventive, diagnostic, and treatment strategies
- Information-sharing about treatment outcomes and patient-centered research in various populations

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DISCUSSION

Patient-Centered Outcomes Research Institute

PCORI Two-Stage Merit Review Process

May Program Announcement

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

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Agenda: PCORI Two-Stage Merit Review Process

1. Goals & Key Attributes
2. PCORI's Two-Stage Merit Review
3. PCORI's Administration
4. Timeline

Goals & Key Attributes

GOAL

To establish (a) a rigorous peer review process that assures all PCORI funded projects are of the highest scientific/technical quality , (b) to provide patients/stakeholders a clear and valued voice in the decision making process, and (c) to determine the potential impact of study to make a difference in the patient-centered healthcare.

KEY ATTRIBUTES

- Allows us to evaluate a large number of proposals in a efficient process, suitable for PCORI's growing operations.
- Two-stage review process is vital to the identification and funding of best patient-centered science.
- Process provides a forum for patients and other stakeholders to have direct impact in funding decisions.

Peer Review Process: Definition

TWO-STAGE REVIEW PROCESS:

Two-stage process requires: (a) Phase I scientific/technical review and (b) Phase II impact review of the applications.

Application and Review Process

Summary:

Application

1. PCORI Online
2. LOI Submission
3. Application Submission
4. Received
5. Internal Quality Control

- Administrative
- Programmatic

Peer Review

1. **Phase I: Scientific/Technical Review**
2. **Phase II: Impact Review**

PCORI Approval

1. PCORI Business Review
2. PCORI Balance Analysis
3. Board Approval

PCORI's Peer Review Process:
Two-stage approach

Phase 1
E-mail Reviewers

- Efficient process to evaluate for scientific rigor.
- Allows for in-depth **science** review of all proposals

Phase 2
In-Person Deliberations

- Focus on evaluating patient-centered outcomes of research proposal
- Focus evaluating **impact** of proposals

Board Approval

PCORI Approval

- PCORI: Business review: budget, funding overlap, others
- PCORI: Balance Analysis
- PCORI prepares recommendations for BoGs

BoGs approve **applications to be funded**

Patient/Stakeholder Involvement

Approach: Patient and stakeholder reviewers are part of the decision making process. All reviewers will be trained in PCORI's mission and processes to advance patient/stakeholder engagement.

Roles	• Review of roles of patients/stakeholders in research proposal
Impact	• Ensures patient/stakeholder **perspective** is included in the merit review process • Ensures that patient/stakeholder **engagement** is included in the research proposal • Ensures that research proposal has a **direct correlation** to **patient-centered outcomes**
Clear, Valued Voice	• Patients and stakeholders will have a clear and valued voice in final recommendations

Patient and Stakeholder Training

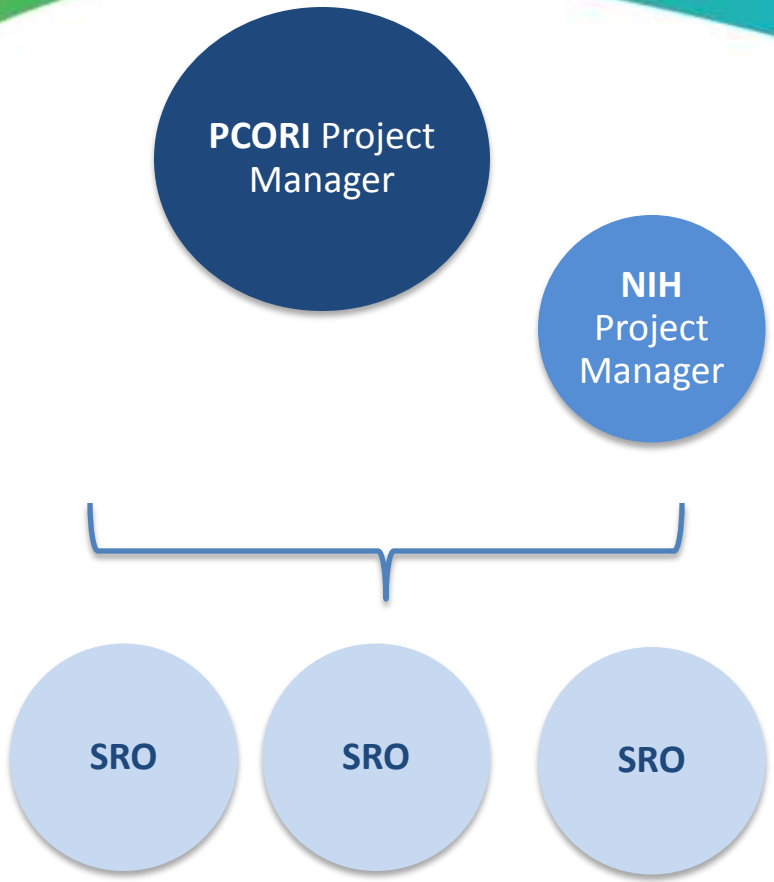
Curriculum

- Patient Center Outcomes Research (PCOR)
- National Priorities
- Program Funding Announcement
- Applications Format
- Critique Format and Scores

Modalities for Training

- Videos
- Webinars
- In-Person

Administration



Roles & Responsibilities:

PCORI Project Manager

- Overall management of PFA review process

NIH Project Manager

- Support to PCORI Project Manager and overall process

Scientific Review Officers (SROs)

- Recruit Reviewers
- Conduct Applications Quality Control
- Lead Applications Assignments
- Oversight of Panel I and II Reviews
- Write the Summary Statement
- Support the Develop of Training Material and Conduct Trainings

PCORI Online System

Patient-Centered Outcomes Research Institute

Complete Letter of Intent
Main - Martin Duenas

- Home
- Main
- PI Information
- Project Information
- Key Personnel
- Additional Information
- Review and Submit
- FAQ
- Log Out

To complete the different portions of the Letter of Intent (LOI) click on the left side navigational links as follows: PI Information, Project Information and Personnel Information. The Validation summary (displayed below) will inform you of the completeness of each section. Click the "Review and Submit" link to review your entry before submitting.

Project Information

Program	Improving Healthcare Systems
Funding Opportunity	Improving Healthcare Systems
Funding Cycle	LOIs are due June 15, 2012 | Applications are due July 31, 2012

Validation Summary

Page Name	Status
PI Information	✗ Incomplete
Project Information	✗ Incomplete
Key Personnel	✗ Incomplete
Additional Information	✗ Incomplete

For technical assistance, please contact us via e-mail or phone xxx-xxx-xxxx.
For program assistance, please contact us via e-mail .
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Advantages for a PCORI Review

1. Increased patient/stakeholder input.
2. Opportunity to guide review for PCORI's needs.
3. Greater flexibility for internal and external reporting of data in new PCORI online system.
4. Enhance PCORI relations with scientific/technical and patient/stakeholder reviewers for future PFAs.

Timeline

Letter of Intent/Application Deadline

- June 15, 2012 (LOI)
- July 31, 2012

Internal Quality Control

- August 1 – 15, 2012

Panel I: Technical Review

- August 15 – October 1, 2012

Panel II: Impact Review

- Monday, November 12, 2012

PCORI Review and Board Approval

- December 3- December 21, 2012

QUESTIONS

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Patient-Centered Outcomes Research Institute

Board of Governors Meeting
Denver, CO
May 21-22, 2012

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Patient-Centered Outcomes Research Institute

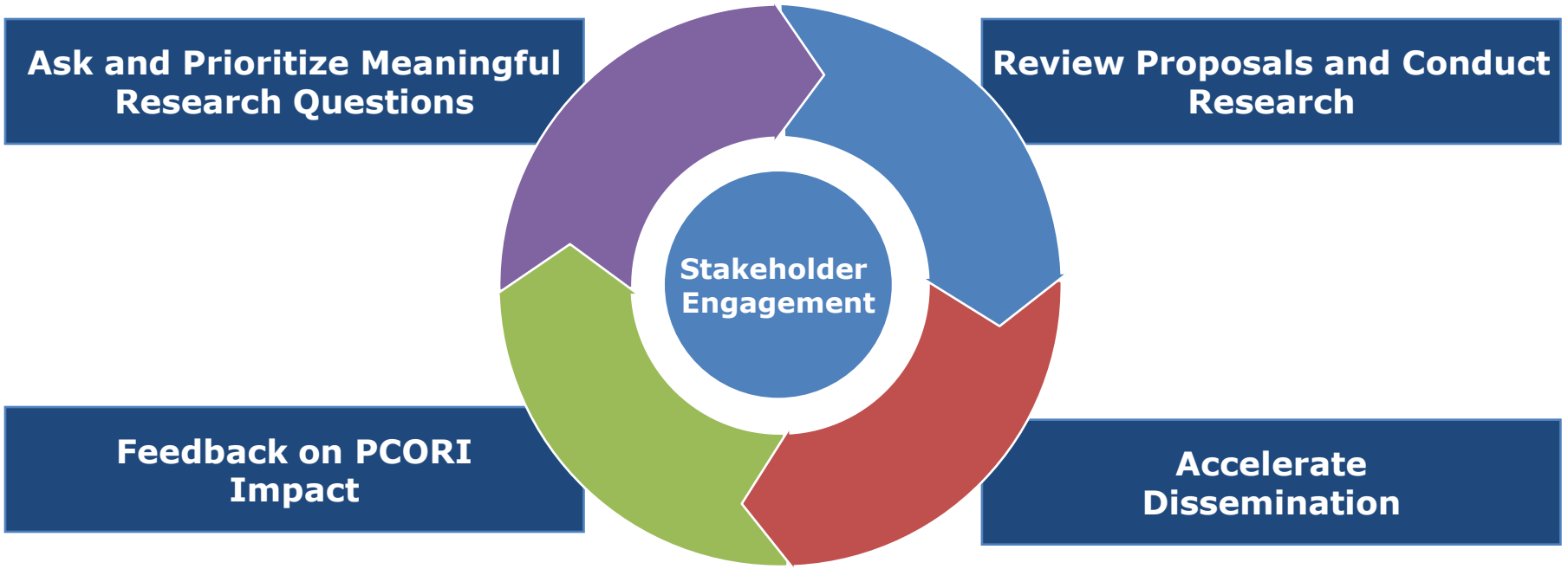
Stakeholder Engagement

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012
Dr. Anne C. Beal
Chief Operating Officer

pcori

Why Engage?

Guiding Principles for Stakeholder Engagement



Stakeholders Defined

A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research. 2012. Concannon. *J. Gen. Intern. Med.*


A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research

"Despite widespread agreement that stakeholder engagement is needed in patient-centered outcomes research (PCOR), no taxonomy exists to guide researchers and policy makers on how to address this need. We followed an iterative process, including several stages of stakeholder review, to address three questions:

(1) Who are the stakeholders in PCOR?
(2) What roles and responsibilities can stakeholders have in PCOR?
(3) How can researchers start engaging stakeholders?

We introduce a flexible taxonomy called the "7Ps of Stakeholder Engagement and Six Stages of Research" for identifying stakeholders and developing engagement strategies across the full spectrum of research activities. The path toward engagement will not be uniform across every research program, but this taxonomy offers both a common starting point and a flexible approach."

Patient-Centered Outcomes Research Institute

Guiding Us: The Voices of Patients and Caregivers

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

Judith Glanz
Director, Patient Engagement

pcori

Presentation Outline

1) Engagement Activities

2) Timeline of Activities

3)Potential Areas for Success

4) Joint Engagement Questions

Engagement Activities Overview

How Are We Engaging Patients and Caregivers in PCORI's Research Enterprise?

Topic Selection	Research Phases	Dissemination	Feedback on Impact
Asking and prioritizing meaningful research questions	Review proposals and conduct research	Accelerate dissemination	Provide feedback to PCORI process and help PCORI become a learning organization

Topic Selection

Soliciting Research Questions

- Invite and support patients and caregivers to frame the questions they want answered
- Determine best method for topic generation
- Solicit patient and caregiver-generated questions in a variety of venues, including online, surveys and meetings, patients and caregiver organizations and with community-based networks
- Reach under-represented and under-served patients and caregivers by convening state-based workshops

Prioritizing Research

- Study PCORI Methodology Report standards for prioritization
- Building on the Methodology Report, convene a workshop on a framework for PCORI research prioritization
- Establish a credible, transparent, equitable multi-stakeholder research prioritization process that includes patients and caregivers as equal partners and that expresses PCORI's values for optimizing patient-centered outcomes with respect for differences in patient preferences.
- Establish multi-stakeholder advisory panels and workshops
- Provide support and resources for patients and caregivers to participate as equal partners on advisory bodies

Research Phases

Recruiting and Training Patient and Caregiver Funding Application Reviewers

- Enlist proposal reviewers through multiple avenues including online and key constituent patient and caregiver organizations
- Identify reviewers with previous research proposal review training
- Identify promising practices for patient and caregiver participation in reviewer training
- Develop PCORI- research reviewer training materials for patients, caregivers **AND** for researchers

▪ Requiring Patient and Caregiver Participation in Conduct of Research

- Require PCORI Funding Applications to include robust, comprehensive plan for patient and caregiver engagement in every phase of the research including in the design, conduct, evaluation and dissemination of findings

Accelerate Dissemination

Getting Evidence to Patients and Their Caregivers

- Identify existing channels for dissemination of evidence
- Work with patients and caregivers to create new pathways to get findings to those who use them: patients, caregivers and their care providers
- Develop partnerships with organizations with significant capacity for outreach to patients/caregivers including to vulnerable populations
- Create the "pull" by engaging patients and caregivers throughout the research enterprise so that they are motivated to actively promote dissemination and uptake by their caregivers of evidence for better decision-making

Feedback on Impact

Provide Feedback to PCORI Process and Help PCORI Become a Learning Organization

- Request feedback from patients and caregivers at regular intervals in-person and on-line
- Evaluate patient and caregiver feedback continuously
- Use input and feedback to revise/refine methods and materials to enhance engagement activities

Specific Questions May Include:

- Understandability of PCORI materials and processes
- Extent of outreach/perceived gaps – success in reaching priority populations
- Relevance and accessibility of training materials
- Level of engagement as partner in PCORI funded research

Patient Engagement: Timeline of Activities

Activity (2012)	Apr	May	Jun	Jul	Aug	Sept
Patient and Caregiver Engagement Plan						
Contact stakeholders personally and via web						
Contract for landscape review of patient training programs; create training program						
Create and populate Contact Management System						
Host roundtables with patient stakeholders (e.g., disability community, NORD on rare diseases)						
Call for reviewers						
Participate in MC report public comment period						
Develop a schedule for regular and predictable engagement						
Conduct patient and caregiver survey						
Patient and caregiver review training program						
Work with Communications Director to develop a plan for systematic communication channels, web-based patient portal, and other social media						
Develop PCORI topic generation process						

Patient Engagement: Timeline of Activities

Activity (2012)	Apr	May	Jun	Jul	Aug	Sept
Patient and Caregiver Engagement Plan						
Hold first regional patient/caregiver workshop focused on topic generation with priority population(s) in Boise, ID				■	■	■
Convene a small workshop on research prioritization methods in collaboration with the MC and key experts to consider best practices	■	■	■	■	■	■
Hold a Caregiver Roundtable						■
Plan patient and caregiver track for PCORI annual conference (and possible ½ day patient and caregiver training workshop)			■	■	■	■

Potential Measures Of Success Through May 2013

Outcomes

- **Knowledge, use and trust of PCOR and other CER results**
  - Data gathered from patient survey

Process

- **Outreach**
  - Establish reliable and ongoing outreach to patients and caregivers
- **Key Contacts**
  - Identify a cross-section of key contacts
- **Partnerships**
  - Partner with key individuals, organizations and networks
- **Research**
  - Insure inclusiveness, accessibility and understandability of PCOR research
  - Include patients and caregivers as equal partners
- **Advisory Panels**
  - Create multi-stakeholder advisory panels and working groups
- **Surveys**
  - Conduct patient and caregiver survey(s)
- **Annual Meeting**

Structure

- **Contact Management**
  - Create Contact Management System to facilitate outreach to individuals and organizations

Patient-Centered Outcomes Research Institute

Stakeholder Engagement Plan

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

Susan Hildebrandt
Director, Stakeholder Engagement

pcori

Presentation Outline

1) Stakeholders Defined

2) Engagement Activities

3) Timeline of Activities (April-September 2012)

4) Potential Areas for Success

PCORI's Definition of Stakeholders (Other than Patients and Caregivers)

This Definition is Based Largely on the Concannon Definition*

- **Clinicians/Clinician Associations** (Physicians, Nurses, Pharmacists, Professional Societies & Associations, and Other Clinicians)
- **Organizational Providers** (Hospitals, Integrated Delivery Systems, Clinics, Community Health Centers, Pharmacies, Nursing Facilities)
- **Purchasers** (Employers, Self-Insured, Government and Other Entities)
- **Payers** (Insurers, Medicare and Medicaid, States and Labor Trusts)
- **Industry** (Drug, Device, Biotechnology and EHR Vendors)
- **Researchers**
- **Policymakers** (US Congress and the Administration, State and Local Government and Policymaking Entities)
- **Educational Institutions**

PCORI realizes that many of the stakeholders come together to participate in quality improvement and performance activities. Consequently, quality organizations or efforts are not listed separately.

*Source: A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research. 2012. Concannon. *J. Gen. Intern. Med*.

Engagement Activities Overview

How Are We Engaging Patients and Stakeholders in PCORI's Research Enterprise?

Topic Selection	Research Phases	Dissemination	Feedback on Impact
Ask and prioritize meaningful research questions	Review proposals and conduct research	Accelerate dissemination	Provide feedback to PCORI process and help PCORI become a learning organization

Ask and Prioritize Meaningful Research Questions

- Contact stakeholders and stakeholder organizations personally and via the Web
- Review MC reports for promising practices for topic generation, prioritization
- Develop PCORI topic generation and prioritization processes
- Convene workshops on key topics (e.g., research questions and prioritization) and form multi-stakeholder advisory panels

Review Proposals and Conduct Research

- Develop a PCORI stakeholder review training program
- Create a cadre of trained stakeholders
- Include trained stakeholders in contract review

Accelerate Dissemination

- Review MC reports for promising practices for dissemination.
- Develop baseline physician survey on knowledge, use, and trust of CER.
- Conduct and implement research on best practices in dissemination.
- Establish close relationships with patient, clinician and provider organizations to determine effective pathways for dissemination.
- Collaborate with the Dissemination Workgroup on communications regarding dissemination.

Feedback on Impact

Provide Feedback to PCORI Process and Help PCORI Become a Learning Organization

- Request performance feedback from stakeholders at regular intervals (e.g., on regular calls, at meetings).
- Evaluate comments from stakeholders on a continual basis.
- Change means of engagement based on stakeholder feedback.

Non-Patient Stakeholder Engagement: Timeline of Activities

Activity (2012)	Apr	May	Jun	Jul	Aug	Sept
Non-Patient Stakeholder Engagement Plan						
Contact stakeholders/organizations personally and via the Web.						
Alert stakeholders to PCORI events and materials.						
Contract for a landscape review of stakeholder training programs; create a training program.						
Create baseline survey of physicians.						
Implement a Contact Management System.						
Develop a schedule for regular and predictable engagement.						
Participate in MC report public comment period.						
Develop a PCORI topic-generation process.						
Review MC reports to identify promising practices for engagement.						
Call for reviewers.						
Establish a stakeholder review training program.						

Non-Patient Stakeholder Engagement: Timeline of Activities

Activity (2012)	Apr	May	Jun	Jul	Aug	Sept
Non-Patient Stakeholder Engagement Plan						
Work with the Communications Director to develop a plan for systematic communication channels, web-based patient portal, and other social media.						
Plan a briefing on Capitol Hill.						
Convene workshop on key topics and form multi-stakeholder advisory panels.						
Establish specific communication channels with state-based policymakers.						
Collaborate with the Dissemination Workgroup on communications regarding dissemination.						
Plan a stakeholder track for the annual PCORI conference.						

Potential Areas for Success Through May 2013

Outcomes

- **Knowledge, use and trust of PCOR and other CER results**
  - Data gathered from clinician surveys

Process

- **Outreach**
  - Establish regular, predictable personal and web-based outreach to all stakeholder groups and monitoring of stakeholder involvement via these means
- **Key Contacts**
  - Create key contacts for all stakeholder groups to allow for immediate feedback when necessary
- **Alerts and Input**
  - Establish a process for alerts to and input from stakeholders on PCORI materials
- **Advisory Panels**
  - Create multi-stakeholder advisory panels
- **Conduct Physician Survey**
- **Annual Meeting**
  - Spring 2013

Structure

- **Contact Management**
  - Implement a Contact Management System to allow targeting and reports on stakeholder contacts

Joint Engagement Questions

Requesting Advice From the Board

- Do you have suggestions for measures of success?
- Can you suggest approaches for engaging the rare disease community?
- Can you suggest approaches for meaningful engagement of priority populations?
- How do you think advisory committees should be structured to ensure adequate stakeholder involvement?
- Other questions?

Patient-Centered Outcomes Research Institute

Board of Governors Meeting
Denver, CO
May 21-22, 2012

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Patient-Centered Outcomes Research Institute

Finance, Audit, and Administrative Committee (FAAC) Report

Audit

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

Agenda

- Independent Auditor's Report

Independent Auditor's Report

McGladrey & Pullen, LLP has issued an unqualified opinion on the PCORI financial statements.

Year 1: November 10 (inception) through December 31, 2010
Year 2: Calendar year ending December 31, 2011

Independent Auditor's Report

Yellow Book

Independent Auditor's Report on Internal Control over Financial Reporting, Compliance and Other Matters and is based on an audit of Financial Statements in accordance with Government Auditing Standards.

Government Auditing Standards (*the "Yellow Book"*) contains standards for audits of government organizations, programs, activities, functions and government assistance received by contractors, nonprofit organizations and other non-government organizations.

ASSURANCE
Internal control over financial reporting
Compliance and other matters

Independent Auditor's Report

Internal Control

Finding 2011-01: Financial Reporting

Questioned Costs: NONE

— Proper recognition of federal government appropriation and interest income —

Corrective Action: All appropriate adjustments were made to PCORI records and the audited financial statements reflect the required changes.

Independent Auditor's Report

Management Response

The timing difference between the two fiscal year ends (GFY vs. CY) gave rise to the required adjustment.

— *Views of Responsible Officials* —

There has never been any confusion or disagreement regarding the nature of the PCORTF or the amount of funds contained in it.

Given the unique nature of PCORI, there has been uncertainty regarding the timing of funding that is received by the PCORTF and the methodology that should be used to establish *when funding is received* and *revenue is recognized*.

PCORI had not accounted for the total funding in the PCORTF because it did not believe that it exercised control over the trust fund.

PCORI must report the entire PCORTF balance because there is no right of refund.

Independent Auditor's Report

Tests of Compliance

Compliance and Other Matters

As part of obtaining reasonable assurance about whether the financial statements were free of material misstatement, tests of compliance were performed with laws, regulations, contracts, and other agreements.

— There were no findings related to Compliance or Other Matters. —

Independent Auditor's Report

Funding

$1.26 billion appropriation PCOR Trust Fund (PCORTF)
Government Fiscal Year (GFY) 2010 — 2019

This amount (less any annual distributions to AHRQ/HHS) is available to PCORI without further appropriation.

GFY begins October 1 and ends September 30.

Inception-to-date: federal appropriation has been *the only source of revenue*.

Revenue is recognized by PCORI on the first day of the GFY, October 1.

Independent Auditor's Report

Financial Highlights

Amounts held by PCOR Trust Fund (PCORTF):

	2011	2010
Beginning balance	$49,638,865	$0
Federal appropriations:		
GFY 2010 Appropriation		10,000,000
GFY 2011 Appropriation		50,000,000
Less AHRQ and HHS share 20% of appropriation		(10,001,322)
GFY 2012 Appropriation	150,000,000	
Less AHRQ and HHS share 20% of appropriation	(30,000,000)	
Interest earned	24,106	10,187
Draws from PCORI	(11,584,000)	(370,000)
	$158,078,971	$49,638,865

Independent Auditor's Report

Financial Highlights

PCORI has $161 million to fund research and operations during its fiscal year: January 1 through December 31, 2012.

Assets	**2011**	**2010**
Cash	$4,483,112	$234,825
Amounts held by PCOR Trust Fund	158,078,971	49,638,865
Prepaid expenses and deposits	763,304	0
Property and equipment, net	159,153	0
	$163,484,540	$49,873,690
Liabilities and Net Assets		
Liabilities		
Accounts payable and accrued expenses	$2,513,990	$315,339
Total liabilities	$2,513,990	$315,339
Net assets		
Unrestricted	$160,970,550	$49,558,351
	$163,484,540	$49,873,690

Independent Auditor's Report

Financial Highlights

GFY appropriations for 2010 and 2011 were deposited to PCORTF in CY 2010.
GFY appropriation for 2012 was deposited to PCORTF in CY 2011.

	2011	2010
Revenue and support:		
Federal appropriations	$ 120,000,000	$ 50,000,000
Interest income	24,106	8,865
Total revenue and support	120,024,106	50,008,865
Expenses:		
Program services:		
Communications, Outreach, and Engagement	1,848,077	620
Methodology	1,410,127	-
Research	1,180,910	-
Supporting services:		
Administrative – general	3,166,048	370,639
Administrative – board	1,006,745	79,255
Total expenses	8,611,907	450,514
Change in net assets	111,412,199	49,558,351
Net assets:		
Beginning	49,558,351	-
Ending	$ 160,970,550	$ 49,558,351

Appendix

Independent Auditor's Report

PCORIFinancial Report 12312011

Patient-Centered Outcomes Research Institute

Board of Governors Meeting
Denver, CO
May 21-22, 2012

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Patient-Centered Outcomes Research Institute

Standing Committee on Conflict of Interest (SCCOI)

PCORI Board of Governors
Denver, CO
Monday, May 21, 2012

pcori

SCCOI Members

Member	Role	Affiliation
Larry Becker	Board of Governors Committee Chair	Xerox
Bob Zwolak	Board of Governors	Dartmouth, Surgeon
Sherine Gabriel	Methodology Committee, Chair	Mayo Clinic, Researcher
Bernard Lo	Ethicist	UC San Francisco – Professor Emeritus
Annette Bar-Cohen	Consumer Advocate	National Breast Cancer Coalition
Art Levin	Consumer Advocate	Medconsumers
Mark Feldstein	Consumer – Media	University of Maryland
Karl Sleight	Counsel to the Committee	Harris Beach, LLC
Lori Frank	Director of Engagement Research	PCORI
Gail Shearer	Senior Advisor	PCORI
Melissa Stern	Director, Strategic Initiatives	PCORI

SCCOI Nomination

Proposal for Membership in the SCCOI:

- **Silvio R. Waisbord**
  - Professor and Associate Director, School of Media and Public Affairs, George Washington University
  - Former Associate Professor and Director of Graduate Programs, School of Media and Public Affairs, George Washington University

About Silvio R. Washboard

Education and Training

- 1993: Ph.D. in Sociology, University of California, San Diego
- 1990: M.A. in Sociology, University of California, San Diego
- 1985: *Licenciatura* in Sociology, Universidad de Buenos Aires, Argentina

Activities

- Edited *Handbook of Global Health Communication,* Wiley, 2012
- Co-author of article about complexity of social mobilization in health communication regarding polio eradication, *Journal of Health Communication,* 2010
- Author of 34 peer reviewed journal articles, 4 books and numerous other publications

Request Motion to Accept Nominees

Nominations for Acceptance
▪ Silvio R. Waisbord

Putting PCORI and COI in Context

- The mission of PCORI transcends any individual or group of individuals
- The integrity and trust of the resulting research is of utmost importance
- Competing for grants in health and health care research is a very competitive field
- Researchers who can successfully compete and produce meaningful results is a pool of scientific talent and expertise in the domain of PCORI is limited
  - We do not want to unnecessarily exclude researchers who have scientific expertise to make significant contributions

There are risks to the PCORI Mission

- There is real or perceived potential for insider knowledge in allowing MC, close relatives (as defined in the Act) of Board or MC, and contractors to compete for PCORI funding, therefore potentially giving these individuals an unfair advantage
  - Board members and the Chair and Vice Chair of the MC are always excluded

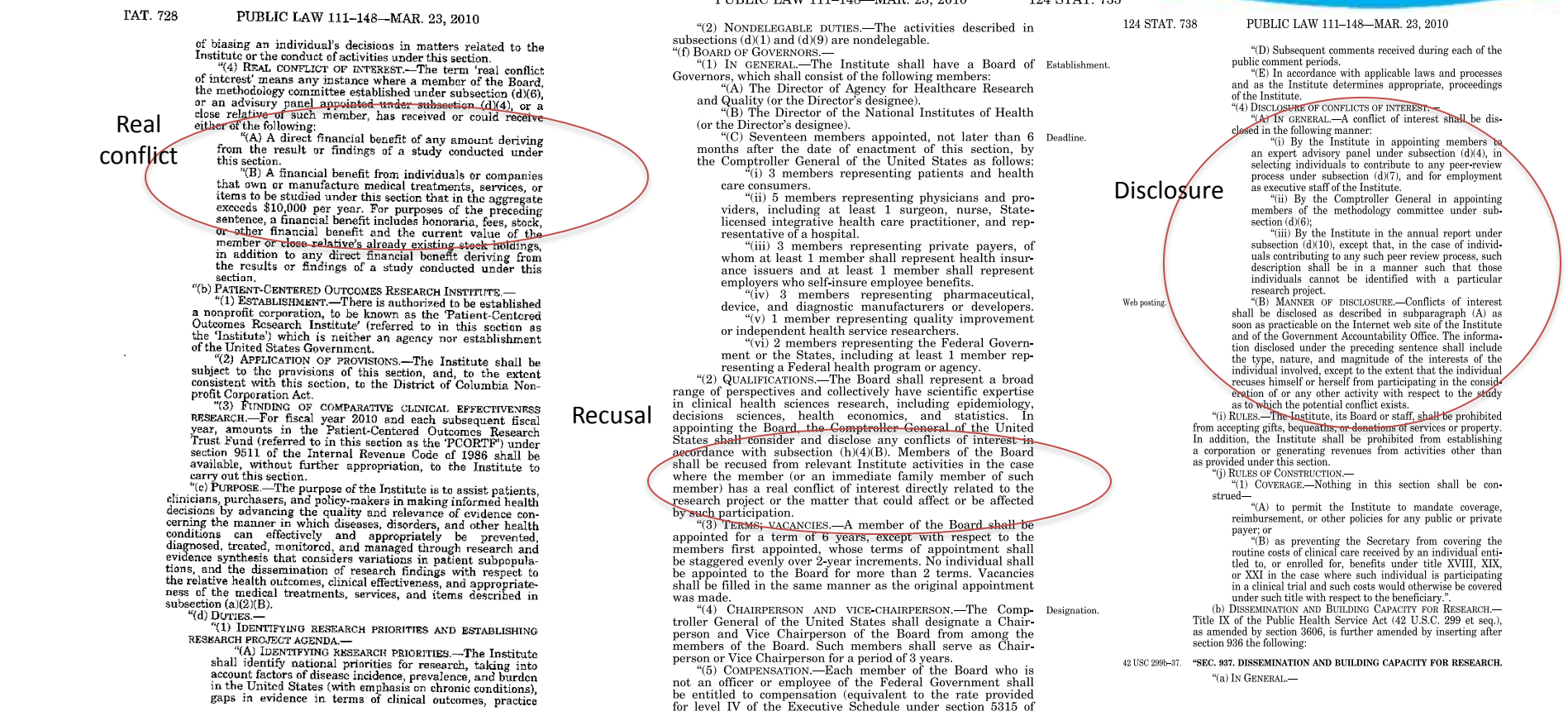
- Rigid eligibility exclusions for MC and close relatives of Board or MC holds potential to exclude some of the country's foremost CER scientists from competing for important grant

There are risks to the PCORI Mission

- Risks stem from the perception of and real advantage from obtaining access to information in advance of others

- The are also the issues of real conflicts involving financial benefit

Determining a conflict of interest – what the law sets out



Real conflict

Recusal

Disclosure

124 STAT. 728 PUBLIC LAW 111–148—MAR. 23, 2010

of biasing an individual's decisions in matters related to the Institute or the conduct of activities under this section.

"(4) REAL CONFLICT OF INTEREST.—The term 'real conflict of intcrest' means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

"(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

"(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds $10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative's already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

"(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—

"(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the 'Patient-Centered Outcomes Research Institute' (referred to in this section as the 'Institute') which is neither an agency nor establishment of the United States Government.

"(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

"(3) FUNDING OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the 'PCORTF') under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

"(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

"(d) DUTIES.—

"(1) IDENTIFYING RESEARCH PRIORITIES AND ESTABLISHING RESEARCH PROJECT AGENDA.—

"(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice

PUBLIC LAW 111–148—MAR. 23, 2010 124 STAT. 735

"(2) NONDELEGABLE DUTIES.—The activities described in subsections (d)(1) and (d)(9) are nondelegable.

"(f) BOARD OF GOVERNORS.—

"(1) IN GENERAL.—The Institute shall have a Board of Governors, which shall consist of the following members: Establishment.

"(A) The Director of Agency for Healthcare Research and Quality (or the Director's designee).

"(B) The Director of the National Institutes of Health (or the Director's designee).

"(C) Seventeen members appointed, not later than 6 months after the date of enactment of this section, by the Comptroller General of the United States as follows: Deadline.

"(i) 3 members representing patients and health care consumers.

"(ii) 5 members representing physicians and providers, including at least 1 surgeon, nurse, State-licensed integrative health care practitioner, and representative of a hospital.

"(iii) 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.

"(iv) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

"(v) 1 member representing quality improvement or independent health service researchers.

"(vi) 2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.

"(2) QUALIFICATIONS.—The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B). Members of the Board shall be recused from relevant Institute activities in the case where the member (or an immediate family member of such member) has a real conflict of interest directly related to the research project or the matter that could affect or be affected by such participation.

"(3) TERMS; VACANCIES.—A member of the Board shall be appointed for a term of 6 years, except with respect to the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments. No individual shall be appointed to the Board for more than 2 terms. Vacancies shall be filled in the same manner as the original appointment was made.

"(4) CHAIRPERSON AND VICE-CHAIRPERSON.—The Comptroller General of the United States shall designate a Chairperson and Vice Chairperson of the Board from among the members of the Board. Such members shall serve as Chairperson or Vice Chairperson for a period of 3 years. Designation.

"(5) COMPENSATION.—Each member of the Board who is not an officer or employee of the Federal Government shall be entitled to compensation (equivalent to the rate provided for level IV of the Executive Schedule under section 5315 of

124 STAT. 738 PUBLIC LAW 111–148—MAR. 23, 2010

"(D) Subsequent comments received during each of the public comment periods.

"(E) In accordance with applicable laws and processes and as the Institute determines appropriate, proceedings of the Institute.

"(4) DISCLOSURE OF CONFLICTS OF INTEREST.—

"(A) IN GENERAL.—A conflict of interest shall be disclosed in the following manner:

"(i) By the Institute in appointing members to an expert advisory panel under subsection (d)(4), in selecting individuals to contribute to any peer-review process under subsection (d)(7), and for employment as executive staff of the Institute.

"(ii) By the Comptroller General in appointing members of the methodology committee under subsection (d)(6);

"(iii) By the Institute in the annual report under subsection (d)(10), except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

"(B) MANNER OF DISCLOSURE.—Conflicts of interest shall be disclosed as described in subparagraph (A) as soon as practicable on the Internet web site of the Institute and of the Government Accountability Office. The information disclosed under the preceding sentence shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of or any other activity with respect to the study as to which the potential conflict exists. Web posting.

"(i) RULES.—The Institute, its Board or staff, shall be prohibited from accepting gifts, bequeaths, or donations of services or property. In addition, the Institute shall be prohibited from establishing a corporation or generating revenues from activities other than as provided under this section.

"(j) RULES OF CONSTRUCTION.—

"(1) COVERAGE.—Nothing in this section shall be construed—

"(A) to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer; or

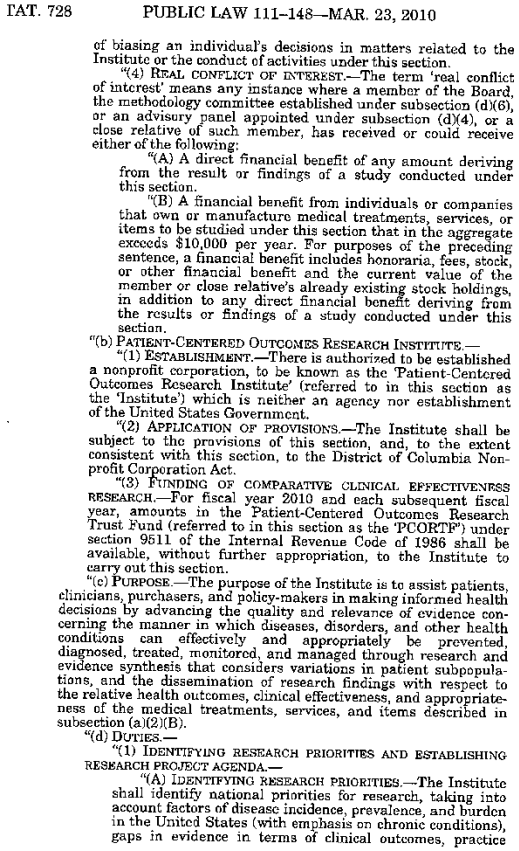
"(B) as preventing the Secretary from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.".

(b) DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by section 3606, is further amended by inserting after section 936 the following:

42 USC 299b–37.

"SEC. 937. DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.

"(a) IN GENERAL.—



124 STAT. 728 PUBLIC LAW 111–148—MAR. 23, 2010

of biasing an individual's decisions in matters related to the Institute or the conduct of activities under this section.

"(4) REAL CONFLICT OF INTEREST.—The term 'real conflict of interest' means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

"(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

"(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds $10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative's already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

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"(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

"(d) DUTIES.—

"(1) IDENTIFYING RESEARCH PRIORITIES AND ESTABLISHING RESEARCH PROJECT AGENDA.—

"(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice

"(4) Real Conflict of Interest. – The **term 'real conflict of interest' means any instance where a member of the Board, the methodology committee** established under subsection (d)(6), or **an advisory panel** appointed under subsection (d)(4), **or a close relative of such member, has received or could receive either of the following:**

"(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

"(B) **A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds $10,000 per year.** For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock or other financial benefit and the current value of member or close relative's already existing stock holdings, in additional to any direct financial benefit deriving from the results or findings of a study under this section. (Bolding added.)

Statutory Basis

- What does the statute tells us?
  - The statute recognized that there will be conflicts
  - The statute provides a mechanism for recusal
  - The statute provided certain limitations / definitions such as $10,000 per annum as financial benefit
- We should use these standards where they exist and are applicable and not create our own
- The statute is silent about receiving money from PCORI

Key Considerations – Awarding Grants

- At every opportunity information should be made public
  - "Information is a market," Dr. Bernard Lo
  - Public knowledge and time with that knowledge mitigates any advantage
  - "Sunlight is said to be the best of disinfectants." Justice Louis Brandeis, 12/20/1913

Key Considerations – Awarding Grants

- Key question to consider: Is there advance knowledge that provides an advantage? Can this be mitigated?
- Clarify and document the specific activities of individuals asked to develop, articulate and score public funding announcements (PFA) e.g., MC, contractors, etc.
  - Provide information about the potential impact to eligibility for PCORI funding for people agreeing to work with PCORI in varied capacities, in advance whenever possible

Key Considerations – Serving the Patient

- The patient is the 'True North'
  - Create clear processes that align with the best interests of patients
  - What policies best protect the patients' interests?
- Communicate a strong conflict-of-interest policy
- Consider a public comment period for our conflict-of-interest policy to obtain input, especially regarding protection of patient interests

Proposal

- Communicate a strong conflict-of-interest policy
- At every opportunity information should be made public – as soon as practical
    - Public means posting, or linking, information at our website www.pcori.org

Proposal

- Develop a series of filters to determine if there is the potential for conflict of interest, specifically a knowledge advantage
  - PFA (Public Funding Announcement) development
  - Setting policies and requirements for funding
  - Developing methods or standards that are required by PFA
  - Criteria for application scoring

Proposal

- Draw a distinction between input and involvement
    - If you are deemed to be involved you are prohibited from applying for grant dollars
- Develop and implement strict policies and firewalls around specific activities
- Those with advance knowledge are prohibited for a defined period of time (MC members, close relatives, contractors, interim researchers, etc.)
- Level the playing field AND allow qualified individuals to contribute their knowledge and expertise to the development of PCOR

Proposal

- All applications continue to be judged on their merits in a blinded process
- The defined period between announcement and eligibility will be the length of one funding cycle
    - Recusal will be required for the first cycle of the PFAs including any PFA for priority #5 regardless of the release date
- PCORI and the SCCOI Committee reserves the right to alter the policy or grant specific waivers, within the confines of the law, by making policy changes or notice of those waivers public
- Put this policy out for public comment following

Proposed Eligibility for PCORI Funding Announcements (PFAs) by Category

Cycle/Time Category	Cycle 1 Priorities 1 – 4 May 2012	Cycle 1 Priority 5 July 2012	Cycle 2 Priorities 1 – 4 November 2012	Cycle 2 Priority 5 February 2013
Board Members	No	No	No	No
Board Member Spouses/Domestic Partners	No	No	Yes	Yes
Methodology Committee Members (Board liaison)	No	No	No	No
Methodology Committee Members (not Board liaison)	No	No	Yes	Yes
Methodology Comm. Spouses/Domestic Partners	No	No	Yes	Yes
Interim researchers, medical editors	No	No	Yes	Yes
Deloitte	No	No	No	No
PFA Contractors (per agreement)	No	No	No	No
Research contractors	Yes	Yes	Yes	Yes
Workshop participants and facilitators	Yes	Yes	Yes	Yes

Proposed Definitions

- *Time period:* Eligibility clock starts when PFA is made public
- *Cycle:* For any specific PFA, an announcement **might** be repeated (e.g., every four months); each new release of a PFA is a new cycle (e.g., cycle 1, cycle 2 etc.)
- *Waiver process:* Submit and rationale to SCCOI.. SCCOI will make recommendation to the Board

Proposed Definitions (con't)

- ***Involved vs. Input:*** "Involvement" means participation in setting policies, requirements, methods standards, criteria. Input means providing expertise and analysis, but bearing no responsibility for final decisions. Research contractors and workshop participants provided input without responsibility for decisions.

Filters

Was there a knowledge advantage?

- involved in PFA development : → ineligible for life
- involved in setting policies and requirements : → ineligible for one cycle
- involved in setting developing methods or standards required by PFA: → ineligible for one cycle
- involved in development of criteria for application scoring: → ineligible for one cycle

Note: New situations could arise for any of the categories in the table, and, as a default, these would be screened through the filters.

Firewalls

- For spouses: statement about lack of discussion
- Create firewalls (e.g., in emails and Evidence) for information about PFAs
- Create standard slide deck
- Training for all who speak publicly about PCORI

DISCUSSION

MOVE TO MAKE THE RECOMMENDATIONS