

Board of Governors Meeting via Teleconference/Webinar

July 18, 2017

12:00 - 1:00 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00 – 12:10	Consider for Approval: Consent Agenda • Minutes of the June 20, 2017 Board Meeting • Revise Patient Engagement Advisory Panel (PEAP) Charter
12:10 – 12:45	Consider for Approval: Shared Decision Making Implementation Initiative
12:45	Wrap Up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director



Motion for Consent Agenda Items

That the Board approve:

- Minutes from June 20, 2017 Board meeting
- Proposed amended Charter for the following PCORI Advisory Panel:
 - Patient Engagement Advisory Panel (PEAP)



Board Vote

Call for a Motion to:

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

Call for the Motion to Be Seconded:

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

Voice Vote:

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



Implementation of Effective Shared Decision Making Approaches in Practice Settings

Request for PFA Development Approval

Debra Barksdale, PhD

Engagement, Dissemination, and Implementation
Committee Chair

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer



Purpose of Proposed Dissemination and Implementation PFA

- To support the targeted implementation and systematic uptake of effective shared decision making (SDM) strategies in healthcare settings and the rigorous evaluation of these efforts
 - Speeding implementation and use of PCORI findings and interventions by end users. Specifically, findings from:
 - PCORI-funded CER of SDM strategies
 - Other PCORI CER, incorporated into existing evidence-based SDM interventions
 - Informing decisions and improving shared decision making at the point of care



PCORI stakeholders have highlighted these specific goals

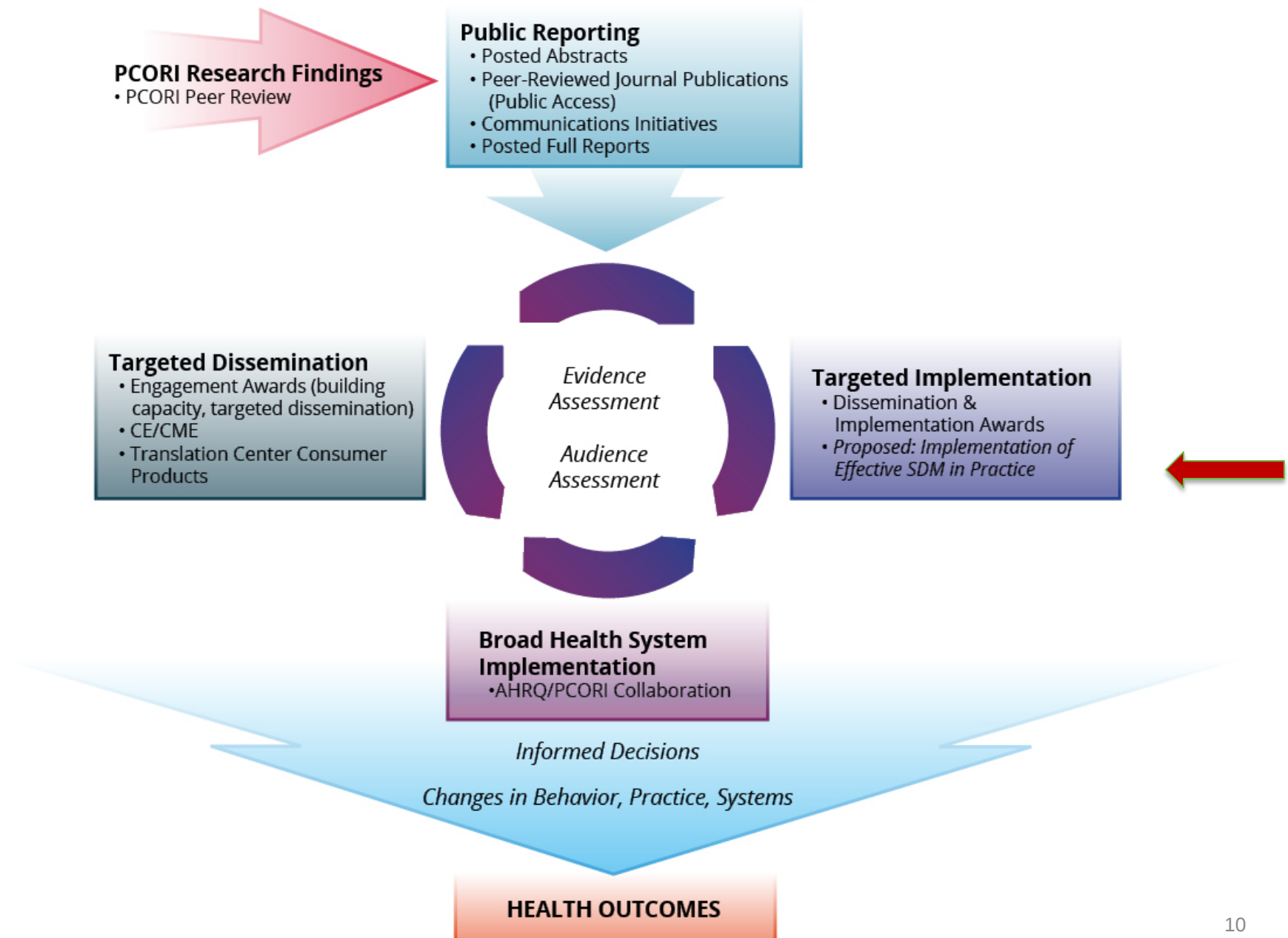
“Information gathered by the Patient-Centered Outcomes Research Institute (PCORI) could be incorporated into certified decision aids and used to provide physicians and patients with valuable information for making health care decisions.

Data about the effectiveness of shared-decision-making techniques could also be ... disseminated by PCORI for continuous improvement of these approaches.”

– Lee & Emmanuel, NEJM 2013 (Perspective)



PCORI DISSEMINATION & IMPLEMENTATION OF RESEARCH RESULTS



Background

- Shared decision making is effective¹:
 - Two decades of research (over 80 RCTs) has established the positive effect of shared decision making approaches on patient knowledge, understanding of risks and benefits, and increased confidence in decisions
- Shared decision making is widely recognized as a key component of patient-centered health care and an important decision making model in the context of uncertainty and preference-sensitive conditions^{2,3}

1 Stacey D, Bennett C, Barry M, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2011. p. CD001431.

2 Elwyn G, Scholl I, Tietbohl C, et al. "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S14. doi:10.1186/1472-6947-13-S2-S14.

3 Spatz E, Krumholz, H, Moulton, B. Prime Time for Shared Decision Making. *JAMA*. 2017; Apr4;317 (13):1309-1310. doi: 10.1001/jama.2017.0616.



PCORI's Research in Shared Decision Making

PCORI has made a significant investment in Patient-Centered Outcomes Research related to shared decision strategies and interventions

- As of July 2017, PCORI has identified **74 PCORI-funded research projects** with a significant shared decision making component.
- **≈\$164M** research investment in these SDM projects
- These research projects address treatment decisions across diverse populations and disease groups.



Select Examples of PCORI SDM Research

1. Shared Decision Making in the Emergency Department: The **Chest Pain** Choice Trial (PI: Erik Hess, Mayo Clinic)
2. Promoting Informed Decisions about **Lung Cancer Screening** (PI: Bob Volk, University of Texas MD Anderson Cancer Center)
3. A Multicenter Trial of a Shared Decision Support Intervention for Patients and their Caregivers Offered **Destination Therapy for End-Stage Heart Failure**: The DECIDE-LVAD Trial (PI: Larry Allen, University of Colorado Denver)
4. Comparative Effectiveness of Decision Support Strategies for **Joint Replacement Surgery** (PI: Karen Sepucha, Massachusetts General Hospital)
5. Shared Decision Making in Parents of **Children with Head Trauma**: Head CT Choice (PI: Erik Hess, Mayo Clinic)
6. Improving Patient Decisions about **Bariatric Surgery** (PI: Amir Ghaferi, University of Michigan at Ann Arbor)
7. Individualized Patient Decision Making for Treatment Choices among **Minorities with Lupus** (PI: Jasvinder Singh, University of Alabama at Birmingham)
8. Comparative Effectiveness of Encounter Decision Aids for **Early-Stage Breast Cancer** across Socioeconomic Strata (PI: Marie-Anne Durand, Trustees of Dartmouth College)
9. Comparative Effectiveness of a Decision Aid for **Therapeutic Options in Sickle Cell Disease** (PI: Lakshmanan Krishnamurti, Emory University)
10. Comparing Traditional and Participatory Dissemination of a Shared Decision Making Intervention for **Asthma Care** (PI: Hazel Tapp, Carolinas Medical Center)



PCORI SDM Results Are Incoming

- We expect that 41 of our 74 funded SDM research projects will have produced results by the proposed due date for applications to the SDM Implementation initiative



First Cycle Funding Announcement Overview

Project Budget	Up to \$1.5M direct costs (≈\$2.1M total)
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Project Period	2-3 years*
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Funds Available	Up to \$6.5M total costs per cycle
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Eligibility	Limited Competition
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**For projects of 3-year duration, PCORI will require interim as well as final submission of evaluation data.*



Goals of the SDM Implementation PFA

- Implement the findings from an area where PCORI has a significant research investment
- Advance the uptake and use of effective shared decision making strategies
- Advance the uptake and use of evidence via SDM strategies to improve informed decision making, successful completion of chosen treatment regimens, and health outcomes.

Definitions: For purposes of this PFA, PCORI defines an SDM strategy as an intervention or approach that:

- draws on and presents available evidence to inform patients of available treatment options and their risks and benefits and...
- either engages patients in a decision making process with their clinician and other members of their healthcare team or promotes their ability to engage in such a process



Eligibility

- Limited competition PFA -- Eligibility is limited to research teams that have previously received PCORI research awards.
- To be eligible for this award, applicants must either:
 - Have completed a PCORI-funded CER of a shared decision making strategy, which is the focus of the proposed implementation project.
 - Have completed a PCORI-funded CER of a prevention, treatment, or other healthcare intervention and have identified an existing (tested) SDM strategy that can incorporate this evidence, which is the focus of the proposed implementation project.



Funding Announcement Requirements

- **Applicant Requirements related to SDM Strategy:**
 - Demonstrate that the proposed SDM strategy has been **developed and tested with rigor and transparency**, in alignment with existing quality standards.
 - Document that the proposed SDM strategy has **demonstrated effectiveness** on patient, caregiver and/or healthcare provider decision making.
 - Propose to implement an SDM strategy informing a **preference-sensitive decision**.



Funding Announcement Requirements

- **Applicant Requirements related to Implementation Approach:**
 - Propose a multi-component implementation strategy, which comprehensively addresses barriers and obstacles to SDM uptake, integration into practice, and maintenance.
 - Conduct a rigorous evaluation of the effectiveness of the proposed implementation approach and the continued effectiveness of the SDM strategy on decisional, healthcare utilization, and clinical outcomes.
 - Incorporate the perspectives and experiences of patients and stakeholders, including individuals living with the disease or condition of interest, and describes how front-line staff, care providers and leadership of host delivery settings have been and will remain involved.



Funding Announcement Requirements: Tracking Impact

We will require metrics across funded projects describing:

- **Effectiveness of implementation strategy**
 - Reports on barriers, facilitators of success
 - Changes in skills, attitudes, culture within implementation setting
 - Reach, adoption, maintenance of multi-component approaches
- **Effectiveness of SDM strategy**
 - Improved decision making process -- patients more informed and involved, less conflicted
 - Improved decision making -- patients more knowledgeable regarding options; decisions concordant with priorities and preferences
- **Outcomes associated with implementation of SDM**
 - Healthcare utilization
 - Proximal health outcomes



Timeline

Action	Date
Engagement, Dissemination and Implementation Committee (EDIC) Endorsement	June 13, 2017
Board of Governors Vote	July 18, 2017
Preannouncement Released	August 1, 2017
PFA Announced	September 6, 2017
Letter of Intent Due	October, 2017
Application Deadline	January, 2018
Merit Review	March, 2018
Awards Announced	July, 2018

- Proposed timeline has been adjusted based on EDIC recommendations, **reducing time to award by 6 months.** (Original timeline was: PFA announcement January, 2018; awards announced November, 2018.)
- We anticipate additional cycles during FY-2018



Board Vote

Call for a Motion to:

- **Approve** the development of a PFA for Implementation of Shared Decision Making in Practice Settings with an initial cycle of \$6.5M (total costs) and additional cycles not to exceed the Board approved budget amounts for the D&I program

Call for the Motion to Be Seconded:

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

Roll Call Vote:

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



Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chairperson, Board of Directors

