Special Board of Governors Teleconference/Webinar

December 3, 2013

12:00 p.m. – 1:00 p.m. ET

Patient-Centered Outcomes Research Institute

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

TIME	AGENDA ITEM
12:00 – 12:05 p.m.	Call to Order and Welcome
12:05 – 12:15 p.m.	Consideration of Advisory Panels' Reauthorization: • Assessment of Prevention, Diagnosis, and Treatment Options • Improving Healthcare Systems • Addressing Disparities • Patient Engagement
12:15 – 12:30 p.m.	Proposal to support statistical modeling to improve understanding of prevention, screening, and treatment interventions in cancer • Consideration of proposal for Approval
12:30 – 12:45 p.m.	PCORI Funding Announcement (PFA) on the Effectiveness of Hospital-to-Home Transitional Care • Consideration of PFA for Approval
12:45 – 12:55 p.m.	PCORI Funding Announcement (PFA) on Obesity Treatment Options in Primary Care for Underserved Populations: Pragmatic Clinical Trials (PCTs) to Evaluate Real World Comparative Effectiveness • Consideration of PFA for Approval
12:55 – 1:00 p.m.	Modifications to the Board and Methodology Committee Member Compensation Policy • Consideration of Modifications for Approval
1:00 p.m.	Wrap-up and Adjournment

Reauthorization and Updated Governance for Four Advisory Panels

Mary Hennessey, Esq., General Counsel
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Background

- In April 2013, the PCORI Board approved charters for these four Advisory Panels:
  - Addressing Disparities
  - Assessment of Prevention, Diagnosis, and Treatment Options
  - Improving Healthcare Systems
  - Patient Engagement
- All panels were authorized for one-year and members were appointed for one-year terms
- All four panels are underway; for planning purposes, it makes sense to re-authorize the panels

Updated Governance Structure and Authorization

- To ensure that each Advisory Panel benefits from having both experienced members and new members, it is proposed that the governance structure be updated:
  - Members will serve 3-year, staggered terms
  - Members will be limited to serving one full 3-year term
- For consistency and planning relating to these panels, it is proposed that:
  - These panels be re-authorized for five years, until December 31, 2018, subject to review, reauthorization, amendment or termination by the Board

2014 Implementation Plan

- To transition into a staggered term structure in 2014:
  - A third of the members will be appointed for a 1-year term, a third for a 2-year term, a third for a 3-year term
  - Appointments will take into account the need to spread stakeholders across the three groups
- Since these four advisory panels are in their inaugural year, current members will be asked if they are interested in being re-appointed
- Slates of proposed members for these four advisory panels will be brought to the Board for appointment in 2014

Review by PCORI Committees

- The following PCORI Committees reviewed and support the proposed reauthorization, updated governance structure, and plan for implementation:
  - Program Development Committee
  - Finance, Audit, and Administrative Committee
  - Communications, Outreach, and Engagement Committee

Board Vote: Approval of Updated Charters for Four Advisory Panels

Call for a Motion to:	• **Approve** the revised charters for the advisory panels on Addressing Disparities, Assessment of Options, Improving Health Systems, and Patient Engagement and the implementation plan
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:	• Roll Call Vote to **Approve** the **Final** Motion
	  • Ask for votes in favor
	  • Ask for votes opposed
	  • Ask for abstentions

Proposal to Co-sponsor with NCI: Cancer Intervention and Surveillance Modeling Network (CISNET)

Bryan Luce, PhD, MBA, Chief Science Officer

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Rationale for Co-Funding

- Opportunity to influence NCI-sponsored CISNET/NCI collaborative consortium of academic modelers to be:
  - More patient (vs. population) centric
  - Increased focus on disparity populations

  (**Aligned with strategic goal #3: Influence other funders**)
- Opportunity to improve PCOR by:
  - Applying sophisticated modeling techniques
  - Linking PCORI awardees to CISNET investigators

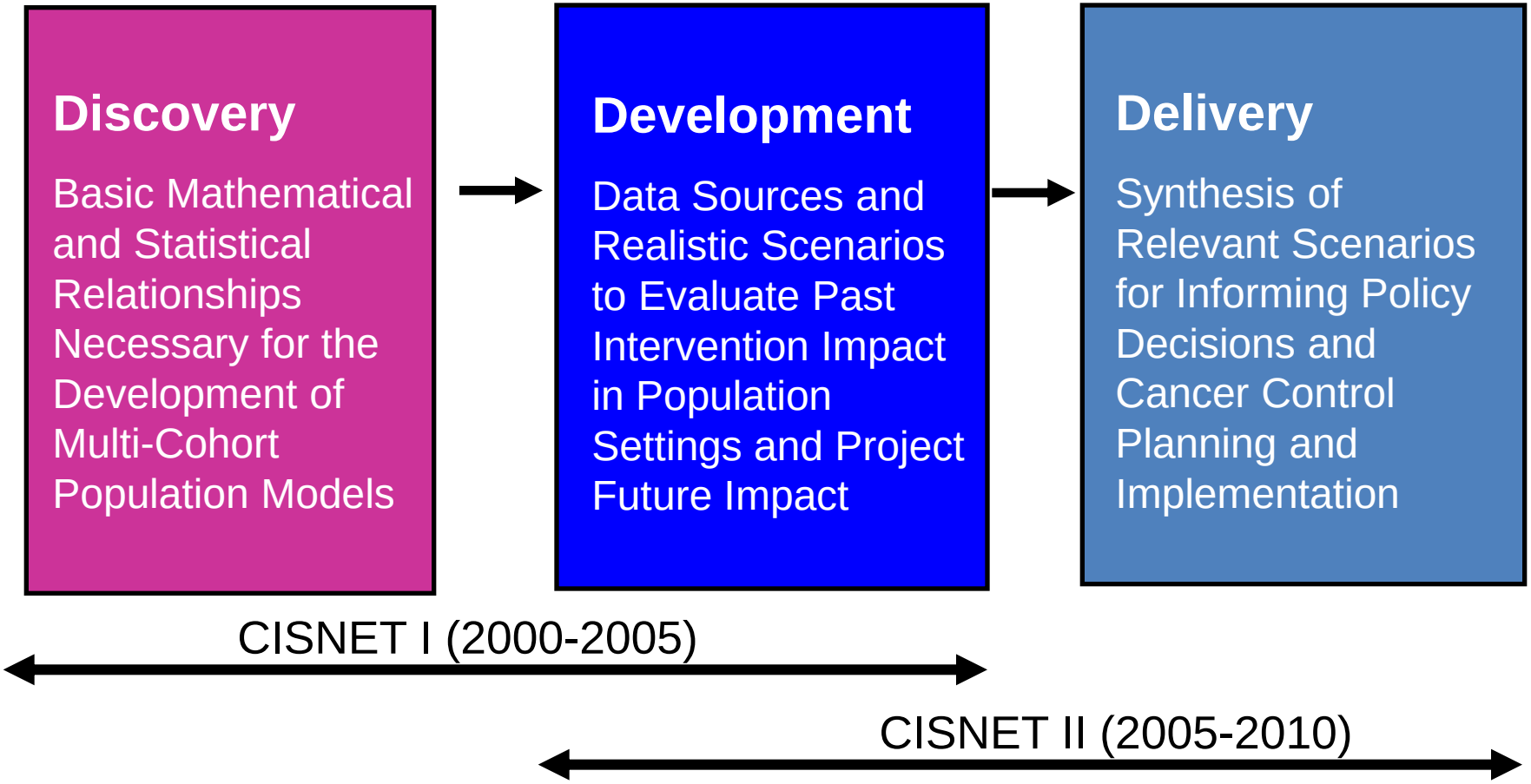
  (**Aligned with strategic goal #1: Increasing PCOR**)

  (Note: CISNET is a high profile, (arguably) best-in-class modeling/simulation collaborative program)
- Modeling is a core CER methodology and needs continued technical support

  (**Consistent with CER methods development mission**)
- PDC conditionally endorsed co-funding CISNET

CISNET Background

- NCI Sponsored since 2000
- Collaborative Consortium of Academic Modelers
- Objective: Using simulation modeling to guide health research and priority setting in cancer


Discovery
Basic Mathematical and Statistical Relationships Necessary for the Development of Multi-Cohort Population Models
Development
Data Sources and Realistic Scenarios to Evaluate Past Intervention Impact in Population Settings and Project Future Impact
Delivery
Synthesis of Relevant Scenarios for Informing Policy Decisions and Cancer Control Planning and Implementation
CISNET I (2000-2005)
CISNET II (2005-2010)

Patient-Centered Focus of CISNET III (2010-2015)

- Incorporating genomic and family history risk profiles;
- Comparative effectiveness and downstream modeling;
- Evaluating diagnostic tests;
- Optimizing biomarker development strategies;
- Suggesting optimal routes to reducing health disparities;
- Including interactive decision-making tools

CISNET III Coordinating Centers (2010-2015)

- Fred Hutchinson Cancer Research Center (Prostate)
- Massachusetts General Hospital (Esophagus)
- Massachusetts General Hospital (Lung)
- Memorial Sloan-Kettering Cancer Center (Colorectal)
- Georgetown University Medical Center (Breast)

Selected CISNET Contributions to Date

- **Supported US Preventive Services Task Force screening guidelines for patient-centered questions in colorectal, breast, and lung cancers**
  - If I have a negative colonoscopy at age 50, do I need to return for subsequent ones every 10 years? (AIM, 2012)
  - How old should a previously unscreened individual consider initiating colorectal cancer screening? (under review)
  - At what age should breast and colorectal cancer screening stop for those with no, mild, moderate, or severe co-morbid conditions? (under review)
  - What is the tipping point in terms of risk of breast cancer for a 40 year old woman so that the harm/benefit ratio matches that of an average risk woman age 50-74 undergoing biennial mammography? (AIM, 2012)

Our Proposal for Board Decision

- Co-fund CISNET with NCI
  - $1M/year for 5 years: Total = $5M
    - Note: subject to annual review and renewal
  - MOU to include issues of importance to PCORI, e.g.:
    - Specification of patient-centered questions/outcomes
    - PCORI role in future CISNET activities (*e.g.* PCORI representative on the Steering Committee)
    - Opportunities to link PCORI awardees with CISNET investigators

Board Vote: Support CISNET Co-funding Proposal

Call for Motion to:	• **Approve co-funding** CISNET subject to development of an MOU that addresses issues of importance to PCORI (in consultation with the PDC)
Once the Motion Is Seconded:	• **Second** the Motion • If further discussion, may propose **Amendment** to the Motion or an **Alternative** Motion
Vote:	• Roll Call Vote to **Approve** the **Final** Motion • Ask for votes in favor • Ask for votes opposed • Ask for abstentions

Targeted Funding Announcement: Transitional Care (TC)

Bryan Luce, PhD, MBA, Chief Science Officer
PCORI Board of Governors Meeting
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Background

Topic Development

- Topic identified through the PCORI “Topic Generation and Research Prioritization Process”
- Commissioned a Topic Brief
- Advisory Panel prioritized TC as one of the top two research topics (4/19-4/20)
- Conducted a literature review
- Expert workgroup convened – 7/12
  - Focus on complex interventions including care in hospital, during transition to home, at home, elsewhere

Components of Good Transitional Care

- **Pre-discharge assessment** of patients' (and caregivers') risks and capacity for participating effectively in transitional care
- **Pre-discharge planning** for the whole transitional phase (not just for the discharge from the hospital)
- **Medication reconciliation** and safe administration
- **Preparation** of patients and caregivers to participate
- **Physiologic monitoring** after discharge
- **Provision** of complete, accurate, timely **information to** the **receiving professionals**
- **Promotion of adequate sleep, nutrition, physical activity, safety and emotional well-being** during transitional care
- **Coordination** of transitional care by a health professional

The Problem

TC consists of unstandardized clusters of component services, resulting in:

- Omissions
- Errors
- Discontinuity
- Stress
- Adverse events
- Emergency department visits
- Potentially avoidable re-admissions
- Increased mortality

Ongoing Efforts

- In U.S.: 500+ hospitals and communities testing TC innovations
  - Community-based Care Transitions Program (CMMI/CMS)
  - Quality Improvement Organizations (CMS)
  - Better Outcomes by Optimizing Safe Transitions (BOOST)
- Main focus: 30 day readmission rate
- Lack of focus: other patient-centered outcomes
- No systematic efforts to determine which TC service clusters are most effective in improving readmission rates and patient well-being, among other patient-centered outcomes:
  - For different sub-populations (e.g., rural, low-income)
  - In different health care contexts (e.g., FFS, capitation)

PCORI's Opportunity

To fund CER to:

- Take advantage of the current widespread TC experimentation across 500+ U.S. sites
- Determine which TC services and/or clusters of services:
  - Are most effective for whom under what circumstances in improving 30-day readmission rates *and* patient well-being; and
  - Which clusters are potentially scalable – in different subpopulations and healthcare contexts

Proposed Targeted PCORI Funding Announcement

PCORI proposes to allocate up to $15 million to fund one 3-year comprehensive study.

- Multi-center randomized trial of innovative and scalable multi-dimensional model(s) of TC
  - Compare components/clusters of different TC models (i.e. pre-discharge assessment and planning, medication reconciliation, post-discharge follow-up, etc.)
  - Role of alternative and lay providers (i.e. social workers, case managers, etc.)
  - Use of technology including telehealth
  - System dash level factors including assessment of provider satisfaction with TC models

Proposed Targeted PCORI Funding Announcement

- The contractor should:
  - Identify specific populations and healthcare contexts with distinct needs for tailored TC programs
  - Draw purposeful samples of well-implemented TC programs in cooperative organizations that are serving those specified populations/contexts
  - Characterize each of these TC program's patient population, healthcare context, and constellation of TC services
  - Measure the TC services received, important PROs, and the re-admission rates before and after implementation of the TC program
  - Compare the re-admission rates of different TC programs that serve similar populations in similar healthcare contexts
  - Measure the independent associations between TC services received and TC programs' effectiveness

Timeline

Action	Date
Release Date	Feb 5, 2014
PCORI Online System Opens	Feb 5, 2014
Applicant Town Hall Session (Webinar)	TBD
Letter of Intent Due	5:00 PM (EST), March 7, 2014
Application Deadline	5:00 PM (EST), May 6, 2014
Merit Review	Week of August 4, 2014
Awards Announced	September 2014

Board Vote: Transitional Care PFA

Call for a Motion to:	• **Approve** the transitional care PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • **If further discussion, may propose Amendment to the Motion or an Alternative Motion**

Vote:	• **Roll Call Vote to Approve the Final Motion**
	  • **Ask for votes in favor**
	  • **Ask for votes opposed**
	  • **Ask abstentions**

Targeted Funding Announcement: Obesity Treatment Options

Romana Hasnain-Wynia, PhD, Program Director, Addressing Disparities

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Obesity treatment options in primary care for underserved populations: Pragmatic Clinical Trials (PCTs) to evaluate real-world comparative effectiveness

Targeted Funding Announcement from Addressing Disparities Program

Background

- Task Force (convened after Ad Hoc Workgroup) Recommendation
  - Focus on addressing treatment options in primary care
- Behavioral treatment including a combination of diet, physical activity, nutrition, and behavioral therapy, is considered the first line of treatment for obesity and has shown to yield clinically significant weight loss in small, well-controlled randomized trials, sustained for up to two years
- Evidence is lacking about the comparative effectiveness of components of behavioral treatments, particularly in primary care settings and for underserved populations such as racial/ethnic minorities and rural populations

Recommendation for Targeted PCORI Funding Announcement

- **Multi-site** pragmatic clinical trials to test the comparative effectiveness of **multi-component behavioral therapy interventions** (case theory-based; cognitive behavioral therapy or other effective behavioral change strategies) set within **primary care** for achieving weight loss in obese patients who are at risk for experiencing disparities in outcomes
  - Racial/ethnic minorities
  - Low SES populations
  - Rural populations

Recommendation for Targeted PCORI Funding Announcement

- Innovative and adaptive pragmatic trials (Bayesian adaptive trial methods as an approach is of particular interest) that:
  - Compare three or more clinically relevant alternatives;
  - Enroll diverse study populations at risk for disparities;
  - Recruit from a variety of practice settings;
  - Measure a broad range of patient-centered, clinical, and structural outcomes;
  - Adapt the intervention being tested to the local context
  - Increase statistical power:
    - Increase randomization to study arms performing well
    - Drop arms for futility

Multi-component Interventions Could Include:

- Comparing behavioral interventions (2-year follow-up)
- Use of technology, such as HIT or smartphones
- The role of the MD, PA, NP, and other clinical professionals (nurses, dieticians, social workers, other) within the practice or in the community
- Practitioner training component
- Reimbursement strategies
- Co-pay limitations
- System-level factors to change practice and care delivery to improve obesity-related outcomes
  - A baseline assessment of what practices look like and how infrastructure changes to deliver care
  - Interventions conducted in different settings can differ in their ability to support different behavioral theories. They may differ in a number of dimensions including in who implements the programs; setting-specific data will be more useful for end users such as policy makers, patients, clinicians

Budget, Project Period, Outcomes

- PCORI expects to commit up to $20 million in total costs to fund one to two multi-site pragmatic trials
- Maximum amount for each trial for five years will be $10 million in total costs
- PCORI encourages projects of shorter duration or requesting less than above amount if they demonstrate that they can meet the objectives of this funding announcement in a shorter timeframe
- It is expected that project budgets and duration will vary depending on the study approach, needs for recruitment and/or primary data collection, required length of follow-up, and analytic complexity
- Outcomes: BMI; ≥5% sustained weight loss; QOL; self-management behaviors; BP, lipids, HbA1c

Timeline

Action	Date
Release Date	Feb 5, 2014
PCORI Online System Opens	Feb 5, 2014
Applicant Town Hall Session (Webinar)	Feb 15, 2014
Letter of Intent Due	5:00 PM (EST), March 7, 2014
Application Deadline	5:00 PM (EST), May 6, 2014
Merit Review	Week of August 4, 2014
Awards Announced	September 2014

Board Vote: Obesity Treatment Options PFA

Call for Motion to:	• **Approve the Obesity Treatment Options PFA as endorsed by the PDC**
Once the Motion is Seconded:	• **Second the Motion** • **If further discussion, may propose Amendment to the Motion or an Alternative Motion**
Vote:	• **Roll Call Vote to Approve the Final Motion** • **Ask for votes in favor** • **Ask for votes opposed** • **Ask for abstentions**

Revisions to Board and Methodology Committee Compensation and Reimbursement Policy

Regina Yan, COO, Chief Operating Officer

PCORI Board of Governors Meeting
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Background

- The PCORI Board of Governors approved a Board and Methodology Committee Compensation and Reimbursement Policy on May 6, 2013
- It establishes compensation and reimbursement for the Board and Methodology Committee members, including a framework for a monthly stipend and calculation of time for Board and Committee meetings and calls
- The Policy specifically provides that payments will be made directly to each Board and Methodology Committee member in his or her individual capacity

Rationale

- The primary proposed changes to the policy allow for increased flexibility of payment directly to an employer upon request of the individual member, subject to certain conditions.
- The employer must agree to PCORI terms, conditions, and policies. For example, PCORI needs to ensure that:
  - A Board or Methodology Committee member's work related to their PCORI service is owned by PCORI, not their employer
  - The employer recognizes that the Board Member or Methodology Committee member has made commitments of confidentiality to PCORI
- Additionally, clarifying language confirms that a Board or Methodology Committee member will be compensated for attendance both at meetings and planning sessions

Compensation and Reimbursement Policy

The most significant modification in the Board and Methodology Compensation and Reimbursement policy is the ability to direct payment to an employer, rather than only to an individual.

(a) Payments: All payments will be made directly to each Board and Methodology Committee member in his or her individual capacity. At the written request of a Board or Methodology Committee member, payments may be made to the member's employer, subject to the employer's agreement to PCORI terms, conditions, and policies, including those addressing intellectual property, confidentiality, and payment. Additionally, a~~A~~ Board or Methodology Committee member may decline ~~must make a request in writing to PCORI if he or she does not want~~ to receive compensation upon written notice to PCORI.

Board Vote: Approval of Proposed Changes to Board and Methodology Committee Compensation and Reimbursement Policy

Call for a Motion to:	• **Approve** the proposed changes to the Board and Methodology Committee Compensation and Reimbursement Policy
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:	• Roll Call Vote to **Approve** the **Final** Motion
	  • Ask for votes in favor
	  • Ask for votes opposed
	  • Ask for abstentions

Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

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