Board of Governors Meeting
via Teleconference/Webinar

August 15, 2017

12:00 - 2:00 pm ET

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Robert Zwolak, MD, PhD

Acting Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:05	**Consider for Approval: Consent Agenda** • Minutes of the July 18, 2017 Board Meeting • Nomination for Committee Appointment
12:05–12:20	**Consider for Approval:** New Advisory Panelists
12:20-2:40	**Consider for Approval:** Cycle 3, 2016 Broad PFA Awards
12:40-1:00	**Consider for Approval:** Cycle 3, 2016 Targeted PFA Award – Opioid Prescribing
1:00-1:20	**Consider for Approval:** Cycle 3, 2016 Targeted PFA Award – Palliative Care
1:20	Wrap up and Adjournment

Consent Agenda Items

Robert Zwolak, MD, PhD

Acting Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Motion for Consent Agenda Items

That the Board approve:

- Minutes from the July 18, 2017 Board meeting

- Nomination by the Governance Committee of Board Member Gopal Khanna to serve on the Engagement, Dissemination and Implementation Committee (EDIC)

Board Vote

Call for a Motion to:	• **Approve** the Motion for Consent Agenda Items
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

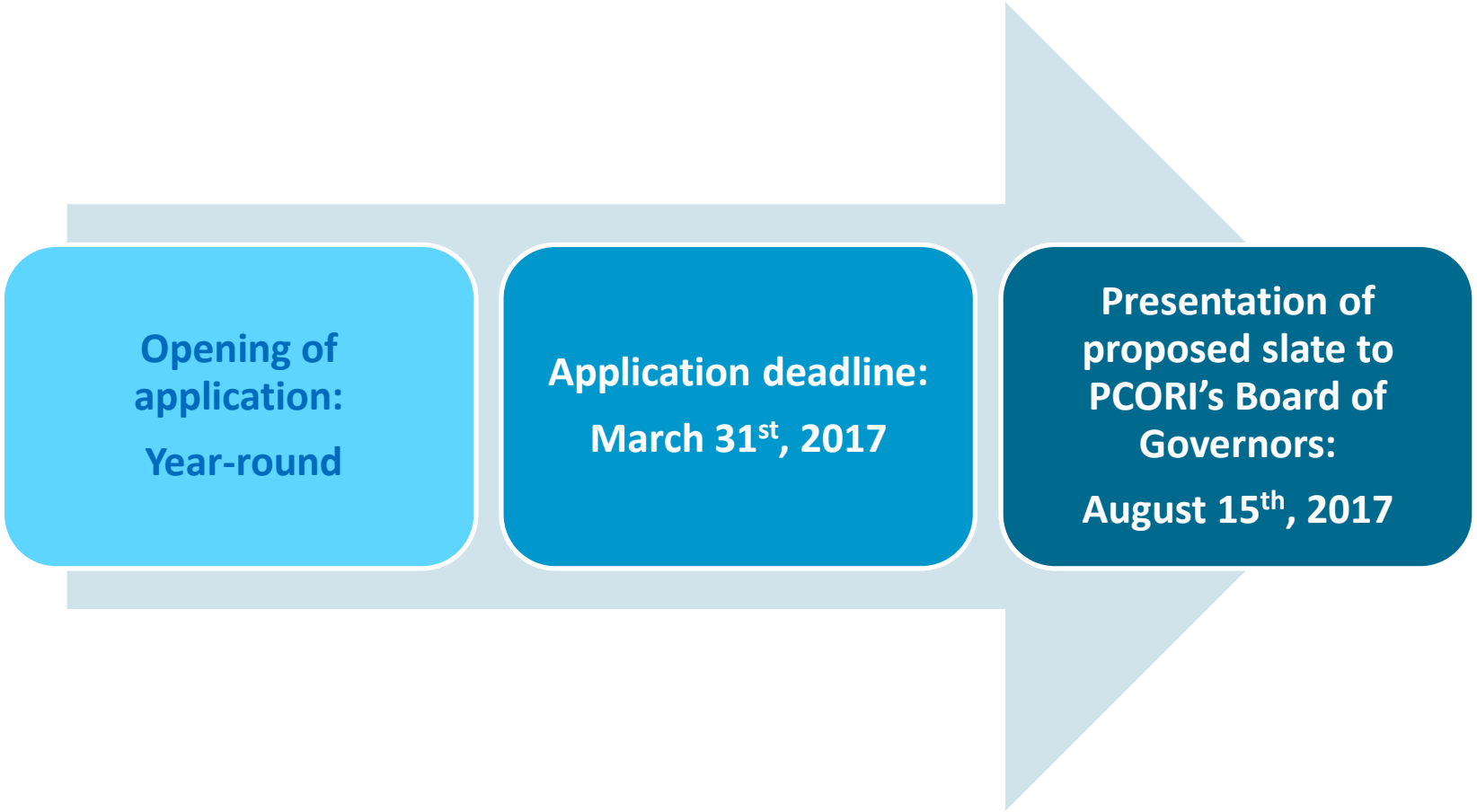
Approving New and Reappointed Advisory Panelists

Evelyn Whitlock, MD, MPH
Chief Science Officer

Objectives

Advisory Panels Application and Selection Process Overview	• Key information regarding the openings and applications received in this cycle of selection
Proposed Advisory Panel Members	• Review and approve proposed Advisory Panel members, positions and terms

Timeline


Opening of application:
Year-round
Application deadline:
March 31st, 2017
Presentation of proposed slate to PCORI's Board of Governors:
August 15th, 2017

Openings and Applications Received

Advisory Panel	Open Positions	Applications Received
Assessment of Prevention, Diagnosis, and, Treatment Options	2 to 9	32
Improving Healthcare Systems	0 to 6	48
Addressing Disparities	1 to 7	51
Patient Engagement	0 to 9	79
Clinical Trials	3 to 8	38
Rare Disease	1 to 7	10
Communication and Dissemination Research	0	4*
TOTAL	7 to 46	151**

***Applications are accepted on a rolling basis, which is why there were application but no openings**
****Applicants were able to apply to a maximum of two Advisory Panels, which is why this number does not equal the sum of the applications received**

3rd Party Nominations Received From:

- American Academy of Nursing
- American Society for Radiation Oncology
- American Urological Association
- Association of Community Cancer Centers
- Celiac Disease Foundation
- Infectious Diseases Society of America
- New York University Langone Medical Center
- North American Spine Society
- North Carolina Department of Health and Human Services- Office of Minority Health and Health Disparities
- Pulmonary Hypertension Association
- UsAgainstAlzheimer's

Advisory Panel on Addressing Disparities: Proposed Panelists and Alternates

Name	Stakeholder Group	Term (in Years)
Nadine Barrett*	Hospital/Health System	3
Cheryl Holly	Researcher	3
Mary Grace Pagaduan	Patient/ Caregiver/ Patient Advocate	3
Alternate Candidate		
Sumedha Chhatre	Researcher	3

***Proposed panelists that were nominated by a third party organization have been marked with an asterisk**

Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options: Proposed Panelists

Name	Stakeholder Group	Term (in Years)
Lawrence Goldberg	Clinician	3
Melissa Hicks	Patient/Caregiver/ Patient Advocate	3
Robin Karlin	Patient/Caregiver/ Patient Advocate	3

Advisory Panel on Clinical Trials: Proposed Panelists

Name	Stakeholder Group	Term (in Years)
Jacqueline Halladay	Researcher	3
Elisa Hurley	Training Institution	3
Hartley Jones	Patient/Caregiver/Patient Advocate	3
Richard Page	Clinician	3
Andrea Troxel*	Researcher	3
F. Todd Wetzel*	Clinician	3

***Proposed panelists that were nominated by a third party organization have been marked with an asterisk**

Communication and Dissemination Research: Proposed Reappointments

Name	Stakeholder Group	Term (in Years)
Reappointed Members		
Nancy Blake	Clinician	3
Neela Goswami	Researcher	3
Helen Osborne	Patient/Caregiver/ Patient Advocate	3
Ruth Parker	Patient/Caregiver/ Patient Advocate	3
Andrew Rosenberg	Patient/Caregiver/ Patient Advocate	3
Sandi Smith	Researcher	3
Cornell Wright	Policy Maker	3

Advisory Panel on Improving Healthcare Systems: Proposed Panelists and Alternates

Name	Stakeholder Group	Term (in Years)
Danielle Brooks	Industry	3
Rachel Raia	Payer	3
James Wharam	Researcher	3
Alternate Candidate		
Mary Kathleen Kenyon	Patient/ Caregiver/ Patient Advocate	3

Advisory Panel on Patient Engagement: Proposed Co-Chair

Name	Stakeholder Group	Term (in Years)
New Co-Chair		
David White	Patient/ Caregiver/ Patient Advocate	1

Advisory Panel on Patient Engagement: Proposed Panelists and Alternates

Name	Stakeholder Group	Term (in Years)
Sonya Ballentine	Patient/Caregiver/ Patient Advocate	3
Katherine Capperella	Industry	3
Brendaly Rodriguez	Patient/Caregiver/ Patient Advocate	3
Beverly Rogers	Patient/Caregiver/Patient Advocate	3
Thomas Scheid	Patient/Caregiver/ Patient Advocate	3
Norah Schwartz	Researcher	3
Freddie White-Johnson	Patient/Caregiver/ Patient Advocate	3
Alternate Candidates		
David Andrews	Patient/Caregiver/ Patient Advocate	3
Betty Scull	Patient/Caregiver/ Patient Advocate	3

Advisory Panel on Rare Disease: Proposed Panelists

Name	Stakeholder Group	Term (in Years)
Julie Abramson	Patient/Caregiver/ Patient Advocate	3
Cindy Luxhoj	Patient/Caregiver/ Patient Advocate	3
Stephen Mathai*	Researcher	3
Marcia Rupnow	Industry	3

***Proposed panelists that were nominated by a third party organization have been marked with an asterisk**

Board Vote

Call for a Motion to:	• **Approve** the proposed slates of members, positions and terms for the following Advisory Panels: AD, APDTO, CDR, CT, IHS, PE, and RD
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

Cycle 3, 2016
Budget Overview

Christine Goertz, DC, PhD
Chair, Selection Committee

Leah Hole-Marshall, JD
Vice-Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Budget Overview – Remainder of Fiscal Year 2017

35 Projects

Board Meeting	Cycle 3, 2016 PFA	Amount Budgeted	Proposed / Estimated Total Budget	Difference
August 15 Board Meeting	**Broad + 2 Targeted PFAs**	$115 Million	$119.4 Million	**+ $4.4 Million**
September 12 Board Meeting	**PCS + 3 Targeted PFAs**	$134 Million	$104.4 Million	**- $29.6 Million**
	TOTAL:	**$249 Million**	**$223.8 Million**	**- $25.2 Million**

Cycle 3, 2016
Broad PFA Slate

Christine Goertz, DC, PhD
Chair, Selection Committee

Leah Hole-Marshall, JD
Vice-Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Overview of Funding Opportunities

Broad Cycle 3, 2016

PFA	Maximum Project Length
Addressing Disparities	3 Years
Assessment of Prevention, Diagnosis, and Treatment Options	3 Years
Communications and Dissemination Research	3 Years
Improving Healthcare Systems	5 Years (Large Studies) 3 Years (Small Studies)
Improving Methods for Conducting Patient-Centered Outcomes Research	3 Years

Broad Cycle 3, 2016

Merit Review Criteria

Broad PFAs (excluding Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
1. Potential for the study to fill critical gaps in evidence	**1. Study identifies critical methodological gap(s) in PCOR/CER**
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care	**2. Potential for the study to improve PCOR/CER methods**
3. Scientific merit (research design, analysis, and outcomes)	3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment	4. Investigator(s) and environment
5. Patient-centeredness	5. Patient-centeredness
6. Patient and stakeholder engagement	6. Patient and stakeholder engagement

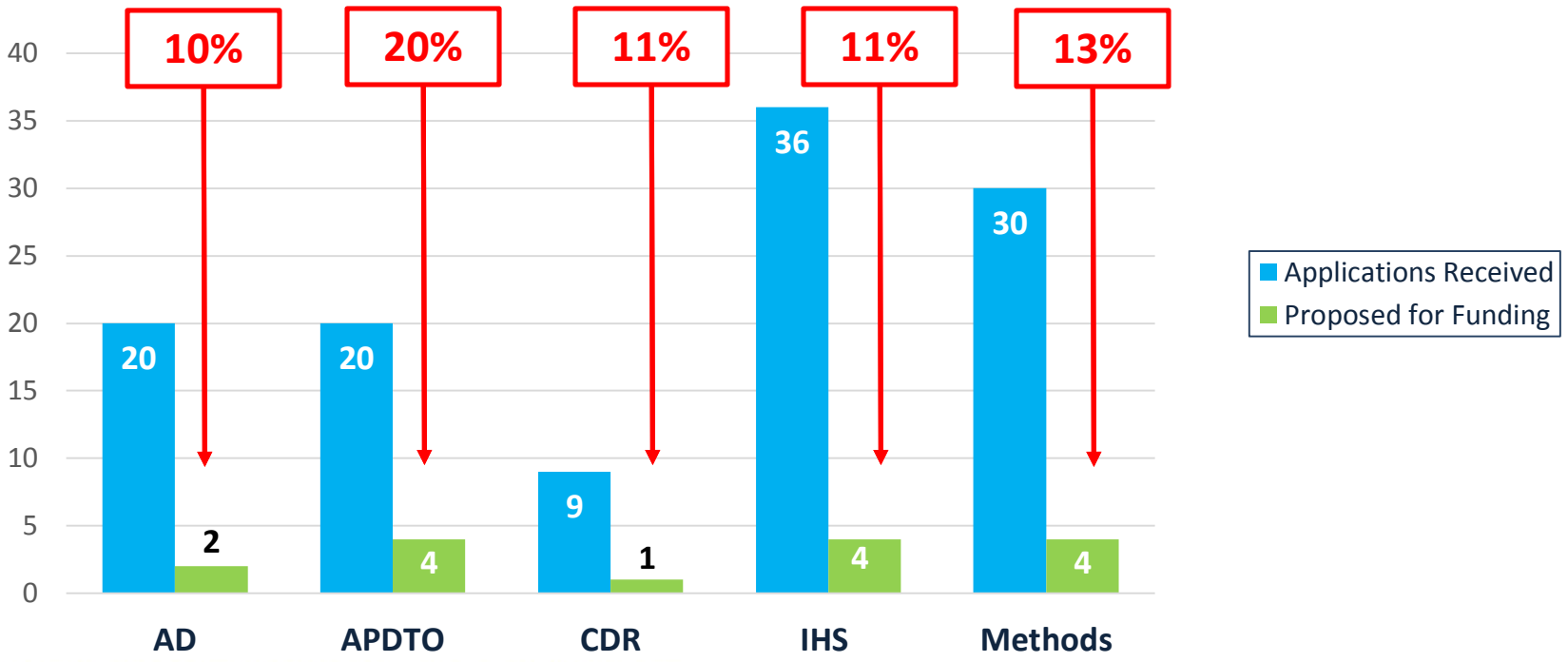
Slate Overview – Broad Cycle 3, 2016

Process Overview

- 236 Letters of Intent (LOIs) submitted
- 151 LOIs invited to submit a full application (**64%**)
- 115 applications were received (**76% of invited LOIs**)

Overall funding rate is 13 percent

- We are proposing to fund 15 applications* out of 115 received applications
  - **47%** (7) of applications recommended for funding are resubmissions



*Recommended by the Selection Committee

Broad Cycle 3, 2016

Financial Overview

15 Projects

PFA	Amount Budgeted	Proposed Total Award	*Difference*	Average Total Project Cost
Cycle 3, 2016 Broad	$37 Million	$36 Million	- $1 Million	$2.4 Million

Addressing Disparities

*2 Recommended Projects**

Project Title
Culturally Sensitive, Primary Care Clinic-Based Interventions by Community Health Workers and Trained Physicians to Promote and Sustain Weight-Loss among Black Women Patients with Obesity
Comparing the Effectiveness of House Calls and Peer Mentorship to Reduce Racial Disparities in Live Donor Kidney Transplantation

* All proposed projects, including requested budgets and project periods, are approved by the Selection Committee subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Assessment of Prevention, Diagnosis, and Treatment Options

*4 Recommended Projects**

Project Title
Prospective Multicenter Observational Cohort Study of Comparative Effectiveness of Disease-Modifying Treatments for Myasthenia Gravis (MG)
Study of Radiation Fractionation on Outcomes After Breast REConstruction (FABREC)
Real World Effectiveness and Safety of Hysteroscopic Compared to Laparoscopic Sterilization
Non-Pharmacologic Approaches to Relieve Pain and Symptom Distress among Diverse Hospitalized Cancer Patients

Resubmissions in bold.

* All proposed projects, including requested budgets and project periods, are approved by the Selection Committee subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Communication and Dissemination Research

*1 Recommended Project**

Project Title
Engaging Parents of Children with Sickle Cell Anemia and their Providers in Shared-Decision Making for Hydroxyurea

* All proposed projects, including requested budgets and project periods, are approved by the Selection Committee subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Improving Healthcare Systems

*4 Recommended Projects**

Project Title
Leveraging Integrated Models of Care to Improve Patient-Centered Outcomes for Publicly-Insured Adults with Complex Health Care Needs
Comparing Patient-Centered Outcomes of Standardized vs Patient-Driven Diabetes Shared Medical Appointments
A Multi-Center Randomized Controlled Trial of Perioperative Palliative Care Surrounding Cancer Surgery for Patients and their Family Members (the PERIOP-PC Trial)
Optimizing Care for Patients with Dementia: A Comparison of Two Non-Pharmacological Treatment Approaches

Resubmissions in bold.

* All proposed projects, including requested budgets and project periods, are approved by the Selection Committee subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Improving Methods for Conducting PCOR

*4 Recommended Projects**

Project Title
Statistical Methods and Designs for Addressing Correlated Errors in Outcomes and Covariates in Studies Using Electronic Health Records Data
Develop Novel Design Methods for Pragmatic Stepped-Wedge Cluster Trials with Patient-Centered Outcomes
Causal Analyses of Nested Case-Control Studies for Comparative Effectiveness Research
"Randomize Everyone": Creating Valid Instrumental Variables for Learning Health Care Systems

Resubmissions in bold.

* All proposed projects, including requested budgets and project periods, are approved by the Selection Committee subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Slate Overview – Cycle 3, 2016

Broad PFAs

15 Projects

Broad PFA	Proposed Total Award*
Addressing Disparities	$3.9M
Assessment of Prevention, Diagnosis, and Treatment Options	$10.2M
Communications and Dissemination Research	$2.2M
Improving Healthcare Systems	$15.4M
Improving Methods for Conducting PCOR	$4.1M
TOTAL:	$35.8M

* The total award amount in Cycle 3, 2016 is within the Board approved budgeted amount.

* All proposed projects, including requested budgets and project periods, are approved by the Selection Committee subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Cycle 3, 2016 Broad PFAs
Call for the Motion to Be Seconded:	• **Second** the Motion • 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

Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain PFA

Cycle 3, 2016 Award Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Leah Hole-Marshall, JD

Vice-Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH

Chief Science Officer

Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing

Objective of the PFA

- This funding initiative addresses important questions regarding strategies for preventing unsafe opioid prescribing in **primary care** among patients with **acute or chronic** non-cancer pain

Priority Research Questions:

- What is the comparative effectiveness of different **payer or health-system strategies** that aim to prevent unsafe opioid prescribing while ensuring access to non-opioid methods for pain management with the goal of reducing pain and improving patient function and quality-of-life outcomes, while reducing patient harm?
- What is the comparative effectiveness of different **patient- and provider-facing interventions** that facilitate improved knowledge, communication, and shared decision making about the relative harms and benefits of opioids and alternative treatments on prevention of unsafe prescribing and **improved patient outcomes**?

- Funds Available: $30 million; 3 years duration

Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing

Merit Review Criteria

1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

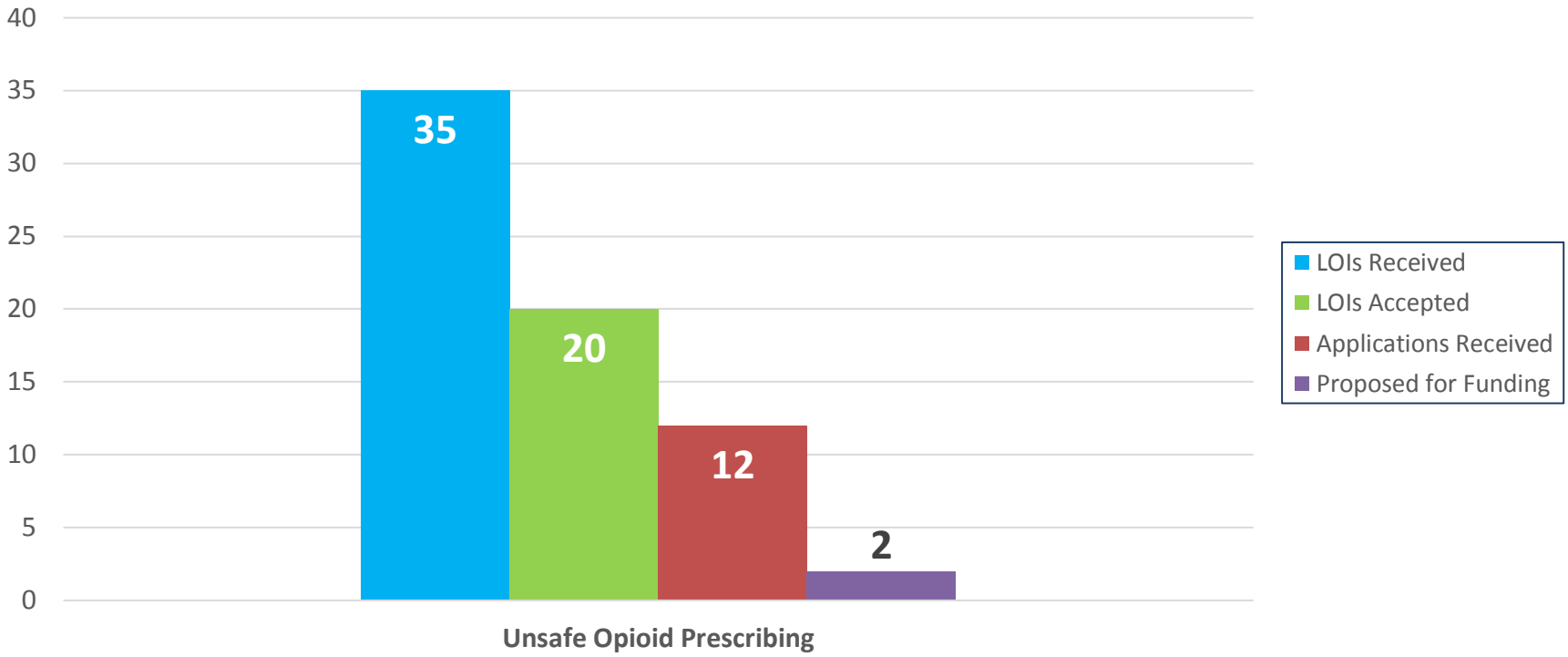
Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing

Process Overview

- 35 Letters of Intent (LOIs) submitted
- 20 LOIs invited to submit a full application (**57%**)
- 12 applications were received (**60% of invited LOIs**)

Overall funding rate is 17 percent

- We are proposing to fund 2 applications* out of 12 received applications



*Recommended by the Selection Committee

Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing

*2 Recommended Projects**

Project
A Naturalistic Experiment Evaluating the Impact of Medicaid Treatment Reimbursement Changes on Opioid Prescribing and Patient Outcomes among Patients with Low Back Pain
Provider-Targeted Behavioral Interventions to Prevent Unsafe Opioid Prescribing for Acute Non-Cancer Pain in Primary Care

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Project 1: A Naturalistic Experiment Evaluating the Impact of Medicaid Treatment Reimbursement Changes on Opioid Prescribing and Patient Outcomes among Patients with Low Back Pain

- **Research Question:** What is the comparative effectiveness of different payer strategies that aim to prevent unsafe opioid prescribing?
- **Population:** Adults with acute or chronic non-specific low back pain (LBP) who are receiving care at 24 matched FQHC clusters in CA and OR
- **Intervention:** Oregon Medicaid payer strategy enacted in July 2016 that enhances access to evidence-based non-pharmacologic treatment options while restricting access to opioids for LBP
- **Comparator:** California Medicaid
- **Outcomes of Interest:** New starts of chronic opioid treatment (*Primary for potential new users)*; rate of change of morphine equivalent dose *(Primary for subpopulation on chronic opioid therapy);* Pain, satisfaction, substance use, service use (*Secondary*)
- **Study Design:** Nested mixed methods quasi-experimental design with control
  - Retrospective interrupted time series for prescribing patterns and resource use (N=48,000);
  - Prospective cohort for pain and other patient-reported outcomes (N=2,500);
  - Qualitative component for barriers and facilitators ~90 patients; ~195 clinic staff
- **Length of Follow-up:** 5 years interrupted time series (pre- post- 2014-2019); 18 months (pain)
- **Total Project Cost:** $5.7M (project duration: 3 years)

Project 1: A Naturalistic Experiment Evaluating the Impact of Medicaid Treatment Reimbursement Changes on Opioid Prescribing and Patient Outcomes among Patients with Low Back Pain

- **Potential Impact:** Evidence about the impact of different policies could help reduce inappropriate prescribing of opioids, particularly among a **vulnerable, socioeconomically-disadvantaged population at high risk for misuse and abuse**, and be broadly applicable to other Medicaid programs
- **Patient-Centeredness:** Patients were involved in developing the application and prioritized endorsed outcome measures such as pain severity, functioning, and patient satisfaction with care
- **Engagement:** This project includes 3 key advisory groups to inform the design, implementation and dissemination of the research: 1) patient and caregiver partners, 2) clinical stakeholders, and 3) state and national stakeholders
- **Implementation/Dissemination or Evaluation Plan:** The involvement of multiple stakeholders in a working group will facilitate dissemination of study findings

Project 2: Provider-Targeted Behavioral Interventions to Prevent Unsafe Opioid Prescribing for Acute Non-Cancer Pain in Primary Care

- **Research Question:** What is the comparative effectiveness of different health system strategies that aim to prevent unsafe opioid prescribing?
- **Population:** Opioid-naïve adult patients with acute uncomplicated musculoskeletal pain or headache
- **Intervention:** Health system provider-targeted behavioral interventions to change opioid prescribing for acute non-cancer pain—using electronic health record (EHR) -based prompts, feedback, and alerts
- **Comparators:** (1) usual care consisting of CDC recommendations for opioid prescribing for acute pain, (2) usual care plus written justification for prescribing an opioid, (3) usual care plus provider feedback, (4) and usual care plus opioid justification plus provider feedback
- **Outcomes of Interest:** Initial opioid script and unsafe opioid prescribing (*Primary);* Receipt of an initial prescription for non-opioid management, patient-reported pain and function (*Secondary)*
- **Study Design:** Cluster randomized controlled trial (RCT): Sample Size: 10,936 (prescribing); 2000 (pain)
- **Length of Follow-up:** 12 months
- **Duration of Active Intervention:** Change to EMR system extends across project period
- **Total Project Cost:** $4.2M (project duration: 3 years)

Project 2: Provider-Targeted Behavioral Interventions to Prevent Unsafe Opioid Prescribing for Acute Non-Cancer Pain in Primary Care

- **Potential Impact:** The impact and reach of study findings could be substantial as the behavioral intervention supports can be delivered efficiently via the EHR, are scalable, and potentially pose little burden to providers
- **Patient-Centeredness:** Patients, providers, health IT experts, and health plan administrators identified the proposed research as critically important and laid the foundation for the application
- **Engagement:** National and local stakeholders, including patients, providers, payers, members of professional organizations and policy representatives have advised on the study since its inception to develop the full proposal. Study will include a Stakeholder Advisory Committee (SAC), and patient stakeholders from each of the 3 sites
- **Implementation/Dissemination:** Patient and provider qualitative interviews will assess barriers and facilitators to implementation of these interventions to inform future dissemination efforts. The SAC will help guide the team's dissemination activities to various end users, including patients, clinicians, and national organizations

Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing

*2 Recommended Projects**

PFA	Amount Budgeted	Proposed Total Award*
Strategies to Prevent Unsafe Opioid Prescribing	**$30 Million**	**$9.8 Million**

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • 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

Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers

Cycle 3, 2016 Award Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Leah Hole-Marshall, JD

Vice-Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH

Chief Science Officer

Cycle 3, 2016 Community-Based Palliative Care Delivery

Objective of the PFA

- To fund multiple, large, multi-site, comparative effectiveness research (CER) studies aimed at facilitating the delivery of community-based palliative care for adult patients with advanced illnesses and their caregivers
- Two areas of emphasis: Advance care planning and models of care delivery
  - **Question 1:** What is the comparative effectiveness of different patient, caregiver, and clinician-directed and combination approaches to facilitating **advance care planning (ACP)** conversations between adult patients living with advanced illnesses, their caregivers, and clinicians on patient-centered and other outcomes over time?
  - **Question 2:** What is the comparative effectiveness of different established **models of palliative care delivery** in community settings on improving patient-centered and other outcomes among adult patients with advanced illnesses and their caregivers?
- Up to $6M in direct costs (Question 1) and up to 5 years in duration
- Up to $10M in direct costs (Question 2) and up to 5 years in duration
- Funds available up to $48M total costs

Cycle 3, 2016 Community-Based Palliative Care Delivery

Merit Review Criteria

1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

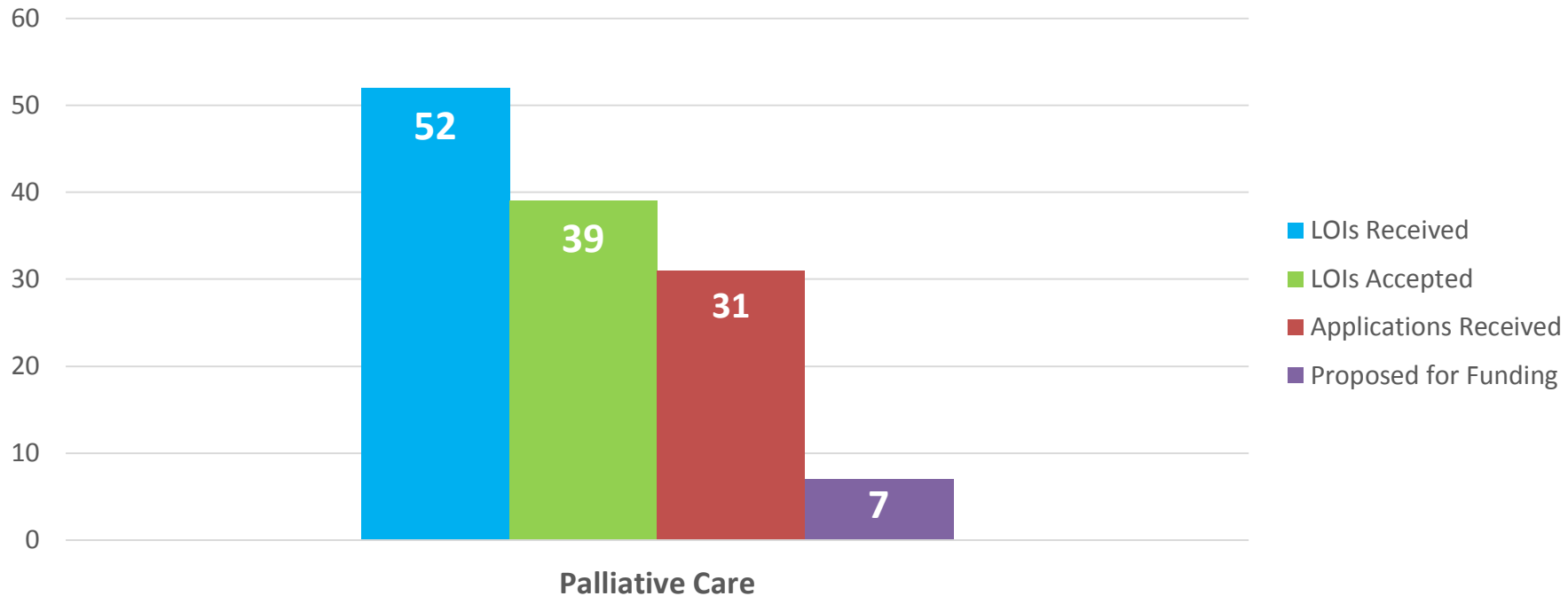
Cycle 3, 2016 Community-Based Palliative Care Delivery

Process Overview

- 52 Letters of Intent (LOIs) submitted
- 39 LOIs invited to submit a full application (**75%**)
- 31 applications were received (**79% of invited LOIs**)

Overall funding rate is 23 percent

- We are proposing to fund 7 applications* out of 31 received applications



*Recommended by the Selection Committee

Cycle 3, 2016 Community-Based Palliative Care Delivery

*7 Recommended Projects**

Project
A Non-Inferiority Comparative Effectiveness Trial of Physician-Led vs. Nurse-Led Home-Based Palliative Care in Older Adults with Advanced Illness and Their Family Caregivers
Population-Based Comparison of Evidence-Based, Patient-Centered Advance Care Planning Interventions on Advance Directive Completion, Goal Concordant Care and Caregiver Outcomes for Patients with Advanced Illness
Reducing Disparities in the Quality of Palliative Care for Older African Americans through Improved Advance Care Planning (EQUAL ACP)
Introducing Palliative Care within the Treatment of End Stage Liver Disease: A Randomized Controlled Trial
A Cluster-Randomized Trial Comparing Team-Based versus Primary Care Clinician-Led Advance Care Planning in Practice-Based Research Networks
Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness
Comparative Effectiveness of Early Integrated Telehealth versus In-Person Palliative Care for Patients with Advanced Lung Cancer

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Project 1: A Non-Inferiority Comparative Effectiveness Trial of Physician-Led vs. Nurse-Led Home-Based Palliative Care in Older Adults with Advanced Illness and their Family Caregivers

- **Research Question:** Is a nurse-led model of home-based palliative care (HBPC) as effective as a traditional physician-led model in improving outcomes for patients with advanced illnesses and their caregivers?
- **Population:** Patients 65+ with advanced heart failure, COPD, end-stage kidney or liver disease, neurodegenerative diseases, or advanced cancer and caregivers
- **Comparators:** (1) Efficient nurse-led HBPC: Palliative care trained RN supported by a social worker provides direct palliative care in the home based on a standard protocol with remote consultation from palliative care physician as needed. (2) Traditional, physician-led HBPC: Palliative care physician along with a RN and social worker makes home visits based on a standard protocol
- **Key Outcomes:** *Primary:* Symptom burden and days at home in the last 180 days of life, *Secondary:* quality of life (QOL), healthcare utilization; caregiver outcomes: caregiver preparedness, QOL, burden, healthcare utilization
- **Study Design:** Cluster randomized controlled trial (RCT) (65 nurse-led, 65 physician-led); qualitative component
  - Sample Size: 10,000 patients, and 4,800 caregivers enrolled from 15 clinics in Southern and Northwest California, all part of the PCORnet/CDRN network
- **Length of Follow-up:** 12 months
- **Duration of Active Intervention:** Minimum 8 weeks, maximum 12 months
- **Total Project Cost:** $14M

Project 1: A Non-Inferiority Comparative Effectiveness Trial of Physician-Led vs. Nurse-Led Home-Based Palliative Care in Older Adults with Advanced Illness and their Family Caregivers

- **Potential Impact:** Evidence of non-inferiority of a nurse-led model compared to the traditional physician-led HBPC could significantly expand access to palliative care services for advanced illness patients experiencing significant functional limitations that prohibit them from receiving care in outpatient settings
- **Patient-Centeredness:** Patients who are homebound in the final years of their life could benefit significantly from HBPC. These services also have the potential to reduce burden on caregivers
- **Engagement:** Patients from PCORnet CDRN and PPRNs, family caregivers, and representatives from purchasers, policy makers, and advocacy groups will be engaged throughout the study. Health system leadership will facilitate adoption of the nurse-led model if successful across all clinics in the system. External stakeholders will facilitate dissemination beyond the health system

Project 2: Population-Based Comparison of Evidence-Based, Patient-Centered Advance Care Planning Interventions on Advance Directive Completion, Goal Concordant Care and Caregiver Outcomes for Patients with Advanced Illness

- **Research Question:** What is the comparative effectiveness of three evidence-based advance care planning (ACP) approaches in facilitating advance directive (AD) completion and goal-concordant care and improving caregiver experience when implemented through primary care clinics in a large health system?
- **Population:** Primary care patients with cancer, heart failure, or COPD and who have had at least two outpatient visits in the past 12 months with a PCP, and their caregivers
- **Comparators: (1)** Advance directive (active control) **(2)** Advance directive + PREPARE website (patient activation), **(3)** Advance directive + PREPARE website + care coordinator facilitated ACP intervention
- **Key Outcomes:** *Primary:* Goal-concordant care, *Secondary:* Caregiver decisional conflict and decisional regret, AD completion
- **Study Design:** Cluster RCT (27 clinic clusters)
  - Sample Size: 900 patients and their caregivers at 27 clinics across 3 University of California sites
- **Length of Follow-up:** 30 months
- **Duration of Active Intervention:** 12 months
- **Total Project Cost:** $8.4M

Project 2: Population-Based Comparison of Evidence-Based, Patient-Centered Advance Care Planning Interventions on Advance Directive Completion, Goal Concordant Care and Caregiver Outcomes for Patients with Advanced Illness

- **Potential Impact:** This study will help large healthcare systems to effectively implement advance care planning efforts for their primary care patients
- **Patient-Centeredness:** This study will provide important information on which approaches to advance care planning will best help patients and their caregivers achieve care consistent with their preferences
- **Engagement:** A Study Advisory Group will guide implementation throughout the study. Study team will also work with other organizations to disseminate results

Project 3: Reducing Disparities in the Quality of Palliative Care for Older African Americans through Improved Advance Care Planning (EQUAL ACP)

- **Research Question:** What is the comparative effectiveness of a facilitated ACP approach vs. a patient-driven self-management ACP approach in enabling formal or informal ACP within two racial subgroups?
- **Population:** 800 adults (equal numbers African Americans (AA) and whites) over 65 living with advanced illness in the Deep South, and their caregivers
- **Comparators: (1)** Respecting Choices: Patients and caregivers will participate in a 60-90 minute in-person facilitated ACP conversation with a lay ACP facilitator, **(2)** Five Wishes: Patients will receive a copy of Five Wishes by mail to complete
- **Key Outcomes:** *Primary:* Formal or informal ACP by patient, *Secondary:* Goal-concordant care, satisfaction with end-of-life care, patient-caregiver congruence re: treatment preferences
- **Study Design:** Cluster RCT with a qualitative component (10 clinic clusters)
  - Sample Size: 800 patient-caregiver dyads (400 African American, 400 white) from 10 primary care practices
- **Length of Follow-up:** 1 year for patient outcomes, up to 4 years for post-bereavement survey
- **Duration of Active Intervention:** 3 months
- **Total Project Cost:** $5.8M

Project 3: Reducing Disparities in the Quality of Palliative Care for Older African Americans through Improved Advance Care Planning (EQUAL ACP)

- **Potential Impact:** Findings will demonstrate whether facilitated ACP improves outcomes in AA and white subgroups, and whether racially concordant facilitation helps reduce disparities
- **Patient-Centeredness:** Studies across diseases, settings of care, and patient demographics consistently document lower rates of ACP among African Americans
- **Engagement:** Patients, bereaved caregivers, community representatives, and advocacy groups have been engaged from the planning stage. Stakeholders helped to develop study aims, hypotheses, design, and dissemination & implementation plan. Stakeholder Advisory Board (SAB) will meet throughout the study

Project 4: Introducing Palliative Care within the Treatment of End Stage Liver Disease: A Randomized Controlled Trial

- **Research Question:** What is the comparative effectiveness on patient and caregiver outcomes of palliative care delivered to patients with end-stage liver disease (ESLD) by their hepatologist (liver disease specialist) trained in palliative care versus receiving consultation from a palliative care specialist?
- **Population:** Adult patients with decompensated ESLD and their caregivers
- **Comparators:** (1) Hepatologist-led palliative care: Hepatologists will receive training in palliative care over 12 weeks via an evidence-based training curriculum and will provide palliative care for their patients during 4 in person visits over 6 months using a structured checklist (2) Consultative palliative care: Hepatologists will refer their patients to a palliative care specialist for 4 in-person visits over 6 months that will utilize a structured checklist
- **Key Outcomes:** *Primary:* Quality of life, *Secondary:* Symptom burden, distress, healthcare utilization, survival; caregiver outcomes: burden, quality of life
- **Study Design:** Cluster RCT (14 clinical centers as clusters); qualitative component
  - Sample Size: 1,260 patients and their caregivers enrolled from 14 sites
- **Length of Follow-up:** 12 months
- **Duration of Active Intervention:** 6 months
- **Total Project Cost:** $14.2M

Project 4: Introducing Palliative Care within the Treatment of End Stage Liver Disease: A Randomized Controlled Trial

- **Potential Impact:** Given that hepatologists provide most of the care to patients with ESLD, integrating delivery of palliative care into existing hepatologist/patient relationships could result in greater access to palliative care for ESLD patients and at the same time reduce burden on a limited workforce of palliative care specialists. Findings have the potential to inform curricula for subspecialty training in hepatology
- **Patient-Centeredness:** Expanding the care provided by their hepatologist could improve patient satisfaction and patient and caregiver receptiveness to engaging with palliative care services
- **Engagement:** The Research Advisory Board (RAB) - 3 patients, 2 caregivers, 1 leader of a patient advocacy organization - and members of a patient advocacy organization have been involved throughout the application development process. The executive committee of the project also includes leadership of multiple hepatology specialty societies as well as healthcare system leaders

Project 5: A Cluster-Randomized Trial Comparing Team-Based versus Primary Care Clinician-Led Advance Care Planning in Practice-Based Research Networks

- **Research Question:** What is the comparative effectiveness of a primary care team-based Serious Illness Care Program (SICP) vs. primary care clinician-focused SICP on concordance of care with patient goals and time spent at home?
- **Population:** Adults living in the community with serious illnesses who have a life expectancy of one to two years from Oregon, Colorado, Iowa, Wisconsin, North Carolina, Quebec, or Ontario, and their caregivers
- **Comparators: (1)** Primary care team-based Serious Illness Care Program (SICP) – team can consist of varied professionals including nurses, social workers, chaplains, peer counselors **(2)** Primary care clinician-focused SICP
- **Key Outcomes:**
  - *Primary:* Goal-concordant care and time spent at home
  - *Secondary*: Quality of life, quality of communication with staff, frequency of care planning discussions; enrollment in hospice, location of death and family bereavement (caregiver); staff satisfaction, confidence in implementing advance care planning, staff burnout
- **Study Design:** Cluster RCT (36 clinic clusters)
  - Sample Size: 790 patients and their caregivers
- **Length of Follow-up:** 2 years
- **Duration of Active Intervention:** 12 months
- **Total Project Cost:** $8M

Project 5: A Cluster-Randomized Trial Comparing Team-Based versus Primary Care Clinician-Led Advance Care Planning in Practice-Based Research Networks

- **Potential Impact:** The results of this study will help practices determine whether a physician-based intervention or a team-based intervention most effectively facilitates advance care planning conversations between clinicians, patients, and caregivers and goal concordant care
- **Patient-Centeredness:** This project will facilitate conversations between patients, caregivers, and providers, and help patients better understand their options for care
- **Engagement:** Practices and stakeholders are connected to statewide practice transformation initiatives such as ACOs and patient-centered medical homes. Payers and policymakers will be included in planning to facilitate wide dissemination and implementation

Project 6: Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness

- **Research Question:** What is the comparative effectiveness of palliative care delivered by a nurse-led telephonic case-management model versus outpatient specialty palliative care on patient and caregiver outcomes for patients with advanced illnesses who are discharged to home after an ED visit?
- **Population:** Patients 65 years or older with advanced cancer or end-stage organ failure and their caregivers
- **Comparators:** (1) Nurse-led telephonic case management: RNs certified in hospice and palliative medicine will deliver palliative care services via phone soon after an ED visit (2) Outpatient palliative care: Following an ED visit, patients will be referred to an outpatient palliative care clinic to receive care based on a standardized protocol from a board-certified palliative care physician and a nurse practitioner
- **Key Outcomes:** *Primary:* Quality of life (QOL), *Secondary:* Symptom burden, healthcare utilization; caregiver outcomes: caregiver strain, QOL, and bereavement outcomes
- **Study Design:** RCT
  - Sample Size: 1,350 patients and 675 caregivers enrolled from 9 emergency departments located in 6 states
- **Length of Follow-up:** 12 months
- **Duration of Active Intervention:** 6 months
- **Total Project Cost:** $12.3M

Project 6: Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness

- **Potential Impact:** Directing patients who use the ED at the end of their lives to evidence-based palliative care services can facilitate the transition process from ED to home and reduce utilization of avoidable healthcare services
- **Patient-Centeredness:** By facilitating access to palliative care services after discharge from ED, findings from this study have the potential to provide patients with an additional layer of support that could significantly reduce the illness burden on patients and their caregivers
- **Engagement:** The Stakeholder Advisory Council includes: Patients with serious, life-limiting illnesses and their caregivers, patient advocates from stakeholder organizations, leadership of health insurers and health plans, and representatives from palliative medicine and emergency medicine specialty societies

Project 7: Comparative Effectiveness of Early Integrated Telehealth versus In-Person Palliative Care for Patients with Advanced Lung Cancer

- **Research Question:** What is the comparative effectiveness of early integration of palliative care delivered via telemedicine versus in person on patient and caregiver outcomes among patients newly diagnosed with advanced lung cancer and their caregivers?
- **Population:** Patients newly diagnosed with advanced non small cell lung cancer and their caregivers
- **Comparators:** (1) Telemedicine Palliative Care: 1st visit with palliative care clinician will be in person in the oncology clinic within one month of enrollment to establish rapport; subsequent visits in patient's home via secure videoconferencing (2) In-person Palliative Care: Patients will be scheduled for 1st visit with the palliative care clinician in the oncology clinic within one month of enrollment
- **Key Outcomes:** *Primary:* Quality of Life (QOL), *Secondary: S*atisfaction with care, communication about end of life care preferences, healthcare utilization; caregiver outcomes: QOL, satisfaction with care, and bereavement outcomes
- **Study Design:** RCT
  - Sample Size: 1,250 patients; 937 caregivers enrolled from 20 cancer centers across 14 different states
- **Length of Follow-up:** 18 months
- **Duration of Active Intervention:** 18 months
- **Total Project Cost:** $11M

Project 7: Comparative Effectiveness of Early Integrated Telehealth versus In-Person Palliative Care for Patients with Advanced Lung Cancer

- **Potential Impact:** This project can provide important information for health systems as they strive to find effective means to expand access to palliative care for patients diagnosed with advanced cancer. Study findings could inform insurers' decisions about reimbursement for telehealth services
- **Patient-Centeredness:** Delivery of palliative care via telemedicine could increase access to palliative care services for cancer patients living in remote geographical areas. Virtual visits could facilitate involvement of family members in caregiving who live in different locations from the patient
- **Engagement:** Patient and stakeholder partners will be involved throughout the study including patients and caregivers, patient advocates, palliative care clinicians, telemedicine experts, healthcare system leaders, health policy experts, and multiple medical insurance providers

Cycle 3, 2016 Community-Based Palliative Care Delivery

*7 Recommended Projects**

PFA	Amount Budgeted	Proposed Total Award*
Community-Based Palliative Care Delivery	**$48 Million**	**$73.7 Million**

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Budget Overview – Remainder of Fiscal Year 2017

35 Projects

Board Meeting	Cycle 3, 2016 PFA	Amount Budgeted	Proposed / Estimated Total Budget	Difference
August 15 Board Meeting	**Broad + 2 Targeted PFAs**	$115 Million	$119.4 Million	**+ $4.4 Million**
September 12 Board Meeting	**PCS + 3 Targeted PFAs**	$134 Million	$104.4 Million	**- $29.6 Million**
	TOTAL:	**$249 Million**	**$223.8 Million**	**- $25.2 Million**

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Cycle 3, 2016 Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • 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

Robert Zwolak, MD, PhD

Acting Chairperson, Board of Governors